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Development of a Novel Virtual Reality Treatment for Emerging Adults with ADHD

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STUDY INFORMATION

- **Title of Project:**
  Development of a Novel Virtual Reality Treatment for Emerging Adults with ADHD
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1.0 Research Design

1.1 Purpose/Specific Aims

The study will refine the algorithms that operationalize on-task behavior and the process of displaying participant performance within the virtual reality (VR) environment, then conduct trials to examine said intervention. We will collect data on feasibility, usability and key mechanisms of action, concentration, motivation, and effort/efficiency. A randomized control trial will be implemented to evaluate the effects of the distraction free VR environment alone and combined with automated contingency management and moderators and mediators of outcomes.

A. Objectives

1. Refine objective virtual reality (VR) data capture techniques, including keyboard and mouse click algorithms, eye gaze tracking, and screenshot capturing.
2. Develop and refine contingency management algorithms and conduct focus groups to determine ways to improve feasibility/usability.
3. Pilot test the feasibility/usability of the VR environment and evaluate impact on target mechanisms.
4. Conduct a parallel group randomized trial with college students with ADHD randomized to 1 of 3 groups: (1) VR environment alone, (2) VR + contingency management or (3) a pass-through VR.

B. Hypotheses / Research Question(s)

Data will inform the use of virtual reality to support the academic performance and mental health of individuals of ADHD. The VR intervention will target specific mechanisms of concentration, homework effort, and homework motivation. Trial data will demonstrate the feasibility/usability of the VR system and associated algorithms to monitor attention and focus in VR.

1.2 Research Significance

ADHD is a highly prevalent neurodevelopmental disorder characterized by significant difficulties with inattention (APA, 2013; Sayal et al., 2018). Individuals with Attention-Deficit/Hyperactivity Disorder (ADHD) have difficulty self-regulating the cognitive and attentional processes required to complete tasks such as homework and studying for tests. There are several evidence-based behavioral treatments designed for adolescents with ADHD that require minimal parent involvement and are implemented by clinicians or school staff (Evans et al., 2016; Langberg et al., 2018; Sibley et al., 2011; 2012; 2016). There are also several clinician-delivered interventions that have demonstrated preliminary efficacy for college students with ADHD (Anastopoulos et al., 2021 [see preliminary studies section]; Hartung et al., 2020; Lacont et al., 2018; Solanto & Scheres, 2021; Van der Oord et al., 2020). These interventions teach organization and planning skills as well as cognitive-behavioral strategies, are effective across a variety of symptom and functional domains and have potential for scaling-up. However, as with most behavioral and cognitive-behavior interventions, maintaining treatment integrity is difficult and costly (Margherio et al., 2021; Sibley, Olson et al., 2016).

The team leading this project invented the FlowLight, a software tool (not a virtual reality headset) that automatically monitors worker activity levels and wards off interruptions using a stoplight system. The FlowLight automatically measures focus based on a combination of computer activity (mouse and keyboard clicks). They have found that wearing a VR headset significantly increases adult worker productivity, even without the feedback provided through FlowLight. If this same technology can be applied to improve the focus and attention of individuals with ADHD, this would be a major research breakthrough.

To date, the majority of VR research with ADHD has evaluated the impact of delivering assessments such as continuous performance tasks (CPT) through VR environments. Reviews of the literature suggest that administration of CPT-like tasks in VR environments has the potential to increase test validity (Romero-Ayuso et al., 2021). However, VR has not been evaluated as an intervention or accommodation to help individuals with ADHD focus and complete tasks more efficiently.

The most commonly implemented evidence-based treatment for ADHD is behavior therapy. Behavior therapy is highly effective but incredibly resource intensive to deliver. Within a VR environment, we can implement aspects of behavior therapy with high fidelity and automate assessment of mechanisms of action. Participants will be placed in a VR environment that is relaxing and minimizes distraction. They can look all around their environment but cannot move from their virtual desk. We can also automate the aspects of behavior therapy that are key to efficacy, but time and resource intensive. Specifically, we can automate frequent and consistent monitoring of on-task behavior and provide frequent feedback to participants to help individuals with ADHD self-regulate and remain focused.

The potential real-world impact of a VR treatment that allows for efficient and effective completion of homework and studying for tests is hard to overstate. Many studies have shown that individuals with ADHD have intellectual capacities within the normal range (e.g., Kaplan et al., 2000). The low and failing grades they experience is largely attributable to difficulties sustaining attention and making careless mistakes when they study and complete work (Langberg et al., 2016).

1.3 Research Design and Methods

The study will take place in 4 phases, each utilizing methodology specific to the phase. Phases are created to improve clarity of expectations for participants entering at different points in the study and clarity of the general research protocol.

- PHASE 1: Refine objective data capture techniques. Key to any VR intervention is the ability to monitor and quantify work productivity behaviors and to establish an accurate baseline. This has been done with adult workers, but we will need to refine the keyboard and mouse click algorithms for use with emerging adults (aged 18-25 years) with ADHD who are completing real homework assignments and studying (n=30 to complete the phase). The study design for this phase will follow an AABBBAABBB design – where A is passthrough control and B is the immersive VR environment. In this way, each participant essentially serves as their own control as they switch between passthrough and VR immersion sessions. The team will also explore whether adding in eye gaze tracking and periodic screenshots improves the accuracy of the algorithms.
- PHASE 2: Develop and refine contingency management algorithms. Once data capture capabilities have been confirmed in emerging adults with ADHD, we must test the ability to combine these data into an algorithm to provide real-time performance feedback to participants and contingency management (n=30 to complete the phase). As with Phase 1, the study design for this phase will follow an AABBBAABBB type design – where A is passthrough control and B is the immersive VR environment. In this way, each participant essentially serves as their own control as they switch between passthrough and VR immersion sessions. The team will also conduct focus groups to determine ways to improve feasibility/usability and to identify strategies and tools that motivate participants to complete work.
- PHASE 3: Pilot test and evaluate impact on target mechanisms. Conduct a small randomized control trial (RCT) to assess the feasibility/usability and preliminary effects of the VR environment alone (n=15) compared to VR environment + contingency management (n=15) and the VR passthrough control (n=15). Proposed mechanisms of action will be measured every session,

including algorithm data plus self-ratings of concentration, homework effort, and homework motivation.

- PHASE 4: Conduct a parallel group randomized trial. Randomize 252 college students with ADHD to: (1) VR environment alone, (2) VR + contingency management or (3) a pass-through VR headset for 6 weeks. Assess target mechanisms at each session and collect ratings of functioning at baseline, intervention outcome and at a 3-month follow-up to facilitate evaluation of efficacy, dose, moderation, and mediation.

All visits will be conducted at participants' homes and the LSU or Rutgers library, Dr. Shepherd's lab at Louisiana State University, or via HIPAA-compliant videoconferencing (e.g., Zoom). Trained study staff will be on-site and available to assist at all times.

A. Research Procedures

This study is taking place at two sites, Rutgers and Louisiana State University (LSU). Rutgers is the "Psychology site" and the PI is a licensed clinical psychologist, and LSU is the "Engineering/VR site" and the PI is in Computer Science. As such, all participant consenting, inclusion/exclusion evaluations, and outcome assessments are handled by the Rutgers site. These portions will be done virtually, via REDCap surveys and teleconference. Approximately half of the participants will be enrolled and use VR at the Rutgers site and half at the LSU site. The scheduling and implementation of the VR sessions is handled by the site/university where participants are located. All data are collected via REDCap and stored at the Rutgers site only. The only exception is the data captured by the VR (keyboard and mouse click data, eye gaze, and screenshot captures), which is maintained and analyzed at LSU.

For the VR intervention provided in each phase, participants will be provided the option of using the VR headset while completing homework and studying either in their rooms/homes or at the library, and at a consistent time each day to help control for natural variations in focus due to chronobiological sleep/wake preferences.

Participants who take psychotropic medications will be asked to remain consistent on the seven days of the trial (i.e., choose to take or not take medications each day that the VR headset is used). The general course of such medication involves such decisions daily, so participants will have received medical consultation from their prescribing physician outside of the context of the study. Participants who have questions about stopping medication will not be advised by the study staff. They will be encouraged to discuss with their prescribing physician. While participating in the VR intervention, they will be wearing a VR headset while completing homework and studying on a laptop. 40 minutes of each session are devoted to work completion. Participants may be offered to complete all 40 minutes at once or to take a 10-minute break. If a session does not meet a 45-minute threshold, the participant will be scheduled to repeat the session.

