PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	ParticiPAte CP: A protocol of a randomized waitlist-controlled trial of a motivational and behaviour change intervention to increase physical activity through meaningful participation in children with cerebral palsy
AUTHORS	Reedman, Sarah; Boyd, Roslyn; Elliott, Catherine; Sakzewski, Leanne

VERSION 1 - REVIEW

REVIEWER	Keiko Shikako-Thomas McGill University, Canada While I have not been involved in any aspects of the current study protocol, I have been invited (while conducting the paper review) to join this project team as an international associate investigator.
REVIEW RETURNED	22-Feb-2017

GENERAL COMMENTS	This is an excellent study protocol describing a carefully designed study testing a very important and timely intervention. My comments are related to improve clarity on some of the study parameters and procedures. **Page 5** “moderate to vigorous physical activity (MVPA) per day for children aged 5-12 years” → explain what moderate to vigorous mean “A study of energy expenditure in eight ambulant children 7-12 years with bilateral CP” →How was energy expenditure measured? During what period? (school time? After school? Weekends?)

	Please develop further what is meant by “typically developing controls [children with any type of disabilities? Recruited from schools?] - in free-living conditions [explain]”
	Page 8:
	Several different age groups were mentioned (previous studies had 5-12, others 7-12) please explain the rationale for choosing the 8-12 age bracket for the current study.
	Methods:
	“ …child and parent perceived performance of and satisfaction with participation in three to five self-identified leisure-time PA participation goals, compared to usual care”
	→ Please justify why parent perception is being collected (And how it will be weighted with or against child’s perception). It seems from background that the active ingredients are intrinsic motivation and goal-oriented plans, would parental perception impact child perceived satisfaction? Does it matter for the study outcomes?
	“Secondarily, the intervention aims to reduce the number and influence of contextual (personal and environmental) barriers to child participation in active community recreation, sports and leisure pursuits, improve objectively measured PA health behaviour (increase levels of HPA and reduce levels of sedentary behaviour), and improve child reported, condition-specific quality of life.”
	→ The goal of reducing the number of environmental barriers is not being contemplated in the hypothesis being tested. Please remove the goal or explain how this is going to be addressed.
	Study sample and recruitment
	Most evidence shows more participation restrictions for children with more severe motor impairments (i.e. GMFCS IV and V), would be important to justify the rationale to include only mild and moderate cases.
	It is not clear if there will be procedures to control for current interventions (rehabilitation, special education) received by participants and baseline PA levels of child participants, and current level of family PA for parents participating (which is known to be a

	determinant of participation) – these are crucial aspects to be addressed, it would be important to consider. It is also not clear what is considered “usual care”. Participants from registry may have very different levels of treatment being received, which could determine very different “usual care” to both groups (I saw later on page 19 that there is a procedure in place to keep track of care received, but how the difference in levels of care received will be controlled for in analysis? This is a major confounder). It would also be important to consider and address the parental arrangement (1 parent household, shared custody, 2-parent or other arrangements) as this will be crucial in adherence to treatment, to keeping track of ACTi graph use and to general opportunities to engage in PA. **Page 23** Has the BPPA – Questionnaire been tested for psychometrics? **Page 25** Not clear how the GAS scores will be used as a predictor? → how will GAS goals relate to COPM, it seems both measures would give the same type of construct measurement, or would be extremely related (not predictive) **Page 28, line 10** Typo on “Knowledge Translation”

REVIEWER	Christine Imms Australian Catholic University Australia I have a strong interest in the field but no conflict of interest with regard to the study reported.
REVIEW RETURNED	04-Mar-2017

GENERAL COMMENTS	This is a predominantly well written paper describing the protocol of an RCT aiming to investigate the effect of an intervention to improve participation outcomes in children with cerebral palsy. The trial rationale is thoroughly described, situating the need for the study in current literature. The method chosen to address the research

