PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Does a brief, behavioural intervention, delivered by paediatricians or psychologists improve sleep problems for children with ADHD? Protocol for a cluster-randomised, translational trial
AUTHORS	Sciberras, Emma; Mulraney, Melissa; Heussler, Honey; Rinehart, Nicole; Schuster, Tibor; Gold, Lisa; Hayes, Nicole; Hiscock, Harriet

VERSION 1 - REVIEW

REVIEWER	Penny Corkum Dalhousie University Nova Scotia Canada
REVIEW RETURNED	01-Oct-2016

GENERAL COMMENTS	Summary: - An interesting translational cluster randomized controlled trial that will assess whether the Sleeping Sound with ADHD intervention will be effective in a real-world context, like it was previously found to be in an efficacy RCT. The protocol is well written and the research design and analytic plan is appropriate to address the research questions. The economic analyses are a great addition to the outcomes for this trial. There are a few items that should be clarified and some more details that should be included, otherwise, the protocol is comprehensive and clear. It will be interesting to learn about the results of this RCT and to see how these results will impact clinical practice in the future. Title and Abstract: - Rather than using the term “sleep problems” in the title (and elsewhere) it would be more accurate to use the term “behavioural sleep problems”. The general term sleep problems would encompass a range of problems including OSA, narcolepsy, etc. - In the abstract can the authors be more specific about how the intervention efficacy was established (e.g., through a RCT) - The authors note that the clinicians are randomized and later say that the clustering is at the level of the pediatrician. This is confusing as based on the title I would assume that clinicians include pediatricians and psychologists and that this is the level of clustering Introduction: - Unsure why the authors start by noting the limitations of melatonin, as this makes it sound like this is the typical treatment for behavioural sleep problems in children with ADHD. While there is a high percentage of children with ADHD being treated with Melatonin, it is not the first line treatment - The Introduction is succinct, covers the relevant background literature, and builds the rationale for the study

	- The research questions and hypotheses were clearly outlined Method: - Further elaboration on the participant inclusion/exclusion criteria would be useful - It is confusing as to whether pediatricians and/or psychologists were involved as the primary caregiver. If both, perhaps it would be best to use the word “clinician” throughout the paper, once defining who this includes - The role of the pediatrician and psychologist became more apparent in the later sections of the Methods section, however, given that this service delivery structure is not standard practice in other countries, it would be best to make this clear from the beginning of the paper - Besides asking pediatricians assigned to the treatment to not share the intervention materials with those pediatricians assigned to the control group, are there any other strategies used to ensure that there is no contamination. Also, are the pediatricians asked about this at any of the follow-up time points? - The “opt out” approach would not be allowed where I conduct research, but it definitely would make this type of research more feasible. Good that the pediatricians were allowed to use an “opt in” approach if they choose - Is there evidence that data collected from online surveys is inter-changeable with data collected using paper-and-pencil surveys? - More information needs to be provided about the “study-designed” questions to assess whether the child met the ICSD criteria for chronic insomnia disorder, delayed sleep-wake phase disorder, or sleep-related anxiety - How is the exclusion criteria of “Major illness or disability (e.g., intellectual disability)” assessed? - How is language proficiency assessed? - Why is randomization stratified on “stratified by the predicted number of enrolled patients”

REVIEWER	Eric Zhou Boston Children's Hospital, USA
REVIEW RETURNED	25-Oct-2016

GENERAL COMMENTS	In the protocol “Does a brief, behavioural intervention, delivered by paediatricians or psychologists improve sleep problems for children with ADHD? A cluster-randomised, translational trial,” the authors have submitted a meaningful effort to examine the translation of a proven intervention into a real world setting. I applaud the authors on their excellent work. It was a well-written manuscript. I have a single major concern related to study design that I would like the authors to discuss further. Specifically, it is not immediately clear to me why there a significant session time difference for pediatricians vs. psychologists (30 minutes vs. 50 minutes). Over the course of 2 sessions, this means that a patient received the intervention from a pediatrician will receive much less individual attention related to their sleep. Minor concerns include: Introduction - Page 5: Define QoL for the first time the abbreviation is used. - Page 8: If this is required by BMJ Open, then ignore. Otherwise, it is not necessary to outline study hypotheses in the manuscript. It is

	repetitious considering that the aims are discussed immediately above. Methods - Page 9: Please explain the rationale for age cut-offs of 5 and 12 years. - Page 9-10: Were providers offered any compensation for their participation?