Initial evaluation: Participants in each phase will complete an initial diagnostic evaluation to confirm eligibility and collect baseline data. The first half of the evaluation will be done via electronic surveys hosted by Rutgers. Subjects will provide contact, demographic, and background information. To measure current symptoms of ADHD and inform diagnosis, they will complete the Barkley Adult ADHD Rating Scale (BAARS-Self). To capture potential risk factors for use of the VR system, prescreening questions will ask about related medical history. To evaluate other services and treatments participants may be receiving, they will complete the Service Utilization for College Student's Questionnaire. To obtain a baseline of treatment targets/mechanisms, participants will complete the Adult Concentration Index, Homework Motivation, and Homework Effort/Efficiency ratings. To measure potential treatment moderators and outcomes, subjects will complete the GAD-7 and PHQ-9, Columbia Suicide Severity Index (CSSI), BDEFS, BFIS, and surveys on Academic Record (self-report only; and GPA & Percentage

of Assignments Completed). Due to NIMH/NDA data-requirements, in phase 4 of the trial, both the DSM-5 Level 1 Cross-Cutting Symptom Measure and WHODAS (World Health Organization Disability Assessment Schedule) are included. If the participant is eligible based on results of the survey data (see inclusion criteria), they will be invited to schedule an assessment interview over videoconferencing with Rutgers study staff. To measure current symptoms of ADHD and common comorbid disorders (e.g., anxiety and depression) and confirm diagnosis, a study staff member will administer the SCID-V RV.

PHASE 1: Refine objective data capture techniques.

VR intervention: After completing the baseline assessment and confirming eligibility, participants will schedule an in-person visit by an engineering graduate student from Dr. Shepherd's research team to either their room/home or the library. Rather than in a lab setting, students will be allowed to use the VR headsets in their natural study environment to increase the likelihood of adherence to the study protocol throughout all sessions and to provide a more real-world test of VR usage while studying. During their first session, the graduate student staff member will teach the participant how to use the VR headset and be present for the entire session in case the participant reports discomfort with fit or side effects (e.g. dizziness) For all projects in this study, participants will answer a question at the end of each VR session (will come up automatically) about whether they experienced any discomfort or dizziness. If this is endorsed, the graduate student will come to the following session to once again adjust the headset and monitor use. Each participant will be asked to use the VR headset at their study location (room/house or library) 10 times over two weeks (max twice a day with a 2-hour break in between) for 1-hour sessions each time. The study design for this phase will follow an AABBBAABBB type design – where A is passthrough control and B is the immersive VR environment. In other words, participants will be in passthrough control mode for Sessions 1, 2, 6, and 7, while in VR immersion mode for Sessions 3, 4, 5, 8, 9, and 10. During their VR sessions, participants will be placed in the base VR environment (a desk within a room with a window). They will be wearing noise-canceling headphones so the only audio stimuli are the sounds of nature. See Section 4.7 for further description of how risks and discomfort will be managed. LSU study staff will run VR intervention visits.

In-Session Assessment: After powering on the VR headset and setting it up, participants will be welcomed to their virtual reality study session and be prompted to first complete 10 minutes of standardized reading comprehension passages and questions as an additional measure of attention and concentration. The reading passages and questions are both sourced from the teacher website *Read Theory Workbooks* and at a 9th or 10th grade-level, which is theoretically an appropriate level of difficulty for college-aged students. Two passages are presented per session, with five content-related multiple-choice questions to complete following each passage. After the allotted 10 minutes, participants will then be automatically prompted on their VR screen to complete 40 minutes of studying in either pass-through or VR immersive mode. After the allotted 40 minutes, participants will then be asked to complete 10 minutes of brief surveys about feasibility/usability of using VR to complete work, attention/concentration, and homework effort. Specifically, participants will complete the 10-item Systems Usability Scale, the Adult Concentration Inventory, the Homework Motivation Index, and the Homework Effort Index each session. Finally, they will answer a question about whether or not they took ADHD medication that day – the Current Day Medication Adherence survey.

Outcome Assessment & Follow-up Interview: Following the 10th session, participants will receive a REDCap link to complete an outcome assessment. To measure ADHD symptoms, they will

complete the BAARS-Self survey. To evaluate other services and treatments the participants may be receiving, they will complete the Service Utilization for College student's questionnaire. To measure treatment moderators and outcomes, they will complete the RCADS, Columbia Suicide Severity Index (required by NIMH), BDEFS, BAI-2, ADHD Impact Model-Adult (AIM-A), and surveys on Academic Record (GPA & Percentage of Assignments Completed), and a Reading Comprehension Standardized Assessment. Questions on feasibility and usability of the VR system will be asked. Outcome assessments will be performed by Rutgers study staff using Rutgers-hosted REDCap. Additionally, only for Phase 1 as part of the pilot process, participants will be asked to conduct a brief 15-min follow-up phone interview with a member of the research team to further elaborate on their questionnaire responses regarding their experiences with the virtual reality headset, the virtual study environment, and any issues they encountered while using the technology. This will provide valuable qualitative information for the LSU VR developer team to then improve the system for future phases of the study.

PHASE 2: Develop and refine contingency management algorithms.

VR intervention: Contingency management is a term that refers to participants receiving feedback and earning points for staying on-task while completing work and studying in VR. After completing the baseline and confirming eligibility (same procedures across all Phases), a new sample of participants will schedule an in-person visit by an engineering graduate student from Dr. Shepherd's research team to either their room/home or the library. During their first session, the graduate student staff will teach the participant how to use the VR headset and be present for the entire session in case the participant reports any discomfort with fit or side effects (e.g. dizziness) Each participant will be asked to use the VR headset at their study location (room/house or library) 10 times over two weeks (max twice a day with a minimum 2-hour break in between) for 1-hour sessions each time. As with Phase 1, the study design for this phase will follow an AABBBAABBB type design – where A is passthrough control and B is the immersive VR environment. In other words, participants will be in passthrough control mode for Sessions 1, 2, 6, and 7, while in VR immersion mode for Sessions 3, 4, 5, 8, 9, and 10. In this project, the algorithms refined in project 1 will be linked with the FlowLight. The baseline contingency management procedure will be where participants receive 1 point for every minute of on-task behavior. This corresponds to 1 minute of the FlowLight being on the green setting. However, we want to encourage participants with ADHD to get back on-task quickly if their mind wanders. Accordingly, 1 point will be earned for 1 minute on green level, but this does not have to be consecutive and will allow for 10 seconds on yellow. In this way, participants whose light switches to yellow are motivated to refocus to get back to green level. Participants earn points to unlock additional VR environments. The base environment is a desk in a room with an open window where the natural environment can be viewed and heard (e.g., birds chirping). Earning points allows participants to unlock additional environments (e.g., beach, forest, fantasy land, and volcano). LSU study staff will run VR intervention visits.

In-Session Assessment: As with Phase 1, participants will first complete 10 minutes of standardized reading comprehension passages and questions before being automatically prompted on their VR screen to complete 40 minutes of studying in either pass-through or VR immersive mode. After the allotted 40 minutes, participants will then be asked to complete 10 minutes of brief rating scales asking about feasibility/usability of using VR to complete work, attention/concentration, and homework effort. Specifically, participants will complete the 10-item Systems Usability Scale, the Adult Concentration Inventory, the Homework Motivation Index, and

the Homework Effort Index each session. Finally, they will answer a question about whether or not they took ADHD medication that day – the Current Day Medication Adherence survey.

Outcome Assessment: Following the 10th session, participants will complete the same outcome assessment outlined under Phase 1, including the BAARS, BAI-2, BDEFS, AIM-A, Columbia Suicide Severity Index, Service Utilization for College Students, and surveys on Academic Record (GPA & Percentage of Assignments Completed), and a Reading Comprehension Standardized Assessment. Questions on feasibility and usability of the VR system will be asked. Outcome assessments will be performed by Rutgers study staff using Rutgers-hosted REDCap.

Focus group: Phase 2 participants will also participate in a focus group via videoconference with Rutgers study staff after completion of the intervention. Three separate 90-minute focus groups with participants (N=10 per group) will be held. Focus groups will include: (1) brief review of intervention rationale and goals; (2) participation in an unstructured discussion about topics generated by members of the group; and (3) participation in a group discussion centering around predetermined questions about the intervention. All participants will be encouraged to attend regardless of whether they completed all of the VR sessions. Questions will focus on ways to improve feasibility/usability and options for providing rewards to motivate focus and hard work. Focus groups will not be video-recorded, though live-transcription will be enabled and saved to collect their responses as data.

PHASE 3: Pilot test and evaluate impact on target mechanisms.

VR intervention: After completing the initial evaluation and confirming eligibility, a new sample of 45 participants will be randomized to 1 of 3 groups and then scheduled to use the VR headset in their room/home or the library. Randomization will be performed (1:1:1) to the three conditions. Randomization will be blocked on ADHD medication status to ensure an equal number of participants taking and not taking ADHD medication in each group. Phase 3 includes a 2-session baseline where all participants complete homework and study outside of VR (total of 12 sessions; 2 non-VR baseline and 10 in VR condition). During each session, participants will complete a set of standardized reading comprehension problems to determine how many they complete and how accurately. LSU and Rutgers study staff will run VR intervention visits at their respective study sites.

Group 1, VR passthrough: After completing the two session non-VR baseline, participants will use the VR headset in their room/home or the library 10 times over three weeks (max twice a day with a minimum 2-hour break) for 1-hour sessions each time. The participant will wear the headset, but it will not be used as usual. The headset will be in “VR passthrough” mode, meaning the participant will see through to the normal environment and laptop (i.e., they can see the real world around them, just wearing a headset).

