Author's response to reviews

Title: Effects of nurse-led Motivational Interviewing of patients with chronic musculoskeletal pain in preparation of rehabilitation treatment (PREPARE)-Concepts and study design of an RCT on societal participation, attendance level and cost-effectiveness

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Author's response to reviews: see over
Author's covering letter for initial submission

Title: Effects of nurse-led Motivational Interviewing of patients with chronic musculoskeletal pain in preparation of rehabilitation treatment (PREPARE)-Concepts and study design of an RCT on societal participation, attendance level and cost-effectiveness

Authors:

Version: 1 Date: 17 January 2013

Comments: see over
Dear Editors-in-Chief,

Hereby you will find our adapted manuscript “Effects of nurse-led Motivational Interviewing of patients with chronic musculoskeletal pain in preparation of rehabilitation treatment (PREPARE) - Concepts and study design of an RCT on societal participation, attendance level and cost-effectiveness” which we re-submit for publication in *Trials.*

We would sincerely like to thank the reviewer for his excellent and constructive content of his review, and do find by adapting the manuscript accordingly, the quality of the manuscript has clearly improved.

Next we will point wise discuss the adaptations we have made to the reviewer’s comments:

**Title**

We changed the title to “Effects of nurse-led Motivational Interviewing of patients with chronic musculoskeletal pain in preparation of rehabilitation treatment (PREPARE) - Concepts and study design of an RCT on societal participation, attendance level and cost-effectiveness”. This is slightly in line with your suggestion.
Participation

The reviewer is right; the commonality of the word participation may cause confusion. As the literature uses ‘participation’ meaning societal participation according to the ICF criterion, we have chosen to explain the used handled definition in the background section. Furthermore, we have added in the abstract that we use the meaning of participation according to the ICF definition. We are now using the word participation throughout the whole manuscript. To be in line with the ICF model, we also changed the term disability towards ‘level of performing daily activities’.

Aims

Formulation primary objective

The formulation of the primary objective is revised. Now, we are focusing on the evaluation of the Prepare study and the effectiveness of the MIP-intervention instead of (cost)effectiveness of this. Evaluating the cost-effectiveness is another aim, but is no longer pronounced as main aim of our study.

Methods

2.4 Sample size

We recognize that this part of the manuscript is not well described. Therefore, the description of the sample size is adapted. As our study is explanatory regarding the use of the USER-P questionnaire, which is our participation-based primary outcome, we have no norm values yet. Also, the clinically relevant change is not known yet. We expect to be able to demonstrate a medium standardized effect size (difference between groups divided by within-group standard deviation) by recruiting 160 participants in our trial. Question 1: The USER-P has three separate scales, each scale is equalized and there is no total score. We have adapted the description by referring to a 10-point change in the subscale Satisfaction. Furthermore, we have extended the description of the USER-P in the primary outcome section. Question 2: As we have no norm values of the USER-P yet, we rely on van Tulder et al. (2000). They found a moderate effect size of behavioral treatments in low back pain. Therefore, we assume a moderate standardized effect size (Cohen’s d) of approximately
0.5 also as a result of our intervention. Therefore, we expect to be able to demonstrate a medium effect size by our chosen sample size.

We agree with the reviewer that the current level of the USER-P can be obtained from the control arm UC. We will make use of this within the Prepare trial. Furthermore, by doing so, it will be possible then to judge the feasibility of our sample size calculation.

2.5 Blinding
The participants of the Prepare trial are not obliged to remain silent about their participation in the Prepare pre-treatment. As patients did not receive a pain rehabilitation treatment in our department before, it is impossible for them to recognise whether they received usual care or MIP. In the information letter both possibilities are presented as two different types of interview, education and counseling sessions. We do therefore not expect that patients can identify which interview is either UC or MIP. To be clear about the situation of blinding, we have added in the methods section of the manuscript that patients are not blinded for study participation but for allocation.

2.6 Treatment
The section is revised to increase clarity. Therefore, the structure of the sub-headings and the order of the description MIP and UC has changed.

Data collection
Reviewing our manuscript it became clear, that we did not give the accurate information about the timing of assessment moments in usual care: We did not describe that also T3 (start of the rehab treatment) is an assessment moment in usual care. The choice to include two other assessment moments compared to usual care was made because we deem them necessary for study objectives. One assessment moment takes place after the two pre-treatment sessions. This is an important moment for our study to check upon the level of self-efficacy, motivation, and some more psychological parameters. The second assessment moment added to usual care takes place 6 months after finishing the pain rehab treatment (called ‘T4’ in our study).
Furthermore, we have added in the manuscript, that the assessment moments t2 and t3 are variable due to clinical practice, changing waiting times, and individual needs of the patient. To illustrate this, table 2 is also adapted.

Furthermore, we agree that a long-term follow-up of 52 weeks would be preferable compared to 24 weeks. Logistical and financial restraints let us choose for a follow-up of 24 weeks after the rehabilitation treatment.

Regarding the remark of questionnaire fatigue: Participants are precisely informed that they have to answer questionnaires at five points in time which takes around five hours in total. We hope to prevent questionnaire fatigue by creating accurate expectations about this part of study participation.

Figure 1
In figure 1 the assessment moments T0-T4 are described in the legend. The figure is in English now.

Minor revisions
All your suggestions in your review containing minor revisions have been implied and marked by underlining.

References
All references are changed according to the Trials bibliography style.

Competing interests
The source of funding is added now.

Table 2
Table 2 is adapted and the usual care assessments are illustrated now.

We believe the paper may be of interest to readers of Trials, because our RCT describes the design and rationale of a Motivational interviewing based pre-treatment. As we lay emphasis on sufficient training and integrity of the provision of MI in the specific field of pain rehabilitation, our approach is rather unique. Furthermore, we think that our
intervention and its specific elements are not only applicable to the field of pain rehabilitation, but can be generalized to other settings as well as other diseases. We hope that the changes according to your comments are satisfactory for the acceptance of our manuscript.

The manuscript has not been published and is not under consideration for publication elsewhere. There is no conflict of interest.

Yours sincerely,
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