	questions - a pragmatic RCT - is appropriate. I note that the trial is registered and has ethics approval, and may have already commenced. I have several comments that I believe need to be considered by the authors, and further justification or explanation provided. Design: 1. The authors describe the planned study as a large pragmatic RCT. Their sample estimates are based on a validated reliable measure - the Canadian Occupational Performance Measure (COPM) with an identified clinically important effect of 2-points (on a 10 point scale). Thus the sample estimate for the primary outcome is n = 36 (18 / group). While well-justified for the primary outcome this is not a large trial. 2. The multiple measures employed (n = 10 +4 demographic measures) each have multiple domains or scales (a total of 40+). The use of all but one of these measures will be to address secondary questions - of which there are 9. To what extent will a trial of 36 children be sufficiently powered to address the secondary questions and hypotheses? 3. Of the multiple hypotheses listed, only the primary outcome has a specified magnitude of effect. What is the hypothesised magnitude of effect on the secondary outcomes? 4. The intervention is appropriately tailored to the individual, but ultimately quite complex as described, and will likely vary greatly between individuals, increasing the potential for highly variable outcomes and impacting on the sample required to find an effect. How has this been accounted for in the design? Intervention 5. What is the rationale for the amount of intervention provided (8 hours) to achieve 3-5 goals? Given the diverse range of interventions that are identified as potentially offered, and the time that could be required to achieve a number (e.g. refer to funding source for equipment; strength/balance training; modify access to the environment; cognitive orientation to motor learning), can further explanation be provided about how these will be managed in the time period identified? 6. Usual care is appropriately considered and logged. How will these data be used in the analyses? 7. The video-recording of intervention sessions provides an opportunity to evaluate the nature of the intervention provided - this is a strength of the program planned because it is a new intervention package - can further explanation be provided about how those viewing the videos will score (?) and analyse the behaviours observed? Measurement 9. Week 1 describes setting goals that are "realistic according to the family context and within the constraints of the intervention and therapist expertise." This appears reasonable, however, is there a mechanism for controlling for the potential bias associated with the

	level at which goals are set given this is the primary outcome measure? 10. The chosen primary measure is difficult to apply with blinded assessment at baseline because it forms part of the process of establishing a therapeutic relationship. It could be assessed by those blind to group allocation at follow-up, but is not - can this be further justified? 11. Can further clarification be provided as to how the GAS scores will be used as a predictor of change (page 25)? 12. Will the analyses be adjusted for the stratification factors used in randomisation? Additional minor comments/suggestions: 1. Page 5, line 2 - the phrase "free-living conditions" requires explanation the first time it is used. Page 5 line 31-34 - this is a complex sentence and would benefit from revision to ease clarity. Page 6 line 40 - the explanation of 'relatedness' in self-determination theory needs a slight revisions for greater clarity of expression. Page 6 line 52 - the grammar of the first sentence of this paragraph needs revision. Page 7 line 19-20 - provide an explanation for the statistic 'g' first time used. Page 9 line 8 - the second question requires a grammar check for clarity Page 9 lines 25-36 - please review for greater clarity of what will be assessed - particularly secondary analysis #1. Page 22. line 55 - please provide an explanation for "Evenson cut-points" first time it is used. This is an important topic in pediatric cerebral palsy and randomised trial evidence is required. This trial, if successfully implemented, has the potential to contribute strongly to the field.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

1. Comment: “moderate to vigorous physical activity (MVPA) per day for children aged 5-12 years” explain what moderate to vigorous means
1. Response: Thank you for your comment. This has been clarified at page 4 line 54 to page 5 line 10 to read:
"Habitual physical activity (HPA) is PA performed during the usual activities of daily living throughout a period of time (day, week, etc.) varying through periods of rest, work, and leisure.23 Habitual Physical Activity may be categorized with intensity-related thresholds (called cut-points). The categories establish the amount of energy expenditure: sedentary (little to no energy expenditure above rest), light PA (LPA, moderate levels of energy expenditure), or moderate-to-vigorous PA (MVPA, highest levels of energy expenditure)."

2. Comment: “A study of energy expenditure in eight ambulant children 7-12 years with bilateral CP” How was energy expenditure measured? During what period? (school time? After school? Weekends?)
2. Response: Energy expenditure was measured using accelerometry in free-living conditions

including all environments (home, school, weekend), and calibrated with basal metabolic rate measured for each individual in a laboratory. Daily activities were recorded in a diary. This has been clarified at page 5 line 23-29:
"A study of energy expenditure measured by accelerometry and calibrated to basal metabolic rate has been completed in eight ambulant children 7-12 years with bilateral CP (GMFCS II-III). Compared to age and sex matched typically developing controls (a convenience sample of children without disabilities), in free-living conditions (unrestricted, usual activity at home, school and weekend), children with CP…"

3. Comment: Please develop further what is meant by “typically developing controls [children with any type of disabilities? Recruited from schools?] - in free-living conditions [explain]”
3. Response: The researchers used a convenience sample of healthy children without disabilities. This has been clarified (see response 2, reviewer 1).

4. Comment: Several different age groups were mentioned (previous studies had 5-12, others 7-12) please explain the rationale for choosing the 8-12 age bracket for the current study.
4. Response: The 8-12 years bracket was chosen for the following reasons: The COPM (primary outcome) has been shown to have validity for self-report in 8years+ and children <8years cannot reliably report on their own quality of life. Children of high school age begin to face different barriers to physical activity participation, and their frequency and diversity of participation decreases with increasing age. This study aims to intervene at an earlier age to modify behaviour and provide problem-solving strategies (with a view to mitigating the decline in participation known to occur in adolescence.

