Author’s response to reviews

Title: Tactile acuity training for patients with chronic low back pain: A pilot Randomised Controlled Trial.

Authors:

Cormac G Ryan (c.ryan@tees.ac.uk)
Nicholas Harland (nick.harland@nhs.net)
Benjamin T Drew (btdrew@googlemail.com)
Denis J Martin (D.Martin@tees.ac.uk)

Version: 2 Date: 24 January 2014

Author’s response to reviews: see over
Author’s response to reviewers

Title: Tactile acuity training for patients with chronic low back pain: A pilot Randomised Controlled Trial.

Authors: Dr. Cormac Ryan Ph.D, Dr. Nicholas Harland Ph.D, Benjamin T Drew, Professor Denis Martin Ph.D.

Email contacts:
c.ryan@tees.ac.uk
nick.harland@nhs.net
btdrew@googlemail.com
d.martin@tees.ac.uk

Version: 2 Date 24th Jan 2014

Author’s Response to reviewers – see over
We would like to thank both reviewers for their helpful feedback on our manuscript. We have attempted to address the comments within the manuscript and the details of this are below. We feel that the suggested revisions have strengthened the paper in a number of key areas.

**Reviewer 1: Chris Roecker**

**Major Compulsory Revisions**

1. Methods, 11th paragraph (Methodology checking measures): Please revise the following sentence to indicate that 100, not 10, represents completely credible. “Treatment credibility was measured using the 0-100mm VAS with 0 indicating not credible and 10 indicating completely credible…”. Please recognize that a VAS is 0-100 mm, but a Numeric Rating Scale (NRS) is 0-10. Please apply this correction throughout the manuscript.

   **Response:** The inclusion of the number 10 in the paper was a typographical error and the number 10 has now been changed to 100 throughout the manuscript to reflect the 0-100mm VAS scale which was used.

**Minor Essential Revisions**

2. Abstract, Results: please correct the inappropriate capitalization in the following sentence” ANCOVA analysis revealed that Individuals in the placebo group improved…”

   **Response:** The word ancova has been removed from the abstract to facilitate other requested changes to the abstract while maintaining the word count below 350words.

3. Introduction, 7th paragraph: consider revising the following sentence to explain what will be evaluated in this pilot RCT that will inform a larger, follow-up RCT. “The aim of this pilot, mixed-methods, randomised controlled trial was to investigate the effectiveness of tactile acuity training…”. If this RCT has sufficient power to determine effectiveness, then I am unsure why it is categorized as a pilot study.

   **Response:** We have changed the wording in this paragraph to reflect that this pilot study aimed to provide preliminary data to inform a fully powered RCT.

4. Methods, 13th paragraph (Data Analysis): please correct the inappropriate
capitalization in the following sentence “Change in Pain and function from pre to post treatment…”

Response: ANCOVAs is the abbreviated term for Analysis of Co-variance which is why it was capitalised, thus we have written the term in full and the put (ANCOVA) after it to denote this.

Discretionary Revisions
5. Please define all acronyms throughout the abstract and manuscript upon first use (e.g. RCT, VAS, ISRCTN, NHS, NRES, CR, BMI, IQR)
Response: All of the above acronyms have been defined on first use. CR (Cormac Ryan) has been removed as an acronym within the paper and replaced with “Ryan” P.5.

6. Abstract, Methods: consider revising the following sentence “All participants/informal carers were invited to a focus group to provide feedback on the intervention.”
Response: Changed to “Participants and their informal carers were invited to a focus group to provide feedback on the intervention.”
Reviewer 2: Kieran O’Sullivan

This is a novel, timely and valuable pilot study. It adds some valuable data to what we know about novel approaches to the management of CLBP. The main limitations of the study have been well acknowledged by the authors. Therefore I believe it is worthy of publication once the authors have made some minor amendments.

Discretionary Revisions

• The use of several different terms for this type of assessment and treatment may confuse the reader. In fairness to the authors, the terms they use are used widely in the literature. However, they might look at the various terms they have used (e.g. Sensory retraining in the title, Acuity training in the running head) and choose one – or as few variations – as possible.

Response: As suggested we have revised the article to use as few variations in terms as possible. The term tactile acuity training is now used throughout the article with some use of other terms where specifically warranted. We have used sensory discrimination training as a broader all-encompassing term and then tactile acuity training as a specific form of sensory discrimination training. We have changed the title of the study and the running head to tactile acuity training.

