Author's response to reviews

Title: Long-term effectiveness and costs of a brief self-management intervention in women with pregnancy-related low back pain after delivery

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Author's response to reviews: see over
To the BioMed Central Editorial Team

Hereby I send you the revision of the manuscript “Long-term effectiveness and costs of a brief self-management intervention in women with pregnancy-related low back pain after delivery”. In the following letter the comments of the reviewers are discussed point-by-point and specified where and how the manuscript and tables is revised.
I hope the questions and suggestions of the reviewers are answered satisfactory.

Yours sincerely,

Caroline HG Bastiaenen, PhD

Comments on reviewer’s 1 (L Nilsson-Wikmar)

1. Page 4
Some references about the prevalence also in the Netherlands are added.

Page 4
The sentence “Is rather a subjective experience is....” is supplemented with “We assume it is rather a subjective experience....”

Page 5
The reviewer wants to know how the measurements were classified according the ICF. That is clarified in the Measurement paragraph (page 9).

We inserted:
Measurement should take place in all relevant domains of the ICF; body functions, limitations in activities, participation restrictions and contextual factors. Movement related body functions are listed during physical examination. Pain, another body function is listed with two Visual Analog Scales [31, 32] and questions about pain localization and duration of pain during history taking. The level of activity is investigated with the Roland Disability Questionnaire (RDQ) [28] and the Main Complaints [29,30]. Restrictions in participation are measured with the Impact of Participation and Autonomy (IPA) [33,34]. Contextual factors include all factors that influence how disability is experienced by an individual like age, social background, profession, past and current experience. Some factors are listed during history taking and by questionnaire in the cohort study, for others measurement scales are used. The used measures are the Beck Disability Inventory (BDI)[43], Pain Catastrophizing Scale (PCS)[42], Negative Emotionality Scale (NEM)
[45], Positive Emotionality Scale (PEM)[45], Tampa Scale for Kinesiophobia (TSK)[35-37], Short Form-36 (SF-36) subscale “general health” [38,39], Pain Behavior Scale (PBS) [26, 27] and Global Perceived Effect (GPE) [29]. Finally the EuroQol covered all domains [40].

2.

Page 5

We added the phrase “at the moment of three weeks after delivery” to the sentence “A woman entered the intervention study (at the moment of three weeks after delivery) after signing informed consent for both the cohort and intervention study during early pregnancy and meeting the in- and exclusion criteria of the intervention study at three weeks after delivery.

Page 6

The sentence “Women diagnosed with relevant specific pathology affecting pain and disability…” is changed in “Women with systematic disease or specific pathology in the region of the pelvic girdle and/or the lower back affecting pain and activities were excluded…….”

Page 7-8

The part of the usual care is amplified with the following information:

Prior to the trial, detailed information is gathered about the contents of the current treatment options in the Netherlands. Part of the information is collected by means of group discussions with experienced physiotherapists and interviews on an individual basis with affected women out of our cohort study [4]. The program is described in detail elsewhere [18] and included:

- An expert role of the physiotherapist in relation to the patient focusing on disease management,
- A pain contingent regime of avoiding and limiting several day-today activities,
- Treatment goals were focused on biomedical factors,
- Stabilizing exercises of the lumber spine and pelvic girdle.

The general practitioner in the Netherlands gives some general information about the health problem concerning the prognosis after delivery. In general, this guidance is limited to one visit.

Page 9-11

The heading “History and physical examination” is changed in “History, physical examination and baseline measurement” to list all the relevant baseline measurements and the information gathered during history and physical examination. A new heading “Outcome measures“ is used to list all the outcome measures.
The information of the standardized clinical examination is extended in the following way: “After history taking a short standardized clinical examination program was performed to exclude specific pathology, list the mobility of the back and lower extremities, a short observation of daily activities as walking, standing and sitting and finally a test of nerve root radiation. Because the limited evidence, specific tests for pain provocation, pelvic stability and hyper mobility were not used as exclusion criteria or to discriminate between pelvic girdle and low back pain.”

The outcome measures are described in detail on the pages 10-13.

The EuroQol is used as an outcome measurement in this study and is completed at baseline and all the follow-up measurements (Tables 1-2). The PBS is only described on page (10).

The part of the follow-up is extended with (page 13):

“The follow-up questionnaires contained the listed outcome measures. Furthermore, items on contents, satisfaction and beneficial aspects of the (experimental) treatment were listed. Co-interventions, medication, aids, additional medical consumption, recurrence of complaints, return to gainful employment and a possible subsequent pregnancy were also registered. Besides, the follow-up questionnaires assessed also how many treatment sessions were followed in the previous period of time”.