REVIEWER	John A Taylor University of Nottingham, UK
REVIEW RETURNED	27-Oct-2016

GENERAL COMMENTS	The protocol paper is very thorough and generally well written, although somewhat lengthy. The majority of my comments which are chronological ought to be addressable by some careful rewording to improve clarity. There is no mention of the word 'protocol' in the title. The 'Introduction' title is missing. Page 6, line 38 - make it clear that 'trained clinician' is in respect of their delivery of the intervention. You infer on page 7, line 37 that your original efficacy trial intervention was delivered by trained researchers rather than clinicians, but on page 6, line 38 that they were trained clinicians (psychologists or trainee paediatricians). Also, you don't state who delivered the interventions in the two additional RCTs you cite (page 7, line 8)? Overall, it isn't instantly clear to me to what extent the delivery model in the 'real life' setting differs from your earlier efficacy trial. This would benefit from further clarification. Page 8, line 52 - use the word 'proportion' rather than prevalence? Ensure that the main headings in the body of the paper correspond to the journal guidelines and those in the abstract, i.e. Methods and Analysis, Ethics and Dissemination etc. Overall Study Design - move the funding and ethics statements in this section to the appropriate sections of the paper. Page 9, line 41 - change 'families of children' to 'children and their families'. Page 10, paragraph 2 - It isn't clear to me whether there is the potential for psychologists in the study to be delivering both the intervention and usual care. For example, you mention them not sharing the intervention materials with 'any other families' (line 35); could these include usual care participants? I would be concerned if psychologists were not kept separate across the intervention and control conditions. Page 11, line 6 - why is an active consent process (opt in) included as an option to the 'opt out'? The randomisation process to which clinician across the intervention

	and control conditions is unclear within the body of the paper. For example, Page 14, paragraph 2 - I do not understand the first two sentences. Also in paragraph 3, you state that control participants receive usual care from a paediatrican, but the flow diagram also includes psychologists. This section isn't clear without reference to the flow diagram and needs rewording. Intervention training - explain what is meant by 'all psychologists' (page 14, line 51). Does this refer to both intervention and control conditions? Intervention delivery - you mention different appointment lengths for paediatricians and psychologists and I note that the former have less time than in the efficacy trial. This will have a potential impact on the delivery of the intervention. How do you intend to address this? Is it a study limitation? Page 16, paragraph 2 - more information would be useful earlier on in terms of how the appointments are made. Follow-up - page 16, line 21 - it isn't clear to me why you're measuring control follow up at median date of intervention follow-up? Why are you not measuring 3 and 6 months from the usual care appointment dates? Dissemination - need to move Ethics information to here (see earlier) and briefly include some ethical and safety considerations. Article summary - also include a few bullet points around Article Focus & Key Messages. There are no supplementary checklists attached to the submission. I would recommend this protocol for publication but only after satisfactorily improving the clarity of certain areas as specified above.

REVIEWER	Samuele Cortese University of Southampton, UK
REVIEW RETURNED	09-Nov-2016

GENERAL COMMENTS	General comment: The authors should be praised for proposing such an important study in the field. After several standard, efficacy RCTs, the implementation of a pragmatical RCT to assess effectiveness of the proposed intervention I real life is much needed. The cost-effectiveness analysis is an important aspect of the study. I have some specific comments, mainly on the inclusion criteria and measures. Specific comments: Abstract (“Up to 70% of children with Attention-Deficit/Hyperactivity Disorder (ADHD) suffer from behavioural sleep problems”) and introduction (“Behavioural sleep problems are common and more persistent in children with ADHD, and associated with poorer child

