PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Study Protocol of a Randomized Trial of Summer STRIPES: A Peer-Delivered High School Preparatory Intervention for Students with ADHD
AUTHORS	Zulauf-McCurdy, Courtney ; Coxe, Stefany; Lyon, Aaron; Aaronson, Ben; Ortiz, Mercedes; Sibley, Margaret

VERSION 1 – REVIEW

REVIEWER	Russell , Abigail University of Exeter
REVIEW RETURNED	16-Dec-2020

GENERAL COMMENTS	This article is a protocol for a randomized trial of a school-based intervention delivered by peers to young people with ADHD. This is an important area where there is good evidence that interventions can lead to measurable improvements in children's functioning, but current interventions are rarely implemented (often due to high delivery costs as the authors point out). The intervention will be developed by adapting two existing interventions, and this study will test the adapted intervention and its effect on ADHD symptoms and other academic outcomes in a randomized trial with a sample of 72 adolescents (36 receiving the intervention). Overall this is a well-designed study with a detailed protocol, however there are some aspects of the study design that I believe the authors could consider or comment on within their protocol. The planned delivery of the intervention by peers is a strength of the intervention design that increases the possibility of this being implemented in school settings. The authors highlight the benefits to peer mentors who participate, as well as those with ADHD. The title of the article should include that it is a study protocol (as from the title alone it could be interpreted as an outcome paper). In the introduction and methods, could the authors clarify the usual age of children in the grades mentioned, and provide detail on at which grade elementary school ends and high school begins, to give international readers some context. There is no mention of which country this trial is to be conducted in. Could the authors provide calendar dates corresponding to the Years of their study (p8 line 17->)?

	The authors plan to exclude children who are in special education classes (which may be the majority of those with ADHD and comorbid conditions), but are aiming to recruit 18 students meeting criteria each school year, per school. Is this recruitment target feasible? Providing detail on the prevalence of children meeting criteria for ADHD and the size of the average school year cohort where the study is to be conducted will aid the reader in understanding whether this is an achievable target. If it is not, do the authors have an alternate plan such as recruiting an additional school? In addition, there is no mention of how the schools will be selected/recruited and any limitation of only using two schools for the study, or what measures are in place to boost recruitment should many participants drop out. The authors suggest that teachers will be blinded to group, however there may be a high chance that students receiving the intervention mention this accidentally within the teachers presence. Have the authors got a strategy to assess whether teachers do stay blind to allocation? Who will be the “school staff sponsor” and what are the eligibility criteria for this, what training will they have? It appears the authors are relying on parents to provide contingency management at home in relation to whether or not the student meets the goals that they set and review with their peer interventionist (p10, line 44). Given that this is a school-based intervention, this appears to be a core component delivered from home. If parents are not engaged in the intervention (either in the trial or in a real-world context), who would be responsible for applying contingency management for the student? Is there existing evidence that parents will engage with this? Is there a citation for RedCap? Why are participating students required to have a medication wash-out period prior to assessment? This could mask positive effects of the intervention that those with ADHD are only able to access or maintain with medication as a combined approach. I would suggest a more detailed examination of the impacts of medication on the effects of the intervention (and the number of eventual participants who are prescribed medication), and potentially repeating assessments with and without a wash-out period. Medication status should also be mentioned in the inclusion/exclusion criteria. I note that the participating students with ADHD are paid the most for the assessment battery, and infer that this means theirs is the longest of all participating groups. Has this been piloted or used before with adolescents with ADHD, how long is it likely to take, and could it be split into multiple shorter assessments to account for the difficulty that those with ADHD will have in attending to these tasks for potentially several hours? Please provide more detail on how these aspects were considered.