Group 2, VR environment only: After completing the two session non-VR baseline, participants will use the VR headset in their room/home or the library 10 times over three weeks (max twice a day with a minimum 2-hour break) for 1-hour sessions each time. The participant will wear the VR headset and engage in homework in the VR environment.

Group 2, VR environment + contingency management: After completing the two session non-VR baseline, participants will use the VR headset in their room/home or the 10 times

over three weeks (max twice a day with a minimum 2-hour break) for 1-hour sessions each time. The participant will wear the VR headset and engage in homework in the VR environment while receiving contingency management (real-time feedback on performance through red or green light FlowLight icon).

In-Session Assessment: As with Phases 1 and 2, participants will first complete 10 minutes of standardized reading comprehension passages and questions before being automatically prompted on their VR screen to complete 40 minutes of studying in either pass-through, VR immersive mode, or VR immersive mode with contingency management. After the allotted 40 minutes, participants will then be asked to complete 10 minutes of brief rating scales asking about feasibility/usability of using VR to complete work, attention/concentration, and homework effort. Specifically, participants will complete the Adult Concentration Inventory, the Homework Motivation Index, and the Homework Effort Index each session. Finally, they will answer a question about whether or not they took ADHD medication that day – the Current Day Medication Adherence. Participants will complete the 10-item Systems Usability Scale after sessions 4 and 12 only.

Outcome Assessment: Following the 12th session, participants will complete an outcome assessment. For the outcome assessment, they will complete some of the same outcome battery described in Phase 1 and 2 (BAARS-Self, BDEFS, BFIS, Academic Records, GPA & Percentage of Assignments Completed). Questions on feasibility and usability of the VR system will be asked in the outcome assessment. Outcome assessments will be performed by Rutgers study staff using Rutgers-hosted REDCap.

Follow-Up Assessment: Three months after the completion of the final session, participants will complete a follow-up assessment visit. The assessment battery will be the same as the outcome battery described in the initial outcome assessment. Follow-up assessments will be performed by Rutgers study staff using Rutgers-hosted REDCap.

PHASE 4: Conduct a larger parallel group randomized trial.

Phase 4 will follow the same procedures as Phase 3 (see above) except instead of n=45, we will randomize n=252 (note, number who consent is higher, to account for those found not eligible after consenting). This will be done across several cohorts. Please see the study timeline figure in section 1.10 for a visual of how many subjects will be in each cohort.

B. Data Points

PHASE 1: Refine objective data capture techniques.

Initial evaluation:

- Contact, demographic, and background information
- Service Utilization for College Students
- Current Day Medication Adherence survey
- BAARS-Self
- Pre-screening questions
- Adult Concentration Index (ACI)
- RCADS
- Columbia Suicide Severity Index

- BDEFS
- BAI-2
- ADHD Impact Model-Adult (AIM-A)
- Academic Records (Homework completion & grades; self-report only)
- GPA & Percentage of Assignments Completed (Homework completion & grades; self-report only)
- Reading Comprehension Standardized Assessment
- ADHD Rating Scale-Parent (childhood; completed by parent or other reporter)
- SCID-V RV
- Parent Contact Form

Each of 10 sessions:

- Key strokes and mouse clicks
- Eye tracking
- Periodic screenshots of participant screens
- 10-item Systems Usability Scale
- Adult Concentration Inventory
- Homework Motivation Index
- Homework Effort Index
- Current Day Medication Adherence

Outcome Assessment:

- Service Utilization for College Students
- Current Day Medication Adherence survey
- BAARS-Self
- RCADS
- Columbia Suicide Severity Index
- BDEFS
- BAI-2
- ADHD Impact Model-Adult (AIM-A)
- Academic Record (GPA & Percentage of Assignments Completed)
- Reading Comprehension Standardized Assessment
- Feasibility and usability of the VR systems

PHASE 2: Develop and refine contingency management algorithms.

Initial evaluation:

- Contact, demographic, and background information
- Service Utilization for College Students
- Current Day Medication Adherence survey
- BAARS-Self
- Pre-screening questions
- Adult Concentration Index (ACI)
- RCADS

- Columbia Suicide Severity Index
- BDEFS
- BAI-2
- ADHD Impact Model-Adult (AIM-A)
- Academic Record (GPA & Percentage of Assignments Completed)
- Reading Comprehension Standardized Assessment
- ADHD Rating Scale-Parent (childhood)
- SCID-V RV
- Parent Contact Form

Each of 10 sessions:

- Key strokes and mouse clicks
- Eye tracking
- Periodic screenshots of participant screens
- 10-item Systems Usability Scale
- Adult Concentration Inventory
- Homework Motivation Index
- Homework Effort Index
- Current Day Medication Adherence

Outcome Assessment:

- Service Utilization for College Students
- Current Day Medication Adherence survey
- BAARS-Self
- RCADS
- Columbia Suicide Severity Index
- BDEFS
- BAI-2
- ADHD Impact Model-Adult (AIM-A)
- Academic Record (GPA & Percentage of Assignments Completed)
- Reading Comprehension Standardized Assessment
- Feasibility and usability of the VR systems

Focus Group

- VR Study Focus Group Questions

PHASE 3: Pilot test and evaluate impact on target mechanisms.

And

PHASE 4: Conduct a parallel group randomized trial.

Initial evaluation:

- Contact, demographic, and background information

- Service Utilization for College Students
- Current Day Medication Adherence survey
- BAARS-Self
- Pre-screening questions
- Adult Concentration Index (ACI)
- GAD-7
- PHQ-9
- Columbia Suicide Severity Index
- WHODAS (Required by NIMH/NDA)
- DSM-5 Level 1 Cross-Cutting Symptom Measure (Required by NIMH/NDA)
- BDEFS – Short Form
- BFIS
- Baseline Homework Motivation Index
- Baseline Homework Effort Index
- Academic Record (GPA & Percentage of Assignments Completed)
- Reading Comprehension Standardized Assessment
- SCID-V RV

Each of 10 sessions:

- Key strokes and mouse clicks
- Reading Comprehension Standardized Assessment
- Periodic screenshots of participant screens
- 10-item Systems Usability Scale (Sessions 4 and 10 only)
- Adult Concentration Inventory
- Homework Motivation Index
- Homework Effort Index
- Current Day Medication Adherence

Outcome Assessments:

- Current Day Medication Adherence survey
- BAARS-Self
- BDEFS – Short Form
- BFIS
- Academic Record (GPA & Percentage of Assignments Completed)
- Feasibility and usability of the VR systems

3-Month Follow-Up

- Current Day Medication Adherence survey
- BAARS-Self
- BDEFS – Short Form
- BFIS
- Academic Record (GPA & Percentage of Assignments Completed)
- Feasibility and usability of the VR systems

C. Study Duration

PHASE 1:
Each participant will be involved for approximately 4 weeks (1 week of initial evaluation, 2 weeks of intervention, 1 week of outcome assessment).

The initial evaluation will take approximately 1.5 hours.
Each VR intervention session will take approximately 1 hour (10 minutes of reading comprehension questions, 40 minutes of intervention, 10 minutes to complete surveys). Across the intervention, they will complete 10 1-hour sessions.
The outcome assessment will take approximately 30 minutes to complete, and the follow-up phone interview with the research team should take 15 minutes.

PHASE 2:
Each participant will be involved for approximately 5 weeks (1 week of initial evaluation, 2 weeks of intervention, 1 week of outcome assessment, 1 week of focus group).

The initial evaluation will take approximately 1.5 hours.
Each VR intervention session will take approximately 1 hour (10 minutes of reading comprehension questions, 40 minutes of intervention, 10 minutes to complete surveys). Across the intervention, they will complete 10 1-hour sessions.
The outcome assessment will take approximately 30 minutes to complete.
Within 6 months of the conclusion of the participation in the intervention, participants will participate in a focus group. The focus group will take approximately 90 minutes.

PHASE 3:
Each participant will be involved for approximately 18 weeks (1 week of initial evaluation, 1 week of intervention baseline, 3 weeks of intervention, 1 week of outcome assessment, then a 3-month follow-up).

The initial evaluation will take approximately 1.5 hours.
Each VR intervention session will take approximately 1 hour (10 minutes of reading comprehension questions, 40 minutes of intervention, 10 minutes to complete surveys). Across the intervention, they will complete 12 1-hour sessions (2 baseline without VR headsets, 10 in the assigned condition).
The outcome assessments will take approximately 30 minutes.
The 3-month follow-up will take approximately 20 minutes to complete.

PHASE 4:
Each participant will be involved for approximately 18 weeks (1 week of initial evaluation, 1 week of intervention baseline, 2 weeks of intervention, 1 week of outcome assessment, then a 3-month follow-up).

The initial evaluation will take approximately 1.5 hours.
Each VR intervention session will take approximately 1 hour (10 minutes of reading comprehension questions, 40 minutes of intervention, 10 minutes to complete surveys). Across the intervention, they will complete 12 1-hour sessions (2 baseline without VR headsets, and 10 in the assigned condition).
The outcome assessments will take approximately 30 minutes.
The 3-month follow-up will take approximately 20 minutes to complete.