5. Comment: “ …child and parent perceived performance of and satisfaction with participation in three to five self-identified leisure-time PA participation goals, compared to usual care” Please justify why parent perception is being collected (And how it will be weighted with or against child’s perception). It seems from background that the active ingredients are intrinsic motivation and goal-oriented plans, would parental perception impact child perceived satisfaction? Does it matter for the study outcomes?
5. Response: The viewpoint of the child is sought primarily. Where the parent’s perception differs from the child, the score is discussed and negotiated. This is important as the intervention applies to the parent-child dyad and not just the child (due to significant parental involvement in child activities at this age). This has been clarified at page 22 line 11-16 in the methods and now reads:
"(lowest) to 10 (highest). The viewpoint, interests and preferences of the child will be taken into account in the primary instance. Where the child’s perception differs significantly from that of their parent/caregiver, this will be discussed and negotiated at the time of setting or scoring goals."

6. Comment: “Secondarily, the intervention aims to reduce the number and influence of contextual (personal and environmental) barriers to child participation in active community recreation, sports and leisure pursuits, improve objectively measured PA health behaviour (increase levels of HPA and reduce levels of sedentary behaviour), and improve child reported, condition-specific quality of life.” The goal of reducing the number of environmental barriers is not being contemplated in the hypothesis being tested. Please remove the goal or explain how this is going to be addressed.
6. Response: The Barriers to Participation in Physical Activities Questionnaire (BPPA) measures the impact of behavioural barriers to participation (as described in the methods). The BPPA contains questions relating to multiple domains of behaviour, covering a broad range of environmental and contextual factors. The BPPA will be used to evaluate against this aim of the study, as described in secondary hypothesis 2.

7. Comment: Most evidence shows more participation restrictions for children with more severe motor impairments (i.e. GMFCS IV and V), would be important to justify the rationale to include only mild and moderate cases.

7. Response: Children with GMFCS I-III are still not as active as they should be according to established guidelines for physical activity. Whilst youth with GMFCS IV-V may face some additional barriers to participation in leisure time physical activities (compared to children with GMFCS I-III), a pragmatic decision was made to focus on GMFCS I-III as a first step to avoid introducing too much complexity to the intervention framework and outcome measurement (especially with respect to accelerometry, which has yet to be fully validated in youth with GMFCS IV-V at this age).

8. Comment: It is not clear if there will be procedures to control for current interventions (rehabilitation, special education) received by participants and baseline PA levels of child participants, and current level of family PA for parents participating (which is known to be a determinant of participation) – these are crucial aspects to be addressed, it would be important to consider.
8. Response: As this is a pragmatic, wait-list RCT, all participants will continue to receive care as usual throughout their involvement in the study. Education setting (Family Background Questionnaire) and hours/content of therapy (Usual Care Diary) are being recorded, and will be compared between groups and reported to assist in interpretation of the results.

9. Comment: It is also not clear what is considered “usual care”. Participants from registry may have very different levels of treatment being received, which could determine very different “usual care” to both groups (I saw later on page 19 that there is a procedure in place to keep track of care received, but how the difference in levels of care received will be controlled for in analysis? This is a major confounder).
9. Response: Based on a large scale wait-list RCT conducted by our research group in a similar population (101 children with hemiplegia 8-17y from a similar geographic area and context), we estimate that few children included in ParticiPAte will receive significant amounts of additional therapy (Mitchell, Ziviani and Boyd 2016). In Queensland, therapy packages for children with CP tend to be associated with Botulinum Toxin-A injections. Based on our experience of the clinical service we are associated with, BoNT-A and adjunct therapy is frequently goal-directed towards improving gait parameters such as equinus (less frequently upper limb ADL’s at this age). Usual care hours, type (PT, OT, SLP, Ex Phys, Psych) and content will be reported for both groups in ParticiPAte to facilitate interpretation of results.

10. Comment: It would also be important to consider and address the parental arrangement (1 parent household, shared custody, 2-parent or other arrangements) as this will be crucial in adherence to treatment, to keeping track of ACTi graph use and to general opportunities to engage in PA.
10. Response: Information about family composition is collected in the Family Background Questionnaire and will be reported for both groups (and compared between groups along with other baseline characteristics). It is not feasible to stratify by family background in a pragmatic RCT, and based on previous experience this is likely to be balanced across both groups (Mitchell et al 2016).

11. Comment: Has the BPPA – Questionnaire been tested for psychometrics?
11. Response: As described in the methods, the BPPA is substantially based on a valid and reliable questionnaire (DIBQ). The BPPA however is used in a different context and has more items. We plan to examine concurrent validity between discrete behavioural domains of the BPPA and other outcome measures being used in the study.

