Author’s response to reviews

Title: Effectiveness of a theory-based multicomponent intervention (Movement Coaching) on the promotion of total and domain-specific physical activity: a randomised controlled trial in low back pain patients

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Author’s response to reviews:

Dear Editors, dear Reviewers,

Thank you very much for the possibility to submit a revised manuscript on the effectiveness of Movement Coaching. We greatly appreciated the valuable comments and constructive criticism of the reviewers. They were very helpful to gain another perspective on our research and to improve the quality of our manuscript.

Please find below our answers to the comments. We revised the manuscript according to the reviewers’ feedback in order to meet the criticism raised. Marked passages in the revised manuscript highlight the changes. In cases where we have not made the suggested changes, our reasons for our decision are described.

Comments Reviewer 1 (Mary F Barbe, PhD)

This is a very interesting study with profound implications, that different approaches are needed to enhance physical activity in subjects with chronic low back pain. The results surprised me, that the multicomponent intervention was not more effective than the low intensity intervention at improving physical activity overall or in the three subdomains. The study was well designed and managed, despite the high drop out rate. The statistics are appropriate and well described. The handling of missing data was appropriately conservative. The authors were very forth coming with all data and findings. Both strengths and limitations in the interpretation were provided. I particularly agree with the interpretation that the overall findings may be due to overestimation of a subject’s own physical activity at baseline. The conclusions clearly match the data and is strong.
Comment 1: There are a few grammatical errors that need correcting:

Page 5, line 83: Add an "at" to "interventions are more effective AT promoting physical activity..."

Page 12, lines 247-250ish: Use of semicolons to separate groups and their definitions would be less confusing than the current "/", which I first interpreted as "divide".

Page 13, line 287. Add a "to" so that it reads: "a higher chance of not replying TO the two postal follow-up..."

AUTHORS’ RESPONSE AND ACTION:

• Thank you very much! We corrected the grammatical errors. Please see line 83, line 249, line 287

Comment 2: Two minor issues: Page 12, line 267 should refer to Figure 2 rather than Figure 1. Page 33, Table 7. Significant results should be bolded, as in the other tables.

AUTHORS’ RESPONSE AND ACTION:

• Thank you, we corrected the reference (line 269)
• Thank you; bolding was adapted (table 7)

Comment 3: One major issue: Why are variables/findings duplicated in Table 5? I am unsure what the two replications of total, workplace, etc, is meant to indicate as each replicate has different results. Perhaps a subheading is missing in the table.

AUTHORS’ RESPONSE AND ACTION:

• In table 5 we presented the results of the base case analysis as well as the results of the intention-to-treat analysis. Obviously our subheadings were not sufficiently explicit. For the clarification we added “(base case and intention to treat analysis (ITT))” in the table caption (table 5 and line 346-347) Additionally, we marked the relevant line in the subheading (according to table 4) for easier understanding (table 5)

Comments Reviewer 2 (Gustavo Almeida)
This manuscript is well written and brings interesting information on the effectiveness of a comprehensive Movement Coaching intervention to promote physical activity in subjects with low back pain. However, this reviewer is very concerned with the methodology, in particular, the statistical analysis and interpretation of the results. See my comments below:

ABSTRACT

Comment 4: page 3 (line 53): results showed a decline in both groups combined? Needs clarification.

AUTHORS’ RESPONSE AND ACTION:

• Please excuse the confusing presentation of the results. We corrected the presentation (lines 52-53)

METHODS

Comment 5: page 12 (line 248): Why didn't you use the threshold of 90 minutes in moderate physical activity that is cited in the sample size calculation? That would make much more sense than having zero as threshold - somebody who increased their physical activity by 5 min/week is an ignorable improvement. A recent publication by Dunlop et al (doi: 10.1002/acr.23181) suggests a minimum threshold of 45 min/week of moderate to vigorous activity in individuals with knee osteoarthritis. Maybe, this threshold will give you a better idea of those who changed or not their physical activity.

AUTHORS’ RESPONSE AND ACTION:

• The threshold of 90 min moderate PA in the sample size calculation referred to the difference between the two groups at six/twelve month follow-up

  o We clarified this by modifying the corresponding sentence into “between the two groups at six and twelve month follow-up, respectively.” instead of “between the groups”(line 211-212).

  • We decided for the “zero-threshold” within the scope of our additional exploratory analysis (question 3). Based on this exploratory approach we aimed at seeing behind the curtain regarding the question “who showed an increase in physical activity at all?”. To make this more comprehensible to the reader, we added a passage in the section „statistical analyses“ (lines 244-246: “To gain insight in factors associated with an increase of physical activity during the study, we additionally pursued an exploratory evaluation using logistic regression models (question 3). […]”
• Notwithstanding the above, we totally agree to your request that an increase by, for example, 5 min/week is an ignorable improvement. To pursue your indication, we extended the discussion (lines 440 – 443): “Hence, regarding the practical implications it needs to be considered, that our additional exploratory evaluation only gives information on factors associated with an increase in physical activity. No information on the amount of increase and its relevance on health can be given.”

RESULTS

Comment 6: page 12 (line 260): What is 44%? 44% of the patients screened? Needs clarification.

