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Running head: SUMMER STRIPES

A Randomized Trial of Summer STRIPES: A Peer-Delivered High School Preparatory Intervention for Students with ADHD

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Abstract

Introduction. High schoolers with attention-deficit/hyperactivity disorder (ADHD) experience substantial impairments, particularly in the school setting. However, very few high school students with ADHD receive evidence-based interventions for their difficulties. We aim to improve access to care by adapting evidence-based psychosocial intervention components to a low-resource and novel school-based intervention model, Summer STRIPES (Students Taking Responsibility and Initiative through Peer Enhanced Support). Summer STRIPES is a brief peer-delivered summer orientation to high school with continued peer-delivered sessions during ninth grade. **Methods and Analysis.** Participants will be 72 rising ninth grade students with ADHD who are randomized to receive either Summer STRIPES or school services as usual. Summer STRIPES will be delivered by 12 peer interventionists in a school setting. Outcomes will be measured at baseline, start of ninth grade, mid-ninth grade, and end-of-ninth grade. At each assessment, self, parent, and teacher measures will be obtained. We will test the effect of Summer STRIPES (compared to school services as usual) on ADHD symptoms and key mechanisms (intrinsic motivation, extrinsic motivation, executive functions), as well as key academic outcomes during the ninth-grade year (GPA, class attendance). **Ethics and dissemination**. Findings will contribute to our understanding of how to improve access and utilization of care for adolescents with ADHD. The protocol is approved by the institutional review board at Seattle Children's Research Institute. The study results will be disseminated through publications in peer-reviewed journals and presentations at scientific conferences.

ClinicalTrials.gov Identifier: NCT04571320; pre-results

Article Summary

Strengths and limitations of this study

- This study will use implementation strategies that fit within existing school infrastructures to assess the effectiveness of Summer STRIPES (an intervention derived from two previously tested interventions).
- This study will assess a theoretical model in which Summer STRIPES intervenes on three key mechanisms: (1) intrinsic motivation, (2) extrinsic motivation, and (3) executive functions.
- Results could be used as a rationale to deliver the Summer STRIPES intervention in school settings in order to overcome barriers to ADHD services for adolescents thus increasing access and utilization of treatment.
- Limitations of the study include the inability to mask participants to treatment group and the modest sample size which prohibits evaluation of treatment moderators.

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Background

High school students with attention-deficit/hyperactivity disorder (ADHD) experience substantial impairments in the school setting[1]. The high school years correspond to a challenging time as adolescents take on more adult-like responsibilities as well as increased academic demands[2]. As a result, academic functioning is often a critically impaired domain for high schoolers with ADHD (e.g., poor grades, difficulty completing assignments[1, 3, 4]). Despite marked impairments, a majority of high school students with ADHD do not receive any treatment (medication or psychosocial[5]). Primary barriers include dislike for stimulant medication[6], parent-teen conflict that curbs family-based services[7], and resource barriers that hamper school intervention delivery[8].

As a majority of ADHD-related impairment occurs at school, high schools are a logical deployment setting for interventions. However, school-based interventions for ADHD (which are widespread in elementary schools[9-10]) are rarely available to high school students and a number of systemic barriers limit access (e.g., overburdened school counselors, high student to teacher ratio[8, 11]). This is especially true of regular education students with ADHD as they are often not the priority for intervention funds.

In high resource settings, interventionists might provide skills training interventions to adolescents with ADHD[12-14]. These interventions target two core ADHD-related cognitive deficits: executive functioning (EF) and motivation[15]. They teach compensatory strategies in organization, time management, and planning (OTP) and include motivational components such as goal-setting, contingency management, and strength-based feedback[16]. However, an

ongoing challenge for schools is identifying qualified and available interventionists who are willing to deliver evidence-based interventions to regular education students with ADHD.

Peers as Interventionists

To overcome known implementation barriers, especially in school settings, we suggest revising the professional roles[17] of those delivering the evidence-based intervention. One group of interventionists who are available, numerous, qualified, and free, may be 11th and 12th grade peers. High schoolers have ample opportunities to interact with peers throughout the school day and unlike school staff, peer interventionists may be highly motivated to deliver interventions (such an experience can enhance college applications and serve as a service-learning leadership experience). There is abundant evidence that high school students can deliver a range of interventions to peers with fidelity[18, 19]. Peers play a central role in the lives of high school students, as adolescents spend decreasing amounts of time with adults[2]. Thus, adolescents with ADHD may be highly interested in engaging with peer interventionists.

Ninth Grade as a Critical Intervention Window

When resources are low, it becomes important to intervene wisely by conserving services for windows that promote maximal impact[20]. Failure to access ADHD treatment may be particularly detrimental to 9th graders. Typical adolescents display a decline in GPA[21], self-esteem[22], and psychological adjustment at the transition to high school[23]. This deterioration is especially marked in students with ADHD, whose 9th grade year marks the low point of their academic performance[1]. Performance during ninth grade is one of the strongest predictors of eventual high school dropout[24]. Thus, 9th grade is a strategic intervention period to prevent escalating school disengagement among students with ADHD.

An orientation model delivered immediately prior to the start of high school may represent a strategic window for setting adolescents up for high school success. As summer often comes with available time it may allow for more active adolescent participation before increased academic demands begin. Furthermore, including social activities that engage adolescents in an enjoyable intervention may promote attendance, introduce them to a culture of prosocial peers, and generate interest in continuing school-year intervention. To this aim, the current study will test the effectiveness of a peer-delivered summer orientation followed by school year components delivered by the same peer interventionist in 9th grade for adolescents with ADHD.

Adaptation and Implementation of Existing Interventions

We propose to merge two existing interventions, Students Taking Responsibility and Initiative through Peer Enhanced Support (STRIPES[16]) with a scaled-down Summer Treatment Program-Adolescent (STP-A[25]). STP-A is an eight-week intensive treatment program for adolescents with ADHD which targets skill development across academic, social, and behavioral contexts and employs contingency management to motivate adolescent skill practice in a summer school context. In a randomized controlled trial[13] we found high attendance for a high-intensity version of the summer treatment program as well as positive outcomes on note taking, parent contingency management, and parent-reported ADHD symptoms. Effects were largest for 9th graders compared to 6th graders. At four-year follow-up[14], the positive effects on ADHD symptoms and OTP problems remained. These results highlight the summer before 9th grade as a key intervention window and indicate the propensity for a pre-ninth grade summer intervention to produce long-term effects on high school trajectory. Unfortunately, the STP-A had one major drawback-- its impractical price tag (see [13]).

STRIPES[16] is a peer-delivered school-year intervention for high schoolers. Like the STP-A, STRIPES targets core EF skills and academic motivation and has shown positive increases in book bag organization, academic motivation, and class attendance. Despite the positive results, 9th grade students often failed to attend STRIPES. Preliminary data indicated that intervention credibility, satisfaction, and student-peer bond were positive indicating that with some refinement to improve engagement and attendance, peer interventionist may serve as a viable option for treatment delivery. The limitations of both STP-A and STRIPES may be solved by the strengths of the other—the low-cost STRIPES interventionists can reduce the STP-A's tremendous expense; the highly engaging STP-A model might boost STRIPES' attendance problems.

The current adaptation effort and resulting clinical trial will pull on human-centered design[26-28] to develop a strategic intervention model, Summer STRIPES, that overcomes known implementation barriers in schools. If the resulting Summer STRIPES model is effective, we would expect to see positive changes in the following outcomes: GPA, class attendance, and ADHD symptoms. Based on theoretical models for skills-based ADHD interventions (see[29]), we hypothesize three primary target mechanisms for the Summer STRIPES intervention: intrinsic motivation, extrinsic motivation, and goal-directed executive functions[30-33]. Our theoretical model is presented in Figure 1.

Study Aims

The primary aim of this study is to adapt and pilot Summer STRIPES (aim 1). We will conduct a randomized trial of Summer STRIPES compared to school services as usual (SSU plus) and test the effect of Summer STRIPES (compared to SSU plus) on ADHD symptoms and key mechanisms (intrinsic motivation, extrinsic motivation, EFs), as well as key academic school

outcomes during the ninth-grade year (aim 2a; GPA, class attendance). We will also test the effect of mechanisms on outcomes (aim 2b). Lastly, we will assess multiple indices of engagement and school fit during the randomized trial (aim 3).