12. Comment: Not clear how the GAS scores will be used as a predictor? How will GAS goals relate to COPM, it seems both measures would give the same type of construct measurement, or would be extremely related (not predictive)
12. Response: The GAS goals relate to specific intervention strategies (which align with a component of the family of participation related constructs, such as activity competence), not the participation outcome itself. GAS goals are being set and scored during the intervention period only and are therefore not compared between groups. Analysis will explore whether GAS goal attainment of activity

competence or behaviour (e.g. scheduling activity during the week), is related to change in COPM performance.

13. Comment: Typo on “Knowledge Translation”
13. Response: Thank you, this has been amended.

Reviewer 2

1. Comment: The authors describe the planned study as a large pragmatic RCT. Their sample estimates are based on a validated reliable measure - the Canadian Occupational Performance Measure (COPM) with an identified clinically important effect of 2-points (on a 10 point scale). Thus the sample estimate for the primary outcome is n = 36 (18 / group). While well-justified for the primary outcome this is not a large trial.
1. Response: Thank you for your comment. The text has been revised to better reflect the size of the trial. The text at page 8 line 32-33 now reads:
"It is important to test participation-focused therapy in a randomized trial"

2. Comment: The multiple measures employed (n = 10 +4 demographic measures) each have multiple domains or scales (a total of 40+). The use of all but one of these measures will be to address secondary questions - of which there are 9. To what extent will a trial of 36 children be sufficiently powered to address the secondary questions and hypotheses?
2. Response: The sample size has been calculated based on the primary outcome as this is a preliminary pragmatic trial. A demonstrated effect on the primary outcome is required to justify a larger randomized trial utilising this style of intervention. Any demonstrated effects on secondary outcomes will also assist in power calculations for future studies. Only specific subscales of each measure, as described, will be used to explore the effect of the intervention. Furthermore, several measures, including the PACQ, MPAM-R, PIS, and SBQ are being used primarily to explore the mechanism of effect of the intervention and are not outcomes in themselves.

3. Comment: Of the multiple hypotheses listed, only the primary outcome has a specified magnitude of effect. What is the hypothesised magnitude of effect on the secondary outcomes?
3. Response: See response 2, reviewer 2 above.

4. Comment: The intervention is appropriately tailored to the individual, but ultimately quite complex as described, and will likely vary greatly between individuals, increasing the potential for highly variable outcomes and impacting on the sample required to find an effect. How has this been accounted for in the design?
4. Response: The process and clinical reasoning framework for the intervention is the same for all participants, as described in the methods. The active ingredients are likely to differ between participating parent-child dyads due to differing barriers and facilitators to physical activity participation. Videos of each session are being taken to facilitate an analysis of intervention contents, which will describe the therapy delivered and the clinical reasoning framework that has been tested. Given the theorized mechanism of effect, we do not believe there will be significant variability in response to treatment on the primary outcome.

5. Comment: What is the rationale for the amount of intervention provided (8 hours) to achieve 3-5 goals? Given the diverse range of interventions that are identified as potentially offered, and the time that could be required to achieve a number (e.g. refer to funding source for equipment; strength/balance training; modify access to the environment; cognitive orientation to motor learning), can further explanation be provided about how these will be managed in the time period identified?
5. Response: The 8-week timeframe was chosen to nestle into school term periods, and so that the study period as a whole would cross all seasons of the year (to reduce potential bias for seasonality

of sporting activities available). ParticiPAte is also completely different to other hands-on interventions which may have established dosage recommendations. Motivational interviewing has been demonstrated to have effects on health-related behaviours in as little as 15 minutes. Additionally, coaching to empower children and caregivers to solve their own problems forms a large part of the ParticiPAte intervention. Whilst some barriers to physical activity participation may not be overcome in 8 weeks (e.g. complex equipment prescription and funding), many barriers can be faced in as little as one week and therefore the 8-week timeframe aims to strike a balance.

6. Comment: Usual care is appropriately considered and logged. How will these data be used in the analyses?
6. Response: Usual care type, duration/frequency, and content (where available) will be used in descriptive analysis of each group and will be compared between groups. We expect, based on our previous studies with this population, that limited additional therapy will be received by these children as usual care at this age and GMFCS level. See response 9, reviewer 1.

7. Comment: The video-recording of intervention sessions provides an opportunity to evaluate the nature of the intervention provided - this is a strength of the program planned because it is a new intervention package - can further explanation be provided about how those viewing the videos will score (?) and analyse the behaviours observed?
7. Response: At least two independent reviewers will view a random selection of videos and code contents based on the Behaviour Change Taxonomy. This will be used to report alongside the intervention as well as describe the intervention and clinical reasoning frameworks. An additional clarification has been added to page 20 line 22-26:
"The Behaviour Change Taxonomy coding framework will be used to categorise behaviour change elements and link to potential mechanisms of action (using the TDF domains) by at least two independent reviewers on a random sample of video recordings."