D. Endpoints

Participants will be removed from the study if they have an adverse reaction to the VR headset, such as nausea or dizziness, that taking breaks and making adjustments to the VR headset is not able to address.

1.4 Preliminary Data

Behavioral Interventions to Address Homework Problems in Adolescents with ADHD. Dr. Langberg published the findings from a large RCT comparing two behavioral interventions to address the homework problems of adolescents with ADHD to a waitlist control (Langberg et al., 2018). One of the interventions, the Homework, Organization, and Planning Skills (HOPS) intervention teaches time-management and organizational skills but like most existing ADHD interventions, does not address focus or efficiency of work completion. The other intervention, Completing Homework by Improving Efficiency and Focus (CHIEF), was specifically designed to improve concentration during homework and studying. In this intervention, a clinician defines on-task behavior and provides frequent and consistent monitoring and rewards using a point system for 20 minutes 2x per week for one academic semester while participants complete homework and study for tests. The intervention was administered individually in a quiet room to reduce distractions. Essentially, the counselor implementing CHIEF is doing what our team proposes to automate.

Adolescents with ADHD in the CHIEF intervention (*N*=111) demonstrated large (*d's* range from .9 to 1.10) effect size improvements on parent ratings of homework problems in comparison to the waitlist and significant improvements in the percentage of homework assignments turned-in (*M* increasing from 69% of assignments to 86% of assignments). This study demonstrates the remarkable potential of VR to significantly improve concentration and academic task completion in emerging adults with ADHD. The VR treatment would be much less time and resource intensive than having a counselor implement the behavioral principles and could individually optimize the delivery of contingency management and ensure a distraction free environment.

FlowLight to Reduce Worker Disruptions. Breaks in concentration lead to significantly reduced worker productivity and creativity. Research suggests that on average if a worker is interrupted at a time of peak performance, it takes up to 20 minutes for them to get back to operating peak performance. Corporations have been working to address this for years, largely through physical barriers such as closed doors or headphones. However, these strategies are not possible to implement in open floor office environments which are the predominant set-up in many office buildings (i.e., cubicles). Dr. Shepherd's team developed the FlowLight, that combines a traffic-light like LED with an automatic interruptibility measure based on computer interaction data. The team developed and implemented multiple computer algorithms to accomplish this. The base algorithm is called FlowTracker, which sums up the computer interaction in the past three minutes according to heuristic weights assigned to each type of event. While the FlowTracker is effective, it may be too sensitive to certain input. For instance, a twenty second burst of typing. Therefore, the team developed a Smoothing algorithm which evaluates whether users were active in each of the last three minutes and exceeded a threshold of 100 combined mouse clicks and key presses in the recent past (between 4 and 7 minutes ago). Finally, the team combined the FlowTracker algorithm with the Smoothing algorithm to achieve the advantages of both approaches. This algorithm is similar to the Smoothing method but instead of using a static threshold, it utilizes the FlowTracker algorithm to determine above threshold values.

In a large longitudinal study with 449 participants from 12 countries (Zuger et al., 2019), the team found that FlowLight reduced the interruptions of participants by 46%, increased their awareness on the potential disruptiveness of interruptions, and most participants never stopped using it. Further, 58.5% of participants reported being more productive and that FlowLight increased motivation to persist with tasks.

Virtual Reality Settings to Foster Flow. Dr. Shepherd and colleagues have also published on the impact of VR to foster worker productivity (Ruvimova et al., 2020). These studies included four different conditions, to specifically isolate the impact of a calming beach as a VR environment. Notably, the virtual beach environment was equivalent to a closed office environment in fostering attention and task completion. It is important to note that this version did not incorporate FlowLight, but simply tested the impact of the distraction free beach environment. Accordingly, the VR environment without FlowLight will also serve as one of the conditions in the proposed study, to identify what aspects of VR are most important for individuals with ADHD.

1.5 Sample Size Justification

PHASE 1: Refine objective data capture techniques. 30 participants completing 10 sessions will allow the team to implement and refine the keyboard and mouse click algorithms needed to ensure that we are tracking attention accurately. Since the goal is to refine the algorithms, no control group is needed.

PHASE 2: Develop and refine contingency management algorithms. 30 participants completing 10 sessions will allow for proper testing of the addition of the FlowLight icon (a stoplight) and box showing points earned within the VR environment. The goal is to understand how and when participants like to receive feedback about their on-task behavior and attention. A secondary goal is to understand how best to motivate participants to stay on-task and to complete work efficiently (e.g, a points system). 10 sessions with 30 participants are sufficient for this along with the focus group, and no control group is needed.

PHASE 3: Pilot test and evaluate impact on target mechanisms. 45 participants randomized to 1 of 3 groups will inform the feasibility and usability of the system tested and refined in phases 1 and 2. Though outcome measures will be collected, power analyses are not required due to the pilot status of the trial. The goal of phase 3 is to calculate effect sizes rather than to run statistical tests to begin to understand the magnitude of effects.

PHASE 4: Conduct a parallel group randomized trial. 252 participants randomized to 1 of 3 groups will allow for appropriate comparison across groups. Power calculations were run to determine this sample size. Power calculations are based upon N = 84 participants in each condition, for a total sample of 252 college students with ADHD. Dr. Langberg's prior intervention studies focused on improving attention produced effect sizes ranging from .6 to 1.12 comparing treatment to waitlist control. For the purposes of these power analyses, we use an effect size of .8 as the expected effect between the VR environment + contingency management group and passthrough control. This effect is also consistent with meta-analyses of behavioral contingency management interventions. Differences between active intervention conditions in our recent trial ranged between .4 to .6. Accordingly, between group effects (i.e., VR environment only to VR passthrough and to VR environment + contingency management) for the current study were estimated at d =.4.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The randomized trial will consist of 3 groups.

1) VR passthrough – participant wears headset but sees through to normal environment and laptop

2) VR environment only – participant wears headset and interacts with VR environment
3) VR environment + contingency management – participant wears headset and interacts with VR environment while receiving contingency management (real-time feedback on performance through FlowLight icon)

B. Dependent Variables or Outcome Measures

On-task behavior will be measured within the VR environment using keyboard and mouse clicks and FlowLight level.
Attention and concentration will be measured by participant survey report.
Homework motivation will be measured by participant survey report.
Homework effort will be measured by participant survey report.

1.7 Drugs/Devices/Biologics

A. Schedule and Administration

N/A

B. Drug/Device Accountability and Storage Methods

The virtual reality headset is not considered a device under evaluation for the purposes of this study. The FlowLight software, under investigation in the present study, is being used on a VR headset. Risks have been outlined in section 4.7 and the consents. Documentation on the use of the device has been included in the eIRB.

1.8 Specimen Collection

A. Primary Specimen Collection

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Processing**: N/A
- **Storage**: N/A
- **Disposition**: N/A

B. Secondary Specimen Collection

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Storage**: N/A
- **Disposition**: N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: Assessments (initial evaluation, outcome visit) and focus groups will be completed via HIPAA-compliant videoconference (e.g., Zoom) with the Rutgers study staff. Electronic questionnaires will be sent directly via secure web-based survey sites (e.g., REDCap). Intervention visits will be completed at participants' homes or the LSU/Rutgers library.
- **Process of Data Collection**: Diagnostic assessments and intervention sessions will be completed by graduate students enrolled in masters or doctoral psychology programs, post-baccalaureate research assistants who have received specialized training, or post-doctoral

fellows. The VR intervention will be supervised by Dr. Shepherd and the diagnostic assessments will be supervised by Dr. Langberg.

- **Timing and Frequency**: Phases will occur in chronological order, with one completing before the next begins. See sections 1.3 C and 1.10 for more information on timing.
  Procedures for Audio/Visual Recording: Audio of the focus groups in Phase 2 will be recorded. No other audio/visual data are being collected.
- **Study Instruments**:
  - PUBLISHED
    - SCID-V RV (First et al., 2015)
    - Service Utilization for College Students (Anastopoulos et al., 2018)
    - BAARS-Self (Barkley, 2011a)
    - ADHD Rating Scale – Parent (childhood; DuPaul et al., 2016)
    - Adult Concentration Index (ACI; Fredrick et al., 2021)
    - Homework Motivation Index (Martin, 2001)
    - Homework Effort Index (Trautwein et al., 2006)
    - RCADS (Ebesutani et al., 2010)
    - Columbia Suicide Severity Index (Posner et al., 2011)
    - BDEFS (Barkley et al., 2011b)
    - BAI-2 (Steer et al., 1997)
    - ADHD Impact Module-Adult (AIM-A; HealthAct, 2007)
    - Systems Usability Scale (Brooke, 1996)
    - GAD-7 (Spitzer et al., 2006)
    - PHQ-9 (Kroenke et al., 2001)
    - BFIS (Barkeley, 2011c)
  - UNPUBLISHED
    - Demographic and Background
    - Current Day Medication Adherence
    - Academic Record (GPA & Percent of Assignments Completed)
    - Reading Comprehension Standardized Assessment
    - Parent Contact Form
    - Subject Contact Form
    - Pre-screening questions
    - WHODAS (Required by NIMH/NDA)
    - DSM-5 Level 1 Cross-Cutting Symptom Measure (Required by NIMH/NDA)

- **Ethnographic Studies, Interviews, Or Observation**: N/A

- **Subject Identifiers**: The kinds of personal identifiers obtained include: names, dates, postal addresses, phone numbers, IP addresses, and email addresses. Person identifiers will be kept electronically in a password protected document on servers or computers that can only be accessed by the study staff. These identifiers will be retained indefinitely if the subject has given consent to be contacted for future research; if the subject does not consent to future contact, identifiers will be discarded when the current IRB protocol expires.