	and family well-being.1-4): I am not sure that all the studies cited by the authors (including the first reference which is a review) have made the distinction between behavioral and "neurological" sleep problems. I would suggest to report the % of behavioral sleep problems from studies that specifically addressed behavioral problems, as opposed to neurological/somatic sleep problems (e.g., RLS, SDB or narcolepsy), if available. Introduction "A number of factors have been associated with sleep problems in children with ADHD": some neurological/somatic conditions (e.g., RLS, SDB or narcolepsy) also continued to sleep disruption Methods "Child aged between 5-12 years at the time of the recruitment call": please provide a rationale supporting the choice of this age range "Child meets DSM 5 criteria for ADHD assessed via the 18-item ADHD Rating Scale IV - a validated scale measuring the core symptoms of ADHD.30 Caregivers need to rate at least 6 of 9 of the inattention and/or hyperactivity/impulsivity items as occurring 'often' or 'very often' in order to meet current symptom criteria. Caregivers are asked to rate symptoms off stimulant medication. Additional questions are then asked to ensure symptoms have been present for at least 6 months, contribute to cross-situational impairment and have age of onset prior to the age of 12.": Unfortunately, this procedure does not allow ruling out differential diagnoses (e.g., mood disorders mimicking ADHD symptoms), which is an essential DSM-5 criterion. Please comment on this. Additionally, how will "contribute to cross-situational impairment" be assessed? "Children are eligible to participate if they are taking melatonin or any other sleep inducing medication, as long as the inclusion criteria are still met despite medication use": will they be allowed to continue melatonin during the intervention? If so, the study will assess the effects of behavioral intervention + melatonin (possible synergistic effects) rather than of the behavioral intervention per se What is, on my view, the main limitation of the study ("Sleep problems assessed using unblinded parent report as opposed to objective measures") is fairly acknowledged by the authors and should be clearly identified in the paper reporting the results of the study. I assume that it was not possible to include objective sleep measures, via actigraphy, due to financial constraints but the authors may want to seek grants to perform actigraphy in at least a subsample of the participants. I wish all the best to the authors for this important project.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1		
1.	Rather than using the term "sleep problems" in the title (and elsewhere) it would be more accurate to use the term "behavioural sleep problems". The general term sleep problems would encompass a range of problems including OSA, narcolepsy, etc.	Thank you for this suggestion. Given that the exact cause of sleep problems, even those that can be addressed with behavioural strategies is likely multi-factorial including biological causes, we use the term sleep problems but now clarify our use of the term in our introduction: *"In this study we use the term sleep problems to denote those difficulties that can be addressed using behavioural interventions"* –paragraph 2, page 4.
2.	In the abstract can the authors be more specific about how the intervention efficacy was established (e.g., through a RCT)	We have now made this clearer in the introduction section of our abstract – see page 2.
3.	The authors note that the clinicians are randomized and later say that the clustering is at the level of the pediatrician. This is confusing as based on the title I would assume that clinicians include pediatricians and psychologists and that this is the level of clustering	We have now made this clearer in the methods section of our abstract: "Clinicians are randomly allocated at the level of the paediatrician to either receive the sleep training or not" – see page 2.
4.	Unsure why the authors start by noting the limitations of melatonin, as this makes it sound like this is the typical treatment for behavioural sleep problems in children with ADHD. While there is a high percentage of children with ADHD being treated with Melatonin, it is not the first line treatment	Thank you for this statement. We have now moved out statement regarding the efficacy of melatonin to our section discussing what is known about the treatment of sleep difficulties in ADHD – see paragraph 2, page 6.
5.	Further elaboration on the participant inclusion/exclusion criteria would be useful	We have now included further detail about our inclusion/exclusion criteria – see bottom of page 11-12.
6.	It is confusing as to whether pediatricians and/or psychologists were involved as the primary caregiver. If both, perhaps it would be best to use the word "clinician" throughout the paper, once defining who this includes	We note at the bottom of page 7 that "Paediatricians are the main care providers for ADHD in Australia" and now state the following in our methods at the beginning of the 'recruitment of health professionals' section and 'randomisation' section: *"Given that paediatricians are the main healthcare provider for children with ADHD, recruitment and randomisation occurs at the level of the paediatrician"* – see bottom of page 10. "*Randomisation occurs at the level of the paediatrician*" – see bottom of page 13.

