Author's response to reviews

Title: Chronic pain treatment in children and adolescents: Less is good, more is sometimes better

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Author's response to reviews: see over
Datteln, 11.09.14

Re: Chronic pain treatment in children and adolescents: Less is good, more is sometimes better
Tanja Hechler¹, PhD, Julia Wager¹, PhD, Boris Zernikow¹, MD, PhD

Dear Professor O'Donovan,

Thank you very much for the opportunity to resubmit our paper on “Chronic pain treatment in children and adolescents: Less is good, more is sometimes better” to BMC Pediatrics.

We hope that this paper might be as often viewed by the readers of your journal as was our previous paper published in BMC Pediatrics on “Characteristics of highly impaired children with severe chronic pain: a 5-year retrospective study on 2249 pediatric pain patients” (BMC Pediatrics, 12, 54).

We have addressed all the issues raised by the two reviewers. A detailed response is attached. We have also highlighted all changes in the paper.

We hope that the paper may now be ready for publication.

Yours sincerely (on behalf of the authors)

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Response to Reviewers’ comments

Reviewer: Deirdre E Logan

The authors have addressed most of my concerns and the revised manuscript is notably improved.

Thank you for this positive comment.

My one outstanding concern is that I do not feel they have adequately addressed the limitations of their methodology in terms of the inherent baseline incomparability between the groups. They have provided more detail about the process of identifying which treatment intensity to recommend for a patient, but I believe they should highlight further the shortcomings of the design in terms of comparing two groups which are created based on a set of baseline characteristics (pain, disability) and then subsequently compared on change in the same set of characteristics. I recognize in a naturalistic study this is a necessary approach but they need to be clear about the limits of what can be learned through this approach.

Following the reviewer’s suggestion, we have now adequately addressed the limitations of our methodology in terms of the inherent baseline incompatibility between our two groups – outpatients vs. inpatients - and discussed ways how to control for potential effects, such as the regression-to-the-mean effect (please see Limitation for details):

In addition, the study design involved a comparison of two groups - outpatients vs. inpatients - which were created among others based on baseline pain and disability and subsequently compared on change in these variables. This is a necessary approach in a naturalistic study but entails the risk of a regression-to-the-mean effect [26] and therefore a greater likelihood to find statistically significant improvements in the more severely affected inpatient group. One way to control for this effect is to compare patients with similar levels of pain intensity and disability, as was done by the comparison of decliners to completers in this study. An additional comparison of outpatients and inpatients with a comparable high level of pain intensity (of \( n=84 \) outpatients and \( n=52 \) inpatients) also revealed a greater reduction in disability in the inpatient-group (\( F_{1,134}=6.80, p=.010 \)). Additional ways to control for this effect which may be implemented in future studies wherever feasible are a random allocation to comparison groups [26].

Also note that on p. 8 line 13 the word interdisciplinary is repeated.

Text changed accordingly.
Reviewer: Gerard Banez

General Comments

1. Consider using either the term naturalistic or uncontrolled, rather than switching between these terms throughout the article.

We have decided to use the term naturalistic throughout the paper.

2. Ensure that you are not using causal language throughout when discussing the results in order to reflect the uncontrolled nature of the study.

We have carefully checked the paper for use of casual language. The paper was already edited by the American Journal Experts Service (see attached Certificate).

3. Figures should include labels on both axes and brief caption describing the figure.

According to the reviewer’s suggestion, we have included labels on both axes of the Figures and provided a brief caption describing the Figure.

4. If I am reading this manuscript correctly, my main concern is that it compares an intensive three-week multimodal inpatient program to one 1 ½ hour psychoeducational session. Comparison of inpatient to outpatient treatment in the field of pediatric pain rehabilitation program is especially important, and I am as interested in reading about this topic as anyone. In this study, however, the treatment doses are so vastly different that a fair comparison cannot be made. It is not apples to apples.

This is a very important point raised by the reviewer. Clearly, the outpatient treatment represents a very low dose of treatment as depicted in the Introduction. This is based on the clinical notion that children referred to outpatient treatment are thought to be able to achieve the requested changes with a less intense therapeutic dose.

Our outpatient treatment comprises of an à priori evaluation of previous assessments and treatments of the child’s pain problem (3-4 hours), the initial 1.5-hour session including different modules tailored to the particular needs of the individual patient, and a treatment plan comprising medical, and psychological treatment recommendations. In accordance to the reviewer’s suggestion, we have better described our outpatient treatment.

The session contains psychoeducational aspects such as identifying and explaining the nature of the chronic pain experience, but also additional strategies such as to providing strategies for pain relief, adaptation of pain medication when necessary, teaching use of distraction techniques, change in parental focus on child’s pain and strategies to attend
school despite pain. We would therefore suggest refraining from labelling this intervention as a purely “psychoeducational session”.

