Reviewer's report

Title: Is sleep disturbance in patients with chronic pain affected by physical exercise or ACTbased stress management? - A randomized controlled study

Version: 0 Date: 14 Jan 2018

Reviewer: Mark Lumley

Reviewer's report:
I had substantial concerns about the presentation of the data in the original manuscript, and in this revision, the authors have substantially improved the manuscript. I applaud the use of mixed model analyses, and the inclusion of those patients who did not complete the trial in analyses. I'm OK with the selective reporting of these four outcomes. I think that the conclusions are generally accurate (although I have some questions about the pain finding).

I do have, however, some suggestions or requests for revisions:

1) The term "stress management intervention" is highly vague and almost entirely without meaning. (See the great review article by Ong et al., 2004, in J of Psychosomatic Research.) Although the authors may have called it SMI in their trial, this appears to be an internal title with no clear referent to what it is for readers or the field. It will have little or no meaning for anyone; it could mean most anything, including CBT. I think that it would be more helpful to the larger field if its connection to ACT were made more explicit in the abstract and text. The description of the intervention components suggests that it indeed is ACT, or at least very similar to ACT and drawing largely on it. As the authors note, this intervention's origins are based on ACT as constructed by Flaxman (or is it Bond et al.? Both are noted.). Therefore, I strongly suggest that the authors call this intervention "ACT" or at least something that reflects that this intervention is based largely on ACT (e.g., "ACT-based stress management"), rather than SMI. If its title is left as SMI, this intervention will not show up in reviews of ACT for chronic pain, and it needs to be recognized as reflecting on
how well or poorly ACT works for chronic pain. Please consider calling it ACT or ACT-based or something similar.

2) The authors conclude that "beneficial significant effects on insomnia and pain intensity were confirmed in the exercise condition." However, I think that the findings on treatment effects on pain are harder to interpret than those on sleep. It appears that BOTH Exercise and CONTROL showed a significant drop in pain, whereas the ACT/SMI condition did not. Given that the control condition improved, and one of the treatment conditions did not, this pattern of findings is most appropriately interpreted as a general improvement in pain (that is, for both Exercise and control) which is prevented (for some reason) by ACT/SMI. If I understand the analyses, exercise is not superior to Control on pain reduction, but is superior to ACT/SMI. Perhaps the conclusion needs to be changed?

3) Randomization: I would like more information on the procedures of randomization. In particular, is it the case that INDIVIDUAL patients were randomized when they were screened into the study? And then when enough people had been randomized to specific treatment condition (e.g., 10 patients) then those patients constituted a treatment group and received the treatment together? Or did the authors wait until they had a pool of 30 patients and then randomize each of them at the same time to one of the three conditions? Or was a group of 10 patients randomized as a cluster?

4) I'm also curious as to the procedures for actually holding the treatment sessions. It is very challenging to form and run treatment groups. How was this done in this trial? Was each group initially 10 patients, or did it vary? (if so, how many patients were there per group)? Is it the case that a certain time / date / location was selected to conduct each treatment, and the hope was that as many randomized patients as possible could make that day / time / place? If so, I am assuming that some assigned patients simply could not make that day / time / place, and this accounts for the people who never showed for any of the treatment. Were sessions held at various times of the day? (This is very relevant for exercise.) Where were sessions held? How many groups or cohorts were conducted for each of the three treatments? I request that the authors add some of this detail to the manuscript.
5) The material in the Methods / Subjects section that presents the definition of a treatment completer and compares conditions in completer prevalence does not fit there well. I suggest that this go early into the Results section.

6) It needs to be made clear how many people in each condition constitute the "completers" and the "completers + non-completers." I am assuming that those who dropped after randomization are being excluded from all outcome analyses. Is that correct? I encourage the authors to note in their discussion that although "intent-to-treat" analyses typically include ALL who are randomized, THEIR approach is excluding those who were randomized but never started a treatment, largely due to issues unrelated to the assigned condition, such as scheduling difficulties. They might even reference a trial by Beverly Thorn (2011; PAIN) that did the same thing.

7) Results: The drop-out rate after randomization was higher in CON than which condition? A post-hoc chi-square likely will show this to be only the ACT/SMI condition.

8) The phrase "non-completer" is not clear….one could also consider those who dropped after randomization to be "non-completers." I suggest defining non-completer more clearly as "treatment non-completer" and "study non-completer" for those who dropped during follow-up. And clarify in that second paragraph under Results that the percentages (SMI: 26% etc.) refer to "treatment non-completers").

9) I'm confused by Table 3. What is the Exercise condition and the SMI condition being compared to? It appears that effect sizes (d) are given for each of those two conditions, but such d values require a comparison condition.

10) In the CONSORT table, reverse the order of the two bullets in each of the three treatment conditions. (Did not receive intervention precedes how many did or did not complete it.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
Yes

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