Web references [posted as supplied by author]


w11 Feldstein A, Valanis B, Vollmer W, Stevens N, Overton C. The Back Injury Prevention Project pilot study - Assessing the effectiveness of back attack, an

Responses to the comments from the editorial meeting and the referees:

* the research question needs further clarification to explain why a systematic review is needed when the primary studies already give the same message

Answer:

We added the following sentences in the end of the introduction section:

"Even though primary studies have not found an effect of training on the incidence of back pain, this could be incidental or due to small sample size. Therefore, it was important to make a review following the systematic and more rigorous Cochrane methodology in searching the literature, selecting interventions and study designs, as well as combining the results."

* please update the review to include the paper cited as reference 15: the full results have been available for a while now, and including it would further strengthen the message as it too showed no benefit

Answer:

According to the evidence that we obtained, this study or any part of it does not meet the inclusion criteria, and it was excluded from the review. The study reports on two cross-sectional surveys and not on a prospective cohort, and no additional data was obtained for the prospective cohort from the author.

* please clarify what outcome(s) the effect sizes actually relate to in fig 2

Answer:

We corrected the legend accordingly:

"For comparisons with similar interventions but with both dichotomous and continuous outcome measurements, we calculated an effect size based on the logarithm of odds ratio for studies with dichotomous outcomes, and on the standardised mean difference for studies with continuous outcomes."

* also please clarify how the quality score was derived and why a threshold of 6 on the score was chosen to denote adequate quality.

Answer:

This has been clarified in the manuscript:
"The methodological quality of the randomised trials was independently assessed by two authors (KPM, JV) using the criteria and classification recommended by the Cochrane Back Review Group [10]. Quality of the study was considered as high, if more than half of the criteria were fulfilled. For the appraisal of cohort studies, another instrument [13] validated for non-randomised studies was used."

Technical editors' comments on style and format:

* please use a new line for each author's address
  
  Answer: changed

* we do not use abbreviations - please spell out MMH, RCT, etc
  
  Answer: changed

* please put the included studies into a separate reference list for publication only on bmj.com (numbered w1, etc) - there's more info below on this
  
  Answer: changed

* in the reference list, please use italics for journal titles and delete the issue numbers in parentheses.
  
  Answer: changed

*.Please follow our style for listing the references. All studies that have been systematically reviewed should be given in a separate list of web references, and these web references should be used throughout the text, tables, and figures -- eg w1, w2, w3 etc in superscript in the paper (but "on the line" in the list of references). These web references should be listed in the order they appear in the text. The list will be “posted as supplied by author” onto bmj.com.

The numbering of web references in the text will not be changed during editing. Other references will remain as normal. Individual references must not have both a "normal" number and a web reference number -- ie, references should appear in one list only (NOT both).

  Answer: changed

* Please write the discussion section of your paper in a structured way to minimise the risk of careful explanation giving way to polemic.

  Answer: changed
1. The review is about prevention which normally presumes that participants are free of the condition at baseline. This is clearly not the case in the van Poppel and Yassi trials, unlikely in Mueller given the title, and unclear in the other trials. I think this needs to be made clear to readers.

*Answer:*

Yes, we were confronted with the problem that no population is free from back pain. Thus prevention would never be possible. Therefore, we chose a different interpretation of prevention as offering an intervention to persons that were not actively seeking for treatment. We added a sentence in the manuscript under description of study characteristics:

"We had originally intended to include only prevention studies with workers without back pain. However, this proved to be too impractical because there were always a varying proportion of workers already suffering from back pain at baseline. Therefore, we changed this inclusion criterion to studies with workers who were not actively seeking treatment for current back pain."