Methods and Analysis

Study Timeline

Patient and Public Involvement

In Year 1, with input from key stakeholders (administrators, teachers, student services staff, student leaders, parents) and content experts, we will create and adapt the protocol for our Summer STRIPES intervention. As adaptation is an important implementation strategy, we will meet regularly with stakeholders to resolve several key questions (e.g., What will be the length of the pre-high school orientation? How will peers be identified?) and develop school-specific manuals that fit within their unique school contexts[26-28].

In Year 2 and Year 3, we will implement the resulting intervention in two high schools in the state of Washington during a randomized trial (N=72) that will assign rising 9th grade students with ADHD to (1) Summer STRIPES or (2) SSU plus. Students will be randomized within school and cohort using a permuted block randomization strategy. In each of the two annual cohorts, 18 students will be recruited for each school (nine randomly assigned to each condition), resulting in a total of 72 participants.

Recruitment

During the spring of participants' 8th grade year, study staff will work with schools to distribute nomination forms and study information to feeder middle school counselors and administrators, inviting the schools to nominate students. As part of this process, parent and teachers will provide background information, DSM-5 ADHD symptom checklists[34], and

measures of student academic impairment[34-36]. Students will be eligible for participation if they display at least six symptoms of either inattention or hyperactivity/impulsivity and significant academic impairment. Participants will be excluded if they are placed in special education classes, as the purpose of this study is to test a low-cost intervention for use in regular education settings. Eligible participants will complete a baseline assessment at their middle school. Participants will be required to demonstrate an IQ > 70 on the Wechsler Abbreviated Scale of Intelligence, 2nd edition(WASI-II[37]).

Selection and Training of Peer Interventionists

Peer interventionists will be nominated by their teachers. Peers will be required to have at least a 3.0 GPA and good behavior at school (defined as no in- or out-of-school suspensions during the past twelve months). Peer interventionists will receive a treatment manual and two full days of training prior to delivering the intervention. They will receive 30 minutes of supervision per day during the summer orientation and 30 minutes per week for 16 weeks during the school year. Supervision will be co-led by a school staff sponsor and our team's school mental health liaison.

Summer STRIPES versus SSU plus

Allocation of groups will be randomized, the intervention model will be parallel assignment and the masking will be single (outcome assessor). Teachers and outcomes assessors will be masked to group; however, it will not be possible to mask parents and adolescents to group because they will be actively receiving a behavioral intervention.

Study Intervention

Full intervention procedures will be finalized in Year 1 and will be based on two manuals, STP-A[13] and STRIPES[16]. The proposed intervention model will be up to two

weeks of daily high school orientation (four hours per day) immediately prior to the start of 9th grade, staffed by peer interventionists and a school staff member. The orientation will be held at the student's school and will contain trimmed STP-A modules (see Table 1). Two parent training sessions will be held during summer orientation with a focus on orchestrating contingency management outside of school to reinforce Summer STRIPES and school year performance. A school staff sponsor will also provide brief daily coaching (phone call up to a five-minutes) on contingency management implementation to the parent after each orientation day. A scaled down version of the STP-A classroom behavior management system will be employed to promote prosocial behavior during the orientation (see Table 1) set by the student and their peer that is incorporated into the contingency management system.

During the school year, participants will continue to meet weekly with their peer interventionists in a group setting under the supervision of the school staff sponsor. The 16-week school year follow-up component will follow the original STRIPES manual[16]. Parent components during the school year will include optional monthly group problem solving sessions with the school staff sponsor and a school mental health liaison and a weekly phone call (up to five minutes) from the school staff sponsor to discuss contingency management. During both the summer and the school year, peers will complete a goal sheet with the 9th grader at each intervention session that indicates whether they met daily (summer) or weekly (school year) goals. Parents will be trained to check this goal sheet and apply contingency management accordingly.

Comparison Condition

As the goal of this study is to see whether a low-burden intervention, Summer STRIPES, is strong enough to improve upon the best-care scenario typical experience of regular education

high school students with ADHD, we chose a school service as usual (SSU plus) comparison condition. Students who are assigned to the SSU plus group will receive school supplies and be referred to their identified school counselor for referral to services available in the school setting. The counselor will be provided with a report from the student's intake assessment that summarizes the student's symptoms and presenting problems. We will systematically track services received in the comparison condition.

Assessment Procedures

Four assessments will occur at baseline (BL; end of 8th grade), start of 9th grade (FU1), mid-9th grade (FU2), and end-of-9th grade (FU3). Student assessments will occur at the school with a trained research team member. Peers, parents, and teachers will complete ratings electronically via RedCap. Direct observation of skills and cognitive and analogue academic tasks will be completed in a private room at the school with a trained research staff member. All students will be required to refrain from taking stimulant medication on the day of their assessment (i.e., 24-hour washout period). Based on the length of their assessment batteries, parents will receive $50 for each assessment, teachers will receive $20, peers will receive $20, and 9th graders will receive $75.

Measures

Outcomes

We will assess two ecological school outcomes at all time points, GPA and class attendance, as well as ADHD symptom severity. Report cards and attendance records will be obtained directly from schools.

Grade Point Average. GPA for each quarter will be calculated by converting academic grades (e.g., English, Math, Science, Social Studies) to a 5-point scale (i.e., 4.0=A to 0.0=F). Grades will not be weighted for the difficulty of the class.

Class Attendance. Number of class absences will be calculated for each quarter.

ADHD Symptoms. Inattention and Hyperactivity/Impulsivity will be measured using a DSM-5 ADHD Rating Scale completed by parents and teachers[34, 38]. Respondents will rate symptoms of ADHD as 0 (not at all) to 3 (very much). Symptom severity is the mean level (0-3) of ADHD subscale items. Psychometric properties of the measure are very good, with empirical support for internally consistent Inattention and Hyperactivity/Impulsivity subscales[34, 38]. In a recent sample, ADHD subscale alphas ranged from .86-.95[29].

Mechanisms

Proposed treatment mechanisms will be measured at all time points: (1) Intrinsic Motivation, (2) Extrinsic Motivation, and (3) EFs. Given the multi-dimensional nature of these constructs, we propose a multi-method measurement strategy (see Figure 1).

Intrinsic motivation. ***Self-Rated Intrinsic Motivation.*** The Expectancy-Value Theory of Motivation Measure-Student Version (EVTMM[39]) is a gold-standard self-report measure of student motivation with excellent psychometric properties that consists of 11 items measured on a 5-point scale. The two "interest" items ("in general, I find working on school work interesting…" "How much do you like doing schoolwork?..") will be averaged to provide an index of academic interest[39]. The combination of these two items has good reliability and validity[40].

Basic Needs Fulfillment. The Basic Psychological Needs Scale is a validated scale that addresses need satisfaction in one's life. The original scale has 21 items concerning needs for

competence, autonomy, and relatedness[41]. We will use a validated 22-item adaptation designed to measure fulfilment of adolescent's basic needs at school[42]. This measure shows strong psychometric properties and is validated in adolescent samples[42].

Extrinsic motivation. ***Self-rated Extrinsic Motivation.*** The EVTMM's two "importance" items (i.e., "for me being good in school is important…" "compared to most of your other activities, how important is it for you to be good in school…") will be averaged[39]. A subscale containing these two items is validated for adolescents[43].

Rewards Processing. A computerized Iowa gambling task (Hungry Donkey Task[44]) will be administered as a measure of risky decision making (i.e., sensitivity to future negative consequences). The task shows good convergent validity in adolescents[44].

Delay discounting was measured using a computerized Choice-Delay Task[45] in which participants will be instructed to make repeated choices between a small variable reward that would be delivered immediately and a large constant reward that would be delivered after a variable delay. After completion of the task, participants receive the total earnings from the examiner. The total amount of money earned serves as an index of delay discounting. This task shows developmental sensitivity[45] and correlates with symptoms of ADHD[46].