7.	The role of the pediatrician and psychologist became more apparent in the later sections of the Methods section, however, given that this service delivery structure is not standard practice in other countries, it would be best to make this clear from the beginning of the paper	We provide a description of the role of the paediatrician and psychologist in healthcare provision in Australia on page 7 of our introduction. We have also hopefully made our design clearer with the amendments made to reviewer comment 6.
8.	Besides asking pediatricians assigned to the treatment to not share the intervention materials with those pediatricians assigned to the control group, are there any other strategies used to ensure that there is no contamination. Also, are the pediatricians asked about this at any of the follow-up time points?	All intervention paediatricians were asked to sign a memorandum of Understanding, agreeing not to share intervention materials with control group paediatricians. We did not ask paediatricians whether they did this or not at follow up. However, we do ask control group families if they accessed any of the study materials.
9.	Is there evidence that data collected from online surveys is inter-changeable with data collected using paper-and-pencil surveys?	We do not believe so as question wording is identical in both formats. Giving participants a choice of response format is a well recognised strategy and ethical way to increase response rates.
10.	More information needs to be provided about the “study-designed” questions to assess whether the child met the ICSD criteria for chronic insomnia disorder, delayed sleep-wake phase disorder, or sleep-related anxiety	See response to reviewer point 5 above.
11.	How is the exclusion criteria of “Major illness or disability (e.g., intellectual disability)” assessed?	See response to reviewer point 5 above.
12.	How is language proficiency assessed?	This was assessed over the phone when completing eligibility screening with parents.
13.	Why is randomization stratified on “stratified by the predicted number of enrolled patients”	We identified early in our discussions with paediatricians that there were a number who saw far more children with ADHD than most (e.g., most paediatricians in the study see 20-50 children with ADHD aged 5-12 in a calendar year, but others saw 100-400). Given randomization is clustered at the paediatrician level we stratified by the predicted number of enrolled patients to ensure approximately equal numbers of patients were randomised to each arm.

Reviewer 2		
1.	I have a single major concern related to study design that I would like the authors to discuss further. Specifically, it is not immediately clear to me why there a significant session time difference for pediatricians vs. psychologists (30 minutes vs. 50 minutes). Over the course of 2 sessions, this means that a patient received the intervention from a pediatrician will receive much less individual attention related to their sleep.	Yes, this is correct. We thought long and hard about this but in reality these consultation times reflect the current practice of paediatricians and psychologists in Australia and there may indeed be variations to these consultation times between individual clinicians. We therefore record the actual duration of each consultation, which will enable us to examine the relationship between intervention dose and outcomes. We now make this explicit in our manuscript: "*The differences in consultation duration reflect real life clinical practice. We record the actual duration of all consultations, which will enable us to examine the relationship between intervention dose and outcomes*" – see bottom of page 15.
2.	Page 5: Define QoL for the first time the abbreviation is used.	This has now been amended – see paragraph 2, page 4.
3.	Page 8: If this is required by BMJ Open, then ignore. Otherwise, it is not necessary to outline study hypotheses in the manuscript. It is repetitious considering that the aims are discussed immediately above.	We have opted to keep this in so that we are explicit about the a priori hypotheses for the study.
4.	Page 9: Please explain the rationale for age cut-offs of 5 and 12 years.	Our sleep intervention has been designed to meet the needs of primary school aged children with ADHD and does not deal with the complexities associated with treating sleep problems in adolescence. We are currently working on an adaptation to this program for adolescents with ADHD and will test the efficacy of this intervention in a separate randomised controlled trial.
5.	Page 9-10: Were providers offered any compensation for their participation?	No compensation was provided to providers or families for participation in the study.