- De-identified data are stored on both the approved secure server (only available to staff) and stored in a password protected shared drive. The shared drive will only be accessible to study staff and approved investigators. All data located on the drive is password protected. For example, participant inclusion/exclusion evaluation reports require a password to open. Only the study coordinator and MPI (Langberg) who prepare the reports have access to the password. In addition, staffs' hard drives are encrypted using encryption software. Encryption

software provides a comprehensive Data Protection Platform to control, manage and protect laptops, desktops and self-encrypting drives.

- Precautions used to maintain the confidentiality of identifiable information: Standard practices are used to protect participant confidentiality and personal health information, including removing identifiers from all data collected, using only numbers to identify participant data, and keeping all data files when not in use in a locked filing cabinet behind a locked office. No names or other identifiers are used in computerized data files. REDCap, the survey tool that will be utilized for this project, has many security measures in place to prevent against inappropriate release of survey data and information. REDCap will be used to contact participants via email, collect survey responses, and record survey completion. To provide an additional layer of protection to participants, the collection of direct identifiers will be assessed separately from the general survey(s). The portable laptops that the research assistants use are only for transmitting data. The REDCap database is password protected. The laptops have no data stored on them, except the temporary file while the browser is open. All REDCap transmissions (to and from) are encrypted.

B. Secondary Data Collection

- **Type of Records**: N/A
- **Location**: N/A
- **Inclusion/Exclusion**: N/A
- **Data Abstraction Form(s)**: N/A

1.10 Timetable/Schedule of Events

	Sep	Oct	Nov	Jan	March	April	May	Summer Semester
Year 1 R61	Project 1 Recruitment (N=30) Inclusion/exclusion evaluations			Project 1 Intervention Sessions Project 2 Recruitment (N=30) Inclusion/exclusion evaluations				Analysis and refinement of algorithms and VR protocol
Year 2 R61	Project 2 Intervention Sessions Project 3 Recruitment (N=45)			Project 3 Intervention Sessions				Analysis and refinement and evaluation of Go/No-Go
Year 3 R33	RCT Cohort 1 Recruitment (N = 63)			Cohort 1 VR Intervention RCT Cohort 2 Recruitment (N=63)				Analysis and dissemination
Year 4 R33	Cohort 2 Intervention RCT Cohort 3 Recruitment (N = 63)			Cohort 3 Intervention Sessions RCT Cohort 4 Recruitment (N=63)				Analysis and dissemination
Year 5 R33	Cohort 4 Intervention Sessions			Analysis and publication				
Note: Total sample = 252; 4 cohorts of 63 participants each; intervention period for each cohort allows for 1 month of cushion for missed and make-up sessions. **December** is not shown as no activities occur over winter break although the study team can recruit and provide intervention for the first 1.5 weeks in December.								

2.0 Project Management

2.1 Research Staff and Qualifications

PI:

Joshua Langberg, PhD, MPI: Dr. Langberg is a Professor of Clinical Psychology and Director of the Center for Youth Social Emotional Wellness (CYSEW) at GSAPP at Rutgers University. He has experience developing novel psychosocial treatments for adolescents and emerging adults with ADHD. He is a licensed clinical psychologist.

Co-investigator:

David Shepherd, PhD, MPI: Dr. Shepherd is an Associate Professor of Computer Science at Louisiana State University (LSU). He developed the algorithm that measures worker productivity which will be used in the VR environment in the current study.

Primary Staff Contact – Study Coordinator

- Sophia Frontale: Sophia has a MPS in Clinical Psychological Science from the University of Maryland College Park, and a BA in Psychology from George Washington University. She has over 3 years of experience in applied social science research.

Study Staff

- Dr. Elizabeth Chan, PhD: Elizabeth is a postdoctoral fellow at the Center for Youth Social Emotional Wellness (CYSEW) at GSAPP.
- Dr. Sydney Baker is a postdoctoral fellow at the Center for Youth Social Emotional Wellness (CYSEW) at GSAPP.
- Nicole Hale: Nicole is a GSAPP Clinical PsyD graduate student, working under the supervision of Dr. Langberg (PI and psychologist) as a student clinician completing participant interviews.

Research Staff Training

The principal investigator is an experienced researcher and clinician of the population this study is examining, and the co-investigator has specific expertise in the application of the technology being utilized. They will provide adequate training and support to the study coordinator and other study team members through their duties.

2.3 Other Resources

In the event that a subject finds the assessments and/or intervention mildly anxiety provoking, research staff members will express empathy and appropriate encouragement and reassurance. Risk of emotional distress will be minimized through effective rapport building and interactions with the subjects. A small percentage of subjects might initially feel disoriented or dizzy in the VR environment. Most subjects adjust quickly after taking a break or working in small chunks of time. Should discomfort become sufficient to pose distress for the subject, the research staff member will discuss these reactions to determine whether the subject wishes to continue completing the research procedures.

*Some of the questionnaires and interviews have items that ask about suicidality, and it is possible that subjects will endorse items pertaining to threat to self. These questionnaires are reviewed at their baseline assessment visit. If any items that endorsed suicidality or threat to self were checked by subjects, then the study staff will consult with the PI (Langberg, who is a licensed clinical psychologist) to complete a risk assessment to determine appropriate actions based on level of risk (e.g., presence of a plan, desire to act on the plan, and access to means to carry out the plan). (see 4.7E for protocol for steps following risk assessment).

2.4 Research Sites

Dr. Langberg's office and space for all study staff is at:
Center for Youth Social Emotional Wellness (CYSEW) at Rutgers University
797 Hoes Lane W
Piscataway, NJ 08854

Dr. Shepherd's lab is in the Engineering building at LSU
2228 Patrick Taylor Hall
Baton Rouge, LA 70803

3.0 Multi-Center Research

The study is a Single IRB with Rutgers University acting as the IRB of record. The following documentation has been completed by Louisiana State University:

- HRP 1812a – Local Clinical Site Information

- HRP 830 – Communication and Responsibilities
- HRP 811 – Basic Site Information
- HRP 890 – Single Study Authorization Agreement

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Recruitment will be performed at Rutgers and Louisiana State University. The study staff will work with university organizations that have access to the student body in various ways (e.g., listservs, counseling services).

B. Recruitment Details

Recruitment information will be disseminated by organizations which support students with ADHD including university counseling services, disability services, and student health services. This will be done flyers posted in physical spaces on campus and electronic spaces such as the counseling services website. Recruitment information will also be distributed more broadly to students via email to reach students who are not already diagnosed with ADHD and physical flyers in general campus spaces.

C. Subject Screening

Interested students will be directed to a secure website platform and are provided information about the study. If they proceed and sign informed consent, they will complete a measure assessing current DSM ADHD symptoms (BAARS) and prescreening questions about medical history related to use of the VR system. If they endorse at least 5 ADHD symptoms of inattention, they will move forward. If they indicate sensitivity to flashing lights, neurological/vestibular issues, or an implanted medical device, they will not move forward. These questions ensures that students with below threshold ADHD symptoms do not complete all the study measures. If students meet criteria on the ADHD symptom screen and prescreening questions, they proceed to complete the remaining study measures. The last page of the online survey provides participants slots to sign-up for a time to be administered the diagnostic interview virtually. If they do not meet criteria on the BAARS, they will be forwarded to a page informing them that they are not eligible for the study. If the participant completes the surveys and interview and are found not eligible, they will be informed via email.

- **Inclusion Criteria**
  - Is assessed to have 5 or more symptoms of inattention on the BAARS.
  - Is assessed to have 6 or more symptoms of inattention on the BAARS childhood.
  - Meets DSM-5 criteria for ADHD
    - participant endorses at least 6 symptoms in the ADHD inattention domain as present and impairing during participant's childhood
    - participant endorses a total of at least 5 symptoms in the ADHD inattention domain as currently present and impairing
    - anxiety and depression is also evaluated to determine if ADHD is primary and whether comorbid conditions are present.
  - Is between the ages of 18 and 25
  - Is enrolled full-time as a student at LSU or Rutgers.
  - Is assessed to have more than 3 symptoms labeled often or very often on the Adult Concentration Index (ACI)
- **Exclusion Criteria**

- Diagnosis of autism spectrum disorders, bipolar disorder, obsessive-compulsive disorder, active substance abuse, or other psychiatric conditions
- History of seizures or clinically significant migraines
- Has an implanted medical device
- Neurological or vestibular issues which affect balance or gait

D. Privacy Protections

All electronic assessment data, initial assessment for eligibility, are hosted on university-approved secure servers (e.g., REDCap); access to the completed forms is only available to study team members via their private Rutgers log-ins.