Minor Essential Revisions

Abstract:

• correct brackets - [RMDQ])

Response: Square brackets have been changed to curved brackets (RMDQ).

• table 2 – why no subject 11?

Response: This was a typographical error. The participant number now goes from 1-15 including 11.

Introduction:

• “Tactile acuity training can improve pain and two-point discrimination performance in patients with CRPS [5].”…compared to tactile stimulation alone?

Response: Sentence has been amended as suggested.
• “needed TO build on this work”?
Response: Sentence has been amended as suggested.

• Provide some brief reasoning (maybe at the end of the 2nd last paragraph) for the inclusion of a qualitative component, as this is first mentioned in the final paragraph.
Response: As suggested, brief reasoning has been provided at the end of the 2nd paragraph for the inclusion of the qualitative component.

Methods / data analysis:
• Add bracket ) after RMDQ
Response: Bracket has been added.

Results:
• Page 12, line 3 - patient’ –typo?
Response: changed to patients

Discussion:
• Page 14 – first sentence of 2nd paragraph – had “a” statistically better outcome?
Response: Sentence has been amended as suggested.

• Limitations section : “generalisabiliyt” – typo?
Response: typo corrected.

• Limitations – no intention-to-treat analysis was performed as far as I can see, despite 9/24 participants being lost to follow-up. This should be acknowledged
Response: This has now been acknowledged in the limitations section as suggested.

Conclusion:
• “Future work, should consider the need for automated devices, to make home delivery more feasible” – remove commas?
Response: commas have been removed.
Major Compulsory Revisions

• I feel that the abstract and conclusion should reflect more clearly that for 3 of the 4 main outcome measures (pain and disability, both in absolute terms and as % change from baseline) there was no difference between the groups. And that the one significant change between the groups was in favour of the placebo control group, suggesting the active intervention was ineffective.

  Response: In the abstract and conclusion we have more strongly emphasised the apparent lack of effect as suggested. We have been able to do this more comprehensively in the conclusion as we were not limited by word count restrictions as in the abstract.

• I feel the authors could emphasise the importance that novel interventions should be capable of being applied in typical settings more strongly. It would seem to me that one of the main differences between their results and that of Moseley et al (on CRPS) is the degree of interaction with a clinician, with Moseley et al having a clinical interaction every weekday. It would appear that the approach used by the authors of this study is much more representative of typical NHS practice, and yet was ineffective. This suggests that trying to integrate this type of intervention into existing practice is not warranted. With this in mind, the study by Johnson et al on graded motor imagery for CRPS treatment in the NHS seems to be a natural fit with their conclusions, and would be worth adding to their discussion.

  Response: The following paragraph has been added to the discussion “In previous tactile acuity training studies [10, 12] the intervention has been delivered on a daily basis by a therapist within a clinical setting. Such a treatment delivery system is not feasible within the current NHS. Thus the current study attempted to tailor the delivery system towards a predominantly home based non-therapist delivered system. Considering the lack of effectiveness shown in this study adapting tactile acuity training in this manner to fit current clinical practice is not warranted. A recent prospective audit by Johnson et al. (2012) [22] investigated the real world effect of graded motor imagery (GMI) for CRPS in clinical practice. The GMI used was based on techniques which had proven successful under RCT conditions but had been adapted to fit with usual clinical practice (e.g. patient-therapist contact time was reduced). The audit found no effect of GMI on pain and highlighted the challenge of translating results of a complex pain intervention requiring a high level of patient compliance from the RCT setting into real world practice. The results of the current
study mirror these findings, in that tactile acuity training was adapted to fit within usual clinical practice delivery systems and this did not produce an effective intervention. Studies such as ours and that of Johnson et al. (2012) [22] highlight the need for pragmatic trials to assess the clinical effectiveness of interventions to facilitate appropriate translation of research into practice. Furthermore, they emphasise the importance of developing interventions that can be easily applied in a typical healthcare setting.”

• The conclusion does not adequately address the possibility (probability??) that in the current formats available, there is no strong evidence to suggest that tactile acuity training techniques are an effective treatment, or treatment adjunct, for CLBP
Response: The conclusion has been reworded to more strongly reflect the lack of effectiveness of this intervention in the form used in this study.