Delay aversion will be measured using the 10-item self-report version of the Quick Delay Questionnaire in which adolescents self-rate their degree of aversion and response to delayed rewards using a 5-point scale[47]. This measure has good psychometric properties[47, 48].

Use of Goal Setting Strategies. Use of goal setting strategies will be measured using the Self-Regulated Learning Interview Schedule (S-RLIS[49]). The goal setting and planning section of the S-RLIS were previously converted by our team to a parent-report and self-report rating scale to measure goal setting (Sibley, Graziano, Ortiz, & Rodriguez, Motivational and EF

Deficits among High School Students with ADHD). Six items measure the extent to which parents observe their children setting short-term and long-term goals during schoolwork, when completing household tasks, and when poorly motivated. In previous adolescents samples with ADHD, alpha for this measure was .87 (Sibley, Graziano, Ortiz, & Rodriguez, Motivational and EF Deficits among High School Students with ADHD).

Home Contingency Management. The Parent Academic Management Scale (PAMS[50]) is a 16-item checklist that measures the frequency of adaptive and maladaptive parental involvement strategies related to adolescent OTP skills[50]. Parents indicate the number of days during the typical school week (0 to 5) that they performed each activity. PAMS possesses strong psychometric properties as evidenced by good internal consistency, concurrent validity, and predictive validity[50].

Executive Functions. ***Functional Indices of EF.*** Research assistants who are blind to intervention group will conduct observations of planner use (or a device if preferred) and bookbag organization. Percentage of classes with recorded homework (or indication of no homework) will be calculated for the last five school days[51]. Observations of bookbag organization will be obtained using the Organization Checklist (OC[52]). Research assistants will assess dichotomously scored items on the organization checklist such as "Is the adolescent's bookbag free from loose papers?" and "Does the adolescent have a folder/binder for each core academic class?" Percentage of items achieved will be calculated. OC scores correlate with teacher ratings of impairment in adolescents with ADHD[52]. Finally, note-taking skills will be measured using an analogue paradigm previously used to measure response to intervention in adolescents with ADHD[13].

The Behavior Rating Index of Executive Function (BRIEF-2) is a well-validated measure of executive function for youth ages 5-18[53]. Parents rate youth executive functions on a three-point scale across nine subscales.

Cognitive Control. Response inhibition will be measured using a go/no-go task that uses both positively and negatively valanced emotional stimuli[54]. The number of commission errors on no-go trials across the whole task will be utilized as a measure of response inhibition. The task shows good convergent validity[55] and has been validated with adolescents[54].

Working memory will be measured using the National Institute of Health (NIH) Toolbox List Sorting Working Memory Test[56] which shows excellent test-retest reliability and convergent and discriminant validity[57].

Cognitive flexibility will be measured using the NIH Toolbox Dimensional Change Card Sort Test[56]. The task shows excellent developmental sensitivity and convergent validity[58].

Use of OTP strategies. The self, parent, and teacher-report versions of the 24-item Adolescent Academic Problems Checklist (AAPC) measures observable secondary-school specific OTP problems and are validated for use in samples of adolescents with ADHD[36]. The AACP possesses two distinct factors (academic skills and disruptive behavior) and a total score, with strong internal reliability and concurrent validity[36].

In the Analogue Note-taking task, `students will listen to a 20-minute history lecture via` video and take notes. Correctly recorded percentage of main ideas and supporting details will be calculated[59]. Four versions of this task exist to reduce practice effects and order of administration will be counterbalanced within group and school. In past examinations using the note-taking task[13], intraclass correlation for this inter-rater reliability probe was .90.

Engagement and Fit

We will assess a variety of indices from the 9th grader, parent, and peer interventionist, as well as direct observation during the intervention and at post-treatment.

Intervention Attendance. Detailed intervention attendance records (student, peer, and school staff supervisor) will be collected by a research assistant at each session.

Fidelity. We will enhance and adapt previous fidelity checklists used in the STP-A and STRIPES trials with an emphasis on implementation features as well as content[13, 16].

Acceptability. Post-intervention treatment credibility will be measured from students using a four-item adaptation of the Client Credibility Questionnaire (CCQ[60, 61]). Students will rate how logical they find treatment and how confident they were in the treatment on a 3-point scale (0 = *Not at all* to 2 = *very much*). In addition, students will also provide ratings of the helpfulness of each STRIPES component using a scale adapted from Sibley and colleagues (2013)[51] on a similar 3-point scale. High scores will indicate stronger credibility. In our past study of STRIPES, alpha for this measure was .79[16].

The degree to which 9th graders enjoyed working with their peer interventionist will be measured using the seven-item Therapist Bond Scale (TBS[62]). The TBS items are rated on a 4-point Likert-type scale, ranging from 1 (*not at all like you*) to 4 (*very much like you*). Internal consistency and convergent validity are strong for this measure[62].

Students will provide ratings of treatment satisfaction post-intervention using a standard satisfaction questionnaire developed for behavioral treatments[63] that has been adapted for adolescents with ADHD[13, 51, 64]. Respondents will indicate their degree of satisfaction for 20 aspects of treatment using a 5-point Likert Scale (1=*Strongly Disagree* – 5=*Strongly Agree*).

Mean satisfaction will be calculated. In our previous STRIPES sample, alpha for this measure was .97[16].

In addition to students, peer interventionist will also complete these measures separately for each of their assigned 9th grader.

Potential Covariates

Medication use during the study will be monitored via a parent and adolescent medication use survey and will be examined as a covariate in analyses. We will also measure the following potential covariates at BL: IQ, parent education level, race/ethnicity, age, gender, parent marital status, and free/reduced lunch status.

Data Analysis Plan

Analyses will be performed using Mplus 7. We will assess missing data prior to analyses. The proposed analysis methods (i.e., multilevel regression with maximum likelihood estimation) are robust to MAR (missing at random) or MCAR (missing completely at random) mechanisms, which will minimize impact of missingness and attrition. Missing data will be handled with full information maximum likelihood (FIML) estimation. We will assess whether data meet all assumptions of analysis (multivariate normality, outliers) and will adjust for any violations using robust methods (such as using bootstrap standard errors).

Aim 2a

Latent growth models will be used to test the effect of Summer STRIPES (compared to SSU plus) on primary outcome measures (ADHD symptoms, GPA, class attendance). Time (months since BL, modeled as a person-specific variable), group (Summer STRIPES or SSU plus), and their interactions will be used as predictors while ADHD symptoms, GPA, and class attendance (at all time points) will be the modeled outcomes. We will explore non-linear and

piece-wise models to consider that Summer STRIPES orientation and its school year follow-up components may enact unique influences on slope over time.

Aim 2b

The mechanisms by which Summer STRIPES leads to improvement in outcomes will be evaluated through latent growth models. Three sets of models will be assessed, according to the three theoretical mechanisms (intrinsic motivation, extrinsic motivation, EFs). The models will assess the effect of Summer STRIPES on primary outcomes (ADHD symptoms, GPA, class attendance; centered at FU3) via indices of intrinsic motivation, extrinsic motivation, and goal-directed EFs (centered at FU2).

Aim 3

We will assess multiple indices of engagement and school fit during the randomized trial (i.e., parent, youth, and interventionist engagement in the intervention; fidelity, perceived intervention utility and burden). The effect of Summer STRIPES on measures of engagement and school fit will be evaluated descriptively (e.g., treatment fidelity).

Statistical Power

The mean effect size for adolescent interventions for ADHD compared to no treatment is approximately d=0.4, as was the mean acute effect for the STP-A compared to low-intensity treatment modules[13]. To substantiate Summer STRIPES as incrementally superior to SSU plus, we will define a d= 0.4 difference between Summer STRIPES and SSU plus as a successful outcome signaling the need for further study in an R01 clinical trial. Power analysis for a mixed effects model with N = 72, power = 0.80 and alpha = 0.05 were conducted using GPower 3.1. Because the power for this analysis depends partly on the correlation between BL and follow-up measures of the outcome, we assessed power for several values of this correlation. The proposed

analysis has power to detect effects of $d = 0.42$, 0.33, and 0.21 for BL to FU correlations of 0.2, 0.5, and 0.8, respectively. In addition, there are 36 subjects per group; Maas & Hox (2005)[65] recommend at least 30 clusters (here, subjects) per group to reduce bias in estimation of growth models, so we expect little bias in models.