	The measures for each outcome of interest are appropriate and well described. Are the authors planning on capturing data on potential adverse effects or harms of participating? For example, may they be inadvertently identified to their peer group as having ADHD, or could the additional support impact negatively on self-esteem? e.g. https://doi.org/10.1521/adhd.2018.26.1.10 Similarly, are the authors going to capture any data to measure the cost of the intervention delivery, or cost-effectiveness of the intervention? Covariates; consider measuring parent ADHD traits as this may be a strong explanatory factor regarding parental engagement/fidelity. Also, do you plan to capture data on ADHD treatment history and co-occurring neurodevelopmental or mental health conditions? Regarding the power calculation and sample size, I am somewhat surprised that an intervention group of 36 is large enough to accurately account for missing data, and to conduct the analysis suggested using latent growth curve models given the varied measures that would be included for each theoretical mechanism. I am not an expert on power calculation and sample size, so I have recommended seeking an expert opinion from a statistician. The analysis plan could be adjusted if the sample size is not sufficient, rather than additional recruitment being required. Are the authors planning to examine the impact of individual strengths and weaknesses of students, and profiles of ADHD symptoms on the effectiveness of the intervention? Ethics and dissemination: what is an R34? Ethics- The participant are giving assent; are the peer mentors (and possibly the adolescents with ADHD) old enough to provide informed consent? More information on the age of the participants and how this relates to whether assent (with parental consent) or adolescent informed consent is required. Finally, the protocol does not mention potential pitfalls or risks that might occur throughout the project and how these would be managed. For example, what if recruitment targets are not reached, what if there is a high attrition rate? What percentage of data need to be collected for a participant for each measure to be viable/included?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

The title of the article should include that it is a study protocol (as from the title alone it could be interpreted as an outcome paper).

We have added “study protocol” to the start of our title and to the running head.

In the introduction and methods, could the authors clarify the usual age of children in the grades mentioned, and provide detail on at which grade elementary school ends and high school begins, to give international readers some context. There is no mention of which country this trial is to be conducted in.

We have added information about the grades of high school and typical ages of students in the US (see 1st page of introduction).

Could the authors provide calendar dates corresponding to the Years of their study (p8 line 17->)?

We have added calendar dates corresponding to the Years of the study (see page 8)

The authors plan to exclude children who are in special education classes (which may be the majority of those with ADHD and comorbid conditions), but are aiming to recruit 18 students meeting criteria each school year, per school. Is this recruitment target feasible? Providing detail on the prevalence of children meeting criteria for ADHD and the size of the average school year cohort where the study is to be conducted will aid the reader in understanding whether this is an achievable target. If it is not, do the authors have an alternate plan such as recruiting an additional school? In addition, there is no mention of how the schools will be selected/recruited and any limitation of only using two schools for the study, or what measures are in place to boost recruitment should many participants drop out.

Dr. Sibley's team has extensive experience overseeing rising ninth grade recruitment from feeder middle schools as a part of IES R324A120169 (n=157 rising ninth graders; Sibley et al., 2018). As part of this study we were able to recruit more students than what was proposed in this study from a single school. As we have two schools we feel confident we will be able to reach our recruitment goals. The base rate of ADHD in adolescence is approximately 7-10% in the U.S. A majority of high school students with ADHD are not enrolled in special education.

Reviewer: 1

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meeting criteria for ADHD and the size of the average school year cohort where the study is to be conducted will aid the reader in understanding whether this is an achievable target. If it is not, do the authors have an alternate plan such as recruiting an additional school? In addition, there is no mention of how the schools will be selected/recruited and any limitation of only using two schools for the study, or what measures are in place to boost recruitment should many participants drop out.

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The authors suggest that teachers will be blinded to group, however there may be a high chance that students receiving the intervention mention this accidentally within the teachers presence. Have the authors got a strategy to assess whether teachers do stay blind to allocation?

We acknowledge this concern and have added additional information (see page 10) about why full masking is not feasible.

Who will be the "school staff sponsor" and what are the eligibility criteria for this, what training will they have?

As part of Year 1 we will work with the schools to identify who will be the school staff sponsor based on the school's preference (there are no eligibility criteria; see page 11). The school staff sponsor will receive two days of training from SCH staff (16 hours) prior to the peer training and 30-minutes of weekly consultation from the SCH school mental health liaison during the intervention period (this information is now clarified on page 10).