Reviewer 3		
2.	There is no mention of the word 'protocol' in the title.	See editor request, point 1.
3.	The 'Introduction' title is missing.	This has now been added on page 4.
4.	Page 6, line 38 - make it clear that 'trained clinician' is in respect of their delivery of the intervention.	This has now been amended – see bottom of page 6.
5.	You infer on page 7, line 37 that your original efficacy trial intervention was delivered by trained researchers	We have now made it clearer in the last paragraph of page 6 that in previous research, clinicians have been hired to deliver the intervention under tightly controlled

	rather than clinicians, but on page 6, line 38 that they were trained clinicians (psychologists or trainee paediatricians). Also, you don't state who delivered the interventions in the two additional RCTs you cite (page 7, line 8)? Overall, it isn't instantly clear to me to what extent the delivery model in the 'real life' setting differs from your earlier efficacy trial. This would benefit from further clarification.	research conditions. In contrast, the current study is a translation trial where we are examining whether this intervention is effective when delivered in 'real life' clinical settings by the child's treating clinician. The person delivering the intervention in the previous trials has now been clarified – see paragraph 1, page 6.
6.	Page 8, line 52 - use the word 'proportion' rather than prevalence?	We have retained the word prevalence given that this matches with what we have listed in our trial registration.
7.	Ensure that the main headings in the body of the paper correspond to the journal guidelines and those in the abstract, i.e. Methods and Analysis, Ethics and Dissemination etc.	We made amendments to ensure that journal guidelines have been followed.
8.	Overall Study Design - move the funding and ethics statements in this section to the appropriate sections of the paper.	We made amendments to ensure that journal guidelines have been followed.
9.	Page 9, line 41 - change 'families of children' to 'children and their families'.	We have now changed this to 'parents of children' in order to ensure the remainder of the sentence makes sense grammatically – see bottom of page 8.
10.	Page 10, paragraph 2 - It isn't clear to me whether there is the potential for psychologists in the study to be delivering both the intervention and usual care. For example, you mention them not sharing the intervention materials with 'any other families' (line 35); could these include usual care participants? I would be concerned if psychologists were not kept separate across the intervention and control conditions.	Whilst we agree this may be a possibility, we think it is very unlikely. There are around 1700 clinical psychologists in Victoria and the chances of a control child seeing one of them and receiving study materials from them, are slim. Further, like the paediatricians, we asked study psychologists to restrict their use of materials to inertevtnions families only.
11.	Page 11, line 6 - why is an active consent process (opt in) included as an option to the 'opt out'?	Our main method of making initial contact with families is to use an opt out approach. This helps to ensure we understand some basic characteristics of the entire population of interest (e.g., child age and sex, socio-economic status). After the identification of eligibility, all participants were required to provide active consent before they were enrolled in the trial. We have now made this clearer at the bottom of page 10.
12.	The randomisation process to which clinician across the intervention and control conditions is unclear within	In order to make these sentences clearer, we now state at the beginning of this section that "Randomisation occurs at the level of the paediatrician" – see bottom of

	the body of the paper. For example, Page 14, paragraph 2 - I do not understand the first two sentences. Also in paragraph 3, you state that control participants receive usual care from a paediatrican, but the flow diagram also includes psychologists. This section isn't clear without reference to the flow diagram and needs rewording	page 13. We apologise for the error in our flow chart, we have now removed psychologists from the allocation component of the flow diagram – see Figure 1.
13.	Intervention training - explain what is meant by 'all psychologists' (page 14, line 51). Does this refer to both intervention and control conditions?	We have now made the role of psychologists clearer by removing psychologists under the control arm of the flow chart (see Figure 1) and making it clearer in the manuscript that psychologists were recruited only for the intervention arm and had no contact with control participants – see paragraph 2, page 9.
14.	Intervention delivery - you mention different appointment lengths for paediatricians and psychologists and I note that the former have less time than in the efficacy trial. This will have a potential impact on the delivery of the intervention. How do you intend to address this? Is it a study limitation?	See response to Reviewer 2, point 1.
15.	Page 16, paragraph 2 - more information would be useful earlier on in terms of how the appointments are made.	We have decided to retain this information here about how appointments are made in the context of also outlining intervention delivery processes.
16.	Follow-up - page 16, line 21 - it isn't clear to me why you're measuring control follow up at median date of intervention follow-up? Why are you not measuring 3 and 6 months from the usual care appointment dates?	This is because there is likely to be variation in usual care delivery. We will be tracking all service use received during the study period for both intervention and control families and will report this in our main trial outcomes paper.
17.	Dissemination - need to move Ethics information to here (see earlier) and briefly include some ethical and safety considerations	We made amendments to ensure that journal guidelines have been followed.
18.	Article summary - also include a few bullet points around Article Focus & Key Messages	We made amendments to ensure that journal guidelines have been followed.
19.	There are no supplementary checklists attached to the submission.	See response to editor comment – point 3.

