Author's response to reviews

Title: Evaluation of a group based cognitive behavioural therapy programme for menstrual pain management in young women with intellectual disabilities: Protocol for a mixed methods controlled clinical trial.

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Author's response to reviews: see over
RE: Response to Reviewer’s Reports

Title: Evaluation of a group based cognitive behavioural therapy programme for menstrual pain management in young women with intellectual disabilities: Protocol for a mixed methods controlled clinical trial.

Dear Sir / Madam,

Thank you for your recent consideration of our amended manuscript and the informed feedback received to date. In response to the additional queries raised, we outline our response below and in the amended manuscript, which is attached:

Reviewer’s Report 2 – Lynn Breau

1. Data Collection - Primary Outcome Measures:

I understand that the Pain Coping Strategies Questionnaire and the Pain Coping Scenarios Questionnaire have been used in only one previous study. However, the authors should include some results from that previous study when describing the measures to help the reader evaluate their psychometrics. If no psychometric analyses were conducted as part of the previous study, this should be stated and a brief description of how they were used should be provided. The authors indicate in their responses that psychometric analyses will be included in the current project – but none are described in the analyses section. Please indicate how the reliability and validity will be assessed quantitatively in this current study. What analyses will be done?
Reply: As no psychometric analyses were conducted in the study by McManus and McGuire (2014), our manuscript has been amended to provide a brief description of how the Pain Coping Strategies Questionnaire and the Pain Coping Scenarios Questionnaire were used in their original study. An overview of the results of the McManus and McGuire (2014) study has also been included in our manuscript which indicates that the measures were sensitive to change as a result of the intervention.

The reliability of these measures will be assessed by Cronbach’s alpha. Ideally, test-retest reliability would be assessed by re-administering questionnaires to participants e.g. after one month, however this was not possible as the intervention took place between baseline and time 2 measure, so a change might be anticipated. With regard to validity, the authors intend to assess this construct by correlating the measures against one other. This information has now been included in the analyses section of the manuscript.

2. Secondary Outcome Measures - Pain Intensity:

I agree with the authors that pain intensity is not likely to be the big factor that is most impacted by this intervention (typically function and coping improve most). However, those less acquainted with typical responses to pain treatment programs may find this counter-intuitive. To help those readers understand the secondary role of pain intensity as an outcome, the authors should provide a brief explanation, referring to outcomes that have been reported for other studies of psychological pain management programs. This will allow the reader to understand why pain intensity is not the key target of the intervention.

Reply: As suggested, the following paragraph has now been included in the manuscript outlining the rationale for the secondary role of pain intensity as an outcome measure:

“Because variability in outcome measures across clinical trials hinders the evaluation of treatments, the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) recommended that six core outcome domains should be considered when designing chronic pain clinical trials. These were defined as pain, physical functioning, emotional functioning, participant ratings of improvement and satisfaction with treatment, symptoms and adverse events and, participant disposition (Turk, 2003). Pain, or pain intensity, is not the key target of the intervention in this study as the goal of CBT based pain

management programmes is not to reduce pain, as such. Rather, it is to enhance adaptive coping and support the individual to resume a more productive and enjoyable life despite pain (Turk, 2003). Lynch-Jordan et al. (2014) demonstrated that the rate of change of functional disability was significantly more rapid than the change in pain intensity over the course of psychological treatment for children with chronic pain”.

3. Secondary Outcome Measures – The Brief Pain Inventory:

The authors now explain that the Brief Pain Inventory will be a modified version. Thank you. Please explain whether this specific modified version has been used before or whether it is being generated for this study.

Reply: The modified version of the Brief Pain Inventory – Short Form used in this study was specifically generated for the purpose of this research project. The specific modifications required included front and back female body outlines to enable participants to identify the areas of the body in which they experienced menstrual pain, omission of some questions e.g. questions regarding pain in the last 24 hours (participants may not be menstruating at the time of administration of questionnaires), changes to the questions on categories assessed (wording changes and additional categories included) and modifications to the response categories by including the use of a visual analogue rating scale in conjunction with a numerical rating scale. Modifications to the original Brief Pain Inventory – Short Form were required to enable it to be understood by and used with people with intellectual disabilities as well as to make it relevant to the assessment of menstrual pain, an intermittent rather than a constant type of pain. The paragraph above has been added to the text of the manuscript.

4. Supplementary Research Methodologies – Self-Efficacy Scale:

Please provide a brief description of the actual psychometric results for the Self-Efficacy Scale from the previous study with children by Bursch et al.

Reply: Bursch, Tsao, Meldrum and Zelter (2006) examined the psychometric properties of child and parent versions of a self-efficacy scale for child functioning despite chronic pain. Reliability was reported in terms of Cronbach’s alpha which was .89 for the 7 items on the
child scale and .90 for the 7 items on the parent scale. Strong evidence for construct validity was also obtained as 23 of the 27 hypothesized correlations were confirmed.

Minor Essential Revisions:

The description of the self-efficacy scale is still somewhat vague. The manuscript now states that it will be completed “with participants”. Does this mean it will be read to them?

Reply: Yes, the modified self-efficacy scale will be read to participants. The manuscript has been modified to clarify this point.

We thank the reviewers again for their considered and expert review of our manuscript. We hope that we have adequately addressed these additional queries and look forward to your response.

Kind Regards,

Susan Kennedy