It appears the authors are relying on parents to provide contingency management at home in relation to whether or not the student meets the goals that they set and review with their peer interventionist (p10, line 44). Given that this is a school-based intervention, this appears to be a core component delivered from home. If parents are not engaged in the intervention (either in the trial or in a real-world context), who would be responsible for applying contingency management for the student? Is there existing evidence that parents will engage with this?

Our research team has extensive experience training parents to provide contingency management for school-based behavioral targets through group and individualized parent training, including by school staff. We now clarify this on page 11 by providing the following references:

Sibley, M.H., Coxe, S.J., Campez, M., Morley, C., Olson, S., Hidalgo-Gato, N…Pelham, W.E. (2018). High vs. Low Intensity Summer Treatment for ADHD Delivered at Secondary School Transitions. Journal of Clinical Child and Adolescent Psychology. 47, 248-265.

Sibley, M.H., Graziano, P.A., Kuriyan, A.B., Coxe, S., Pelham, W.E., Rodriguez, L.M. et al., (2016). Parent-Teen Behavior Therapy + Motivational Interviewing for Adolescents with ADHD. Journal of Consulting & Clinical Psychology, 84, 699-712.

Sibley, M.H., Rodriguez, L.M., Coxe, S.J., Page, T., & Espinal, K. (2020). Parent-Teen Group versus

Dyadic Treatment for Adolescent ADHD: What Works for Whom? Journal of Clinical Child and Adolescent Psychology, 49, 476-492

Is there a citation for RedCap?

We have added citations for RedCap (see page 11)

Why are participating students required to have a medication wash-out period prior to assessment? This could mask positive effects of the intervention that those with ADHD are only able to access or maintain with medication as a combined approach. I would suggest a more detailed examination of the impacts of medication on the effects of the intervention (and the number of eventual participants who are prescribed medication), and potentially repeating assessments with and without a wash-out period.

We appreciate the reviewer's feedback and will keep this in mind for a future larger-scale RCT that will be fully powered to examine medication effects. On page 12, we now provide a reference that it is standard practice to require a 24-hour medication washout period for the collection of cognitive task data because performance on these tasks is dramatically impacted by medication and the variable of interest in this study is cognitive performance in the absence of medication. Most students in this study are not expected to be taking medication based on our past similar samples.

Isiten HN, Cebi M, Sutcubasi Kaya B et al. (2017) Medication effects on EEG biomarkers in attention-deficit/hyperactivity disorder. Clinical EEG Neuroscience 48:246–250. https://doi. org/10.1177/1550059416675232

Medication status should also be mentioned in the inclusion/exclusion criteria.

We now clarify on page 9 that both medicated and unmedicated students will be permitted to enroll in the trial.

I note that the participating students with ADHD are paid the most for the assessment battery, and infer that this means theirs is the longest of all participating groups. Has this been piloted or used before with adolescents with ADHD, how long is it likely to take, and could it be split into multiple shorter assessments to account for the difficulty that those with ADHD will have in attending to these tasks for potentially several hours? Please provide more detail on how these aspects were considered.

We now provide a reference on page 12 for batteries of similar length that our team administered to patients. The battery is expected to take about 90 minutes to two hours and adolescents are permitted to take breaks as needed.

Are the authors planning on capturing data on potential adverse effects or harms of participating? For example, may they be inadvertently identified to their peer group as having ADHD, or could the additional support impact negatively on self-esteem? e.g. https://doi.org/10.1521/adhd.2018.26.1.10

We thank the reviewer for drawing our attention to the importance of measuring adverse effects of behavioral treatments. As the reviewer alludes to, we will be in a position to explore adverse effects of the treatment with both acceptability and efficacy data that will be collected. We now note on page 20 that adverse effects of treatment are not hypothesized, consistent with previous work on behavioral treatments for high school students with ADHD.

Sibley, M.H., Coxe, S.J., Stein, M.A., Meinzer, M.C., & Valente, M. (in press). Predictors of Treatment Engagement and Outcome among Adolescents with ADHD: An Integrative Data Analysis. Journal of the American Academy of Child and Adolescent Psychiatry.