Page 14

The statistical paragraph on page 14-15 is enlarged with the information about confounders:

“Multivariable analyses were performed to examine the effects for potential confounding factors measured at baseline in addition to time after baseline, baseline measurement of the scale and groups. Potential confounding factors were age, education, profession, BDI, PCS, NEM and PEM”.

Results of the mixed models are presented in table 3 as estimated regression coefficient with 95% CI and p-value and not as mean and SD. The statistical paragraph is added with a sentence about the GPE.

For the categorical outcome variable GPE a chi-square test is used. A cut-off point for distinguishing between improved and not improved is chosen. Fully recovered and much improved are considered to be improved.

The reviewer makes a comment that statistical analyses are problematic when using questionnaires. I think she want to pay attention to the fact that it could be problematic that a categorical variable as the sum score of a questionnaire will be considered as a continue variable in the statistical analyses. Non-parametric testing should be preferable in that case. However, the RDQ is a 24 item scale and is worldwide analyzed and investigated in several different populations as a continue variable. Responsiveness of the scale turned out very good several
times. Of course the assumptions of normality must be checked. In this case the assumptions of normality were acceptable and we added a sentence about normality of the RDQ in the result section that pointed out that information.

3

Page 16-17

Results are in a somewhat different way presented using the heading: Description of the study population and subheadings (a) Baseline characteristics, (b) Follow-up and (c) Co-intervention, recurrence of pain, return to gainful employment and a possible subsequent pregnancy.

Page 17-18

The reviewer suggested the word “extensive” could be taken away but it the word refers to the extensive within subject improvement on the RDQ in both groups over time. The sentence is changed in:

“Other estimated treatment assignment effects were not significant different although there was an extensive within-subject improvement on the primary outcome RDQ (about 10 points improvement on the RDQ from baseline to one year after delivery) in both study groups and on several secondary outcomes (Tables 1-2)”.

The word total is added to the sentence:’ in the total score of the TSK and subscale Activity Avoidance”.

Tables 2 and 3

The layout of the tables is improved.

Abstract

The abstract is adjusted to the comments and the conclusion is rephrased:

“Brief self-management techniques applied in the first 3 months after delivery may be a more viable first-line approach but further research is needed to draw inference on costs and to determine whether no care is a better option in the long term.”

Comments on reviewer’s 2 (Mitchell Haas)

General:

The reviewer refers to the fact that in the usual care group a no treatment choice was left open and that the study would have been better designed if participants were randomized directly to no care in a third group. We agree with the reviewer and it was an important point of consideration before the start of the RCT. We investigated that point more in detail in a small survey with affected women out of our cohort study and during group discussions with physiotherapists. Unfortunately, it became clear that is was not wise to design a study with a third group with no
intervention options. Women that gave birth to a child recently and still having pain in the lower back and/or the pelvic girdle were in great demand for a referral to a physiotherapist in the Netherlands. An option with a no treatment group in the study was not negotiable for those women or the physiotherapists and would seriously hamper the number of participants in the study. Maybe the results of our study let in the possibility of a next study with a no treatment option in the near future. We added the following sentences about this topic in the discussion on page 21:

‘Unfortunately, it was not possible to design a study with a third group receiving no treatment after delivery because there was a strong urge to leave open the possibility of a referral to a physiotherapist already in the first month after delivery, in the Netherlands. The urge did not only come from the potential participants but also in an even greater extend from the physiotherapists. All included women in the study wanted to be referred to a physiotherapist at the moment of enrollment in the intervention study. Nevertheless, a considerable number of women of the usual care group did not go to a physiotherapist afterwards. This was quite unforeseeable and has not only influenced the primary outcome but also the huge variation in costs in the usual care group.

And on page 22:

“The findings of this study and the underpinning results of the subgroup analyses lead to a future study question including a brief self-management approach compared to a no intervention and a usual care option.”

The reviewer emphasized also interpretation of the results. We rephrased the interpretation as follows:

Page 17-18 (results) “The estimated treatment assignment effect demonstrates a statistical significant effect in the RDQ, for the experimental group compared to usual care. However there does not appear to be a clinically important difference in change in advantage of the experimental intervention over time (one year delivery)”.

Page 19 (discussion) “In spite of the large confidence intervals of costs due to sick leave within both study groups, the mean costs of sick leave in the usual care group were about doubled compared to the experimental intervention group; however not statistically significant.”

Page 19 (discussion) “In spite of the statistical significant estimated treatment effect of the RDQ for the experimental group compared to the usual care group, the difference is too small to be clinically relevant over time (one year after delivery)”.

Page 21 (conclusions) “Brief self-management techniques applied during the first 3 months after delivery are probably a viable first-line approach for the management of pregnancy-related low back pain, but further research is needed to get more insight into the interference of the costs
and a comparison with a no treatment option. Secondary results indicate that it is a temporary disorder with a good functional prognosis especially in the first months after delivery”.

