Adolescent Responses to Varying Environments in Virtual Reality Simulations

NCT04465240

March 28, 2024

Informed Consent Form

USC Suzanne Dworak-Peck School of Social Work
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INFORMED CONSENT FOR RESEARCH

Study Title: Adolescent Responses to Varying Environments in Virtual Reality Simulations [or THe Research In Virtual Environments Study (THRIVE) Study]

Principal Investigator: Daniel A. Hackman, Ph.D.

Department: School of Social Work

Study ID: UP-19-00205 Valid From: 5/12/2023 To: 5/11/2024

INTRODUCTION

If you are reading this form as the parent of a participant, "you" refers to your child.

We invite you to take part in a research study which is referred to as THe Research In Virtual Environments Study (THRIVE Study). Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not you should participate. More detailed information is listed later in this form.

1. Being in this research study is voluntary – it is your choice.

2. You are being asked to take part in this study because you are an adolescent that is 14-17 years old, and we want to learn more about how neighborhood environments influence stress and development among adolescents. The purpose of this study is to examine how different neighborhood environments influence adolescents' emotions, stress and physiological responses, and behavior. Your participation in this study will include online questionnaires which should take about 1 hour and one in-person study session which should take about 3 hours to complete. Study session procedures include participating in a virtual reality experience of a neighborhood environment, providing a small hair sample and multiple saliva samples, wearing sensors that measure how your heart and nervous systems respond, and completing some behavioral tasks. You and your parent will be asked to fill out a number of questionnaires and also provide a history of the addresses you have lived in at different times.

3. There are risks from participating in this study. The most common risks are discomfort answering personal questions, wearing the sensors, and/or providing the hair and saliva samples. You may also experience some slight motion sickness, boredom, and/or anxiety while exploring the virtual reality

environment. More detailed information about the risks of this study can be found under the “Risks and Discomforts” section.

4. You may not receive any direct benefit from taking part in this study; however, your participation in this study may help us learn about how neighborhoods impact adolescent development.

5. If you decide not to participate in this research, your other choices include not participating in the study.

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DETAILED INFORMATION

PURPOSE

Neighborhoods are an important environment for children and adolescents as they develop, and this research is being conducted to help us understand more about how and why different environments may influence adolescent health and development. We are interested in how adolescents’ emotions, their stress and physiological responses, and behavior are related to different kinds of environments. We are also interested in the role played by stressful experiences, by the neighborhoods you have lived in, and other aspects of your family experiences and your characteristics, such as how you handle emotions. You are invited as a possible participant because you are a healthy adolescent between the ages of 14 and 17. About 130 participants will take part in the study. This research is being funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

PROCEDURES

If you decide that you would like to take part, this is what will happen:

First, you and your parent will complete a set of questionnaires online that will take roughly one hour to finish. Second, you will be asked to come for a single study session visit. This visit will take place at either the USC Institute for Creative Technologies (12015 Waterfront Drive Playa Vista, CA 90094) or at the USC University Park Campus in Los Angeles. The study session is expected to take up to 3 hours and starts in the afternoon. You will be given a set of instructions on how to prepare for your visit.

Questionnaires:
You will also be asked to complete a number of questionnaires. This will include several different types of questions such as those about you and your background, aspects of family life and childhood, neighborhoods you have lived in, your school, stressful or difficult experiences you may have had, your perceived stress levels, and may include sensitive topics such as pregnancy, abortion, STDs, psychological conditions, arrest, and drugs. It will also include some questions about your mental and physical health, your relationships, how you regulate emotions and cope with stress, about experiences or behaviors that may impact your hair and saliva samples,

your experiences playing video games, emotions you felt in the VR neighborhood, what you perceived or thought about in the VR neighborhood, and other behaviors. Some of the questionnaires you complete will be done online before the study session, and others will be completed during the session. Please complete these questionnaires in a quiet, private space, to ensure the most thoughtful responses.

