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Graduate School of Applied and Professional Psychology

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

NCT06454604

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Development of a Novel Virtual Reality Treatment for Emerging Adults with ADHD
Principal Investigator: Joshua Langberg, PhD

STUDY SUMMARY: This online consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to evaluate the feasibility, acceptability, and effectiveness of a virtual reality-based treatment for symptoms of ADHD. If you take part in the research, you will receive 1 of 3 types of intervention, described in this consent form. You will be asked to complete questionnaires, reading comprehension passages, interviews, 2 baseline sessions, and 10 intervention sessions. Your time in the study includes completing the eligibility assessment (1-1.5 hours using VR to complete homework and study 12 times over three weeks (up to twice a day with a minimum 2-hour break) for 1 hour at a time, a post-intervention assessment (30 minutes), and a follow-up assessment 3 months after completing the intervention (20 minutes).

Possible harms or burdens of taking part in the study may be frustration or psychological distress when completing questionnaires or interviews and discomfort while wearing a virtual reality headset. Other risks include a loss of confidentiality following a breach in data security or as a result of the study team learning that you are at high risk of harming yourself or others. Should this occur, we will be legally obligated to inform emergency services.

Possible benefits of taking part may include improvements in efficiency and effectiveness of homework and studying and increased motivation for completing your schoolwork. You will also receive a summary evaluation report of your initial diagnostic evaluation.

Is there an alternative to taking part in the research study? Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

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Who is conducting this study?
Dr. Langberg is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Langberg may be reached at jl3079@gsapp.rutgers.edu. Dr. Langberg's office is at 797 Hoes Lane, Piscataway NJ.

Dr. Shepherd is also an investigator on this study. He can be reached at dshepherd@lsu.edu. Dr. Shepherd's office at LSU is 3272W Patrick F Taylor Building, Baton Rouge, LA.

Sponsor of the Study: The National Institute of Health is sponsoring this study.

Why is this study being done?
The purpose of this study is to evaluate the feasibility, acceptability, and effectiveness of a virtual reality-based treatment for symptoms of ADHD.

Who may take part in this study and who may not?
Louisiana State University and Rutgers University students who are 18-25 years old may take part in this study. They must meet criteria for Attention Deficit/Hyperactivity Disorder and have difficulty concentrating when completing work and/or studying. Participants do *not* need a prior diagnosis of ADD or ADHD to participate because this will be determined as part of the study assessment. People who have been diagnosed with Autism Spectrum Disorder (ASD), Bipolar Disorder, Obsessive-Compulsive Disorder (OCD), or schizophrenia will not be able to participate. People who actively abuse substances such as alcohol or other drugs will not be able to participate. This will also be assessed at the beginning of participation. People with a history of seizures or migraines will also not be able to participate.

Why have I been asked to take part in this study?
You have been invited to participate in this study because you expressed interest opening this consent form, have or suspect you might meet criteria for ADD/ADHD, and feel like you might benefit from completing work and studying in an environment that reduces audio and visual distractions and provides structure.

How long will the study take and how many subjects will take part?
Up to 610 people will participate in the overall study and up to 400 people will participate in this part of the study. Each individual's participation in this part includes completing the eligibility assessment (1-1.5 hours), completing 12 1-hour homework and study sessions over three weeks (up to twice a day with a minimum 2-hour break) (2 baseline sessions without VR and 10 in VR, for 12 total), completing a post-intervention assessment (30 minutes), and a follow-up assessment 3 months after completing the intervention (20 minutes). In total, each participant will be involved in the study for approximately 18 weeks.

What will I be asked to do if I take part in this study?

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If you choose to participate in the study, the following is what will happen:

- **Eligibility questionnaires and assessment visit**
  - After completing this consent form, you will be asked to complete a questionnaire on your thoughts, feelings, and experiences.
  - If your answers meet certain initial criteria, you will be forwarded to additional questionnaires.
  - If you complete all of the questionnaires, you will be invited to schedule a virtual interview with study staff. If your answers do not meet criteria, you will be forwarded to a page letting you know.
  - You will meet with study staff via videoconference to answer interview questions on your thoughts, feelings, and experiences.
  - Study staff will review if you meet criteria for ADD/ADHD and are eligible to participate in the study.
  - The eligibility visit will take approximately 1.5 hours total (including both the questionnaires and the virtual interview).
  - After completing all of the above steps, you will be paid $40 for your participation.
- **Group assignment**
  - If you are found eligible, you will be assigned to 1 of 3 study conditions:
    1. treatment sessions in the VR environment
    2. treatment sessions in the VR environment while receiving feedback on study performance
    3. treatment sessions wearing a VR headset without seeing the VR environment
  - The condition you are assigned to will be random. The study will balance the proportion of people taking ADHD medication in each group.
- **12 study treatment sessions**
  - You will complete 12, 1-hour sessions, over 3 weeks (about 4-5 a week) in either your room/home or the library.
  - The first session will involve a study team member coming to your study location of choice to teach you how to use the VR headset and assess throughout the session if you are experiencing any discomfort, dizziness, or other side effects.
  - The first 2 sessions will consist of 10 minutes of reading comprehension passages and questions, 40 minutes of studying and 10 minutes of completing surveys to understand your experience. For the first two sessions, you will study and complete work without the VR headset.
  - The next 10 sessions each will consist of 10 minutes of reading comprehension passages and questions, 40 minutes of studying, and 10 minutes of surveys to understand your experience. Your VR experience will be dictated by the group you are assigned, described above.
  - After completing 7 sessions within 2 weeks, you will receive $60, then an additional $50 after completing all 12 sessions within 3 weeks. Payment will happen at the end of the study participation period of 3 weeks and after

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completion of the post-intervention outcome questionnaires (see below) as a single e-gift card.
    - *For participants in the VR + feedback group, those who maintain at least a 25% increase in focus over their baseline sessions (1 & 2) will receive a $10 bonus. You 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.
- **Outcome questionnaires**
    - After session 12, you will complete online post-intervention questionnaires to report on your thoughts, feelings, and experiences. Questionnaires are estimated to take 30 minutes at outcome. After completing the 12 VR study sessions and outcome questionnaires, you will be paid an additional $110 for your participation.

