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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Version: 3 Date: 20 May 2008

Author's response to reviews: see over
Hereby I send you the second 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 reviewer L. Nisson-Wikmar is discussed point-by-point and specified where and how the manuscript and tables are revised. I hope the questions and suggestions of the reviewer are answered satisfactory.

Yours sincerely,

Caroline HG Bastiaenen, PhD

Comments on reviewer L. Nilsson-Wikmar

2. The information in brackets is included in the sentences.
In the part of how the measurements are connected to the ICF (page 8-9) is the following phrase is changed in: “Personal factors are measured with 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].”

3. The reviewer judged the first parts about “Recruitment and “Description of the study population” are not a result.
When reporting the results of this trial the recommendations of the CONSORT-statement are followed when possible. The CONSORT-statement (www.consort-statement.org) represents an evidence-based minimum set of recommendations for reporting RCT’s. It offers a standard way for authors to prepare reports of trial findings. The CONSORT-statement comprises a 22-item checklist and a flow diagram. In our paper, Figure 1 represents the flow chart. The items of the checklist focus on reporting how a trial was designed, analyzed and interpreted (BMC Medical Research Methodology 2001, 1:2).
Following the checklist, in the first part of the Results section the following items should be discussed:

- Item 13: Participant flow and description of the protocol deviations, item 14: Dates defining the periods of recruitment and follow-up and item 19 adverse events. Item 13 and 14 should be including information about the participants concerning the four stages of the trial: enrolment, intervention allocation, follow-up and analysis. Knowing when a study took place and over what period participants were recruited places the study in a historical context. Besides knowing the rate at which participants were recruited is also useful information (as turned out in our study).

We reported these items as:

“Recruitment

- Self-administrated questions about limitations in activities and the perceived need for treatment among women from the cohort study (n=7526) resulted in 869 possibly eligible participants, in the first week after delivery. On basis of history taking by telephone two weeks after delivery, 743 women were excluded from participation (Figure 1). The majority of them were excluded because of a spontaneous remission within the first two weeks after delivery (n = 650). History taking by telephone resulted in 147 home visits about three weeks after delivery. Based on these home visits, 21 women were excluded. Finally, from May 2001 until July 2003, 126 women were included in the intervention study three weeks after delivery.”

- Follow-up

After randomization, 64 women were assigned to the usual care group and 62 to the experimental intervention group. For 114 women (90%) data were available for all outcome measures 3 months after randomization (Figure 1). In 94% of the women of the experimental group records showed that they had received the techniques defined a priori as relevant to this intervention. Not one adverse event of the experimental intervention was recorded. 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. In 105 women (83%) all outcome measures were complete at six months and one year after delivery. The prognostic status at baseline of women who were lost to
follow-up and women who filled out all the outcome measures was highly similar.

- Co-intervention, recurrence of pain, return to gainful employment and a possible subsequent pregnancy

Nineteen women of the usual care group did not receive any treatment in the year after delivery. Nineteen women of the same group received treatment in the follow-up period (between three months after randomization and one year after delivery). Four women in the experimental intervention group received treatment in the follow-period.

In both groups a considerable number of women reported pain flare-ups after they became free of any pain. (usual care n = 18, experimental group n = 15). 34 women of the usual care group and 45 of the experimental group reported return to gainful employment one year after delivery. 11 women of the usual care group and 5 of the experimental group applied for a benefit due to the disorder. Four women of the usual group and six of the experimental group did not return to gainful employment because they were out of a job. Six women (three in both study groups) reported a subsequent pregnancy one year after delivery.

- Item 15: Baseline demographic and clinical characteristics of each group.

We reported this item as:

“Description of the study population

- Baseline Characteristics

Baseline status of the participants is given in Table 1. Both groups were highly similar in prognostic variables and baseline values of outcome measures.”

We report the relevant information conform the CONSORT-statement in the result section. It is not clear what the reviewer means by the first parts about the “Recruitment” and “Description of the study population” are not a result.

Clarifying the tables.

There is a full legend added to all tables. The terms primary and secondary outcomes are added in the tables 1-3.

GPE is not reported in Table 3 because this table represents the outcomes of the longitudinal analyses for main linear mixed models. The outcome variable of the GPE is to be considered as a
dichotome variable with a defined cut-off point, so a linear mixed model is not a right method of analysis.

We adopt the proposal of Mitchell Haas to replace the results of the chi-square of the GPE with logistic regression in table 2. In the result section is added on page 17:

“Results of binary logistic regression with the dichotome outcome variable GPE did not show statistical significant difference between the both groups at 3, 6 and 12 months. The BDI is a significant co-variable at three months after delivery (p=.018); 73.7% is correctly classified. At 6 months 79.8% is correctly classified and at 12 months 84.5 %. There were no significant co-variables”.

Finally, some language corrections have taken place.