Ethics and Dissemination

This R34 is focused on using known implementation strategies to adapt two evidence-based interventions (STP-A and STRIPES) into Summer STRIPES and to pilot its feasibility in schools. If this trial indicates that Summer STRIPES meets sufficient metrics for preliminary efficacy the next steps will be to proceed with a full scale clinical trial to test the efficacy of Summer STRIPES with more detailed attention to mediators and moderators (stage implementation scale up[17, 66])

The protocol (#2087) is approved by the Institutional Review Board (IRB00000277 & IRB00009311) at Seattle Children's Hospital (FWA #00002443). Eligible students will be enrolled and randomized into the study only after giving assent and collecting parental consent to participate. We have registered our clinical trial on ClinicalTrials.gov (NCT04571320) and will work with Seattle Children's Research Institute to submit results in accordance with the required timelines. Informed consent and assent documents will include a statement indicating that trial information, devoid of identifying information, will be posted at ClinicalTrials.gov. All data will be submitted to the National Institute of Mental Health Data Archive (NDA; https://nda.nih.gov/). Additionally, results from the proposed project will be disseminated widely through traditional dissemination to the scientific community, first through conference presentations targeting both academics and school educators and mental health professionals, as

well as peer-reviewed publications in academic journals. Dissemination to community stakeholders will occur through presentations for local and statewide school district officials.

Authors' contributions statement

CAZM drafted the manuscript. MHS conceptualized the study and wrote the grant funding. SC conceptualized, wrote, and provided feedback on the analytic plan. ARL and BA are co-investigators of the grant and contributed to the conceptualization of the project. MO is the project coordinator and organized the measurement battery. CAZM, MHS, AL, BA, MO wrote or revised sections of the manuscript. All authors approved the final version of the manuscript.

Competing interests' statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Data Sharing Statement

We have registered our clinical trial on ClinicalTrials.gov (NCT04571320) and will work with Seattle Children's Research Institute to submit results in accordance with the required timelines. All data will be submitted to the National Institute of Mental Health Data Archive (NDA; https://nda.nih.gov/).

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Table 1

Core Summer STRIPES components (all group-based)

Summer Teen (1-2 weeks/5 days a week)	**School Year Teen (16 weeks/1 day a week)**
Note-taking (30 mins)	Goal setting (10 mins)
Materials management (15 mins)	Organization check (5 mins)
Tracking homework (15 mins)	Homework tracking (5 mins)
Time management (15 mins)	Reviewing progress through online gradebook (10 mins)
Study skills (30 mins)	
Rec period (1 hour)	
Goal Setting (15 mins)	
Summer Parent	**School Year Parent (16 weeks)**
Contingency Management I (90 mins)	Monthly Prob. Solving Session (60 mins—4 months)
Contingency Management II (90 mins	Weekly Coaching (5 mins- 16 weeks)
Daily Coaching (5 mins)	

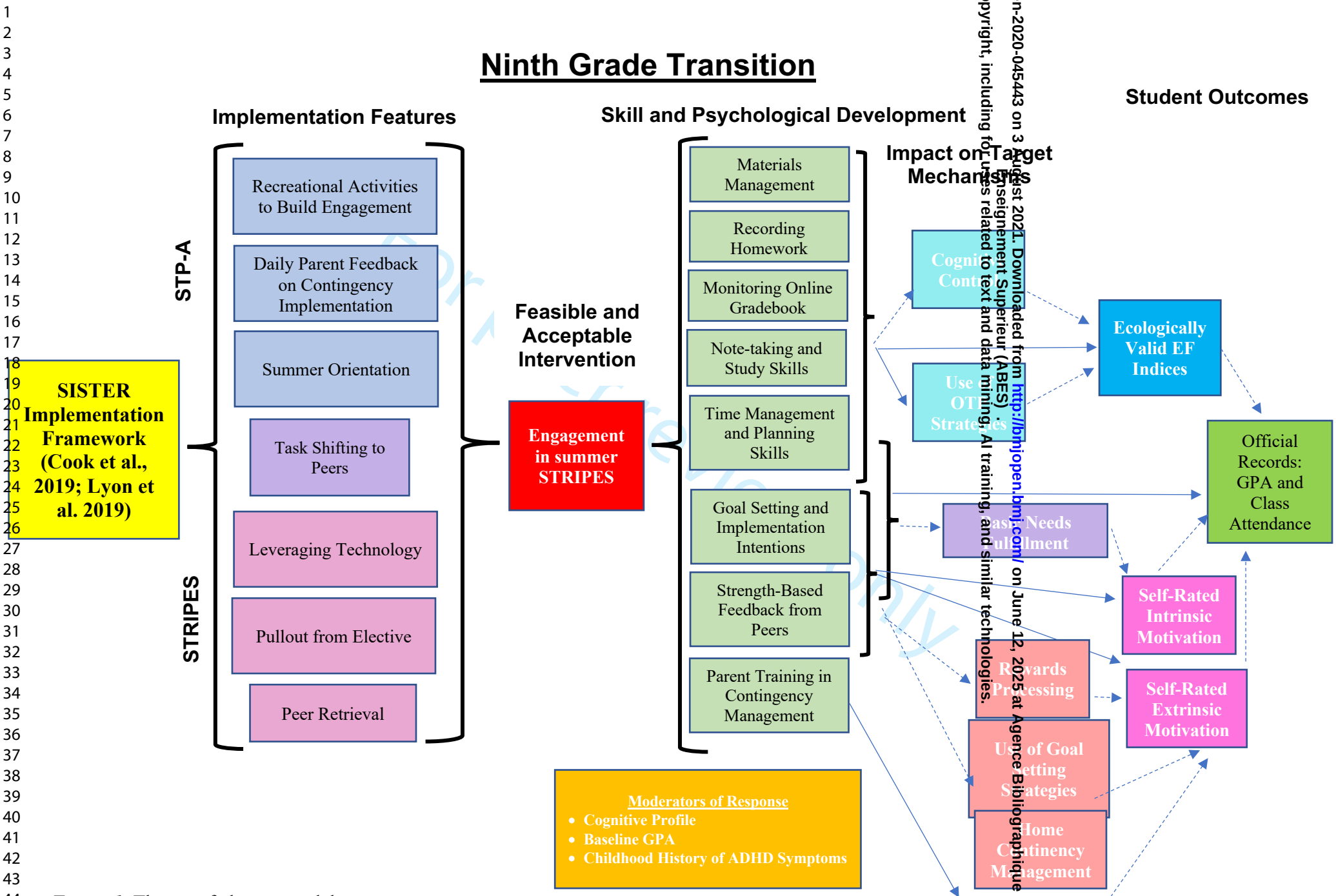

Figure 1. Theory of change model

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10-11
Objectives	#7	Specific objectives or hypotheses	8
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	8-10
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8-10

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-11
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be	N/A

		provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-9
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-18
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	11
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17-18

Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17-18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17-18
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	19
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19

Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	20
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	n/a
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

BMJ Open

Study Protocol of a Randomized Trial of Summer STRIPES: A Peer-Delivered High School Preparatory Intervention for Students with ADHD

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Running head: PROTOCOL SUMMER STRIPES

Study Protocol of a Randomized Trial of Summer STRIPES: A Peer-Delivered High School Preparatory Intervention for Students with ADHD

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Abstract

Introduction. High schoolers with attention-deficit/hyperactivity disorder (ADHD) experience substantial impairments, particularly in the school setting. However, very few high school students with ADHD receive evidence-based interventions for their difficulties. We aim to improve access to care by adapting evidence-based psychosocial intervention components to a low-resource and novel school-based intervention model, Summer STRIPES (Students Taking Responsibility and Initiative through Peer Enhanced Support). Summer STRIPES is a brief peer-delivered summer orientation to high school with continued peer-delivered sessions during ninth grade. **Methods and Analysis.** Participants will be 72 rising ninth grade students with ADHD who are randomized to receive either Summer STRIPES or school services as usual. Summer STRIPES will be delivered by 12 peer interventionists in a school setting. Outcomes will be measured at baseline, start of ninth grade, mid-ninth grade, and end-of-ninth grade. At each assessment, self, parent, and teacher measures will be obtained. We will test the effect of Summer STRIPES (compared to school services as usual) on ADHD symptoms and key mechanisms (intrinsic motivation, extrinsic motivation, executive functions), as well as key academic outcomes during the ninth-grade year (GPA, class attendance). **Ethics and dissemination**. Findings will contribute to our understanding of how to improve access and utilization of care for adolescents with ADHD. The protocol is approved by the institutional review board at Seattle Children's Research Institute. The study results will be disseminated through publications in peer-reviewed journals and presentations at scientific conferences.