- **3-month follow-up questionnaires**
    - 3 months after your final treatment session, you will complete online questionnaires to report on your thoughts, feelings, and experiences. Questionnaires are estimated to take 20 minutes.
- After completing the 3-month follow-up questionnaires, you will be paid an additional $25 for your participation.
- **Time Estimates.** The times noted above are estimates and will vary by individual. If you have concerns about the amount of time it takes for you to complete questionnaires, you can tell a member of the study team.

What are the risks of harm or discomforts I might experience if I take part in this study?
You may experience discomfort or psychological distress when completing questionnaires about your thoughts, feelings, and experiences or when completing the interview during the videoconference visit. When filling out questionnaires, you can skip any question that you feel uncomfortable with or do not wish to answer. During the videoconference, you can tell the study examiners that you want to move on to something else.

The virtual reality headset can cause discomfort for some people. Some people report feeling dizzy or eye/muscle twitching. People with a history of seizures, migraines, or serious medical issues should not use the headset. You can stop using the headset at any time. You should immediately stop using the headset and email or call study staff if you experience dizziness or discomfort. After each session, you will answer a question reporting to study staff if you experienced any discomfort using the VR headset. Study staff will be available on-call to help you if you feel discomfort or uncomfortable using the VR headset.

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. It will be important that you select a private area to complete the virtual interview so that you can speak openly without risk of being overheard. If you need help identifying a private space, the study staff will help you.

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Your personal information may be given out if required by law. For example, if the study team has concerns that you are at risk for harming yourself or someone else, we may be required to disclose information about you to other doctors or the police. Also, authorized representatives of Rutgers University may review your research data for the purpose of monitoring or managing the conduct of this study.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be improvements in efficiency and effectiveness of homework and studying. You will also receive a summary evaluation report of your initial diagnostic evaluation. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
When you complete the study, if you want to know how the virtual reality intervention worked based upon your ratings, you can contact the study team to receive a summary.

Will there be any cost to me to take part in this study?
There will be no cost to you to take part in this study. You will be responsible for costs associated with internet access to complete questionnaires and participate in the videoconferences.

Will I be paid to take part in this study?
Yes. As listed above, you will be compensated a total of $175 (or $195 for VR + feedback participants) in e-gift cards for your complete participation:

- $40 for completion of the initial evaluation
- $110 for completion of the intervention and outcome questionnaires, with the intervention payments given in two parts: $60 after completing 7 sessions, and an additional $50 after completing all 12 sessions
- *VR + feedback group only: $20 for completion of 25%+ increase in focus compared to baseline sessions given in two parts: $10 at the end of 7 sessions based on performance up to that point, and then again at the end of 12 sessions
- $25 for completion of follow-up measures 3 months after the final treatment session

How will information about me be kept private or confidential?

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All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. If information from this study is published or presented at scientific meetings, your name and other personal and identifying information will not be used. Your personal information may be given out as required by law, our institution or funding agencies.

We will use secure, password-protected websites, to collect and forward your responses to us. Only study staff will have access to these databases. To protect your identity, we will remove all information that could identify you, such as your name, address and phone number and replace it with the unique identifier. Dr. Langberg's team at Rutgers University will store the information you provide during the study.

We will use a secure videoconferencing platform, such as Zoom Health, to conduct and record the initial evaluation. These data will be directly saved to a secure university drive. These data files are labeled with a unique study identifier code.

Confidentiality may be broken if research staff determines that you are at imminent risk of harming yourself or someone else. If information you share during the evaluation suggests that you are at serious risk of harming yourself, we may have to break confidentiality to ensure your safety. In these cases, we may share info with the following groups:

- Provided Emergency or Clinical Contact(s)
- Local Police or Emergency Services
- University Police Department
- University Counseling Center

In such cases, you will be asked to go to the emergency department or someone may come to your residence to help ensure your safety.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Dr. David Shepherd's research team at Louisiana State University
- The National Institutes of Health

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the study design and results. You can search this website at any time.

What will happen to my information—data, recordings and/or images—collected for this research after the study is over?

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is

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removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

The information may also be shared with other researchers to be used in other analyses. After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Langberg at jl3079@gsapp.rutgers.edu.

At any time, the study PI can take you out of this study because it would not be in your best interest to stay in it. Your study PI can stop treatment even if you are willing to stay in the study.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Research Coordinator: Sophia Frontale, sf924@gsapp.rutgers.edu, Graduate School of Applied & Professional Psychology, 797 Hoes Lane, Piscataway NJ.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

Please print out this consent form if you would like a copy of it for your files.

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If you do not wish to take part in the research, close this website address. If you wish take part in the research, follow the directions below:

By beginning this research, I acknowledge that I am 18 years of age or older and have read and understand the information. I agree to take part in the research, with the knowledge that I am free to withdraw my participation in the research without penalty.

☐ I Agree
☐ I Do Not Agree

Electronic Signature Add signature

Click on SUBMIT below to begin the initial evaluation.

Submit