Similarly, are the authors going to capture any data to measure the cost of the intervention delivery, or cost-effectiveness of the intervention?

Like the reviewer we are very interested in measuring the cost-effectiveness of this intervention compared to standard practice. This project is an R34 funded by the National Institute of Mental Health in the U.S., which has a tiered system for testing the efficacy of interventions. The R34 mechanism is essentially the second tier of the intervention testing process and is designed to establish proof of concept and is focused on acceptability and basic efficacy of the intervention. The cost analyses will be conducted in the next phase of the trial (the R01 phase), which is the third and final tier of the intervention testing process. We now state on page 20 that if the summer STRIPES intervention demonstrates promise of basic efficacy, mediators, moderators, and cost data will be examined in a future full-scale RCT.

Covariates; consider measuring parent ADHD traits as this may be a strong explanatory factor regarding parental engagement/fidelity. Also, do you plan to capture data on ADHD treatment history and co-occurring neurodevelopmental or mental health conditions?

We thank the reviewer for these suggestions, which will be incorporated into future studies.

Regarding the power calculation and sample size, I am somewhat surprised that an intervention group of 36 is large enough to accurately account for missing data, and to conduct the analysis suggested using latent growth curve models given the varied measures that would be included for each theoretical mechanism. I am not an expert on power calculation and sample size, so I have recommended seeking an expert opinion from a statistician. The analysis plan could be adjusted if the sample size is not sufficient, rather than additional recruitment being required.

We appreciate the reviewer's careful attention to the integrity of our power analysis. First, the power analysis was conducted by a quantitative psychologist with 20 years of experience conducting clinical trials research. The power analysis was also already approved by the National Institute of Mental Health (NIMH which is the funding agency for this proposal). It is important to note that for the R34 mechanism, the goal is to estimate effects for a future large scale clinical trial. However, we have done substantial work in the area of this intervention previously demonstrating medium to large expected effects that permit the smaller sample size that will be used in this trial.

Are the authors planning to examine the impact of individual strengths and weaknesses of students, and profiles of ADHD symptoms on the effectiveness of the intervention?

Although this is not in the scope of the current R34 we acknowledge this is a good consideration for the R01 or future studies.

Ethics and dissemination: what is an R34?

We have now specified that an R34 is "a National Institute of Mental Health Planning Grant (R34)" and provide additional data about the scope of NIMH R34s (see page 20)

Ethics- The participant are giving assent; are the peer mentors (and possibly the adolescents with ADHD)

old enough to provide informed consent? More information on the age of the participants and how this relates to whether assent (with parental consent) or adolescent informed consent is required.

We thank the reviewer for pointing out our lack of clarity on this point. We now clarify on page 21, that all adolescents who are receiving the intervention/control are in 9th grade (approximately 14-15 years old) they will not be old enough to consent. However, if a peer interventionist (11th or 12th grader) is over the age of 18 they will provide consent. Parent consent will be obtained for all minors in this study, along with youth assent.

Finally, the protocol does not mention potential pitfalls or risks that might occur throughout the project and how these would be managed. For example, what if recruitment targets are not reached, what if there is a high attrition rate? What percentage of data need to be collected for a participant for each measure to be viable/included?

We thank the reviewer for this prompt. As we now clarify on page 9, we will extend the trial for an additional year of the recruitment targets are not initially met. Attrition from the attendance is an outcome in the study (see Aim 3), and so we will measure this variable naturalistically. We also mention that students will still be assessed even if they discontinue attendance at the intervention and all analyses will be intent to treat. We also now state on page 19 that we will be using full information maximum likelihood estimators in our models, which can accommodate missing data at high levels. Based on our team's 15 years of experience conducting similar trials with very high retention (90-95% across seven multiple year RCTs in school and community settings), we have developed established procedures to maximize study engagement and retention.

VERSION 2 – REVIEW

REVIEWER	Russell , Abigail University of Exeter
REVIEW RETURNED	19-Jul-2021

GENERAL COMMENTS	The authors have addressed my prior comments comprehensively. I have nothing further to add.