ClinicalTrials.gov Identifier: NCT04571320; pre-results

Article Summary

Strengths and limitations of this study

- This study will use implementation strategies that fit within existing school infrastructures to assess the effectiveness of Summer STRIPES (an intervention derived from two previously tested interventions).
- This study will assess a theoretical model in which Summer STRIPES intervenes on three key mechanisms: (1) intrinsic motivation, (2) extrinsic motivation, and (3) executive functions.
- The study will include a randomized-clinical trial in two high-schools.
- It will not be possible to mask participations to treatment groups as they are receiving a behavioral intervention.
- The modest sample size may prohibit evaluation of treatment moderators.

PROTOCOL SUMMER STRIPES

Study Protocol of a Randomized Trial of Summer STRIPES: A Peer-Delivered High School Preparatory Intervention for Students with ADHD

Background

High school students (approximately 14 to 19 years of age) with attention-deficit/hyperactivity disorder (ADHD) experience substantial impairments in the school setting[1]. The high school years (grades 9-12) correspond to a challenging time as adolescents take on more adult-like responsibilities as well as increased academic demands[2]. As a result, academic functioning is often a critically impaired domain for high schoolers with ADHD (e.g., poor grades, difficulty completing assignments[1, 3, 4]). Despite marked impairments, a majority of high school students with ADHD do not receive any treatment (medication or psychosocial[5]). Primary barriers include dislike for stimulant medication[6], parent-teen conflict that curbs family-based services[7], and resource barriers that hamper school intervention delivery[8].

As a majority of ADHD-related impairment occurs at school, high schools are a logical deployment setting for interventions. However, school-based interventions for ADHD (which are widespread in elementary schools[9, 10]) are rarely available to high school students and a number of systemic barriers limit access (e.g., overburdened school counselors, high student to teacher ratio[8, 11]). This is especially true of regular education students with ADHD as they are often not the priority for intervention funds.

In high resource settings, interventionists might provide skills training interventions to adolescents with ADHD[12-14]. These interventions target two core ADHD-related cognitive deficits: executive functioning (EF) and motivation[15]. They teach compensatory strategies in organization, time management, and planning (OTP) and include motivational components such

as goal-setting, contingency management, and strength-based feedback[16]. However, an ongoing challenge for schools is identifying qualified and available interventionists who are willing to deliver evidence-based interventions to regular education students with ADHD.

Peers as Interventionists

To overcome known implementation barriers, especially in school settings, we suggest revising the professional roles[17] of those delivering the evidence-based intervention. One group of interventionists who are available, numerous, qualified, and free, may be 11th and 12th grade peers. High schoolers have ample opportunities to interact with peers throughout the school day and unlike school staff, peer interventionists may be highly motivated to deliver interventions (such an experience can enhance college applications and serve as a service-learning leadership experience). There is abundant evidence that high school students can deliver a range of interventions to peers with fidelity[18, 19]. Peers play a central role in the lives of high school students, as adolescents spend decreasing amounts of time with adults[2]. Thus, adolescents with ADHD may be highly interested in engaging with peer interventionists.

Ninth Grade as a Critical Intervention Window

When resources are low, it becomes important to intervene wisely by conserving services for windows that promote maximal impact[20]. Failure to access ADHD treatment may be particularly detrimental to 9th graders. Typical adolescents display a decline in GPA[21], self-esteem[22], and psychological adjustment at the transition to high school[23]. This deterioration is especially marked in students with ADHD, whose 9th grade year marks the low point of their academic performance[1]. Performance during 9th grade is one of the strongest predictors of eventual high school dropout[24]. Thus, 9th grade is a strategic intervention period to prevent escalating school disengagement among students with ADHD.

An orientation model delivered immediately prior to the start of high school may represent a strategic window for setting adolescents up for high school success. As summer often comes with available time it may allow for more active adolescent participation before increased academic demands begin. Furthermore, including social activities that engage adolescents in an enjoyable intervention may promote attendance, introduce them to a culture of prosocial peers, and generate interest in continuing school-year intervention. To this aim, the current study will test the effectiveness of a peer-delivered summer orientation followed by school year components delivered by the same peer interventionist in 9th grade for adolescents with ADHD.

Adaptation and Implementation of Existing Interventions

We propose to merge two existing interventions, Students Taking Responsibility and Initiative through Peer Enhanced Support (STRIPES[16]) with a scaled-down Summer Treatment Program-Adolescent (STP-A[25]). STP-A is an eight-week intensive treatment program for adolescents with ADHD which targets skill development across academic, social, and behavioral contexts and employs contingency management to motivate adolescent skill practice in a summer school context. In a randomized controlled trial[13] we found high attendance for a high-intensity version of the summer treatment program as well as positive outcomes on note taking, parent contingency management, and parent-reported ADHD symptoms. Effects were largest for 9th graders compared to 6th graders. At four-year follow-up[14], the positive effects on ADHD symptoms and OTP problems remained. These results highlight the summer before 9th grade as a key intervention window and indicate the propensity for a pre-ninth grade summer intervention to produce long-term effects on high school trajectory. Unfortunately, the STP-A had one major drawback-- its impractical price tag (see [13]).

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STRIPES[16] is a peer-delivered school-year intervention for high schoolers. Like the STP-A, STRIPES targets core EF skills and academic motivation and has shown positive increases in book bag organization, academic motivation, and class attendance. Despite the positive results, 9th grade students often failed to attend STRIPES. Preliminary data indicated that intervention credibility, satisfaction, and student-peer bond were positive indicating that with some refinement to improve engagement and attendance, peer interventionist may serve as a viable option for treatment delivery. The limitations of both STP-A and STRIPES may be solved by the strengths of the other—the low-cost STRIPES interventionists can reduce the STP-A's tremendous expense; the highly engaging STP-A model might boost STRIPES' attendance problems.

The current adaptation effort and resulting clinical trial will pull on human-centered design[26-28] to develop a strategic intervention model, Summer STRIPES, that overcomes known implementation barriers in schools. If the resulting Summer STRIPES model is effective, we would expect to see positive changes in the following outcomes: GPA, class attendance, and ADHD symptoms. Based on theoretical models for skills-based ADHD interventions (see[29]), we hypothesize three primary target mechanisms for the Summer STRIPES intervention: intrinsic motivation, extrinsic motivation, and goal-directed executive functions[30-33]. Our theoretical model is presented in Figure 1.

Study Aims

The primary aim of this study is to adapt and pilot Summer STRIPES (aim 1). We will conduct a randomized trial of Summer STRIPES compared to school services as usual (SSU plus) and test the effect of Summer STRIPES (compared to SSU plus) on ADHD symptoms and key mechanisms (intrinsic motivation, extrinsic motivation, EFs), as well as key academic school

outcomes during the ninth-grade year (aim 2a; GPA, class attendance). We will also test the effect of mechanisms on outcomes (aim 2b). Lastly, we will assess multiple indices of engagement and school fit during the randomized trial (aim 3).

Methods and Analysis

Study Timeline

Patient and Public Involvement

In Year 1 (January 2022), with input from key stakeholders (administrators, teachers, student services staff, student leaders, parents) and content experts, we will create and adapt the protocol for our Summer STRIPES intervention. As adaptation is an important implementation strategy, we will meet regularly with stakeholders to resolve several key questions (e.g., What will be the length of the pre-high school orientation? How will peers be identified?) and develop school-specific manuals that fit within their unique school contexts[26-28].

