Reviewer's report

Title: Instrumented gait analysis and individually tailored interdisciplinary interventions for children with cerebral palsy: A randomised controlled trial protocol

Version: 2 Date: 9 June 2015

Reviewer: Claire Kerr

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Study protocol

Instrumented gait analysis and individually tailored interdisciplinary interventions for children with cerebral palsy: A randomised controlled trial protocol


Thank you for the opportunity to review this protocol for a randomised controlled trial that aims to evaluate whether the use of instrumented gait analysis to guide interdisciplinary intervention in children with cerebral palsy, results in improvements in gait pattern compared with 'care as usual', which is described as interdisciplinary intervention without gait analysis.

I note that the authors have already responded to some comments with regard to peer review, ethical approval etc and so have not focused this review on these areas.

Overall the paper is quite well written and typically provides sufficient detail on the methods and measurement processes and tools. The authors are to be commended on their clear description of the procedure for the experimental group; however I feel that the paper is missing adequate justification in a couple of areas.

In summary, this is an interesting and complex study. It is also a pragmatic study, and sometimes ‘randomised, controlled’ does not live happily with ‘complex, real-world’, particularly when you add in a heterogeneous condition, children and families, and multiple teams of health professionals.

I can see that it has been challenging for the authors to articulate the crux of this study and their attempts to control any possible confounding variables. Nonetheless I feel that some further clarifications and justification would strengthen their manuscript, and have listed some suggested revisions below.

Minor Essential Revisions

1. Firstly, and critically, the authors need to define what they mean by
‘interdisciplinary intervention’. Does this mean the four services outlined (surgery, spasticity management, physio and orthotics) all work independently based on the findings of individual examinations (or a centrally available examination report such as CPUP or IGA)? Do these disciplines discuss the case together? Do they refer to one another? Is this client-centred – are the child and family involved in any of these care or service provision decisions? These details are important and adequate description of the service model is required as different regions have different names for the same processes.

2. Secondly, the authors highlight on page 4, paragraph 2, that IGA is an important investigation for children with CP, and provide several references that demonstrate the effect IGA has on planned orthopaedic surgery in children with cerebral palsy. Thus the impact of IGA on one element of the ‘interdisciplinary intervention’ appears to be established already. The surgical emphasis is echoed by defining the ‘start of intervention’ as the date of the most invasive intervention (and within 26 weeks of baseline). To truly reflect the uptake of IGA recommendations on all four ‘interdisciplinary interventions’ (as opposed to measuring the effect of surgery etc) then I would suggest that the ‘start of intervention’ occurs when the report is released – that is when the IGA report can be taken into account in service planning. Justification for the decision of the ‘start of intervention’ is required. Additionally, even with the current delayed ‘start’ (presumably to permit scheduling of more invasive interventions) you might consider an 18 month follow up as well. It is my understanding (and experience) that many children are typically just achieving their pre-surgical functional gait capacity at 12 months post-op.

3. Thirdly, the description of gait outcome measures is muddled at times (GDI, GPS and GVS). It is important to be clear as to what the GDI is – ‘a multivariate measure of overall gait pathology’ (Schwartz & Rozamulski 2008), not a ‘gait pattern’. The gait measures need to be clearly articulated and then consistently applied in the measures, exploratory measures and discussion section.

4. Finally, consideration of the compliance risks is warranted and discussed by the authors. I personally feel that the greatest risk is contamination of the ‘care as usual’ group, however perhaps a little description on how services are typically configured for children in the region would allay some reader concerns about cross-contamination and potential non-compliance.

5. Page 10, line 226: remove ‘gait pattern’ and replace with ‘gait deviation index’ (GDI is not gait pattern). Also provide some comment as to why GDI was selected rather than Gait Profile Score (especially given the background and description of ‘individualised’ approach for both control and experimental group subjects). See point 3 above.

6. Page 11, line 255; clarify in the text if you plan to use the PEDI or the PEDI-CAT (the new online version). The last sentence of this paragraph (lines 259-261) should be deleted as it is not relevant to the Mobility Scale of the PEDI.

7. Page 15, line 350: remove ‘patient satisfaction’ or replace with terms that more
closely reflect the outcomes being assessed in this study.

8. Page 12, line 227: Exploratory outcome measures
This section is very muddled. The Gait Variable Score section needs to be described properly – highlighting what GVS and GPS are, how they differ from GDI, and why it would be relevant to look at them in an exploratory way. See points 3 and 5 also.

9. Page 16, line 369-73: I do not see how participating in this study will ‘encourage attendance’ in CPUP, which is the type means of review in the region. Please consider removing this statement and consider revising the remainder of this paragraph for clarity.

Discretionary Revisions

10. Page 5, line 110: Suggest you omit ‘explorative hypotheses’ – appears very speculative

11. Page 8, line 193: remove the last sentence. It is highly unlikely that there will not be consensus, and it would be inappropriate to conduct an examination like IGA without providing a report and treatment options (if not a single recommendation)

12. Page 13, line 308: change ‘two intervention arms’ to ‘experimental and control groups’

13. Page 13, sample size: why not use the Gait Profile score and then calculate your sample size based on the published MCID for this (The minimal clinically important difference for the Gait Profile Score. Gait Posture 2012 Apr 4;35(4):612-5. Epub 2012 Jan 4.Richard Baker, Jennifer L McGinley, Mike Schwartz, Pam Thomason, Jill Rodda, H Kerr Graham)?

**Level of interest:** An article of importance in its field

**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 that I have no competing interests.