2. The data in Figure 2 are unclear because there is no legend. It appears from the text on page 9 that the authors have used Chinn’s method of converting odds ratios to effect sizes. I do not believe that this is a particularly helpful transformation in this case and I would advise against it for the following reasons.

a. Chinn advised the use of this approach to permit meta-analysis, but as no pooling was undertaken for the data in Figure 2 it could be said there is no need to transform the data this way.

b. Chinn advised the use of this approach to allow pooling of continuous data and dichotomised continuous data for the same outcome. This is clear in the example in the Chinn paper related to blood loss. The authors appear to apply this approach to quite different outcomes such as intensity of back pain and injury rates. Describing conceptually different outcomes on the same unit-less scale does not make sense to me. Additionally this approach has made the results quite unclear. When I am reading the results of a trial that is aiming to prevent an injury I would like to see the control injury rate and experimental injury rate and a summary measure such as the odds ratio. I think readers will find it hard to appreciate the results if all that is presented is the log of odds ratios.
As stated above, all the effect sizes were ln(OR) except for Müller where it was mean diff/sd. We would like to thank the reviewer for pointing out our mistake: we forgot to divide by 1.81. However, all the outcomes were conceptually the same: all indicating some rate of back injury or frequency of back pain, but measured in different ways (as number of episodes per month (van Poppel), frequency on a VAS scale (Müller) or as an injury rate). Different cultures exist in the reporting of back pain recurrence; injury rate is used in the UK and North America, whereas frequency of back pain is mainly used elsewhere. Based on the referees' comments, we decided to leave the study by Müller out and present the results of the rest of the studies as odds ratios. Only for the disability studies we still used the effect-sizes.

c. An additional problem is that many of the trials have multiple back pain outcomes and it is unclear which one, or ones, were used to create the summary effect size for that trial. For example the authors summarise the advice vs no advice contrast in the van Poppel trial with an effect size of 0.01 (-0.51 to 0.52) and this study had four back pain outcomes: number of subjects with low back pain, number of days per month with low back pain, number of subjects with sick leave because of low back pain, number of days per month of sick leave because of low back pain. What one was used?

Answer:

Apologies for being so unclear here. We hope that the corrected legends have solved the problem.

I think the authors should present the original results of the trials because they are more meaningful. To be quite honest I found it much more informative reading the short section of text in each study that contained the results.

Answer:

We have left the effect-sizes out in the main graph presenting the results (Figure 3). We hope that this solves the problem.

3. I think the authors need to be more accurate in their description of the interventions. They have used brief phrases that often omit key components of the intervention. I will demonstrate this with the description of the Daltroy trial. The experimental intervention is described as ‘Training and ergonomic site visit’ in Table 1 and the training is described as ‘proper lifting and carrying
techniques’ in Table 2. The trial described the training curriculum as “…principles of back safety, correct lifting and handling, posture, exercises, and pain management…”. Additionally there were multiple ergonomic site visits, not just one.

*Answer:*

We admit, that due to short descriptions of the interventions in the original studies and the limitations in the length of the review, the interventions are described only briefly. Tables 1 and 2 support each other in giving as informative picture of the intervention as possible. We tried to describe especially the part of the training that aims at a change in the lifting technique. In Table 2, the possibility of multiple ergonomic interventions has now been included.

4. I would prefer to be told the items in the methodological quality scales and be given the score for each item, not just a total score. Many people do not believe that it is sensible to sum the components.

*Answer:*

We added a reference to the full review in the Cochrane Library, where this information can be found.

5. Can you explain how rater disagreements were resolved.

*Answer:*

We added in the end of "selection and validity assessment":

"Disagreements between assessments were resolved by discussion until consensus was reached."

6. It is unclear why you pooled the disability data in Figure 3 but not the same studies in Figure 2. Could this be explained please. I also do not understand what data from these two studies were considered disability data. I can see Oswestry scores in the Yassi trial but could not find anything similar to this in the van Poppel study.

*Answer:*

The reviewer is correct here that this was a bit unclear. It was due to the software that did not allow us to show some subtotals only. We have solved this now by presenting three figures: a meta-analysis for the back pain/injury outcome, the individual studies and a meta-analysis for the disability/sickness absence outcome.
7. I checked one effect size in figure 2 and it appears wrong. I cannot replicate the numbers for Kraus advice versus no advice. Following Chinn’s method I get -0.08 (-0.24 to 0.07) whereas the authors provide -0.15 (-4.48 to 4.19). Inspecting the point estimate I think the authors have calculated the ln(odds ratio) whereas Chinn advises to calculate (ln(odds ratio))/1.8. Even allowing for the failure to divide by 1.8, I do not understand why the confidence interval is so broad and spans implausible effect sizes for such a large study. Can the authors please recheck their data.