In Year 2 and Year 3, we will implement the resulting intervention in two high schools in the state of Washington during a randomized trial (N=72) that will assign rising 9th grade students with ADHD to (1) Summer STRIPES or (2) SSU plus. Students will be randomized within school and cohort using a permuted block randomization strategy. In each of the two annual cohorts, 18 students will be recruited for each school (9 randomly assigned to each condition), resulting in a total of 72 participants.

Recruitment

During the spring of participants' 8th grade year (January-May 2022), study staff will work with schools to distribute nomination forms and study information to feeder middle school counselors and administrators, inviting the schools to nominate students. As part of this process, parent and teachers will provide background information, DSM-5 ADHD symptom

checklists[34], and measures of student academic impairment[34-36]. Students will be eligible for participation if they display at least six symptoms of either inattention or hyperactivity/impulsivity and significant academic impairment. Participants will be excluded if they are placed in special education classes, as the purpose of this study is to test a low-cost intervention for use in regular education settings. Both medicated and unmedicated students will be permitted to enroll in the trial. Eligible participants will complete a baseline assessment at their middle school. Participants will be required to demonstrate an IQ > 70 on the Wechsler Abbreviated Scale of Intelligence, 2nd edition(WASI-II[37]). Although we do not anticipate this, if the recruitment targets are not initially met we will extend the trial for an additional year.

Selection and Training of Peer Interventionists

Peer interventionists will be nominated by their teachers. Peers will be required to have at least a 3.0 GPA and good behavior at school (defined as no in- or out-of-school suspensions during the past twelve months). Peer interventionists will receive a treatment manual and two full days of training prior to delivering the intervention. They will receive 30 minutes of supervision per day during the summer orientation and 30 minutes per week for 16 weeks during the school year. Supervision will be co-led by a school staff sponsor and our team's school mental health liaison. The school staff sponsor will receive two days of training from research staff (16 hours) prior to the peer training and 30-minutes of weekly consultation from the school mental health liaison during the intervention periods.

Summer STRIPES versus SSU plus

Allocation of groups will be randomized, the intervention model will be parallel assignment and the masking will be single (outcome assessor). Teachers and research assistants conducting observations during assessments will be masked to study group. However, full

masking is not feasible in this trial because: (1) it is impossible to mask parents and adolescents to treatment group because they will be participants in the intervention and (2) it is possible that teachers, who are informants in this study, will learn of the student's group status from the student or school staff and peer interventionists who are involved in the project.

Study Intervention

Full intervention procedures will be finalized in Year 1 and will be based on two manuals, STP-A[13] and STRIPES[16]. The proposed intervention model will be up to two weeks of daily high school orientation (four hours per day) immediately prior to the start of 9th grade (Fall 2022), staffed by peer interventionists and a school staff member (to be identified by schools in Year 1; no exclusion criteria). The orientation will be held at the student's school and will contain trimmed STP-A modules (see Table 1). Two parent training sessions will be held during summer orientation with a focus on orchestrating contingency management outside of school to reinforce Summer STRIPES and school year performance. A school staff sponsor will also provide brief daily coaching (phone call up to a five-minutes) on contingency management implementation to the parent after each orientation day. A scaled down version of the STP-A classroom behavior management system will be employed to promote prosocial behavior during the orientation (see Table 1) set by the student and their peer that is incorporated into the contingency management system.

During the school year, participants will continue to meet weekly with their peer interventionists in a group setting under the supervision of the school staff sponsor. The 16-week school year follow-up component will follow the original STRIPES manual[16]. Parent components during the school year will include optional monthly group problem solving sessions with the school staff sponsor and a school mental health liaison and a weekly phone call (up to

five minutes) from the school staff sponsor to discuss contingency management. During both the summer and the school year, peers will complete a goal sheet with the 9th grader at each intervention session that indicates whether they met daily (summer) or weekly (school year) goals. Parents will be trained to check this goal sheet and apply contingency management accordingly. The 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[13, 14, 38].

Comparison Condition

As the goal of this study is to see whether a low-burden intervention, Summer STRIPES, is strong enough to improve upon the best-care scenario typical experience of regular education high school students with ADHD, we chose a school service as usual (SSU plus) comparison condition. Students who are assigned to the SSU plus group will receive school supplies and be referred to their identified school counselor for referral to services available in the school setting. The school counselor will be provided with a report from the student's intake assessment that summarizes the student's symptoms and presenting problems. We will systematically track services received in the comparison condition.

Assessment Procedures

Four assessments will occur at baseline (BL; end of 8th grade), start of 9th grade (FU1), mid-9th grade (FU2), and end-of-9th grade (FU3). Student assessments will occur at the school with a trained research team member. Peers, parents, and teachers will complete ratings electronically via RedCap[39, 40]. Direct observation of skills and cognitive and analogue academic tasks will be completed in a private room at the school with a trained research staff member. All students will be required to refrain from taking stimulant medication on the day of

their assessment (i.e., 24-hour washout period which is standard practice[41]). Based on the length of their assessment batteries, parents will receive $50 for each assessment, teachers will receive $20, peers will receive $20, and 9th graders will receive $75. The 9th graders battery is expected to take about 90 minutes to 2 hours and adolescents are permitted to take breaks as needed[16, 25].

Measures

Outcomes

We will assess two ecological school outcomes at all time points, GPA and class attendance, as well as ADHD symptom severity. Report cards and attendance records will be obtained directly from schools.

Grade Point Average. GPA for each quarter will be calculated by converting academic grades (e.g., English, Math, Science, Social Studies) to a 5-point scale (i.e., 4.0=A to 0.0=F). Grades will not be weighted for the difficulty of the class.

Class Attendance. Number of class absences will be calculated for each quarter.

ADHD Symptoms. Inattention and Hyperactivity/Impulsivity will be measured using a DSM-5 ADHD Rating Scale completed by parents and teachers[34, 42]. Respondents will rate symptoms of ADHD as 0 (not at all) to 3 (very much). Symptom severity is the mean level (0-3) of ADHD subscale items. Psychometric properties of the measure are very good, with empirical support for internally consistent Inattention and Hyperactivity/Impulsivity subscales[34, 42]. In a recent sample, ADHD subscale alphas ranged from .86-.95[29].

Mechanisms

Proposed treatment mechanisms will be measured at all time points: (1) Intrinsic Motivation, (2) Extrinsic Motivation, and (3) EFs. Given the multi-dimensional nature of these constructs, we propose a multi-method measurement strategy (see Figure 1).

Intrinsic motivation. ***Self-Rated Intrinsic Motivation.*** The Expectancy-Value Theory of Motivation Measure-Student Version (EVTMM[43]) is a gold-standard self-report measure of student motivation with excellent psychometric properties that consists of 11 items measured on a 5-point scale. The two "interest" items ("in general, I find working on school work interesting…" "How much do you like doing schoolwork?..") will be averaged to provide an index of academic interest[43]. The combination of these two items has good reliability and validity[44].

Basic Needs Fulfillment. The Basic Psychological Needs Scale is a validated scale that addresses need satisfaction in one's life. The original scale has 21 items concerning needs for competence, autonomy, and relatedness[45]. We will use a validated 22-item adaptation designed to measure fulfilment of adolescent's basic needs at school[46]. This measure shows strong psychometric properties and is validated in adolescent samples[46].

Extrinsic motivation. ***Self-rated Extrinsic Motivation.*** The EVTMM's two "importance" items (i.e., "for me being good in school is important…" "compared to most of your other activities, how important is it for you to be good in school…") will be averaged[43]. A subscale containing these two items is validated for adolescents[47].

Rewards Processing. A computerized Iowa gambling task (Hungry Donkey Task[48]) will be administered as a measure of risky decision making (i.e., sensitivity to future negative consequences). The task shows good convergent validity in adolescents[48].

