Dear Dr. Richard Sands,

We have now revised the manuscript (bmjopen-2011-000412) entitled "Effect of specific resistance training on forearm pain and work disability in industrial technicians: Randomized controlled trial" according to the review comments.

Comment from the managing editor:
Further to the reviewers' comments below, we would also like the reporting of the trial to be more transparent and thorough.

In particular, how does it overlap with ref 15, which is in press at a BMC journal? Is that just reporting the baseline results? There should now be a reference for this if it has been accepted (at least a DOI?).
OUR REPLY: Ref 15 provides information on the baseline population and results from the intervention on neck/shoulder pain. Thus besides some of the baseline results there are no overlap between ref 15 and the present results. Ref 15 has now been accepted and published, and the ref has been updated in the reference list of the present manuscript.

Comment from the managing editor:
Although BMC journals are open access, it's unhelpful to refer readers there for all the details of randomisation etc. Please revise the paper in line with the CONSORT statement for cluster randomised trials (eg on method of random allocation, allocation concealment, and blinding). It's at http://www.consort-statement.org/extensions/designs/cluster-trials/
OUR REPLY: We have now provided this information in a new section, "The cluster randomization procedure" in the Methods.

Comment from the managing editor:
The completed CONSORT checklist is the generic one, and doesn't cover cluster RCTs. It should also only state what is explicitly reported in the paper - for example it states that various aspects are reported on p5, whereas this is actually the BMC reference.
OUR REPLY: We have now checked this more carefully and used the checklist for cluster RCT's. The checklist is uploaded as a supplementary file.

Comment from the managing editor:
Finally, please structure the abstract in line with CONSORT.
OUR REPLY: We have now structured the abstract in line with CONSORT.

Comment from the managing editor:
The contributorship statement says that all authors drafted the protocol. However, authorship should meet all three criteria as laid out by the ICMJE: http://www.icmje.org/ethical_1author.html
OUR REPLY: We have now checked this more carefully and changed accordingly.

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Reviewer: Anna Sjörs

Senior Developer
Institute of Stress Medicine
Göteborg, Sweden

The study design and execution seem sound. There are, however, some important details missing in the methods section. Please provide details on the randomization, the procedure for exercise intervention, and the adherence to the protocol (see below).

Comment from reviewer Dr. Anna Sjörs:
An inherent problem with this study is the focus on reducing pain and disability in a population with already low pain and disability scores. If the exercise program is, eventually, intended for treatment of pain in patients with a diagnosed pain condition, the current study population is not representative of actual patients that would receive the treatment. One cannot generalize these findings to a population with more severe pain. The authors argue that the exercise intervention may still be important from a public health perspective. I would like to see a more thorough discussion to justify this statement. If, on the other hand, the main focus is to prevent development of pain in healthy workers, I believe that 20 weeks is a rather short intervention time period, which the authors have addressed briefly in the discussion.
OUR REPLY: It is true that this working population has a relative low mean pain rating. This is why we have conducted a sub-analysis among those with a pain rating greater than 30 mm VAS at baseline. This group approaches pain patients and shows to have particular benefit from the training by having an odds ratio (OR) for complete recovery at follow-up in the training group compared to the control group of 4.6 (95% CI 1.2 to 17.9). This finding is even more convincing regarding the analysis on a sub-group regarding disability. These analyses underline the relevance of this study also for patient groups.

Article summary

Comment from reviewer Dr. Sjörs:
1. Please change arm/hand to forearm pain since hand pain was not the focus of this study.
OUR REPLY: This has now been changed

Introduction

Comment from reviewer Dr. Sjörs:
2. The numbers given on incidence and prevalence of forearm pain are from 2003 and may not apply to the current study population. Please provide more recent data or soften the statement to indicate that the percentages may have changed.
OUR REPLY: We have now softened this statement.

Methods

Comment from reviewer Dr. Sjörs:
3. Information on the number and percentages of subjects with pain and disability > 3 could be given in table 1.
OUR REPLY: We have now added columns to Table 1 showing baseline characteristics of pain-cases and disability-cases for the control and training groups, respectively.

