

Title: Development and Evaluation of a Virtual Reality Tool for At-Risk Trauma Exposed Young People

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**Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT**

TITLE OF RESEARCH: Development and Evaluation of a Virtual Reality Tool for At-Risk Trauma Exposed Young People

Adolescent & Young Adult Participants

If participants include those under 18 years of age: 1) The subject's parent or legal guardian will be present when the informed consent form is provided. 2) The subject will be able to participate only if the parent or legal guardian provides permission and the adolescent provides his/her assent. 3) In statements below, the word "you" refers to your child or adolescent who is being asked to participate in the study.

If you are over 18 years of age, "you" refers to yourself who is being asked to participate in the study.

CONCISE SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This is a research study to find out if a refined virtual reality tool (RVRT) is acceptable and practical to use. A virtual reality tool allows users to immerse themselves in a computer-generated environment. The tool will ultimately be used in substance use treatment to improve substance refusal skills and better understand risky behaviors among adolescents and young adults who have experienced stressful/traumatic events.

If you choose to participate, you will complete 3 study visits (approximately 5 hours total) over the course of 3 weeks. You will be asked to complete interviews, questionnaires, undergo a training for emotion regulation skills, and use a virtual reality headset to undergo the RVRT simulation.

There are no direct benefits to you from participating in the study; however, we may gain information that can help improve treatments in the future.

There are risks to participation, including: emotional or physical discomfort, motion sickness, and breaches of confidentiality.

Your alternative to participating in this study is to not participate.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand.

The purpose of this study is to implement a refined virtual reality tool (RVRT) to determine if it is valid (i.e., does what it is supposed), acceptable (i.e., how well it meets its intended purpose), and practical (i.e., if it's easy to use and understand) and to explore changes in certain factors (e.g., ability to manage and respond to emotions) from the initial study visit to after using the RVRT. Virtual reality allows users to immerse themselves in a computer-generated environment. This is a pilot study of the RVRT, meaning that we are exploring the initial feasibility and acceptability of the tool with a small sample of individuals.

You are being asked to participate in this study because you are 15–30 years old, you have used substances within the past 6 or 12 months, you are currently sexually active/reasonably expect to be within the next 12 months, and/or you identify as someone who is romantically attracted to individuals who identify as men.

The investigator in charge of this study is Dr. Carla Kmett Danielson. The study is sponsored by a grant from the National Institute on Drug Abuse (NIDA), a subdivision of National Institutes of Health (NIH). Portions of Dr. Carla Kmett Danielson's and her research team's salaries will be paid by this grant. The study is being done at one site. Approximately 50 people will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. If you meet initial eligibility criteria and you choose to participate, you will be invited to a baseline assessment session (i.e., the first study visit where you will be administered the first round of assessments) in person or via telehealth. Telehealth is a process in which you will be connected to study staff from the comfort of your home or other setting by using MUSC-approved video technology.
2. The baseline assessment session will last approximately 1.5–2 hours. You will be asked to complete some questionnaires and interviews with a member of the study team. These questionnaires and interviews will ask you about your mental health, exposure to trauma and/or stressful situations, and use of alcohol and substances. You do not have to answer any questions you do not want to answer. The baseline visit may be completed in 2 separate sessions if needed.
3. If you are eligible after the baseline visit, we will schedule a laboratory session approximately 1 week after the baseline visit is completed. If you turn 18 years old between the baseline and lab visits, you will be asked to sign a new consent document.
4. The lab session will last approximately 2 hours and takes place in person on the MUSC campus. You will be asked to repeat some of the same assessments you completed at your baseline visit. During the lab session, you will be led through stress management training. You will learn how to use three stress management techniques: deep breathing, muscle relaxation, and how to manage unwanted thoughts, behaviors, and emotions related to substance use cravings. You will also be led through a simulation (RVRT) twice using a virtual reality headset. You will be guided through a party scene by an avatar (i.e., character). Different avatars will

approach you during the simulation and ask you questions, and you will observe other avatars' interactions. You will be asked to complete some questionnaires before, during, and after the RVRT simulation about your distress and substance craving. During the first trial of the RVRT simulation, you'll also be asked to identify trauma cues (i.e., people, places, things, etc. that remind you of a past stressful/traumatic event) in the party environment. You can stop the session at any time.