4.2 Obtaining Identifiable Information About Non-Subjects

Identifiable data will not be collected about Non-Subjects. However, participants will be given the option to provide the contact information of a parent/caregiver or other reporter (e.g., teacher) so the reporter can be sent an electronic survey on the participant's ADHD symptoms. This procedure is outlined in section 4.4 B below. Participants will still be able to continue participation if they do not want the research team to contact a parent/other reporter.

4.3 Number of Subjects

A. Total Number of Subjects

We anticipate consenting and completing the eligibility/baseline assessment for more individuals than the number that complete the study. This is because a portion will not meet diagnostic criteria for ADHD, as outlined in section 4.1 C. The following numbers reflect the number of subjects who complete the consent and are therefore considered subjects.
Phase 1: 60 subjects (maximum 30 complete the phase)
Phase 2: 60 subjects (maximum 30 complete the phase)
Phase 3: 90 subjects (maximum 45 complete the phase)
Phase 4: 400 subjects (maximum 252 complete the phase)

B. Total Number of Subjects If Multicenter Study

Though the study is multicenter, all participants will complete consent with the main site: Rutgers University. Rutgers will receive all data from LSU and will be the sole host of PHI.

C. Feasibility

All participants who complete the inclusion/exclusion evaluation process will receive a report summarizing diagnoses met according to DSM-5 criteria. This provides a major service to participants as this type of report is required for accommodations but the university does not offer diagnostic assessments. As such, students are motivated to participate not only for the chance to receive innovative treatment to support homework and studying, but also because obtaining such a report in the community costs hundreds to thousands of dollars. Accordingly, given that Rutgers and LSU are large public universities both with over 26,000 students, it is feasible to recruit the sample over the study period. In our pilot work, we required students to come to a lab setting to use the VR headset which posed a feasibility challenge for students. In this study, we are allowing students to use the VR headset in their homes or in a public library to increase feasibility and also increase ecological validity of the outcome data collected.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**

Initial consent will take place online without direct contact with the study staff, though the consent includes information to contact the study team should they have questions about the consent.

- **Ongoing Consent**

Participants will be encouraged to keep a copy of their consent form, which will include contact information for the lab in case they have any questions or would like to reconsider participating in the study at any time during the data collection period.

Upon initial direct contact with the study team (i.e., during the virtual administration of the SCID interview), participants will be reminded of the details of the consent and asked if they have questions. The study staff will answer all questions before moving forward with the study procedures.

- **Individual Roles for Researchers Involved in Consent**

Members of the study staff conduct informed consent.

- **Consent Discussion Duration**

There is no set amount of time allocated for consent discussion. The study team acknowledges that all potential subjects may require different amounts of time to process and ask questions about the information being provided.

- **Coercion or Undue Influence**

To protect against coercion or undue influence, the following points are written in the consent/assent documents:

1. Emphasis participation in the study is strictly voluntary and that the participant can choose to withdraw their participation from the study at any time.
2. It will further be emphasized that any decision to withdraw will not affect the adult's ability to make use of clinical services at Rutgers or LSU and will not impact any current or future relations with Rutgers or LSU.
3. Description of study procedures and treatments will be provided, and questions from the adults will be encouraged.
4. The participants will be made aware that the alternative to participating in the study is to not participate.

- **Subject Understanding**

  Study staff will be trained to review all aspects of the consent form with the participant and to obtain verbal indication from participant that they understand the material. As part of the procedure, study staff will verbally ask questions confirming comprehension of consent at the initial direct contact with the participant (i.e., at the evaluation interview). See document [Consent comprehension.docx]. Participants will be asked to verbally respond, and anything the participant does not understand will be explained.

- **Protecting Privacy**

  During the virtual assessments, participants will be reminded to ensure they are in a private space and given the suggestion to use headphones so that anyone nearby cannot overhear the study team member.

B. Waiver or <u>Alteration</u> of Consent <u>Process</u>

- **Waiver or <u>Alteration</u> Details**

  N/A
- **Destruction of Identifiers**

  N/A
- **Use of Deception/Concealment**

  N/A

a. **Minimal Risk Justification**
N/A
b. **Alternatives**
N/A
c. **Subject Debriefing**
N/A

C. **Documentation of Consent**
- **Documenting Consent**
Each phase (1-4) has a unique consent form. Participants will complete the electronic consent form in the REDCap system. REDCap functionality allows for participants to sign as they would a physical signature, and this will be enabled. The consent forms include wording that encourages the participant to download a copy for their records. A PDF copy of the consent form will be available to the participant upon request.
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
N/A

4.5 Special Consent Populations

A. **Enrolling Minors-Subjects Who Are Not Yet Adults**
- **Parental Permission**
N/A
- **Non-Parental Permission**
N/A
- **Assent Process**
N/A
- **Documentation of Assent**
N/A
- **Reaching Age of Majority During Study**
N/A

B. **Enrolling Wards of the State**
N/A
- **Research Outside of NJ Involving Minors**
N/A

C. **Enrolling Non-English-Speaking Subjects**
N/A
- **Process for Non-English-Speaking Subjects**
N/A
- **Short Form Consent for Non-English Speakers**
N/A

D. **Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)**
N/A
- **Assessing Adult Capacity to Consent**
N/A
- **Selecting a Surrogate & Consent Process**
N/A
- **Subject Assent**
N/A
- **Selecting a Witness to the Surrogate Consent Process**

N/A

- **Removing a Subject**
  N/A

E. Special Consent Considerations
N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
Subjects will not be charged for their participation in this study, including the assessment and treatment sessions.

B. Compensation/Incentives
PHASE 1.

- Subjects will be paid $40 for completion of all the baseline inclusion/exclusion measures and the SCID interview.
- Participants will be paid $110 for completion of the intervention and all of the post-intervention measures. This is appropriate given that participants are devoting 1 hour of time 10 times over two weeks (max twice a day with a minimum 2-hour break) and 45 minutes for the outcomes questionnaires and follow-up phone interview.

PHASE 2.

- Subjects will be paid $40 for completion of all the baseline inclusion/exclusion measures and the SCID interview.
- Participants will be paid $110 for completion of the intervention and all of the post-intervention measures. This is appropriate given that participants are devoting 1 hour of time 10 times over two weeks (max twice a day with a minimum 2-hour break).. They will receive an additional $25 gift card for participation in the focus group.

PHASE 3 and PHASE 4.

- Subjects will be paid $40 for completion of all the baseline inclusion/exclusion measures and the SCID interview.
- Participants will be paid $110 for completion of the intervention and all of the post-intervention measures in two parts: $60 after completing 7 sessions within 2 weeks, and an additional $50 after they complete all 12 sessions within 3 weeks. Payment will happen at the end of the study participation period of 3 weeks as a single e-gift card. This is appropriate given that participants are devoting 1 hour of time 12 times over three weeks (max twice a day with a minimum 2-hour break).
- Participants in the VR + feedback group will be paid up to $130 if they maintain at least a 25% increase in focus over their baseline sessions 1 & 2 for a $10 bonus. They can receive this bonus at the end of 7 sessions based on performance up to that point, and then again at the end of 12 sessions for a total reward compensation of $20.
- They will receive an additional $25 gift card for completion of follow-up measures 3 months post the final treatment session.

C. Compensation Documentation
E-gift cards will be sent electronically (i.e., a code will be emailed to participants, no emails will be given directly to the company [e.g. Amazon]). A record of codes sent to subjects will be kept.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  - We have designed this study in a way to minimize and avoid risks. We do not anticipate any serious risks to be associated with participation. Consent will be an ongoing process in the study and participants will be reminded that they are able to stop a session or withdraw from the study if they change their mind about participating or are experiencing discomfort related to the study device. Possible risks are outlined below, in addition to how we plan to minimize such risks.
  - Risk 1: Minimal distress related to assessments: The assessment portions of the study are expected to pose minimal risk, but participants could become upset while discussing symptoms of emotional and behavioral problems. **Plans**: The assessments are not expected to be any more upsetting than any standard clinical interview used in a usual counseling settings. Further, standard questionnaires and interviews have been chosen that are developmentally appropriate and low risk. In addition, all participants will be reminded that participation is voluntary and that any participant is free to withdraw at any time without penalty.
  - Risk 2. Medical distress associated with virtual reality device: According to the device manufacturer, people should not use the device if they are under the influence of alcohol or drugs or have a migraine or headache. Some people (about 1 in 4000) may have severe dizziness, seizures, eye or muscle twitching or blackouts triggered by light flashes or patterns, and this may occur while they are watching TV, playing video games or experiencing virtual reality. **Plans:** Participants with a history of seizures, migraines, and serious medical issues will be pre-screened utilizing the pre-existing condition screening tool and are not eligible to participate. During the active consent/check-in process before each session, study staff will ask participants about their health and well-being and proceed with rescheduling if any of the aforementioned ailments are disclosed. Study staff will disinfect and inspect headsets before each usage. At the beginning of each VR session, study staff instruct participants to raise their hand or to take off the headset if they feel discomfort.
  - Risk 3. Mild and temporary distress associated with virtual reality device: The virtual reality device creates a mixed or virtual reality which limits the participant's ability to see their actual surroundings. This headset can feel heavy and may cause discomfort if not adjusted. Some people using virtual reality report dizziness. **Plans:** The study team will work to make sure the area in which the participants are conducting their sessions is clear of any hazards, and they will make sure to supervise each session by remaining in close proximity to observe. Study staff will take the time to adjust/fit the headset with each participant before each session. If participants still feel discomfort after adjustment and readjustment, the session will be suspended, and staff will discuss the participant's ability to withdraw participation if they would like. The virtual reality sessions will last for one hour, which is brief usage. The study is creating a calm, virtual reality homework setting. Excessive or forceful movements will not be required during the study sessions. However, if a participant reports discomfort, adjustments will be made immediately and a discussion about voluntary participation. At any sign of physical/medical distress the staff will stop the simulation, make sure the participant is secure and call emergency medical services.
  - Risk 4. Exposure to loud sounds: Hearing loss due to exposure to loud sounds is considered a risk of virtual reality equipment. **Plans:** The study environment is designed