Comment from reviewer Dr. Sjörs:
4. Please provide details on the randomization procedure.
OUR REPLY: We have now provided this information in a new section, "The cluster randomization procedure" in the Methods.

Comment from reviewer Dr. Sjörs:

5. Please provide more details on how the training was performed. Individually or in groups? Were the participants able to choose location and time of day?
OUR REPLY: We have now provided detailed information of this in the section, "intervention" in the Methods.

Comment from reviewer Dr. Sjörs:
6. Please also give information on adherence to the protocol. How was this monitored?
OUR REPLY: This was monitored by weekly logbook registrations. This information has now been added to the manuscript.

Comment from reviewer Dr. Sjörs:
7. The choice of cut-off for pain cases seems arbitrary and needs to be justified.
OUR REPLY: Kaergaard and coworkers found that for four complaint questions on a 10-point scale a sum of 12 (i.e. average 3 for each of the four questions) was significantly associated with clinical findings. Because we used scales from 0-100 we then used a cut-off at 30. We have now explained this in "Forearm pain and work disability" in the Methods section.

Comment from reviewer Dr. Sjörs:
8. Likewise, justify the cut-off for disability cases.
OUR REPLY: We used the same definition and rationale for disability cases as for pain cases.

Comment from reviewer Dr. Sjörs:
9. How were the individual regressions of pain over time used in the analyses? Were they entered in the GLIMMIX analyses? I cannot find the results of these regressions.
OUR REPLY: we used linear regression for each participant to estimate the trend over time, and thereby determined the change from baseline to follow-up by multiplying the slope with the number of weeks. The individual changes from baseline to follow-up were then entered in the GLIMMIX procedure. This has now been specified in the Statistics section.

Results

Comment from reviewer Dr. Sjörs:
10. Please specify the number of pain cases in each group and not just the total number of 54 pain cases (could be presented in table 1, as suggested above).
OUR REPLY: This information has now been added to Table 1.

Comment from reviewer Dr. Sjörs:
11. Specify the number of disability cases in each group accordingly.
OUR REPLY: This information has now been added to Table 1.

Comment from reviewer Dr. Sjörs:
12. Please report the mean pain and disability scores among cases at the start of the study.
OUR REPLY: This information has now been added to Table 1.

Comment from reviewer Dr. Sjörs:
13. As more of a comment, I would like to point out that Figure 2 is somewhat misleading as the VAS on the Y-axis actually ranges from 0 to 100. Changes in pain scores appear larger than they actually are.

OUR REPLY: True. We have now mentioned in the legend of Figure 2 that the scale ranged from 0 to 100

Discussion

Comment from reviewer Dr. Sjörs:
14. Please clarify if the prevalence of pain and disability (10 % and 21 %) concerns the total population or one of the subgroups.
OUR REPLY: This concerns the control and training group together. This has now been specified and discussed in relation to the generalisability.

Comment from reviewer Dr. Sjörs:
15. The choice of and discussion of the limit of clinical relevance is somewhat confusing. The sample size calculation uses the limit 15 % change in pain (no reference) as a relevant change. Does this refer to a 15 % difference between groups in pain improvement or to a 15 % change within group? This should be clarified as the comparison between groups in pain improvement is essential, given the study design. In the discussion, however, a reduction of 20 mm (within the training group) is considered clinically relevant (without relating it to the concurrent change in the control group). Since the mean pain intensities among cases before and after the intervention and percentage of change in pain are not reported, it is not possible to relate the results to the given limit of 15 %.
OUR REPLY: The sample size calculation was performed prior to the study and was based on a 15% change as the least relevant change. In hindsight, this calculation should have been based on actual changes between groups rather than percentage change. However, to allow sufficient power even in a cluster randomization design with cluster size below 10 we doubled the number of partipants in both groups resulting in approx. 30 clusters and in each group with a total sample size of more than 500. We have now added the calculations for the sample size regarding cluster considerations in the manuscript, and also in more detail the aspect of clinical relevance in the Discussion.