AUTHORS’ RESPONSE AND ACTION:

• Sorry for the confusing description. We hope to clarify this by changing the sentence into “Overall, 912 patients were assessed for eligibility, whereof 412 patients (44 %) gave informed consent to the study participation and completed the baseline questionnaire.” (lines 260-261)

Comment 7: page 12 (line 265): 65% of follow-up data missing? So, your results are mostly based on baseline data, as those data were carried forward? That's intriguing.

AUTHORS’ RESPONSE AND ACTION:

• Of course you are right about the high percentage of missing follow-up data. In our manuscript we faced this problem by reporting profoundly both, the base case as well as the intention-to-treat analyses. To avoid misleading interpretation by carrying forward baseline date (intention-to-treat analysis with last observation carried forward) we decided to primarily report base case analysis and report the intention-to-treat results in terms of sensitivity analysis.

• To avoid intriguing information, we added a section in the study limitations (Discussion) o “Second, due to the associated problem of imputing missing values, especially the results regarding the decline of physical activity during the course of the study should be interpreted very cautiously. Third, a potential bias resulting from the non-reply to the postal six and twelve month follow-up questionnaires needs to be taken into account.” (Lines 457-461)

• Please also see our response on comment 12

Comment 8: page 17 (line 332): I suggest that a post hoc sample size calculation be determined to verify if you were powered for the base case analysis. The significant finding may be misleading.
AUTHORS’ RESPONSE AND ACTION:

• As we did not achieve the number of samples required according to our sample size calculation there is no doubt that our base case analysis is underpowered. We hope to face your concerns by extending the corresponding section on study limitations (Discussion, lines 453-466)

• Please also see our response on comment 12

Comment 9: page 17 (line 334): the decline was in total physical activity from the movement coaching group. Please revise

AUTHORS’ RESPONSE AND ACTION:

• We deleted the sentence “The base case analysis showed a statistically significant decline in total physical activity from baseline to twelve month follow-up (p = 0.01)” (line 335: deleted) and only focused on the decline within the groups instead of the whole base case sample

DISCUSSION

Comment 10: page 19 (line 400): This is intriguing! Maybe you should describe what type of work most of the subjects were performing. If most of them work at their desk I believe that they will be more sedentary.

AUTHORS’ RESPONSE AND ACTION:

• Thank you for this important point. We revised this section in the discussion:

  o “In retrospect, for example, the comparatively low level of education in our sample would have needed further consideration for tailoring the intervention. As a low level of education tends to be associated with higher workplace activity ([Froboese 2016 #316]) as well as a lower physical activity during leisure time ([O’Donoghue 2016 #317], [Lampert 2008 #318]), ([Froboese 2016 #316]) the question arises, whether interventions promoting physical activity targeting persons with low level of education should rather focus on leisure time physical activity instead of total physical activity. (lines 398-404)

Comment 11: page 20 (line 409): "the substantial decrease..." - this is certainly because 65% of the follow-up data were inputed from baseline, which implies no change. Additionally, you are probably not powered to detect changes in the base case analysis done. Therefore, this information may not be true.
AUTHORS’ RESPONSE AND ACTION:

• We qualified this statement by deleting the passage “As far as the authors know, the substantial decrease in physical activity during the study period had not been shown before in a study on physical activity promotion and provides important implications for the future field of research on physical activity promotion” and keeping our aspects on the problems of an accurate self-assessment of physical activity (lines 418 ff.)

• Additionally, please also see our response on comment 12

Comment 12: page 21 (line 447): "the high number of dropouts..." - this should be your main limitation.

AUTHORS’ RESPONSE AND ACTION:

• Thank you for this remark. We pointed out the high dropout rate as the main limitation and also described its possible consequences more comprehensively, especially as this comment seems to be related to the comments 7, 8 and 11

"Certainly, the main limitation of the present study is the high drop-out. This has several consequences regarding the interpretation of the results. First, the findings should be interpreted with caution due to the fact that we did not achieve the calculated sample size and therefore the study is underpowered to detect the assumed between group differences at six and twelve month follow-up, respectively. Second, due to the associated problem of imputing missing values, especially the results regarding the decline of physical activity during the course of the study should be interpreted very cautiously. Third, a potential bias resulting from the non-reply to the postal six and twelve month follow-up questionnaires needs to be taken into account.” (Lines 453-466)

Comment 13: page 21 (line 455): how about the many other studies that did not have this problem? Furthermore, this reviewer was wondering if the authors took all necessary measures to follow-up with the subjects to collect the questionnaires. Maybe the authors should comment on that.

AUTHORS’ RESPONSE AND ACTION:

• We took several measures into account to increase response rate:

o If the participants did not answer the postal questionnaire, we repeated the sending two weeks later
Additionally, we tried to increase the response rate with the help of incentives: All participants who sent back the postal six month follow-up questionnaires went into the draw to win a tablet computer or a voucher for a wellness-weekend and, again, all participants who sent back the postal twelve month follow-up questionnaires went into the draw to win a tablet computer or a voucher for a wellness-weekend.

- We added in our manuscript:

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“We were not successful to increase the response rate during the conduction of the study, even though we integrated a repeated sending of the questionnaire if the participant did not reply within two weeks as well as incentives (all participants who sent back the postal six/twelve month follow-up questionnaires went into a draw to win a tablet computer and a voucher for a wellness-weekend).” (lines 461-466)
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