8. Comment: Week 1 describes setting goals that are "realistic according to the family context and within the constraints of the intervention and therapist expertise." This appears reasonable, however, is there a mechanism for controlling for the potential bias associated with the level at which goals are set given this is the primary outcome measure?
8. Response: As this is a pragmatic trial, the method applied is that typically used in clinical practice whereby the practitioner is collaboratively involved in the process of goal-setting. This necessitates discussion between the parties of what might be a realistic goal (e.g. a child describing that they would like to ride their tricycle for 20 minutes with friends 3 times per day, including school days, is obviously not practical nor realistic). The COPM goals and GAS goals are being reviewed for appropriateness of scaling and content by an independent rater who does not know the identity of the participants. This will help to ensure that the goals are being set at an appropriate and realistic level, and also identify any COPM goals which do not align with participation as defined in the Family of Participation-Related Constructs.

9. Comment: The chosen primary measure is difficult to apply with blinded assessment at baseline because it forms part of the process of establishing a therapeutic relationship. It could be assessed by those blind to group allocation at follow-up, but is not - can this be further justified?
9. Response: We agree that a blinded rater at follow-up would further strengthen the design of the study, however this was not possible to include due to the additional costs associated with having a blinded rater. Potential for bias will be discussed as a part of the reporting of the trial outcomes. This suggestion is a potential improvement to the design of the trial that may be implemented in future.

10. Comment: Can further clarification be provided as to how the GAS scores will be used as a predictor of change (page 25)?
10. Response: This has been clarified in the hypotheses (see response 17 reviewer 2).

11. Comment: Will the analyses be adjusted for the stratification factors used in randomisation?
11. Response: Stratification was used as a means to balance the potential confounders across trial groups. The stratification factors will therefore not be used to adjust analyses.

Additional minor comments/suggestions:
12. Comment: Page 5, line 2 - the phrase "free-living conditions" requires explanation the first time it is used.
12. Response: See response 2, reviewer 1.

13. Comment: Page 5 line 31-34 - this is a complex sentence and would benefit from revision to ease clarity.
13. Response: This has been amended to:
"Compared to typically developing peers, children and youth with CP experience more barriers to access to and participation in leisure-time PA.16-19"

14. Comment: Page 6 line 40 - the explanation of 'relatedness' in self-determination theory needs a slight revisions for greater clarity of expression.
14. Response: This has been amended to:
"and (iii) relatedness (the feeling of being connected to others and experience of meaningful reciprocal relationships)."

15. Comment: Page 6 line 52 - the grammar of the first sentence of this paragraph needs revision.
15. Response: This has been amended to read:
"Interventions based on SDT have been tested in a number of studies. These interventions have been aimed to increase leisure-time PA participation or levels of HPA in typically developing children, and have demonstrated positive outcomes.36-38"

16. Comment: Page 7 line 19-20 - provide an explanation for the statistic 'g' first time used.
16. Response: This has been amended to read:
"Based on effect size calculations (Hedge's g thresholds; small<0.2, medium<0.5, large>0.8), there were modest, significant effects on both physical (g=0.18, 95% CI 0.17, 0.20) and psychosocial (g=0.22, 95% CI 0.19, 0.25)"

17. Comment: Page 9 line 8 - the second question requires a grammar check for clarity Page 10 lines 25-36 - please review for greater clarity of what will be assessed - particularly secondary analysis #1.
17. Response: At page 9 line 8 this has been amended to read (second part of sentence removed):
"This intervention would identify and target child and family-specific barriers and facilitators (across all domains of the ICF-CY and TDF) to individually defined participation goals."
At page 9 line 51 to page 10 line 11 this has been amended to read:
"Attainment of incremental, individualized treatment goals during the intervention measured by Goal Attainment Scaling (GAS). Goals will align with identified barriers to participation across body structure and function, activity, personal and environmental domains of the ICF-CY and/or behavioural domains of the TDF (Aggregate T-scores)."

18. Comment: Page 22. line 55 - please provide an explanation for "Evenson cut-points" first time it is used.
18. Response: See response 1, reviewer 1 for addition to explanatory text in introduction. The methods text at page 23 lines 10-17 has been amended to read:
"Evenson cut-points demonstrate high classification accuracy for PA intensity in adolescents with CP GMFCS I-III,79 however due to limitations in study design and analysis, have the potential to misclassify PA for youth with CP, especially those with GMFCS II and III.86 Activity counts will be

transformed via the best available GMFCS-specific cut-points available at the time of analysis, to time spent in sedentary behaviour, LPA and MVPA."

Currently the best available GMFCS-specific cut-points have been published by Trost and colleagues (2016).