to improve focus and will not include loud sounds. The volume of the headset will be adjusted based on participant comfort.

- Risk 5. Privacy. Study participation may also be learned by others because up to 3 participants will complete a session simultaneously. Parallel participation in such a way is an essential part of this intervention due to the large sample size and goal of examining the feasibility of large-scale use. **Plans**: To address this, study staff will set up participants individually, and participants will sit in privacy booths with vision to other participants blocked while sitting in the booth.
- Risk 6. Breach of confidentiality. Breach of confidentiality due to inadvertent release of personal information is also possible. The steps detailed in **Section 6.2 Data Security** will be taken to minimize these risks. Risk of breach of confidentiality will be minimized through de-identification of subject responses and separate storage of identifiers and research data.

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  - As this is a research study focusing specifically on the ADHD population, all subjects participating in the intervention will meet diagnostic criteria for ADHD. Some may also have co-occurring mental health conditions (e.g., depression, anxiety), though this is not an explicit part of the recruitment criteria. All staff engaging with the subjects are trained in working with adults with ADHD, including those with co-occurring mental health conditions. Because participation in this study is considered minimal risk, there are no additional risks in this study that would increase by having ADHD.
- **Other Foreseeable Risks of Harm**
  See above for a detailed description of risks of harm.
- **Observation and Sensitive Information**
  See above for a detailed description of risks of harm.

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
See above for a detailed description of risks of harm and study team response.

As questions probing relevant topics are included in the assessment procedure, participant may divulge suicidal ideation or other concerns for self-harm. These outcomes are likely to be infrequent since participants are not specifically recruited for having a clinical diagnosis of a depression or suicide risk. However, if elevated distress or suicidal thoughts or behaviors are reported, the maser's level or higher student clinician will conduct a risk assessment following these procedures:

- If suicidal thoughts or behaviors are reported during an assessment visit, the study staff member will conduct a risk assessment before the visit ends.
  - The assessment focuses on determining if the participant, 1) is at imminent risk and needs emergent mental health evaluation, 2) requires further evaluation but is not at imminent risk, or 3) is deemed low risk, and receives resources and possible mental health referral for the future. The interview always begins with the assessor genuinely praising and thanking the participant for being open and honest about their thoughts. Questions are asked such as, has the participant made prior suicidal attempts. If so, was the attempt more than a year ago? Has the participant received or is currently in mental health care? Participants are also interviewed about whether they have thought about how they might commit

suicide and when these types of thoughts or planning last occurred. For participants who have had thoughts about actions/planning within the last month, a safety plan is initiated as part of the assessment process. In addition, those participants files are flagged for a safety check within 72 hours of the assessment. Additional questions are asked to understand the nature of the plan, including the level of detail and feasibility of the plan

- The study staff member will contact a designated on-call licensed psychologist, for example Dr. Langberg. If possible, the psychologist will immediately join the assessment and ask additional follow-up questions. This will happen in most cases. If this is not possible, a meeting between a licensed clinical psychologist and the participant will always occur within 24 hours.

- If suicidal thoughts or behaviors are reported during the intervention, study staff will acknowledge as appropriate, and conduct a risk assessment before the visit ends. The risk assessment will be conducted in a private space to protect the participant's privacy.

In any of the above cases, the study staff will do a risk assessment and consult with Dr. Langberg with one of the following outcomes:

1. If participants are at low or no risk, we will remind participants of the resources available to them (i.e., provide a sheet of psychological references commonly used in research and clinical practice)
2. If it appears that participants are at moderately high, but not imminent risk for suicide, we will refer them to the appropriate places (e.g., going to the counseling center, filing a concern report with the university). The psychologist consults with the psychiatrists at Student Health and counselors at University Counseling Services via telephone to determine what action should be taken and to connect them to services that day.
3. If participants are at imminent risk for suicide, we will do the following, depending on their location:
    a. Call the Rutgers or LSU counseling center, the counseling center's emergency number (if outside of business hours), or Rutgers or LSU PD. This is a highly unlikely scenario, but in the case that we do need to take these actions, we will obtain on the consent form participants' permission to release information to these parties.
    b. If this is enacted, study staff will remain on videoconference or in the room with the participant to explain until they have direct crisis support. The participant will be made aware of who is being called and what is expected to happen next (e.g., if someone is being sent to the home).

These procedures are in line with what is used in clinical practice and psychological research. It is extremely rare and the steps outlined are unlikely to be needed, but the procedure is in place to keep all participants safe.

Additionally, on-going monitoring will ensure there is not significant deterioration from baseline in any subject's psychopathology (e.g., depressive symptoms). An increase of 25% or greater on measures of internalizing symptoms triggers a conference and review of records. In addition, participants who are in the top 10% of the sample at baseline are automatically reviewed at each timepoint. Further, any participant who endorses any of the items related to suicidal thinking is automatically reviewed at each timepoint to ensure there have been no increases (e.g., from sometimes to often).

E. Minimizing Risks of Harm

See above for a detailed description of risks of harm and study team response.

- **Certificate of Confidentiality**
  N/A
- **Provisions to Protect the Privacy Interests of Subjects**
  The study will use HIPAA-compliant videoconference software to protect subjects' privacy interests. As will also work with subjects to identify private spaces and optimal times to complete all telehealth visits. While participating at a physical study site, subjects intervention sessions will take place in a private space.

F. Potential Direct Benefits to Subjects

The study has potential direct benefits to the subjects.

Benefits to the participants in this study include anticipated improvements in efficiency and effectiveness of homework and studying which could lead to improved overall academic performance and increased academic motivation. Importantly, even though in the two RCTs 1/3rd of students are randomized to passthrough VR control, they are still being provided the a quiet space to study and added structure of having a dedicated time to complete work and study each day. As such, it is likely that even participants assigned to control will experience some academic benefit.

Participants may also benefit from greater self-knowledge after considering the items on the questionnaires. They may also learn more about the conditions under which they study most effectively (e.g., structure and routine) regardless of VR intervention efficacy. In addition to their own eligibility evaluation summary report, participants will be offered a copy of the final research report that emerges from the study. At any time during the project, participants may contact the PI or other project staff to gather additional study information.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

N/A

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. Special Populations

- Students: The study is recruiting students at Rutgers University and Louisiana State University. The study staff will take every measure to minimize risk of coercion or undue influence by reminding subjects that they can change their mind at any time in the future regarding their enrollment in the study without any penalty to their status as a Rutgers or LSU student, and that their grades, student status, or the care they receive from a Rutgers or LSU program (e.g., Disability Services), and that their decision will not be communicated to anyone outside of the research staff.

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

Preliminary data analyses will include patterns of missing data, dropout rates, distributional properties of measures, and correlations among assessment measures. Continuous variables showing significant skewness or kurtosis will be transformed.

Phase 1: In addition, to calculating effect sizes, the ACI concentration items will be scored and examined for trends across VR sessions in relation to objective typing and mouse click algorithm and to questionnaires asking about homework effort and efficiency. The convergent validity threshold will be >.50 for associations between VR objective on-task assessment and self-report of concentration. This threshold is being used rather than >.70 given the multi-method nature of the comparison (i.e., objective to self-report). In addition, we will refine the algorithm by comparing scores to other objective metrics such as time spent on nonwork related websites and social media during each session. Dr. Shepherd accomplished this in pilot work using a combination of Google Chrome Plugins and a service such as Cyren which codes and categorizes websites accessed. To address the feasibility/usability aspect of the aim, participants will complete the Systems Usability Scale (Brown, 1996) and spend 10 minutes after each session with research staff providing feedback on ways to improve feasibility/usability of using the VR environment to complete homework and study for tests. The team will also explore whether adding in eye gaze tracking improves the accuracy of the algorithms.