Major Compulsory Revisions

1. Abstract: “Intention-to-treat outcomes showed significantly better estimated regression coefficients RDQ -1.6 [-2.9;-0.5], MC -4.9 [-10.3;04], VAS pain this week -3.6 [-9.3;2.0], associated with treatment, as well as better IPA subscale autonomy in self-care -1.0 [-1.9;-0.03] and TSK -2.4 [-3.8;-1.1] but were not clinically relevant over time”.

“Conclusions

Brief self-management techniques applied in the first 3 months after delivery may be a more viable first-line approach but further research is needed to draw inference on costs and to determine whether no care is a better option in the long term.”

2. Usual care. The choice of a no treatment option into the usual care option is already discussed in the general part.

3. Usual care. A brief description about the usual care and no treatment options is added (page 7):

“Prior to the trial, detailed information is gathered about the contents of the current treatment options in the Netherlands. Part of the information is collected by means of group discussions with experienced physiotherapists and interviews on an individual basis with affected women out of our cohort study [4]. The program is described in detail elsewhere [18, 19] and included:

• An expert role of the physiotherapist in relation to the patient focusing on disease management,
• A pain contingent regime of avoiding and limiting several specific day-to-day activities,
• Treatment goals were focused on biomedical factors,
• Stabilizing exercises of the lumbar spine and pelvic girdle.

The general practitioner in the Netherlands gives some general information about the health problem concerning the prognosis after delivery and pays attention to the possibility to be referred to a physiotherapist for treatment. In general, this guidance is limited to one visit

4. Primary outcomes were selected before the inclusion of the participants of the study. The primary focus of interest is disability. The information about the clinical important
change is added on page 15: “A clinical important change on the primary outcome RDQ was considered a change of 2 points.”

5. We used an adapted version of the MPQ-DLV with 100-points VAS-scales. That is added to the text on page 12.

6. Statistical analyses. We added some extra information in this paragraph on page 14 and 15:
   “The times after baseline (in months), group and baseline measurement of the scale under investigation were treated as fixed effects. Multivariable analyses were performed to examine the effects for potential confounding factors measured at baseline in addition to time after baseline, baseline measurement of the scale and groups. Potential confounding factors were age, education, profession, treatment expectancy, BDI, PCS, NEM and PEM.”
   “Normality of the residuals was examined using normal probability plots and histograms”.

7. We added a sentence about adjustment for multiple comparisons on page 17: “Adjustment for multiple comparisons (Bonferronni correction) alpha would have been .016; the estimated treatment effect is still statistical significant (table 3) but the clinical relevance did not change.”

8. Sample size. We added the information about the sample size and power on page 15:”
   Power calculations showed that to detect a difference of 2 in changes scores of the RDQ at 80% power and with alpha=0.05 a total sample size of 124 is needed. When alpha=0.1 with 80% power a total sample size of 90 is needed”.

9. Economic analyses. The primary focus of our study was on the disability level. The unexpected differences in costs between the groups because of sick leave were probably for the most part influenced by so far unknown (and therefore not measured) variables. We added rephrased information about this topic to page 19-20 (discussion) to explain why we did not used mixed models for the estimation of the differences in costs:
   “In spite of the large confidence intervals of costs due to sick leave within both study groups, the mean costs of sick leave in the usual care group were about doubled compared to the experimental intervention group; however differences were not statistically different. Differences remained stable in the subgroup analyses. Maybe, the experimental intervention has some influence on sick leave. Physiotherapists of the experimental intervention were instructed in detail about the advice return to work. They were not allowed to advice against return to work but were asked to
encourage the women in their intention to return to work with the support of goal-orientated action plans. In the usual care group, return to work was a regular topic of conversation but left to the appraisal of the physiotherapist to advice a woman. At the same time, there were still many other unknown reasons why a considerable number of young mothers were reluctant to return to gainful employment after finishing maternity leave. More research in this field in general and especially in the Dutch situation is necessary to investigate potential prognostic variables that influence the duration of sick leave related to pregnancy and childbirth. We decided not to perform mixed models in this evaluation because we had not enough information about probably influential confounders. Results of the economic evaluation in this trial were therefore of limited significance.

10. Usual care received (page 16): 42 participants received treatment from a physiotherapist and 3 participants received guidance by the general practitioner.

11. Effectiveness. The re-arrangement of the result section is done as advised (page 17-18)
12. Effectiveness. The statement “significant faster reduction” is deleted. The lack of clinical important difference between the groups is discussed on page 17:”The estimated treatment assignment effect demonstrates a statistical significant effect in the RDQ, for the experimental group compared to usual care. However there does not appear to be a clinically important difference in change in advantage of the experimental intervention over time (one year delivery).”