VERSION 2 – REVIEW

REVIEWER	Christine Imms Australian Catholic University I know the researchers and conduct research in this field but have no conflict of interest.
REVIEW RETURNED	01-May-2017

GENERAL COMMENTS	The authors have provided a response to the prior review comments and made some changes to the paper that have clarified the reporting. The paper is well written and easy to follow. I have a few remaining questions, mostly minor. In general, although the authors have addressed concerns raised by the reviewers in their comments in reply, they have not consistently added justifications / explanations to the manuscript itself. In many cases I think this is required and would strengthen the paper. It may be that a slightly longer discussion would allow some elements to be addressed in the paper (including a limitations section), or justifications can be added to the methods. Abstract: In the abstract, the trial should be clearly defined as a pragmatic randomised trial. GMFCS acronym can be used in the third paragraph. Literature review: Page 4 lines 32-34 - the newly inserted phrase beginning " Compared to typically developing peers,..." requires a grammar check and revision. Page 4, lines 56-59: the authors responded to a request to explain Evenson cut points, by adding new information (which is helpful) but removed the reference to Evenson at this point. It is then used later, and so still needs to be described (or simply add it to the earlier description). In this section, the HPA acronym can be used as it has already been explained. Page 5, paragraphs 1/2 - the requested explanation of 'free living conditions' has been provided, but has been included at the second occasion of reference to the idea - please move it up to the first occasion (paragraph 1 rather than 2 of page 5). Page 7 lines 6-10 - the requested grammar check in the sentence about SDT has not resolved the concern. The sentence "These interventions have been aimed to increase leisure time PA participation ...." is awkward. Suggest deleting the words "have been" from this sentence to address this. Page 7 lines 30-33 - The explanation requested for Hedge's g

	thresholds has been provided. However, given that the criteria set by Hedge's g indicates that values <0.2 are small - the word "modest" in the sentence following, that describes the findings, needs to be changed to "small". Methods: In response to queries regarding the power of the study to address secondary outcomes, the authors provide a rationale related to this being a 'preliminary pragmatic trial'. The rationale provided however, has not been added to the manuscript. This should be added in the methods, or in a limitations section within the discussion (which currently does not have a limitations section). The response to the query raised about the hypothesised magnitude of effect of secondary measures does not address the query. Even though it may not be anticipated that the trial will have sufficient power to detect a statistically significant effect, it is still possible to consider and hypothesise the magnitude of expected effects (ie effect sizes). If there is no idea about these potential effects, that could be stated more clearly. Page 9 - paragraph on secondary analyses to explore predictors of goal attainment has been adjusted, but this section still lacks clarity. In part this may be due to the use of the phrase 'predictors of "goal attainment" ' when I think the authors refer to predictors of increased performance and satisfaction with performance of participation goals (ie COPM data). If that is so, then suggest this section should be rephrased as at present it reads as if 'goal attainment' (as measured by the Goal Attainment Scale) will be used to predict goal attainment. In addition, Aggregated T scores are planned for these analyses and a description provided about GAS goals being aligned with ICF domains - will the aggregated T scores be all GAS scales together, or will T scores be computed for GAS goals within the domains they are aligned to? The explanation provided to the reviewer about how GAS will be used is clear, but has not been added to the manuscript. Page 11: Response to queries related to sample estimates have been provided to the reviewer, but the justification has not been added to the manuscript. Suggest that this should occur (in the sample size section). Intervention: the authors have provided a rationale for the decisions about intervention methods and time frames, but this does not appear in the manuscript. Suggest it is added either to methods or discussion. This also relates to the responses to review related to setting of Goals (scaling and appropriateness) and COPM assessment at the end of the trial. Both these responses could be re-crafted and included in a discussion (limitations/design considerations) section. Analyses: The query re how potential differences in usual care between groups will be handled in the analyses has been addressed by indicating descriptive analyses will be undertaken, but this does not address the potential for confounding if there are real differences in this variable. The authors also describe a plan to assess 'best

	responders' and it would be appropriate to consider any differences in this variable (among others) between groups as a covariate in those analyses.

VERSION 2 – AUTHOR RESPONSE

Reviewer's comments: Reviewer 2
Abstract:
1. Comment: In the abstract, the trial should be clearly defined as a pragmatic randomised trial. GMFCS acronym can be used in the third paragraph.
1. Response: The acronym for GMFCS has been written out in full on page 2 line 36-37. The text has also been amended at page 2 line 13-15 to
"The proposed study aims to compare the efficacy of a participation focused therapy (ParticiPAte CP) to usual care in a pragmatic, randomized waitlist controlled trial."