Phase 2: This project incorporates the contingency management procedures. Trends in motivation across sessions will be evaluated in relation to objective and rating scale metrics of attention and to FlowLight data. Focus groups will be audio-recorded and transcribed verbatim. The focus group data will be analyzed inductively for information relevant to feasibility and acceptability of the protocol. Two study personnel will separately code notes taken during the focus groups for emerging concepts and themes. Initial analysis will consist of identifying concepts found within the data through open coding. Inter-rater reliability checks will be used to compare the themes generated. Coding will continue until the point of saturation, that is, when no new concepts emerge. Data will be systematically analyzed according to the principles of thematic analysis, a method commonly used in qualitative research of this nature.

Phase 3. Because these analyses will focus on evaluating preliminary intervention effect sizes, outcome analyses will be conducted separately for each target mechanism. To compare groups, the variable (e.g., objective attention) will be entered analysis of variance (ANOVA), which will yield effect sizes for time and for interactions of time by intervention. The primary dependent variables will be objective assessment of attention and ratings of concentration, as well as ratings of homework effort and homework motivation. We will also compare trajectories of objective attention data across the three conditions.

Phase 4. The mixed model methodology planned and incorporated by the SAS GLIMMIX procedure can accommodate missing response data, thus allowing us to make use of all available data; note that covariate measurements are taken at baseline and should not be missing. Using Bayes' estimation, individuals with more data are given more weight in the calculation. This procedure is preferable in comparison to listwise or pairwise deletion in analyses where portions of the developmental curve are represented by differing individuals. In addition, we will check to see whether missing observations are missing at random, where we will test whether treatment group or any other covariate has an effect on the missing information. Any covariate associated with missing data will be included in the final model. Mediational models

analyzed using MPlus will address missing data using full information maximum likelihood estimates. This approach makes full use of available data and is one of several procedures considered the state of the art for addressing missing data.

Intent to Treat Analysis: An intent-to-treat approach will be used to analyze the data, wherein each participant will be kept in the group to which they were randomized for analysis, regardless of treatment compliance. A mixed-effects model will be used to account for the repeated-measure nature of the study design. Time will be treated as a dummy-coded categorical variable using baseline as the reference. A student-level random effect will be included and modeled using an auto-regressive covariance structure to account for within-subject dependence due to repeated measurements. The models will also include treatment condition as a student-level fixed effect, and condition x time interaction effects. This modeling will allow us to compare baseline to 8-week (post) changes, and the extent to which these changes differ across conditions.

Mediator Analyses: Mediational analyses will be conducted using structural equation modeling. There are advantages of a structural equation modeling approach to estimating and determining the significance of indirect effects within meditational models and outlined specific estimation procedures that are available in MPlus. All analyses will be conducted in MPlus which provides estimates that partition the total effect of an independent variable on a dependent variable into the direct and indirect effects using bootstrap estimation procedures. Preliminary analyses will be conducted separately for each mediator. scores on the mediator will be modeled as a function of pretest scores on the mediator, intervention condition, and covariates. The intervention's effect can then be partitioned into the direct effect on changes (e.g., on school grades) at posttest and follow-ups and the indirect effects via the mediator. These initial analyses will be used to guide a more comprehensive model that will incorporate mediators that emerge as significant within the individual models. Primary mediation analyses will focus on whether change in the proposed mechanisms of action mediates improvement in AIM total scores and BDEFS.

Moderator Analyses: Moderators will be examined in separate models incorporating each potential moderator variable into the previously described mixed effects models. Specifically, we will grand-mean center baseline scores on each moderator and incorporate both the main effect and Moderator x Group interaction term into each equation in the Level 2 model. For continuous measures, a significant interaction will imply moderation, with the size of the estimated coefficient reflecting the moderated change in treatment effect. Significant interaction effects can be followed up by testing the significance of the intervention effect across various levels of the moderator (e.g., 25th, 50th, and 75th percentile). For discrete measures, a significant interaction will again imply moderation, where we can directly compare the treatment effects between different levels of the potential moderator to gauge that moderator's effect.

6.2 Data Security

Data collection and entry will be done using REDCap (Research Electronic Data Capture). REDCap is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as

branching logic and calculated fields. REDCap is approved by Rutgers as an electronic data capture (EDC) tool to collect and manage sensitive data. Per Rutgers regulations, only faculty, staff and sponsored students and affiliates may be granted access to REDCap Database. Application level security includes project level user permissions, event logging, and de-identification capabilities which facilitate the export and exchange of data in a coded manner. All REDCap data are stored on university database servers, which are backed-up and maintained following best practices. REDCap will be managing the system that supports this project, the study staff will be responsible for identifiable data collection, management, user rights, determining who has access and all logistics related to data collection and reporting.

There are safeguards in place to prevent accidental or inappropriate release of information. All staff are CITI and REDCap trained and supervised on how to handle confidential data. All identifiable information will only be saved on an approved secure server (the server is HIPAA compliant for security set up, the shared folder will only be browseable and accessible by the authorized person, each authorized person has their own account to log on server through Web VPN then work on the shared folder). The key will be password protected. Only the PIs and main study coordinator will know the password.

De-identified data are stored on both the approved secure server (only available to staff) and stored in a password protected shared drive (e.g., Rutgers-hosted Microsoft OneDrive). The shared drive will only be accessible to study staff and approved investigators. All data located on the drive is password protected. For example, participant inclusion/exclusion evaluation reports require a password to open. Only the study coordinator and MPI (Langberg) who prepare the reports have access to the password. In addition, staffs' hard drives are encrypted using encryption software. Encryption software provides a comprehensive Data Protection Platform to control, manage and protect laptops, desktops and self-encrypting drives.

Precautions used to maintain the confidentiality of identifiable information: Standard practices are used to protect participant confidentiality and personal health information, including removing identifiers from all data collected, using only numbers to identify participant data, and keeping all data files when not in use in a locked filing cabinet behind a locked office. No names or other identifiers are used in computerized data files. REDCap, the survey tool that will be utilized for this project, has many security measures in place to prevent against inappropriate release of survey data and information. REDCap will be used to contact participants via email, collect survey responses, and record survey completion. To provide an additional layer of protection to participants, the collection of direct identifiers will be assessed separately from the general survey(s). The portable laptops that the research assistants use are only for transmitting data. The REDCap database is password protected. The laptops have no data stored on them, except the temporary file while the browser is open. All REDCap and OneDrive transmissions (to and from) are encrypted.

Per Rutgers IRB policy, data will be stored on the systems identified above for 6 years.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan
N/A

B. Data/Safety Monitoring Board Details
N/A

6.4 Reporting Results

A. Individual Subjects' Results
N/A

Aggregate Results
N/A

B. Professional Reporting
Study results will be shared by submitting manuscripts to scientific, peer-reviewed journals and through presentations at professional conferences. This data may also be used as preliminary evidence for future grant proposals.

C. Clinical Trials Registration, Results Reporting and Consent Posting
Phases 3 and 4 are clinical trials. They will be registered at clinicaltrials.gov and all relevant information reported and available.
The study PI will be responsible for ensuring compliance with ClinicalTrials.gov requirements for this project. The PI or his designee will register the trial prior to enrolling the first participant. Once a record is established, the PI will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. The PI will also be responsible for aggregate results reporting and Adverse Event reporting at the conclusion of the project.

6.5 Secondary Use of the Data
This project will include prospective longitudinal data from emerging adults with ADHD that includes data related to mental health and academic functioning. Given the large sample size, de-identified data could be used for many secondary analyses. Individual subject-level data and item-level data will be shared. Prior to sharing, all data will be de-identified so that it is HIPAA-compliant. Data sets will be carefully reviewed to make sure that information such as age and sex cannot be used to gather additional information that could potentially identify individual participants.

7.0 Research Repositories – Specimens and/or Data

Per NIH protocol, The NIMH Data Archive (NDA) will serve as the primary data repository for the study. Per NDA guidelines, we will obtain informed consent and assent from participants. NDA language will be included in the consent/assent forms to ensure that participants are aware that data will be entered in a de-identified form into a public registry. We will collect the necessary identifying information to create a Global Unique IDentifier (GUID). Should individuals or organizations request the dataset directly from the investigators, those requests will be directed to the NDA to retrieve the data.

As recommended by the NDA, raw/descriptive data not related to the primary aims of the study will be submitted in cumulative packages every six months and shared after a four-month quality assurance period. Analyzed/experimental data related to the primary aims of the study will be submitted when a publication on the data is accepted, or the project period ends, and shared when published or one year after the project period ends, whichever comes first in both cases. In addition, consistent with NIH recommendations, we will create an NDA Study for each publication resulting from data collected and analyzed as part of the proposed study and will share the Study at the time of publication.

8.0 Approvals/Authorizations

The study is a Single IRB with Rutgers University acting as the IRB of record. A SMART IRB has been initiated. The following documentation has been completed by Louisiana State University and is included in the eIRB:

- HRP 1812a - Local Clinical Site Information
- HRP 830 - Communication and Responsibilities
- HRP 811 - Basic Site Information
- HRP 890 - Single Study Authorization Agreement

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