Reviewer 4		
1.	Abstract (“Up to 70% of children with Attention-Deficit/Hyperactivity Disorder (ADHD) suffer from behavioural sleep problems”) and introduction (“Behavioural sleep problems are common and more persistent in children with ADHD,	Thank you for this comment. We have now removed reference to the term ‘behavioural’ sleep problems given the multi-factorial aetiology of sleep problems in children with ADHD. We now use the term sleep problems but now clarify our use of the term in our

	and associated with poorer child and family well-being.1-4): I am not sure that all the studies cited by the authors (including the first reference which is a review) have made the distinction between behavioral and "neurological" sleep problems. I would suggest to report the % of behavioral sleep problems from studies that specifically addressed behavioral problems, as opposed to neurological/somatic sleep problems (e.g., RLS, SDB or narcolepsy), if available.	introduction: *"In this study we use the term sleep problems to denote those difficulties that can be addressed using behavioural interventions"* – paragraph 2, page 4.
3.	"A number of factors have been associated with sleep problems in children with ADHD": some neurological/somatic conditions (e.g., RLS, SDB or narcolepsy) also continued to sleep disruption	Thank you. We have now provided further clarification about these potential causes at the bottom of page 4.
4.	Child aged between 5-12 years at the time of the recruitment call": please provide a rationale supporting the choice of this age range	See reviewer 2, point 4.
5.	"Child meets DSM 5 criteria for ADHD assessed via the 18-item ADHD Rating Scale IV - a validated scale measuring the core symptoms of ADHD.30 Caregivers need to rate at least 6 of 9 of the inattention and/or hyperactivity/impulsivity items as occurring 'often' or 'very often' in order to meet current symptom criteria. Caregivers are asked to rate symptoms off stimulant medication. Additional questions are then asked to ensure symptoms have been present for at least 6 months, contribute to cross-situational impairment and have age of onset prior to the age of 12.": Unfortunately, this procedure does not allow ruling out differential diagnoses (e.g., mood disorders mimicking ADHD symptoms), which is an essential DSM-5 criterion. Please comment on this. Additionally, how will "contribute to cross-situational impairment" be assessed?	The reviewer is correct; we were are unable to rule out differential diagnoses using our ADHD case definition method and have now explicitly noted that at the page 12 (paragraph 2). We have now included more details about how the other criteria for ADHD were assessed – see page 11.
6.	"Children are eligible to participate if they are taking melatonin or any other sleep inducing medication, as long as the inclusion criteria are still met despite medication use": will they be allowed to continue melatonin during the intervention? If so, the study will assess the effects of behavioral intervention + melatonin (possible synergistic	It would be unethical to ask families to stop taking melatonin during the intervention period, particularly given that the aim of this trial is to assess effectiveness of the intervention in real world clinical situations. We will monitor melatonin use for both children in the usual care and intervention groups and will be able to examine the effects of this on outcomes.

	effects) rather than of the behavioral intervention per se	
7.	What is, on my view, the main limitation of the study ("Sleep problems assessed using unblinded parent report as opposed to objective measures") is fairly acknowledged by the authors and should be clearly identified in the paper reporting the results of the study. I assume that it was not possible to include objective sleep measures, via actigraphy, due to financial constraints but the authors may want to seek grants to perform actigraphy in at least a subsample of the participants.	Thank you for this suggestion. We chose not to include Actigraphy due to feasibility issues given the large size of this sample. We attempted to collect Actigraphy data in our original efficacy trial and were only able to collect useable data for ~30 of 244 participants. Similar to other groups attempting to use actigraphy devices in children with developmental problems (Gringras et al., 2010), encountered several practical issues despite adequate funding including children refusing to wear, destroying, or losing the device. Thus we opted to rely on parent report on this trial, especially given that this drives real life service use.

