Reviewer's report

**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.

**Version:** 2  
**Date:** 14 April 2014

**Reviewer:** Lynn Breau

**Reviewer's report:**

This report outlines a proposed study to evaluate CBT provided for women who have mild to moderate intellectual disabilities (ID) and suffer from menstrual pain. This is an area where little research exists and is very worthy of the effort. Working with this population also requires a great deal of planning and accommodation to ensure that the individuals who are taking part can provide valid and reliable information to the researchers, which means that many researchers do not include these individuals because of the complexity of study design. The authors are to be applauded for taking on this difficult task.

**Major Compulsory Revisions:**

**Background:**

The background is easy to read and helpful, but does not provide a great deal of information to support the use of CBT with this group. The authors should add discussion of research indicating those with mild to moderate ID can participate in CBT delivered in a group format, whether for pain or other issues.

**Research Hypotheses:**

The rationale for Hypothesis 3 is not provided. Why is it expected that parent catastrophizing will affect the participants' behaviour? Which behaviour is it expected to affect? Please describe relevant studies that support this hypothesis in the Background section and/or this section.

The rationale for Hypothesis 4 is also not described. Please provide a discussion of the relevant literature that supports the expectation that the participants will adopt more behavioural than cognitive strategies in the Background section and/or this section.

**Recruitment and Eligibility:**

We are told that the participants will provide consent “via a visual participant information sheet and consent form”. It is very likely that most participants will not be able to read. Please explain if the information will also be provided verbally.

**Inclusion Criteria:**

Please describe in more detail what the level of speech will be of participants. Is this being formally assessed? It would be appropriate to know both their Receptive and Expressive verbal abilities because they will be expected to learn
during the CBT and to provide verbal responses to questionnaires.

Some of the participants may be as young as 12 years, suggesting they may only have begun to menstruate recently. This means they may have had very few experiences with menstrual pain. This may impact their pain perception, as we know that past pain affects our perception of pain now. It may also impact their ability to take in the information provided during the CBT because they will have less experience with the situation. How will this be accounted for in the data analyses?

Research Design:

Please indicate how the information regarding what is done for the control group will be monitored. It is very important to know if any will be taking analgesics, as this may reduce the difference found between groups.

Data Collection:

Primary Outcome Measures:

The authors report no psychometrics for the Pain Coping Strategies Questionnaire, the Pain Coping Scenarios Questionnaire and the Pain Knowledge Questionnaire and do not report any published analyses to indicate these are valid and reliable. This is a serious problem because they are the primary outcomes. Information should also be provided regarding how they are scored, etc.

Secondary Outcome Measures:

A pain score should be a primary outcome, but is only included here as a secondary outcome. It is likely that a good number of the participants will not be able to use the VAS described reliably. De Knecht et al. (2013) found that only 32%-61% of adults with ID could use a 0-10 numerical scale and Fanurik et al. (1998) found that no children with moderate ID could use a 0 – 5 pain scale reliably. Although it is admirable that the authors are attempting to include self-report, and pain is the target of the intervention, they should consider also including a proxy measure by parents. Further, most adults without ID find it difficult to retrospectively report “average” pain. Asking about “worst pain” and “least pain” would be better. Also, are the authors sure that pain intensity is the most likely thing that will change? Could pain intensity remain high, but duration of pain reduce? It is advisable to re-evaluate how pain will be measured.

The Brief Pain Inventory – Short is a tool designed for people without ID. It is very probable that few of the participants in this study will be able to comprehend and respond on this questionnaire. The use of a 0 – 10 likert response format is also beyond the numerical understanding of most individuals with moderate ID.

Supplementary Research Methodologies:

Moderator Analyses:

It is unclear whether the self-efficacy scale will be completed by the participant or the parent. Please provide more detail regarding the questionnaire, and evidence that it has good psychometric properties with adults with moderate ID, or even with individuals who would have a similar mental age equivalent.
The reference given for the Pain Catastrophizing Scale – parent refers to the original self-report scale developed by Sullivan. Please provide a reference and describe the psychometrics of the parent version. As mentioned regarding the hypotheses, no rationale is provided to support the idea that parent catastrophizing may predict child pain or child pain behaviour. Please describe some here. Also, please specify what exactly parent catastrophizing is expected to predict (e.g. pain severity, pain coping, self-efficacy?).

Data Analyses:
Quantitative Analyses:
The MANOVA should include baseline scores as a covariate to allow for regression to the mean.
Please indicate what type of regression will be used. Please provide a discussion of power / how many predictors will be included. Please outline the specific analyses that will be conducted; what are the dependent variables of interest? Will predictors be entered blockwise/stepwise? What order will be used? Will they be forward/backward entry? Will demographic characteristics (e.g. age, ID level) be included?
The description of counter balancing is difficult to understand. Is this across the three treatment groups? Please clarify.
Will the process analyses be conducted by comparison to baseline or to the previous assessment?
Minor Essential Revisions (not for publication):
There are several places where the tense switches from future to present, or, in some cases, to the past tense. This is confusing and should be addressed. If some parts of the data have already been collected, please state so specifically.
Background:
The discussion of differences in brain structure due to dysmenorrhea is difficult to follow. It is unclear which cited reference contains the results described and it is not clear what the differences were or if these are long-term or only occur during specific points in the menstrual cycle. Please re-write this section.
Recruitment and Eligibility:
Please indicate what framework the diagnoses of ID will be based on (DSM vs. ICD). Please indicate the IQ ranges that will be included.
In this section, it is stated that the participants will provide “consent”, but later, this is described as ‘assent’. Please be consistent.
Table 1: It would be helpful to include the times of the “time points” (e.g. “baseline, 5 weeks, etc.”).

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare I have no competing interests.