5. After the lab visit, we will schedule a post-intervention (PI) session approximately 1 week after the lab visit lasting approximately 1 hour. This visit can be completed in person or via telehealth. You will be asked to repeat some of the questionnaires that you completed at the baseline and lab visits. This visit can be completed in 2 sessions if needed.
6. If you indicate during the assessment questionnaires or interviews (during the baseline, lab, or PI visits) that you might harm yourself or someone else, we will ask you to complete a safety plan with a member of the study team. It may be possible that we need to share this information with a legal guardian for minors (17 years of age and under) or appropriate authorities. The safety plan outlines steps you can take to protect yourself/someone else if you feel as though you may harm yourself or someone else. This plan will include information on when to call an emergency number we give you or 911. We can also provide a list of local treatment referrals. If you do not agree to the safety plan, a member of the study team will escort you to the Emergency Department to help ensure your safety.
7. The PI reserves the right to discontinue study participation for any individual who is determined to be a threat to self, staff, other study participants, or who is unable to complete the study assessments or provide informed consent/assent.

C. DURATION

Participation in the study will take about 5 hours total across 3–4 visits over a period of approximately 3 weeks.

D. RISKS AND DISCOMFORTS

Interviews and surveys

Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question. You may also experience some physical or emotional distress during the interviews or laboratory visit. If you feel significant distress at any time, you may stop filling out the questionnaires or decide to stop the lab visit. You do not have to answer any questions that you do not want to answer. You may become tired or bored while completing some of the assessments.

Motion sickness with RVRT

Some individuals report feeling nauseous ("motion sickness") while using a virtual reality tool. The study team will screen for motion sickness prior to enrolling you in the study. Study procedures will immediately cease if you experience intolerable levels of motion sickness during the lab visit.

Breaches of confidentiality

There is a risk of loss of confidentiality of your information that is used in this study. All study records will be kept on a secure, MUSC-approved cloud server or within the MUSC-approved web-based application, REDCap. Your participation in the study and the information you provide will be treated as confidential. The information the study team collects (e.g., questionnaires and interviews) will contain a code number and not your name to protect your confidentiality. Codes linking numbers and names will be kept in a password-protected file and will not be accessible to anyone outside the research team.

Another risk concerns the legal limits of confidentiality. You should also know that if you threaten to harm yourself or others or give information about child or elder abuse/neglect, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect yourself and others as mandated by law. If you are a minor, the study team may share information about harm to self or others with your legal guardian.

Risks of increased substance craving/emotional distress

Throughout the RVRT simulation, you will be offered substances and alcohol and will be placed in situations that could be related to past traumatic experiences. It is possible that these situations can increase in-the-moment substance craving and emotional distress. If the last SUDS ratings for distress/craving are significantly greater than the baseline (i.e., pre-RVRT) ratings, you will be guided through exercises to decrease your craving/distress before leaving the appointment.

Unknown risks due to use of an investigational technology

The RVRT may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating.

E. CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information

released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort during this study, you will be paid for participating. If the baseline or post-intervention visits are split into 2 visits, you will be compensated after the second visit is completed.

Payment Schedule		
Visit 1 Baseline	Visit 2 Lab visit	Visit 3 Post-intervention visit
\$50	\$100	\$50



For participants who complete the study, you may also earn a \$25 bonus for each individual referred who enrolls in the study.

You may be compensated through cash, gift card, or ClinCard.

Payment for study visits may be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the

payment schedule above. Details of the debit card system are explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive *from MUSC reaches or exceeds \$600.00 in a calendar year, you will be issued a Form 1099.*

I. ALTERNATIVES

Your alternative is to not participate in this study. While this is not a treatment study, we can provide you will referrals to community centers who provide treatment services for mental health and substance use.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Clinically relevant research results, including individual research results, will not be disclosed to you.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;

- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
 - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

N. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

O. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

P. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Other researchers associated with the lead researcher in this study may also request to contact you for other research opportunities. In this event, your contact information will be shared. Please initial by your choice below:

____ Yes, I agree to be contacted

____ No, I do not agree to be contacted

Q. TEXT MESSAGING

You have the option of receiving appointment reminders and links to study surveys through text messages. Should you elect to receive text messages, normal cellular data usage and rates will apply. Please indicate your choice below, or scroll down to the bottom of the screen and select your choice electronically:

- ☐ Yes, I agree to be contacted via text message.
- ☐ No, I do not agree to be contacted via text message

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or

insurance is not available, you will be responsible for payment for all services rendered to your child.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact **Dr. Carla Kmett Danielson at (843) 792-3599**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Printed Name of Adult Participant

Signature of Adult Participant

Date

Signature of Participant's Personal
Representative (if applicable)

Date

Printed Name of Personal Representative (if applicable)

Relationship: ____ Spouse ____ Parent ____ Next of Kin ____ Legal Guardian* ____ DPOA for
Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf
of the patient)*

*For Minors 12-17 years of age: "My participation has been explained to me, and all of my questions
have been answered. I am willing to participate."

*Printed Name of Minor Participant

Signature

Research Staff Only

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date