Answer:
This has been corrected.

8. One issue that is not discussed is that the control event rate is markedly different in the studies. In Kraus it was 1.5% and in the van Poppel study it was 35%. These sound like very different cohorts to me or very different definitions for an episode of LBP. I think this issue needs to be considered.

Answer:
We added a sentence in the discussion:
"As a limitation of our review, the measurement of the outcomes in the primary studies varied leading to considerable differences in the incidences of back pain (1.28 per 100 person years for back injuries in Kraus’ study\(^4\), 7.4 per 100 person years for back related injuries in Yassi’s study\(^6\), and 70 per 100 person years for self-reported back pain in van Poppel's study\(^5\))."

9. The authors quite correctly say that the data they present are imprecise and the review lacked power however I do not understand how they can then conclude that a type II error is unlikely. Could they explain the basis for this assertion?

Answer:
We changed the text in the discussion section to the following:
"The confidence intervals show that we cannot exclude the possibility that the studies and the review lacked the power to detect a small but possibly relevant difference in incidence. However, almost all studies showed an odds ratio that was near to one and the comparisons were all quite similar, especially when taking into account that back belt use is comparable to no intervention in preventing back pain [18]. This makes it highly unlikely that, even if it had been possible to pool the results of more studies, this would have led to a significant
beneficial effect. Only one study \cite{6} showed a more positive, but still non-significant, outcome. This could possibly be related to the type of the intervention being different from the rest ("no strenuous lifting")."

10. Could the authors provide more descriptive legends for all figures and tables?

   Answer: Corrected

11. The opening sentence, that manual material handling at work results in an increased risk of back pain, is attributed to Kuiper et al. Kuiper was actually less definitive than the authors. She wrote in the abstract

   “The amount of evidence on the risk of exposure to combined manual materials handling was only moderate. It was concluded that, based on the criteria applied in this study, epidemiologic evidence for manual materials handling as risk factor of back disorders is present, but largely based on cross-sectional studies with inherent methodological weaknesses. More longitudinal studies need to be performed in which special attention is given to accurate exposure measurements, valid assessment of back disorders, and dose response relations.” I think the authors need to be more careful in their citing and also allow readers to know that the injury model for LBP is not universally accepted. There are many who believe that low back pain is not due to a physical injury (eg see paper by Fraser in latest issue of Spine). This would explain why injury prevention strategies as summarised in this review do not seem to prevent episodes of low back pain.

   Answer:

   We added a sentence in the introduction and came back to this in the discussion.

   Unfortunately we could not find the given reference.

   "Manual material handling at work increases the risk of back pain \cite{1}. Even if this has not been universally accepted, optimal working techniques are emphasized to prevent back pain and injuries in case manual handling of heavy loads or patients cannot be avoided \cite{2,3}."

12. The authors need to note what their review adds to previous reviews. What does this study add to the existing literature?

   Answer:

   We made the before mentioned addition in the introduction:
"Even though primary studies have not found an effect of training on the incidence of back pain, this could be incidental or due to small sample size. Therefore, it was important to make a review following the systematic and more rigorous Cochrane methodology in searching the literature, selecting interventions and study designs, as well as combining the results."

13. The authors should explain why they omitted two education RCTs included in the van Poppel review. They should explain why they omitted two other RCTs included in the Bos review. There could be good reasons for this but the reader needs to be told this given the small number of RCTs included.

