Reviewer’s report

Title: (Cost-)effectiveness of PREPARE (PRe-PAin REhabilitation), design of a Motivational Interviewing (MI)-based nurse-led intervention in patients with chronic musculoskeletal pain, a RCT

Version: 1 Date: 18 November 2012

Reviewer: Rolf Wahlstrom

Reviewer’s report:

BMC Trials

Review

(Cost-)effectiveness of PREPARE (PRe-PAin REhabilitation), design of a Motivational Interviewing (MI)-based nurse-led intervention in patients with chronic musculoskeletal pain, a RCT

Reviewer: Rolf Wahlström

General

The study aims to test the hypothesis that patients with chronic musculoskeletal pain selected for rehabilitation treatment, who take part in a preparatory motivational interview (MI) with specific technique, will increase their level of societal participation compared to the same type of patients, who take part in a concurrent standardised preparatory interview. The point of outcome measurement is six months after the end of the rehabilitation treatment; the same for both groups.

Secondary, it will be tested whether non-adherence to the rehabilitation treatment and drop-out rate will decrease significantly in the intervention arm compared to the control arm.

Thirdly, data will be collected for cost-effectiveness and cost-utility analysis.

Fourth: a process evaluation will be conducted.

Major revisions

Title

The title is misleading and must be changed. It is not appropriate to start with a bracket. The title does not give a clear understanding what the study is about.

Suggestion:

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

“Participation”
In my assessment, the authors need to revise the usage of the word “participation” throughout the article. I will justify my recommendation by looking at the use of the word in the Abstract.

Background and Objective: The stated justification is that the “non-adherence and drop-out are major problems in pain rehabilitation” and that MI might “tackle these problems”. However, the objective states that the aim is to achieve “an increase in the level of societal participation and decrease of drop-out”. The word “participation” is here used as one of the components of Functioning and Disability according to ICF, where it is defined as “involvement in a life situation”, although this is not mentioned until the Discussion part of the main text. The commonality of the word participation may cause confusion, as it might be interpreted as participation in the pain rehabilitation treatment itself.

In my view, it would be quite easy to avoid this potential confusion, for example by adding “societal” wherever it is not totally clear what is meant. An alternative could be to define the term in detail in the beginning of the article (and in the abstract).

Aims

– The formulation of the primary objective should be revised. In my view, the primary aim is to determine whether MI (or more precisely: MIP) is effective in relation to the primary outcome. Cost analyses are secondary.
– 1.1.2: “MI),” should be “MIP”

Methods

2.4 Sample size

– This part must be clarified in more detail. It is clear that the calculation is based on the primary outcome measurement: the Utrecht Scale for Evaluation of Rehabilitation – Participation (USER-P). The calculation is based on the assumption that there will be a mean positive change of “10 points” in the intervention arm and “five points” change in the control arm. However, it is not mentioned what the “points” refer to.

Question 1: The USER-P has three separate scales (according to Post et al, 2012 (reference #50): Frequency (12 items = 4 items for vocational activities; 8 items for social and leisure activities); Restrictions (10 items); Satisfaction (9 items). Each scale has a sum score, which is equalised to minimum 0 and maximum 100. There is no total sum score in USER-P according to Post et al. It is therefore not clear to me what “10 points” refer to.

Question 2: What is the assumption of a change of “five points” in the control arm based on? The “intervention” in the control is as described the current recommended treatment model and it would therefore be possible to measure the current level of USER-P in this population, with the advantage of having accurate data and a much “safer” sample size calculation.

2.5 Blinding

Can the patients really be blinded? At least some will understand that they are
encountering a new style of dialogue with the nurse. And if patients know they may tell the rehabilitation team. Will patients be instructed not to do that?

2.6 Treatment

This section is not clearly structured as sub-headings are partly numbered, partly in bold. Should there be three main sub-headings: Current care in pain rehabilitation; PREPARE conditions (with two further sub-headings: MIP intervention condition; Usual care); Nurses? My recommendation is that this whole section is revised to increase clarity.

The authors should comment why six months post-treatment was chosen for assessment instead of the three and twelve months already included in the usual care structure. Isn’t there a risk of questionnaire fatigue among the patients with all these different forms at relatively close proximity?

Figure 1:

Could be clearer and include more information.

Not necessary to show box with “No indication for treatment” as it is not part of the study to assess these numbers.

Delete Dutch word (TIJD).

Add time for components; Explain T0-T4 in figure or legend

Minor revisions

General: Use British spelling consistently. Avoid paragraphs with one sentence in running text. Conduct proper proof-reading to avoid spelling and spacing mistakes (both between words and lines). Pages should be numbered.

Abstract:

Study design – it is recommended to use the term intervention only for the MI arm as the other arm follows standard care.

Objective – Delete “(cost)”.

“Main study parameters/endpoints” – Replace the slash sign with the appropriate word: the reader should not guess if you mean “and” or “or” or something else.

– Primary outcome: Should be the “change in level”

– Please clarify the description of the first mentioned secondary outcome: “adherence/ treatment drop-out”.

Keywords:

It is generally not necessary to repeat words in the title among the keywords.

“Patient Compliance” should be revised as the word “compliance” has become quite obsolete in current scientific terminology. Make similar change in the main text (7th paragraph in Background).

Background:

3rd paragraph, 1st sentence: “learn” is used incorrectly. Change to “teach” or something like “engage the patient in a learning activity”.
Methods:
2.9.5 Possible moderators, 2nd paragraph: The sentence starting: “The credibility and the patient’s expectancies …” is not clear;
-- 3rd paragraph, 2nd sentence: should be “… in treatment.”
2.1 Statistical evaluation; Economic evaluation; 1st paragraph, 3rd sentence: change to “observed costs will be …”

Discussion:
1st paragraph: not needed as it is already described in Methods

Funding:
Source of funding should be stated, even if it is internal.

References:
Needs to be revised. There are several errors.
The journal’s Instructions have not been followed in two aspects:
All authors’ names up to 30: Ref #9,93
Titles of books and reports should be in italics not bold: #5,16,38,61,62,63

Other errors:
Journal name missing: #6,8,10,23,27,34,51,56,58,65,66,78,7,82,89,96
Journal name not abbreviated: #44,74,94
Publisher missing: #36,40,57
Place of publication missing: #63
Words in titles should not be capitalised: #44,53,79
BMJ should be capitalised: #3,4 (compare #84, where it is correct)
All non-English text should be translated: #34,38,53,62,80,88
Specifics: #61 (title should be in italics and not bold), #63 (delete “pp. 1-28”), #64 (reduce to two initials per author as in other references by same authors; only two initials in the author list in the article), #77 (clarify “R.A. S”; should it be “Steer RA”?), #88 (source of publication missing)

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare I have no competing interests.