References

Comment from reviewer Dr. Sjörs:
For the discussion of clinical relevance I recommend the following article: Ruyssen-Witrand, A., Tubach, F., & Ravaud, P. (2011). Systematic review reveals heterogeneity in definition of a clinically relevant difference in pain. [doi: 10.1016/j.jclinepi.2010.06.008]. Journal of Clinical Epidemiology, 64(5), 463-470.
OUR REPLY: We have now included this relevant reference in the manuscript.

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Reviewer: A.J. van der Beek, PhD
Professor of Occupational Epidemiology
Department of Public and Occupational Health
EMGO Institute, VU University Medical Centre
Van der Boechorststraat 7
NL-1081 BT Amsterdam
The Netherlands

Comment from reviewer Professor van der Beek:
It is recommended to add four columns to table 1, i.e. for participants with and without pain greater than 30 mm VAS at baseline in the training group and for participants with and without pain greater than 30 mm VAS at baseline in the control group. The reader should, in my opinion, have more insight in the

characteristics of these important subgroups, in particular since the study presents relevant results for those with pain at baseline.
OUR REPLY: We have now added columns to Table 1 showing baseline characteristics of pain-cases and disability-cases for the control and training groups, respectively.

Comment from reviewer Professor van der Beek:
I would appreciate a little more information about the actual work being performed by these, most often female, technicians. The title mentions industrial technicians, whereas the Discussion speaks about laboratory technicians. I suggest to add a few sentences to the first paragraph of the Methods.
OUR REPLY: This information has now been added to the first paragraph of the Methods.

Comment from reviewer Professor van der Beek:
Furthermore, more information should be given about the number and size of the clusters. How many participants were in the largest cluster and how many in the smallest?
OUR REPLY: We have now provided this information in a new section, "The cluster randomization procedure" in the Methods.

Comment from reviewer Professor van der Beek:
Finally, it is not fully clear how representative the participants were for the actual working population in the companies at stake. Out of the 854 workers, 211 + 237 replied to the follow-up questionnaire. Although this not bad at all for studies in the occupational setting, it is recommended to pay more attention to differences between subjects who were included in the final analysis and those who did not reply/declined participation/withdrew.
OUR REPLY: Results and discussion on differences and similarities between those who declined and agreed to participate in the study, respectively, have been published in the BMC article. In brief, those who agreed to participate had more pain symptoms. We have now mentioned this in discussion of the present manuscript.

Comment from reviewer Professor van der Beek:
Also, I expect that several participants have one or more missing measurements in the weekly pain ratings. In the first paragraph of the Results it should be mentioned how many measurements were missing for how many participants. And, most importantly, to what extent did this and the loss to follow-up influence the results?
OUR REPLY: The average number of weekly pain ratings is now provided in the Results section. The loss to follow-up is a limitation, which we have emphasized in the limitations section prior to the conclusion.

Comment from reviewer Professor van der Beek:
- It should be mentioned in the legend of Figure 2 that the scale ranged from 0 to 100!
- page 2, line 0: 'Arm/hand is' should be 'Arm/hand pain is'.
- page 4, line 23: 'involves' should be 'involve'.
- page 8, line 50: 'performs' should be 'perform'.
- page 9, line 31 and 35: 'preventative' should (in my opinion) be 'preventive'.
- several times: 'compared with' should be 'compared to' or 'in comparison with'.
OUR REPLY: This has now been changed

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Reviewer: Anneli Ojajärvi
Senior Specialist

Finnish Institution of Occupational Health
Finland

Comment from reviewer Dr. Ojajärvi:
In methods, the authors could explain briefly how they performed the cluster randomized controlled trial.
OUR REPLY: This has now been explained in more detail in the manuscript.

Comment from reviewer Dr. Ojajärvi:
In statistics, the authors have used a generalized linear mixed model controlled only for gender, not age, to determined differences in the main outcomes between the two groups from baseline to follow-up.
OUR REPLY: True. As shown in Table 1 there were more men in the control group than the training group. Age was similar. Therefore we only controlled for gender.