*Answer:*

*They did not fulfil our inclusion criteria:*

*Because the main focus of education in some of the included studies was other than MMH advice and MMH assistive devices, only two RCTs (Daltroy 1993; Reddell 1992) and one non-RCT (Feldstein 1993) are included in both van Poppel 1997 and the present review.*

*The review by Bos (2006) included 13 studies. Compared to the present review, four of them (Fanello 1999; Feldstein 1993; Hartvigsen 2005; Yassi 2001) are included, three (Lynch 2000; Videman 1989; Wood 1987) are excluded (Lynch and Videman studies did not have concurrent control groups, the Wood study had not sufficient information), and six more studies were not eligible (study design was not appropriate, MMH advice or assistive device was not the main intervention, or required outcomes were not measured).*

**Reviewer 2 Comments...**

Name: Niels Wedderkopp

Position: Consultant, The Back Research Center, Ringe, Denmark

Review of Training and assistive devices for preventing back pain in manual material handling: systematic review

By: Kari-Pekka Martimo, Jos H Verbeek, Jaro Karppinen, Andrea D Furlan, Esa-Pekka Takala, Paul FM Kuijer, Merja Jauhiainen, Eira Viikari-Juntura
•Originality — does the work add enough to what is already in the published literature? The work is original, and summarises the best research knowledge inside the area of interest.

•Importance of the work to general readers — does this work matter to clinicians, patients, teachers, or policymakers? Is a general journal the right place for it? The work is important to the general reader. To me there are two important facts 1. Only six randomised studies has been performed in on an important topic 2. No positive results with an effect of an intervention has been found.

This manuscript should be published in a general journal. Back problems is a "disease" that is very common, and the general practitioner has several of these patients in his clinic. It is important new knowledge for him or her and will be important in the guidance of his or her patients.

•Scientific reliability: The research question is clearly defined and appropriately answered. The overall design of study is adequate. The studies included are adequately described and their strengths and shortcomings described in a clear and adequate manner.

The methods are well described and follow the Cochrane instructions.

The results adequately answer the research question, and are well presented.

The interpretation and conclusions are straight forward and warranted by and sufficiently derived from the data.

The message from the manuscript is clear.

The references are up to date and relevant, and I find no glaring omissions.

The abstract accurately reflects the message of the manuscript.

In conclusion in my opinion the manuscript merits publication in BMJ.

Answer:

We are happy with the positive comments

Reviewer 3 Comments...

Name: Simon French

Position: Research Fellow, Australasian Cochrane Centre

The review was assisted by Ms Hayley Barnes, Research Assistant, Australasian Cochrane Centre

General comments
Overall this is a very well conducted systematic review of a widely used intervention for an important and common health condition (low-back pain). It adds significantly to what is already known. It is an important work to clinicians, consumers, researchers and policymakers. Because this review is adapted from one published in the Cochrane Library, our main concerns, we suspect, relate to how the review has been reduced in size to fit within BMJ guidelines and there are areas that have not transferred all that well to this new format. We outline our concerns below.

Specific comments
1. In the Introduction the authors build an argument that this intervention (MMH) is common practice, however only cite data from the European Union. It would be useful to provide evidence of its wider use in other parts of the world, eg North America, Australasia.
   
   *Answer:*
   
   *Reference to EU has been deleted and an example of NIOSH recommendations is added*

2. The search strategy is not included and thus is not reproducible by readers. This should be available, and if proceeds to publication perhaps the full strategy available as an online supplement. At a minimum the text should include the search terms used for the intervention because this is not available in the paper cited.

   *Answer:*
   
   *We added a reference to the full review in the Cochrane Library.*

3. The search date for the review is November 2005. If this manuscript proceeds to publication then the review will probably be at least two years out of date. Can the authors perform an updated search? If a full update of the review is not feasible, then one option may be that the authors conduct an updated search and provide some details of studies that would be included in a future review.

   *Answer:*
   
   *Cochrane methodology requires that the literature search is made in a systematic way. Therefore, we cannot include newer studies if they are not results of a systematic search and accepted independently by two researches. This process, however, is very time consuming. Therefore, we have added and discussed later studies in the discussion part of the review.*
"Two randomised controlled trials have been published recently lending support to the results of this review. One showed no effect of transfer technique training on back pain among eldercare workers after two years follow-up [20]. In the other trial, behaviour-based lifting training in a distribution centre did not result in a difference in back injury rates during one year follow-up [21]."