Delay discounting was measured using a computerized Choice-Delay Task[49] in which participants will be instructed to make repeated choices between a small variable reward that would be delivered immediately and a large constant reward that would be delivered after a variable delay. After completion of the task, participants receive the total earnings from the examiner. The total amount of money earned serves as an index of delay discounting. This task shows developmental sensitivity[49] and correlates with symptoms of ADHD[50].

Delay aversion will be measured using the 10-item self-report version of the Quick Delay Questionnaire in which adolescents self-rate their degree of aversion and response to delayed rewards using a 5-point scale[51]. This measure has good psychometric properties[51, 52].

Use of Goal Setting Strategies. Use of goal setting strategies will be measured using the Self-Regulated Learning Interview Schedule (S-RLIS[53]). The goal setting and planning section of the S-RLIS were previously converted by our team to a parent-report and self-report rating scale to measure goal setting[54]. Six items measure the extent to which parents observe their children setting short-term and long-term goals during schoolwork, when completing household tasks, and when poorly motivated. In previous adolescents samples with ADHD, alpha for this measure was .87[54].

Home Contingency Management. The Parent Academic Management Scale (PAMS[38]) is a 16-item checklist that measures the frequency of adaptive and maladaptive parental involvement strategies related to adolescent OTP skills[38]. Parents indicate the number of days during the typical school week (0 to 5) that they performed each activity. PAMS possesses strong psychometric properties as evidenced by good internal consistency, concurrent validity, and predictive validity[38].

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Executive Functions. ***Functional Indices of EF.*** Research assistants who are blind to intervention group will conduct observations of planner use (or a device if preferred) and bookbag organization. Percentage of classes with recorded homework (or indication of no homework) will be calculated for the last five school days[55]. Observations of bookbag organization will be obtained using the Organization Checklist (OC[56]). Research assistants will assess dichotomously scored items on the organization checklist such as "Is the adolescent's bookbag free from loose papers?" and "Does the adolescent have a folder/binder for each core academic class?" Percentage of items achieved will be calculated. OC scores correlate with teacher ratings of impairment in adolescents with ADHD[56]. Finally, note-taking skills will be measured using an analogue paradigm previously used to measure response to intervention in adolescents with ADHD[13].

The Behavior Rating Index of Executive Function (BRIEF-2) is a well-validated measure of executive function for youth ages 5-18[57]. Parents rate youth executive functions on a three-point scale across nine subscales.

Cognitive Control. Response inhibition will be measured using a go/no-go task that uses both positively and negatively valanced emotional stimuli[58]. The number of commission errors on no-go trials across the whole task will be utilized as a measure of response inhibition. The task shows good convergent validity[59] and has been validated with adolescents[58].

Working memory will be measured using the National Institute of Health (NIH) Toolbox List Sorting Working Memory Test[60] which shows excellent test-retest reliability and convergent and discriminant validity[61].

Cognitive flexibility will be measured using the NIH Toolbox Dimensional Change Card Sort Test[60]. The task shows excellent developmental sensitivity and convergent validity[62].

Use of OTP strategies. The self, parent, and teacher-report versions of the 24-item Adolescent Academic Problems Checklist (AAPC) measures observable secondary-school specific OTP problems and are validated for use in samples of adolescents with ADHD[36]. The AACP possesses two distinct factors (academic skills and disruptive behavior) and a total score, with strong internal reliability and concurrent validity[36].

In the Analogue Note-taking task, students will listen to a 20-minute history lecture via video and take notes. Correctly recorded percentage of main ideas and supporting details will be calculated[63]. Four versions of this task exist to reduce practice effects and order of administration will be counterbalanced within group and school. In past examinations using the note-taking task[13], intraclass correlation for this inter-rater reliability probe was .90.

Engagement and Fit

We will assess a variety of indices from the 9th grader, parent, and peer interventionist, as well as direct observation during the intervention and at post-treatment.

Intervention Attendance. Detailed intervention attendance records (student, peer, and school staff supervisor) will be collected by a research assistant at each session.

Fidelity. We will enhance and adapt previous fidelity checklists used in the STP-A and STRIPES trials with an emphasis on implementation features as well as content[13, 16].

Acceptability. Post-intervention treatment credibility will be measured from students using a four-item adaptation of the Client Credibility Questionnaire (CCQ[64, 65]). Students will rate how logical they find treatment and how confident they were in the treatment on a 3-point scale (0 = *Not at all* to 2 = *very much*). In addition, students will also provide ratings of the helpfulness of each STRIPES component using a scale adapted from Sibley and colleagues

(2013)[55] on a similar 3-point scale. High scores will indicate stronger credibility. In our past study of STRIPES, alpha for this measure was .79[16].

The degree to which 9th graders enjoyed working with their peer interventionist will be measured using the seven-item Therapist Bond Scale (TBS[66]). The TBS items are rated on a 4-point Likert-type scale, ranging from 1 (*not at all like you*) to 4 (*very much like you*). Internal consistency and convergent validity are strong for this measure[66].

Students will provide ratings of treatment satisfaction post-intervention using a standard satisfaction questionnaire developed for behavioral treatments[67] that has been adapted for adolescents with ADHD[13, 55, 68]. Respondents will indicate their degree of satisfaction for 20 aspects of treatment using a 5-point Likert Scale (1=*Strongly Disagree* – 5=*Strongly Agree*). Mean satisfaction will be calculated. In our previous STRIPES sample, alpha for this measure was .97[16].

In addition to students, peer interventionist will also complete these measures separately for each of their assigned 9th grader.

Potential Covariates

Medication use during the study will be monitored via a parent and adolescent medication use survey and will be examined as a covariate in analyses. We will also measure the following potential covariates at BL: IQ, parent education level, race/ethnicity, age, gender, parent marital status, and free/reduced lunch status.

Data Analysis Plan

Analyses will be performed using Mplus 7. We will assess missing data prior to analyses. The proposed analysis methods (i.e., multilevel regression with maximum likelihood estimation) are robust to MAR (missing at random) or MCAR (missing completely at random) mechanisms,

which will minimize impact of missingness and attrition. Missing data will be handled with full information maximum likelihood (FIML) estimation, which can accommodate missing data at high levels. We will assess whether data meet all assumptions of analysis (multivariate normality, outliers) and will adjust for any violations using robust methods (such as using bootstrap standard errors).

Aim 2a

Latent growth models will be used to test the effect of Summer STRIPES (compared to SSU plus) on primary outcome measures (ADHD symptoms, GPA, class attendance). Time (months since BL, modeled as a person-specific variable), group (Summer STRIPES or SSU plus), and their interactions will be used as predictors while ADHD symptoms, GPA, and class attendance (at all time points) will be the modeled outcomes. We will explore non-linear and piece-wise models to consider that Summer STRIPES orientation and its school year follow-up components may enact unique influences on slope over time.

Aim 2b

The mechanisms by which Summer STRIPES leads to improvement in outcomes will be evaluated through latent growth models. Three sets of models will be assessed, according to the three theoretical mechanisms (intrinsic motivation, extrinsic motivation, EFs). The models will assess the effect of Summer STRIPES on primary outcomes (ADHD symptoms, GPA, class attendance; centered at FU3) via indices of intrinsic motivation, extrinsic motivation, and goal-directed EFs (centered at FU2).

Aim 3

We will assess multiple indices of engagement and school fit during the randomized trial (i.e., parent, youth, and interventionist engagement in the intervention; attrition; fidelity,

perceived intervention utility and burden). The effect of Summer STRIPES on measures of engagement and school fit will be evaluated descriptively (e.g., treatment fidelity). Although no adverse effects are expected [69] we will monitor this using both the acceptability and efficacy data.

Statistical Power

The mean effect size for adolescent interventions for ADHD compared to no treatment is approximately *d*=0.4, as was the mean acute effect for the STP-A compared to low-intensity treatment modules[13]. To substantiate Summer STRIPES as incrementally superior to SSU plus, we will define a *d*= 0.4 difference between Summer STRIPES and SSU plus as a successful outcome signaling the need for further study in an R01 clinical trial. Power analysis for a mixed effects model with N = 72, power = 0.80 and alpha = 0.05 were conducted using GPower 3.1. Because the power for this analysis depends partly on the correlation between BL and follow-up measures of the outcome, we assessed power for several values of this correlation. The proposed analysis has power to detect effects of *d* = 0.42, 0.33, and 0.21 for BL to FU correlations of 0.2, 0.5, and 0.8, respectively. In addition, there are 36 subjects per group; Maas & Hox (2005)[70] recommend at least 30 clusters (here, subjects) per group to reduce bias in estimation of growth models, so we expect little bias in models.