Literature review:
2. Comment: Page 4 lines 32-34 - the newly inserted phrase beginning "Compared to typically developing peers,..." requires a grammar check and revision.
2. Response: This has been amended at page 4 line 32-35 to read:
"Compared to their typically developing peers, children and youth with CP experience a greater number of barriers to participation in leisure-time PA"

3. Comment: Page 4, lines 56-59: the authors responded to a request to explain Evenson cut points, by adding new information (which is helpful) but removed the reference to Evenson at this point. It is then used later, and so still needs to be described (or simply add it to the earlier description).
In this section, the HPA acronym can be used as it has already been explained.
3. Response: Evenson cut-points refers to those cut-points (e.g. number of vertical axis counts per epoch) published by Evenson et al for typically developing children. All sets of cut-points have the same basic concept, though are often named for the publishing author (in this case Evenson). The paragraph at page 24 line 6-18 has been reworded to reduce confusion and now reads:
"Cut-points published for typically developing children have been used to classify PA in children and adolescents with CP GMFCS I-III80 These cut-points may, however, have the potential to misclassify PA for youth with CP, especially those with GMFCS II and III.24 Activity counts will therefore be transformed via the best available GMFCS-specific cut-points available at the time of analysis, to time spent in sedentary behaviour, LPA and MVPA."
4. Comment: Page 5, paragraphs 1/2 - the requested explanation of 'free living conditions' has been provided, but has been included at the second occasion of reference to the idea - please move it up to the first occasion (paragraph 1 rather than 2 of page 5).
4. Response: This has been amended (see page 5)

5. Comment: Page 7 lines 6-10 - the requested grammar check in the sentence about SDT has not resolved the concern. The sentence "These interventions have been aimed to increase leisure time PA participation ...." is awkward. Suggest deleting the words "have been" from this sentence to address this.
5. Response: This has been amended at page 7 line 7-11 to read:
"Interventions to increase leisure-time PA participation or levels of HPA in typically developing children that are based on SDT have demonstrated positive outcomes"

6. Comment: Page 7 lines 30-33 - The explanation requested for Hedge's g thresholds has been provided. However, given that the criteria set by Hedge's g indicates that values <0.2 are small - the word "modest" in the sentence following, that describes the findings, needs to be changed to "small".
6. Response: this has been amended at page 7 line 36 to read:

"Based on effect size calculations (Hedge's g thresholds; small<0.2, medium<0.5, large>0.8), there were small, significant effects on both physical…"

Methods:
7. Comment: In response to queries regarding the power of the study to address secondary outcomes, the authors provide a rationale related to this being a 'preliminary pragmatic trial'. The rationale provided however, has not been added to the manuscript. This should be added in the methods, or in a limitations section within the discussion (which currently does not have a limitations section).
7. Response: The following has been added to the end of sample size section at page 12 line 6-12:
"This study has been powered to detect a difference on the primary outcome of interest. Effects on secondary outcomes are not able to be accurately estimated due to limited previous evidence, and the results of this trial will assist in power calculations for future studies"

8. Comment: The response to the query raised about the hypothesised magnitude of effect of secondary measures does not address the query. Even though it may not be anticipated that the trial will have sufficient power to detect a statistically significant effect, it is still possible to consider and hypothesise the magnitude of expected effects (ie effect sizes). If there is no idea about these potential effects, that could be stated more clearly.
8. Response: See above response to comment 7

9. Comment: Page 9 - paragraph on secondary analyses to explore predictors of goal attainment has been adjusted, but this section still lacks clarity. In part this may be due to the use of the phrase 'predictors of "goal attainment" ' when I think the authors refer to predictors of increased performance and satisfaction with performance of participation goals (ie COPM data). If that is so, then suggest this section should be rephrased as at present it reads as if 'goal attainment' (as measured by the Goal Attainment Scale) will be used to predict goal attainment.
9. Response: This has been amended as suggested to reflect the outcome at page 9 line 44-46:
"Secondary analyses will explore potential predictors of increased participation goal performance and satisfaction for pooled data from intervention and wait-list groups following completion of ParticiPAte CP."

10. Comment: In addition, Aggregated T scores are planned for these analyses and a description provided about GAS goals being aligned with ICF domains - will the aggregated T scores be all GAS scales together, or will T scores be computed for GAS goals within the domains they are aligned to?
10. Response: An explanatory sentence has been added at page 26 line 48 to clarify this:
"Outcome scores on an individual's goals will be converted to an aggregate T score (regardless of the domain to which the GAS goal is aligned) which will be the unit of analysis."

11. Comment: The explanation provided to the reviewer about how GAS will be used is clear, but has not been added to the manuscript.
11. Response: The reviewer response has been integrated into the methods section to add clarity at page 26 line 33-38:
"Three to five GAS goals will be set, each linked to identified barriers to the overarching COPM participation goal and therefore specific intervention strategies (which align with a component of the Family of Participation Related Constructs, such as activity competence), not the participation outcome itself."