4. It is not clear as to the difference in the authors’ classification of “CCTs” and “prospective cohort studies with concurrent control groups”. Could all of these studies come under the heading of “non-randomised studies”? The use of the term “cohort” is confusing.

   Answer:
   Controlled clinical trials are intervention studies with a comparison group, but the assignment to the groups has not been properly randomized, whereas in prospective cohort studies no randomization is even attempted. In order to avoid confusion, we left reference to CCTs out of the review, as none of them were found.

5. Under heading “Validity assessment”, the authors state “using the criteria recommended earlier (9)”, however this criteria is not mentioned earlier. The paper is cited previously but in a different context.

   Answer:
   Clarified as follows:
   "The methodological quality of the randomised trials was independently assessed by two authors (KPM, JV) using the criteria and classification recommended by the Cochrane Back Review Group [10]."

6. On page 9 the authors write “We assumed that the interventions would have a similar working mechanism among nurses handling patients and workers handling luggage or mail”. The point of this sentence is not clear, and a statement about the intervention more broadly would be preferred.

   Answer:
   Clarified as follows:
   "In all jobs studied, the participants had sufficient strain on the back leaving ample room for alleviation by effective interventions."
7. Page 10. Statement “After two authors (EPT, JK) screened the titles and abstracts for eligibility…” should be in methods because when reading the manuscript it wasn’t clear this was carried out until this point.

   Answer:
   Changed

8. Table 2 refers to the use of Burke classification of the training methods used. However this classification is not referred to in any other aspect of the manuscript. A comment in the methods about its utility and validity would be helpful.

   Answer:
   Comment added in discussion:
   "According to Burke et al. [19], as training methods become more engaging, workers show greater knowledge acquisition and reductions can be seen in injuries. Following Burke, we classified the training methods based on learners’ participation, but we did not find a more positive outcome for studies that involved more intense training methods."

9. Presentation of results under heading “Quantitative data synthesis”. The presentation of the results could be improved. Because there are no subheadings, it is not immediately clear how the results are being presented. Is it by comparator, by type of intervention, or what? At the moment, this section feels like the results are just being presented in a simplistic way, ie this RCT showed this, this one showed that, etc. Perhaps the results from this section could tabulated and some summary text could refer to this.

   Answer:
   Quantitative data synthesis as well as Table 3 has been revised according to the comments.

10. Discussion 1st paragraph. The term “biomechanical back strain” is used here for the first time with no explanation of its meaning. A more appropriate term or a discussion of this would be appropriate.

   Answer:
   This has been changed to strain on the back.
11. Discussion 1st paragraph. The authors say “The results of all included studies were negative…” however the results were not “negative”, the studies showed no effect.

   Answer:
   Changed to "showed no effect".

12. Page 14. Results about compliance are presented here for the first time. Move to results section.

   Answer:
   Changed according to the referee's suggestion.

13. In concluding paragraph authors say “There is a need for more high quality research in this area”. More specific direction would be useful for other researchers.

   Answer:
   This part has been revised:
   "There is a need for more and high quality research which should incorporate a better standardised outcome measurement, appropriate power, taking into account the cluster effect, and they should be directed at a "no lifting policy"."

14. There is no comment about the heterogeneity of the included studies, in particular the study populations and interventions used. It would be useful for the authors to comment on this heterogeneity and how they think this might have affected the results.

   Answer:
   We changed the text in the discussion section about most comparisons not being really different and yielding very similar results except for one that appears to different. See comment 9 reviewer 1.

15. At the beginning of the 2nd paragraph for the Discussion, it would be useful to have an opening comment for clarity about why the authors believe that no effect for the intervention was shown.

   Answer:
   We added the following in the discussion section:
   "This is because the advocated techniques do not actually reduce the risk of back injury, or training does not lead to adequate change in manual handling technique."
16. The title for Table 3 is confusing.

   Answer: *We have done our best to improve the legends of the tables and figures*