In accordance to the reviewer’s suggestion, we have added the aspect of low treatment dose to the Discussion section. We also discussed treatment access, which we would expect to be higher with a brief intervention at a specialized treatment centre compared to interventions with more frequent appointments, and the role of adherence to the recommended treatments for the outpatient group.

5. Was the manuscript submitted a draft document? The highlighting on several sections of the paper made me wonder whether this was the final or a draft.

This manuscript has been previously reviewed. The editor suggested submitting a substantially revised version which would be reviewed again. This is why there were highlighted sections in the manuscript.

Methods Section

1. Consider relabeling/reorganizing the subsections in order to provide better clarity for readers (currently 3 subsection headings include the word procedure).

According to the reviewer’s suggestion, we have reorganized the subsections of the Method section to provide a better clarity for the readers.

2. A description of various procedural details is currently spread throughout the methods section. It may be helpful to organize into specific paragraphs on the sample, measures/evaluation, procedure (potentially separating out general center procedures versus procedures specific to this sample), treatment, etc.

We have organized specific paragraphs as suggested by the reviewer.

3. On page 10, line 4: Was any pharmacological treatment offered during treatment or was it all ‘following treatment?’ Was this treatment recommended for pain, mood, sleep, or something else?

Pharmacological treatment constitutes one of the six modules of the intensive interdisciplinary pain treatment at our institute (see also [4] for details). Pharmacological treatment is limited to pain due to inflammation or physical disease proven to response to analgesics. We have added this aspect to the Method section.

4. On p. 10, line 4: Similar question about physiotherapy: was physiotherapy offered during treatment or just ‘following treatment?’
Physiotherapy in our program is used whenever advanced chronicity along with pronounced avoidance behaviour results in impaired functioning or impaired movement [4]. Physiotherapy is designed as an active therapy during which physical activity and active coping are enhanced. We have added this aspect to the Method section.

5. Also on p. 10 under Measures/Average pain intensity: were participants asked to rate an average pain rating for the four week period, or were daily ratings averaged over a four week period?

Children were asked to rate an average pain rating for the four week period. We have changed the text accordingly.

6. Last subsection on page 11 titled Procedure appears to have some redundant information that has been previously discussed earlier in this section. As with previous comments, I would consider reformatting to allow for better flow for readers throughout this section.

Please see our previous response to this comment (comment 1 & 2).

7. On page 14, lines 1 & 2: the raw change of -1 on the NRS does not appear to be a ‘cut-off’ score in the way that the 23.09 on the P-PDI is. Please clarify. Do the authors mean that a change of 1 on this measure is considered clinically significant?

Hirschfeld et al. [5] recently showed within a group of 153 adolescents with severe chronic pain that raw changes of 1 NRS point can be considered as a minimally clinically significant difference. We have clarified this aspect in the paper.

Results Section

1. May be useful to mention non-significant findings for completers vs decliners in the low and high school absence categories, rather than only mentioning the significant finding.

We have mentioned the non-significant finding in the decliners and completers with initially low and initially high school absence.

2. Clinical significance??

In the result section, we have compared the number of children with clinically significant changes in pain intensity and disability according to the concept of Jacobson and Truax [6].

Where applicable, we have also reported effect sizes to be able to interpret the relevance of our statistical findings (please see Tables for details)
Discussion Section

1. In the first sentence, the “( )” around interdisciplinary are unnecessary.

We have changed the text accordingly.

2. In limitations, consider addressing generalizability issues pertaining to socialized healthcare and self-selected assignment of different treatments (versus driven by insurance). It would also be helpful to discuss how self-selection could have influenced the results of the completers vs decliners.

We have added the limited generalizability pertaining to socialized healthcare and self-selected assignment of different treatments (versus driven by insurance) to the Limitations.

We have added to the discussion how self-selection could have influenced the results of the completers vs. decliners.

3. Perhaps consider listing as a limitation the brevity of the outpatient treatment program, as this is not a typical length of an outpatient program.

We have added this aspect to the limitations.

4. In the conclusions section, be careful not to overextend conclusions that can be drawn based upon the aims and methodology of the study. The results cannot “confirm” the necessity of either treatment. Further, the results of this study did not examine how to allocate patients to a specific treatment group and cannot attest to the importance of “allocating appropriately.”

Following the reviewer’s suggestions, we have carefully edited the Conclusions to avoid overextending our conclusions.

5. Future directions could also include studies with more rigorous experimental designs and comparison of inpatient programs versus lengthier outpatient programs.

We have added this aspect to the Discussion as suggested by the reviewer.