12. Comment: Page 11: Response to queries related to sample estimates have been provided to the reviewer, but the justification has not been added to the manuscript. Suggest that this should occur (in the sample size section).
12. Response: As clearly stated in the hypotheses at page 9-10 the GAS, PICQ, MPAM-R, PACQ and

Stage of Behaviour Change are being used primarily to explore the mechanism of effect of the intervention in post-hoc analyses, and are not outcomes in themselves. The study has been powered on the primary outcome of interest. Also see response 7.

Intervention:
13 Comment: the authors have provided a rationale for the decisions about intervention methods and time frames, but this does not appear in the manuscript. Suggest it is added either to methods or discussion.
13. Response: A rationale for intervention dosage has been added to the text at page 15 line 54 to page 16 line 7:
"The dosage for ParticiPAte CP has been chosen to strike a balance between efficacy of intervention components and feasibility. An average of four sessions of MI have been demonstrated to have effects on health-related behaviours in a paediatric population.43 It is possible that some identified barriers to physical activity participation may not be overcome in eight weeks (e.g. complex equipment prescription and funding)."

14. Comment: This also relates to the responses to review related to setting of Goals (scaling and appropriateness) and COPM assessment at the end of the trial. Both these responses could be re-crafted and included in a discussion (limitations/design considerations) section.
14. Response: The section detailing how goals will be rated for adherence to fPRC and technical proficiency has been expanded to clarify how this will reduce bias at page 26 line 51 - page 27 line 8:
"As recommended by Kiresuk, Smith & Cardillo, (1994) a technical proficiency checklist will be employed and a second independent rater familiar with the fPRC (LS, CE) will (i) review all COPM goals to determine whether they are measuring a concept of participation (attendance, involvement, engagement, and/or preference) and all GAS goals to determine whether they are measuring a related construct (activity competence, sense of self, context, and/or environment), and are (ii) technically proficient (no overlapping or gaps between levels, measurement of only one variable, clarity on how the variable is measured/scaled). Goals not meeting these standards will be excluded from analysis."

The following sentence has also been added at page 12 line 53 - page 13 line 5 to clarify blinding for the COPM:
"As this is a pragmatic study, the COPM is being completed as it would be in a clinical scenario (set and scored by the treating therapist). The COPM and GAS goals are however being assessed by a blinded rater against criteria for goal content, scaling and technical proficiency (see Goal Attainment Scaling)."

Analyses:
15. Comment: The query re how potential differences in usual care between groups will be handled in the analyses has been addressed by indicating descriptive analyses will be undertaken, but this does not address the potential for confounding if there are real differences in this variable. The authors also describe a plan to assess 'best responders' and it would be appropriate to consider any differences in this variable (among others) between groups as a covariate in those analyses.
15. Response: As detailed in response 7 and 12, the sample size and statistical analysis sections, the hypotheses, sample size and statistical methods have been stated. This has been informed from consultation with a biostatistics expert, Dr Robert Ware. The statistical test used for the GAS T scores was edited at page 29 line 16-20 to be coherent with the hypotheses and methods sections. Additions have been made at page 29 line 6-11 to clarify the exact test used and all of the co-variables:
"This method takes into account the repeated measures on each participant and the potential for missing data. The distributional family with be Gaussian and the identify link will be used. For the COPM performance score, the co-variables will be time (3 level – 0, 8, and 16 weeks), stratification factors (GMFCS, sex), and group (immediate treatment and wait-list), with a group*time interaction

(which will test for the differences between groups at different time points)."

Based on the hypothesized mechanism of action for the intervention and our planned analyses, it would be inappropriate to include ‘dosage of usual care’ as a co-variate. Indeed, the trial has been designed to be coherent with our experience in previous RCTs – that children of this age and at this functional level are not receiving any substantial amount of usual care therapy unless it is associated with a BoNT-A injection and/or serial casting. The therapy, in that case, is directed largely towards either impairments in Body Structures and Functions (e.g. maintaining calf/wrist extensor length) or activity competence in the domain of Activities of Daily Living (e.g. walking at school, tying shoelaces). As described in the introduction, these types of impairment-focused therapies have not demonstrated effects on participation in active physical recreation (whether intended or otherwise). The primary analysis, therefore for this trial will include only treatment allocation group as the main effect in the primary model, and the only co-variables will be time point and stratification factors (GMFCS, sex).

We thank you again for this opportunity and look forward to your response.

VERSION 3 – REVIEW

REVIEWER	Christine Imms Australian Catholic University I know the researchers and their work, and research in the area myself. I have had no involvement in any work associated with this project or manuscript.
REVIEW RETURNED	23-Jun-2017

GENERAL COMMENTS	Thank you for the opportunity to review this revised manuscript. The authors have responded well to all the queries raised at this time. In particular, there is much greater clarity about the goal setting and analysis intent. I have no further queries and look forward to seeing the paper published, and indeed, the results in due course.