Your parent will also answer a number of questionnaires, such as questionnaires about you and your family's background, their characteristics and the characteristics of other caregivers, some of the stressful experiences they have had, your own neighborhood, your overall well-being and mental health, and others.

Residential History:
Because our study seeks to understand your perception of different neighborhoods, it is important for us to understand what types of neighborhoods you have lived in. Your parent will also be asked to fill out some questionnaires about the addresses you have lived in across your life. You may be asked to fill out this questionnaire as well.

To minimize the amount of time you are putting into the survey, we may use publicly available information on the internet to prefill your address information and then ask you to verify the information. This will be used to connect to other data sources to be able to estimate the characteristics of the neighborhood that you live in, such as those in US Census or American Communities Survey, air pollution, or community violence. Similarly, data sources about your school and your school's neighborhood may be used.

Virtual Reality Task:
During the session, you will navigate a neighborhood environment in virtual reality (VR) on a computer screen or using a head mounted device. You will be assigned to one of two different possible neighborhoods, and the neighborhood you will be assigned is picked by chance. This is called randomization and is done pretty much like flipping a coin. Before you explore the VR neighborhood, you will be given some time to learn how to move in the neighborhood and to practice, and you will also watch a nature video. In the VR neighborhood, you will be asked to follow a route, marked by a series of arrows, while finding "tokens" throughout the city, similar to what you might do in a VR video game. The system will automatically record what you do in the virtual city, such as the movements that you make and your location in the virtual city, as well as the tokens you pick up. This may also include your eye movements and where they look. After you finish this task, you will watch a nature video again.

Other Behavioral Tasks:
In addition, you will complete some short behavioral tests to examine attention, working memory, and other cognitive abilities. These are done using a computer or iPad and should take about 20 minutes overall.

Physiological Measures:

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Before and throughout the in-person study session, we will collect data and samples to understand how your mind and body interact. Your height and weight will also be measured.

At multiple times you will be asked to give a saliva sample in order to measure stress hormones. You will give two samples before the VR task and then additional samples throughout until the end of the nature video.

You will wear sensors, such as electrodes and a blood pressure monitor, that measure things like how your heart, blood pressure, and nervous system respond to the video and the VR task.

You will also be asked to provide a sample of your hair, in order to allow us to measure overall levels of stress hormones over the past 1-3 months. This sample will be cut from the scalp and is small – about ¼ inch in diameter– and taken from a place that should not be visible.

Please Note: Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include:

Surveys/Questionnaires/Interviews: Some of the questions may make you feel uneasy or embarrassed, and you and your parent may feel uncomfortable answering personal questions. You can choose to skip or stop answering any questions you do not want to. Your data will not be shared with your parent, nor will your parent's data be shared with you.

Virtual Reality Experience. You may feel something similar to motion sickness when viewing the virtual neighborhood, or may feel some mild stress or anxiety, or boredom, but this should not be any worse than what you might experience when playing an immersive video game. You can stop and take a break or end your participation if needed.

Physiological Measures. The experience of giving hair or saliva samples or having the sensors placed on your body might cause some mild discomfort or annoyance. The area of cut hair may be visible; however, this is minimized by cutting hair underneath the top layers and/or taking more cuts but fewer hairs.

Breach of Confidentiality: There is a risk that people who are not connected with this study will learn your identity or your personal information. You may provide highly sensitive, personal information in this study. If people not connected with the study learn

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this information, you could have problems getting a new job, keeping your current job, finding housing, and other risks currently unknown.

Reproductive risks: We do not know whether this study has any risks for pregnant mothers or an unborn baby. However, only participants that are not pregnant will be participating in this study due to eligibility criteria. Pregnancy or suspicion of pregnancy will be assessed by self-report during eligibility screening.

Unforeseen Risks: There may be other risks that are not known at this time.

BENEFITS

There are no direct benefits to you from taking part in this study. You may enjoy the VR experience and task, as it resembles a video game. However, your participation in this study may help us learn more about how environmental contexts relate to adolescent development.

PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) may review your records. Organizations that may also inspect and copy your information include the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

The investigators are required to report certain cases with the potential of serious harm to you, or others, such as suicidality or child abuse to the appropriate authorities.

In order to protect confidentiality, your data or specimens will be stored and labeled with a code so that you cannot be identified by anyone that is not part of the research team. Data will be stored with safeguards, such as locked cabinets or restricted areas, and password protected computers and computer networks. Your data will not be shared with your parent, nor will your parent's data be shared with you.

Your information and data collected as part of this research, including all data on stress hormones from hair and saliva samples, will be used or distributed for future research studies without your additional informed consent. Any information that identifies you (such as your name) will be removed from your private information before being shared with others.

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Your samples collected as part of this research will only be used or distributed for future research studies with your additional informed consent provided under Optional Permission on Page 8.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

ALTERNATIVES

An alternative would be to not participate in this study.

PAYMENTS

You will receive $75 for full participation in this study, and your parent will receive $15 for completing all questionnaires, which will be provided after completion of the in-person session. You will also receive free parking or parking reimbursement for the study session. If you complete the online set of measures but do not attend the session, you will be compensated $15. If you do decide at some point that you no longer want to participate in the session, you will receive payment for the time you have completed – $20 for each hour completed. If your blood pressure is high at rest before you start the virtual reality task, the study will be stopped, and you will receive the full $75 for participation. Compensation will be at the end of the session in the form of cash or a cash card, such as a ClinCard.

Payments for research participation are considered taxable income and participants may be required to pay taxes on this income. If participants are paid $600 or more in total within a calendar year for participation in one or more research studies, the University will report this as income to the IRS and participants may receive an Internal

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Revenue Service (IRS) Form 1099. This does not include any payments you receive to pay you back for expenses like parking fees.

COST

There are no costs related to participation.

INJURY

If you think you have been hurt by taking part in this study, tell study personnel and/or the Principal Investigator, Daniel A. Hackman, Ph.D., immediately. In the case of an emergency contact 911, and if it is during the study session study personnel will assist you in obtaining emergency care. If you require other medical care/treatment because you were injured from participating in this study, you are responsible for seeking treatment and are encouraged to do so. You or your health plan/insurance will be responsible for the cost of any treatment or care. Costs for medical care from research-related injuries will not be paid by the sponsor or funder. There are no plans to offer any type of payment for injury.

However, by signing this form you have not given up any of your legal rights.

VOLUNTARY PARTICIPATION

It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled. If withdrawal must be gradual for safety reasons, the PI (Daniel A. Hackman) will tell you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can continue to collect data from your records. If you agree, this data will be handled the same as the research data. No new information or samples will be collected about you or from you by the study team without your permission.

The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study principal investigator, Daniel A. Hackman, Ph. D, by calling (213) 821-3112.

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This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

☐ I agree to be re-contacted for future studies.

Minor/Youth Participant (Ages 14-17 years)
If your child agrees to participate, have your child sign here.

Name of Child	Child's Signature	Date Signed (and Time*)

Name of Parent	Signature	Date Signed (and Time*)

☐ **Second parent/legal guardian is not available to sign because he/she/ze is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child (45 CFR 46.406).**

Name of Second Parent	Signature	Date Signed (and Time*)

OPTIONAL PERMISSION:
In this study, we will be gathering saliva samples in order to measure stress hormones. However, in other analyses we may also be interested in other biological measures, such as other hormones, inflammation, or your genes and what might impact gene expression. Future use of your samples would be linked to the coded information collected from this study.

Genetic Research: You are being asked to participate in genetic research. Results of this genetic research will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor.

Please mark how your saliva samples may be used in future research studies.

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☐ My saliva samples may be used for research that DOES NOT include genetics:
Initials: _____

OR

☐ My saliva samples may be used for research that DOES include genetics:
Initials: _____

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