VERSION 2 – REVIEW

REVIEWER	John A Taylor NIHR Nottingham Hearing Biomedical Research Unit, University of Nottingham, UK
REVIEW RETURNED	15-Dec-2016

GENERAL COMMENTS	I am satisfied that my comments on the original review have been addressed and am now happy to recommend this revised protocol for publication. However, I note the following remaining minor issues that need to be addressed first: Page 4 - 'children with ADHD are largely comprise' - correct grammar Page 5 - 'parents likely are affected' - correct grammar Page 7 - should be "out of pocket costs" Page 8 - Hypothesis 1 - 'proportion' rather than 'prevalence' Page 8 - 'Participants include parents' - change 'include' to 'are' Page 9 - end of first paragraph needs rewording to make it clear what the paediatricians are agreeing to dependent on allocation to condition. e.g. (2) deliver the sleep program to intervention families OR USUAL CARE or refer the child to a psychologist to deliver the sleep program IF ALLOCATED TO THE INTERVENTION (3) not share intervention materials with control group paediatricians IF ALLOCATED TO THE INTERVENTION. Page 10 - lines 28 & 53 - it is not clear what they are consenting to. Also lines 35 and 39 indicate two further optional consents. Are there separate consent forms for these? Pages 11-12 - check tense on point c. - 'needed' should be 'need', 'were' should be 'are'. Also, etc should be followed by a full stop. Page 12 - point d. - Final two sentences are explaining what happened, not what will happen.

REVIEWER	Samuele Cortese Southampton University
REVIEW RETURNED	19-Dec-2016

GENERAL COMMENTS	No further comments

VERSION 2 – AUTHOR RESPONSE

Reviewer 1		
1.	Page 4 - 'children with ADHD are largely comprise' - correct grammar Page 5 - 'parents likely are affected' - correct grammar Page 7 - should be "out of pocket costs"	Thank you. These errors have both been corrected.
2.	Page 8 - Hypothesis 1 - 'proportion' rather than 'prevalence'	The wording in both the aims and hypotheses has been changed to 'prevalence' in order to be consistent with our trial registration details.
3.	Page 8 - 'Participants include parents' - change 'include' to 'are'	This has been changed.
4.	Page 9 - end of first paragraph needs rewording to make it clear what the paediatricians are agreeing to dependent on allocation to condition. e.g. (2) deliver the sleep program to intervention families OR USUAL CARE or refer the child to a psychologist to deliver the sleep program IF ALLOCATED TO THE INTERVENTION (3) not share intervention materials with control group paediatricians IF ALLOCATED TO THE INTERVENTION.	We have changed point 2 to: 'deliver the sleep program to intervention families ***or*** refer the child to a psychologist to deliver the sleep program if allocated to the intervention' but have not included the point regarding usual care as this was not part of our MOU with paediatricians. We have made the changes to point 3.
5.	Page 10 - lines 28 & 53 - it is not clear what they are consenting to. Also lines 35 and 39 indicate two further optional consents. Are there separate consent forms for these?	We have added further clarification on page to address these points – *'Eligible families are sent a parent information statement and consent form (to participate in the RCT and for optional consents outlined below) as and a baseline survey'*
6.	Pages 11-12 - check tense on point c. - 'needed' should be 'need', 'were' should be 'are'. Also, etc should be followed by a full stop.	Many thanks. We have made these changes.
7.	Page 12 - point d. - Final two sentences are explaining what happened, not what will happen.	Many thanks. We have made these changes.