

# **Practice Experiences for School Reintegration: An Immersive Virtual Reality Program to Enhance Skill Development of Hospitalized Adolescents**

**NCT number** NCT05934396  
**Document Date** 08/23/2024

**University of North Carolina at Chapel Hill  
Assent to Participate in a Research Study  
Phase 3 Minor Subjects (7-14 yrs)**

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**Consent Form Version Date:** 7/12/2023

**IRB Study #** 20-3464

**Title of Study:** Practice Experiences for School Reintegration: An Immersive Virtual Reality Program to Enhance Skill Development of Hospitalized Adolescents

**Person in charge of study:** Marisa Marraccini

**Where they work at UNC-Chapel Hill:** School of Education Deans Office

**Other people working on this study:**

The people named above are doing a research study.

**These are some things we want you to know about research studies:**

Your parent needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

Sometimes good things happen to people who take part in studies, and sometimes things happen that they may not like. We will tell you more about these things below.

**Why are they doing this research study?**

The reason for doing this research is to create and improve an intervention to help adolescents while they are in the hospital.

**Why are you being asked to be in this research study?**

You are being invited to participate because you are an adolescent who is currently in a hospital and will be attending a middle or high school following discharge.

**How many people will take part in this study?**

If you decide to be in this study, you will be one of about 48 people at this institution that will take part in this part of the research study. We are also piloting this intervention with approximately 5 clinician-adolescent pairs.

**What will happen during this study?**

You will be randomly selected to either receive treatment as usual, part of the mixed reality intervention, or all of the mixed reality intervention. In all cases, you will complete several interviews and questionnaires, and receive a packet of worksheets teaching therapeutic skills to complete during your hospital stay. If you are selected to receive part or all of the intervention, you will also meet with a researcher to learn and practice therapeutic skills using a mixed reality

intervention. During the sessions, you will first learn a skill, then participate in a virtual scenario designed to mimic stressful school experiences, and practice using that skill in the scenario. At the end of each session you will review your experience with the researcher. At the conclusion of all sessions, you will collaborate with the researcher to complete a safety planning intervention, and you and your family can decide to share the intervention with the school. Your participation will be observed and audio recorded to help identify ways to improve the intervention.

Specifically, the meeting(s) may involve:

- Completion of a series of self-report questionnaires addressing your mental health, understanding of therapeutic schools, and school experiences (before and after the intervention if you receive the intervention).
- Completion of clinical interviews that ask about suicidal thoughts and behaviors.
- Participation in the mixed-reality intervention. A trained researcher will be present to conduct and observe the session that will also be audio recorded. (See below for how recordings are handled.)
- An interview that asks you about the intervention, including your experience, its content and how to improve it. The interview will be audio-recorded so we can capture comments in a transcript for analysis.
- Completion of surveys and feedback forms that ask you to rate the intervention idea and share how you are feeling.
- Completion of daily assessments of skill use for two weeks following school reintegration.
- Completion of follow-up assessments at approximately 2-weeks following school re-entry that include the self-report questionnaires and clinical interviews already described.
- Completion of follow-up assessments at approximately 3-months following school re-entry that include the self-report questionnaires and clinical interviews already described.

Check the line that best matches your choice:

OK to record me during the study

Not OK to record me during the study

You may be eligible to participate in a related study that will take place within the next two years. Please check the line that best matches your choice for being contacted by the study team about this future research opportunity:

OK to contact me about related study opportunity

Not OK to contact me about related study opportunity

**Who will be told the things we learn about you in this study?**

We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else.

**What are the good things that might happen?**

Research is designed to benefit society by gaining new knowledge. You may enjoy taking part in this study, but there may be no direct benefit from being in this research study. It is possible that you may benefit through increased monitoring of your feelings and behaviors during the follow up meetings.

**What are the bad things that might happen?**

Sometimes things happen to people in research studies that may make them feel bad. These are called “risks.” These are the risks of this study:

- You may feel uncomfortable using the game and can stop playing it at any time.
- You may feel uncomfortable when describing your ideas and can refuse to answer questions that make you feel uncomfortable.
- It is possible that we will need to tell someone else about the information you share with us in confidence if we learn that there is something that could be dangerous to you or someone else.
- Some survey or interview questions may be sensitive, you do not have to answer any question that makes you feel uncomfortable, you may stop the interview at any time.

Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. You should report any problems to the researcher

**Will you get any money or gifts for being in this research study?**

You will be receiving up to \$145 (\$50 for the baseline assessments, \$15 for the daily assessments and a bonus of \$10 for over 75% completion, \$30 for the two week follow-up, and \$40 for the three month follow-up) when taking part in this study. Any payment provided for participation in this study may be subject to applicable tax withholding obligations. In the event that you withdraw from the study prior to completing a full meeting, payment will be based on your proportion of completing each meeting's procedures. For example, if you were to complete the baseline assessments but did not participate in anything else, you would receive \$25.

**Who should you ask if you have any questions?**

If you have questions you should ask the people listed on the first page of this form. If you have other questions, complaints or concerns about your rights while you are in this research study you may contact the Institutional Review Board at 919-966-3113 or by email to [IRB\\_subjects@unc.edu](mailto:IRB_subjects@unc.edu).

If you sign your name below, it means that you agree to take part in this research study.

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— Date

Sign your name here if you want to be in the study

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— Print your name here if you want to be in the study

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— Date

Study team member signature obtaining assent

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— Printed name of study team member obtaining assent