Ethics and Dissemination

This project is funded as a R34 mechanism 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 a Planning Grant designed to establish proof of concept and is focused on acceptability and basic efficacy of the intervention. Therefore, the current proposal is focused on using known implementation strategies to adapt two evidence-based interventions (STP-A and STRIPES) into

Summer STRIPES and to pilot its feasibility in schools. If this trial indicates that Summer STRIPES meets sufficient metrics for preliminary efficacy the next steps will be to proceed with a full scale clinical trial (NIMH R01 Research Project Grant) to test efficacy, mediators, moderators, and cost analysis of Summer STRIPES in a larger full-scale RCT (stage implementation scale up[17, 71]).

The protocol (#2087) is approved by the Institutional Review Board (IRB00000277 & IRB00009311) at Seattle Children's Hospital (FWA #00002443). Eligible students will be enrolled and randomized into the study only after giving assent and collecting parental consent to participate. All adolescents who are enrolled in the trial will be 9th graders (approximately 14-15 years old) so 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. We have registered our clinical trial on ClinicalTrials.gov (NCT04571320) and will work with Seattle Children's Research Institute to submit results in accordance with the required timelines. Informed consent and assent documents will include a statement indicating that trial information, devoid of identifying information, will be posted at ClinicalTrials.gov. All data will be submitted to the National Institute of Mental Health Data Archive (NDA; https://nda.nih.gov/). Additionally, results from the proposed project will be disseminated widely through traditional dissemination to the scientific community, first through conference presentations targeting both academics and school educators and mental health professionals, as well as peer-reviewed publications in academic journals. Dissemination to community stakeholders will occur through presentations for local and statewide school district officials.

Authors' contributions statement

CAZM drafted the manuscript. MHS conceptualized the study and wrote the grant funding. SC conceptualized, wrote, and provided feedback on the analytic plan. ARL and BA are co-investigators of the grant and contributed to the conceptualization of the project. MO is the project coordinator and organized the measurement battery. CAZM, MHS, AL, BA, MO wrote or revised sections of the manuscript. All authors approved the final version of the manuscript.

Competing interests' statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Data Sharing Statement

We have registered our clinical trial on ClinicalTrials.gov (NCT04571320) and will work with Seattle Children's Research Institute to submit results in accordance with the required timelines. All data will be submitted to the National Institute of Mental Health Data Archive (NDA; https://nda.nih.gov/).

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PROTOCOL SUMMER STRIPES

Table 1

Core Summer STRIPES components (all group-based)

Summer Teen (1-2 weeks/5 days a week)	**School Year Teen (16 weeks/1 day a week)**
Note-taking (30 mins)	Goal setting (10 mins)
Materials management (15 mins)	Organization check (5 mins)
Tracking homework (15 mins)	Homework tracking (5 mins)
Time management (15 mins)	Reviewing progress through online gradebook (10 mins)
Study skills (30 mins)	
Rec period (1 hour)	
Goal Setting (15 mins)	
Summer Parent	**School Year Parent (16 weeks)**
Contingency Management I (90 mins)	Monthly Prob. Solving Session (60 mins—4 months)
Contingency Management II (90 mins	Weekly Coaching (5 mins- 16 weeks)
Daily Coaching (5 mins)	

Figure Legend:

Figure 1: Theory of Change Model

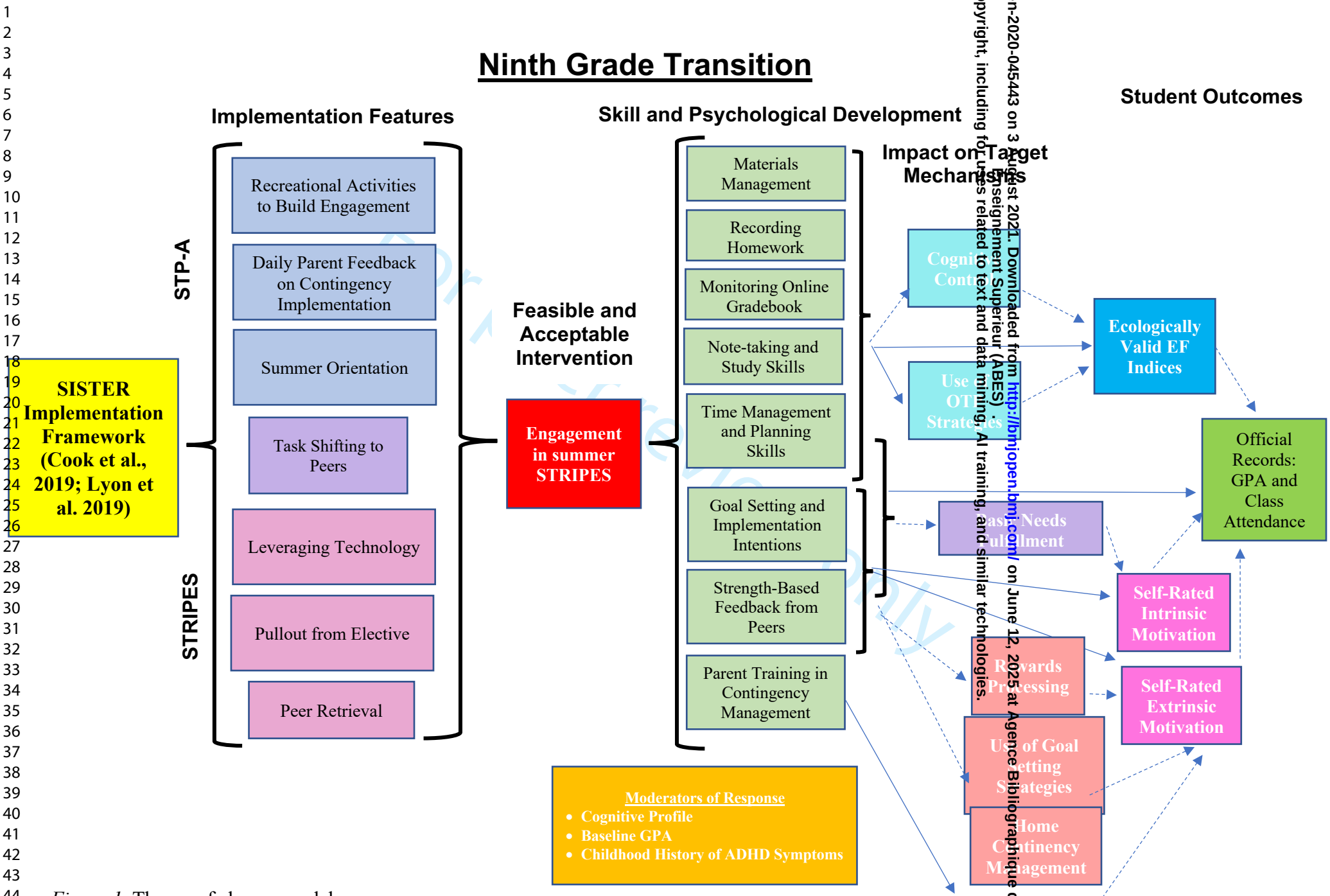

Figure 1. Theory of change model

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	#3	Date and version identifier	N/A
Funding	#4	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1

Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	N/A
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-8
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	10-11
Objectives	#7	Specific objectives or hypotheses	8
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	8-10
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8-10

Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8-9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	N/A
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9-11
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8-9
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for	N/A

		stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8-9
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-18
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where	11

		details of data management procedures can be found, if not in the protocol	
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17-18
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17-18
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17-18
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n/a
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	19
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	19

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	20
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	n/a
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	n/a
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	provided as supplemental
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the	n/a

current trial and for future use in ancillary studies, if applicable