However, there was a clinically important within subject improvement in both groups over time. That is discussed on page 18:”there was an extensive within subject improvement on the primary outcome RDQ (about 10 points improvement on the RDQ from baseline to one year after delivery) in both study groups and on several secondary outcomes (Tables 1- 2”).

13. Total costs are identified as primary cost outcomes (page 15): “Total costs are considered the primary total cost outcome.”

14. The conclusion is rephrased (page 23) in: “Brief self-management techniques applied during the first 3 months after delivery are probably a viable first-line approach for the management of pregnancy-related low back pain, but further research is needed to get more insight into the interference of the costs and a comparison with a no treatment option. Secondary, results indicates that it is a temporary disorder with a good functional prognosis especially in the first months after delivery.”
Comments on reviewer’s 3 (Jeremy Fairbank)

General:
The reviewer likes to see information about one potential confounding factor; the use of peripartum epidurals. We indeed collect in our intervention study information about the delivery including the use of epidural anesthesia. Midwives filled out a questionnaire ten days after delivery (cohort study) with a lot of items about the delivery (including the use of medication/epidural anesthesia) and the period of lying in. The local situation concerning the use of epidurals in the Netherlands is somewhat different from most other Western countries. Until today, a necessary condition for the use of epidural anesthesia is a prescription of a gynecologist based on medical reasons. Only a minority of the deliveries will be supervised by a gynecologist (the ones with complications). Normal deliveries will be supervised by a midwife at home or in an outpatient center. Epidural anesthesia is not available in that situation.

Only 9.2% of the women in our cohort study (n=7526) used epidurals during the delivery. The number of women that participated in the intervention study and used epidurals was 11; 5 in the intervention group and 6 in the control group. It was therefore not relevant to enter this variable in the analyses. We added that information on page 14: “In the usual care group 42 women received treatment from a physiotherapist and 3 women received guidance from a general practitioner, in the first three months, 19 women preferred the no treatment option in that period.”

The reviewer has some questions about the presentation of the RDQ data. How many of the participants scored 24? At baseline the mean of the whole group was 13.4 SD 4.4, range 23 (1-24) with one person scoring 24 and one person 21. We added the following text to page 18:

“Floor or ceiling effects are considered to be present if more than 15% of the respondents achieved the lowest or highest possible score. At baseline, only one participant showed the highest possible score (24) on the RDQ and no one the lowest possible score (range 23). With a mean of 13.4, SD 4.4 for the total group and inspection of the histogram, the normal distribution of the baseline variable was also acceptable. There were no floor or ceiling effects of the RDQ to be present at baseline”.

The discussion is rearranged and the following subheadings are used: key findings, experimental intervention, limitations of the study, strengths of the study, research and clinical implications, conclusions.
A part of the discussion is devoted to the collaborative partnership between a woman and her therapist. This approach is unique for the experimental intervention and in contrast with the approach in the usual care group. In spite of the fact that it is described elsewhere we added on the pages 6-7 more information is about the approach in the experimental intervention and the usual care:

Usual care:

- An expert role of the physiotherapist in relation to the patient focusing on disease management,
- A pain contingent regime of avoiding and limiting several specific day-to-day activities,
- Treatment goals were focused on biomedical factors,
- Stabilizing exercises of the lumbar spine and pelvic girdle.

The general practitioner in the Netherlands gives some general information about the health problem concerning the prognosis after delivery and pays attention to the possibility to be referred to a physiotherapist for treatment. In general, this guidance is limited to one visit.

Experimental intervention:

Women, allocated to the experimental intervention group, were immediately referred to a participating physiotherapist in their own neighborhood. We provided an individualized self-management approach of 7-9 sessions for 30 minutes in a period of time of 12 weeks. Self-management refers to the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent to living with a chronic condition [22-24]. A relationship in which the physiotherapist and the woman make health care decisions together was a basic assumption of this intervention. The program was based on brief self-management [22-24] and fear-avoidance techniques [25] and described in detail elsewhere [18] and included:

- Standardized information by means of a protocol for the therapists and booklets for the patients specially developed for this study,
- Simple complaint-related problem-solving techniques that engaged women in identifying day-to-day problems or limitations related to the complaints under investigation,
- Setting personal goals by action planning,
- Reviewing the action plans and progress towards goals,
- A shift from an expert role of the physiotherapist to an equal partnership between physiotherapists and patients. The physiotherapist becomes a teacher in the development patient’s skills to manage her health problem,
- A hierarchy of individual fear-eliciting movements and activities,
- Specific skills such as specific stabilizing exercises of the lumber spine and pelvic girdle and building up fitness training.

I hope this information contributes to the relevance of discussing the shift from a biomedical to a biopsychosocial approach in the experimental intervention. One of the other reviewers judged this part of the discussion as very useful.