

NCT03996642

MCC-18-14462

Feasibility of Delivering an Avatar Life-Review Intervention to Support Patients with Active Cancer

Informed Consent Form, IRB approval date: 5/31/2019

## RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

**Title:** Feasibility of Delivering an Avatar Life-review Intervention to Support Patients with Active Cancer

**VCU IRB PROTOCOL NUMBER:** MCC-18-14462

**INVESTIGATOR:** Egidio G. Del Fabbro, M.D., Danielle M. Noreika, M.D., Semi Ryu, MFA.

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.** This consent form is meant to assist you in thinking about whether you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.**

If any information contained in this consent form is not clear, please ask the study doctor or the study staff to explain any information that you do not fully understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision. In this consent form, “you” always refers to the research participant. If you are a legally authorized representative, please remember that “you” refers to the study participant.

Your participation is voluntary. You may decide to not participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

**Consent For:** Patients ( $\geq 18$  yrs of age) with active cancer in outpatient palliative care

### PURPOSE OF THE STUDY

Patients with cancer face many challenges such as physical, psychosocial, and spiritual pain. While there are many medications that help with physical discomfort (e.g., pain, appetite, shortness of breath), there are not many ways to help with psychosocial and spiritual distress.

The purpose of this research study is to evaluate the likelihood of using an Avatar based therapy, a non-medicine-based intervention, to support patients with active cancer. Movement-based, creative expression has been shown to reduce stress and depression. By projecting movement-based actions onto an avatar, this can serve as a tool to express emotional distress, address satisfaction with care, and view cancer in a different light.

This type of research is a feasibility study which will help us to understand the basic benefits and challenges of combining movement-based Art and Avatar-Technology to improve quality of life.

### DESCRIPTION OF THE STUDY

In this study, you will be asked to create an avatar and answer questions that will help you to engage in reflection and storytelling. This study will utilize VoicingHan, an interactive technology that will capture your gestures, movements, and voice and project it on an avatar. This real-time motion capture technology will allow you to freely act out representations of yourself, significant

others, or family members. You can freely improvise your story or explore new possibilities of creative storytelling,

The study will consist of an unknown number of avatar recording sessions each lasting for 20-60 minutes. The length of each session will depend on your level of engagement. Immediately before the intervention, you will complete questionnaires that addresses physical, spiritual, and psychosocial well-being. During the Avatar Session, you will create and design an Avatar, and engage in a storytelling session. You can request a recording of your Avatar session(s) for your personal use.

Immediately after the avatar session, a member of the research team will ask open-ended questions to identify any challenges you may have during the intervention (setup, length of intervention, barriers to engagement). Interviews will be audio-recorded. The number of Avatar sessions you will participate in will be determined by the research team after evaluating your responses to the questionnaires and open-ended interview questions. If deemed appropriate by the research team, you will participate in another Avatar session. Each session will be 2-4 weeks apart. You will return in a month after the final Avatar session for a final follow-up session to evaluate any sustained effects of the intervention.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

**Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.**

## **PROCEDURES**

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered. At the time you enroll in this study, you will be asked do the following things:

1. Attend your scheduled palliative care appointment
2. Complete questionnaires that ask about your symptoms (e.g., fatigue, disturbed sleep, anxiety, depression, distress), and health-related quality of life
3. Engage in a facilitated avatar recording session. We will video record you to capture your voice and movements for the purposes of projecting them onto the Avatar. We will also place sensors on your body that allow the motion-capture technology to work.
4. Post-interview follow up to provide feedback and your overall experience. Interviews will be audio-recorded.
5. If deemed acceptable for another Avatar session as determined by the research team, follow up with scheduled appointment in 2-4 weeks
6. Final follow up appointment 1 month after the last Avatar session.

## **RISKS AND DISCOMFORTS**

There is minimal risk for this non-medicine-based, intervention study. We take extreme measures to ensure your privacy when collecting and storing data, including storing all study related materials either in a locked file cabinet in a locked office that is accessible only to team

members or on a secure server that is backed up daily. Thus, risk of confidentiality breach is low.

There is a chance that discussing your experience may cause emotional sadness or distress. The questionnaires and interview questions are sensitive in nature and may make you feel uncomfortable. You may learn things about yourself that you did not know before and that could affect how you think about yourself. If this occurs, we will provide you with the opportunity to speak with an experienced psychologist available with Massey Cancer Center.

You may also feel temporary discomfort from the sensors that will be strapped around your arms, chest, legs, and groin. However, these sensors are lightweight and designed to promote movement. At any point you feel physically or emotionally uncomfortable during the avatar session, you are free to immediately stop participating in the study.

### **BENEFITS TO YOU AND OTHERS**

We hope that this innovative intervention, which integrates art and technology, will provide a platform to support you and your family. There is no guarantee that you will receive any benefits from being in this study. However possible benefits include lower levels of anxiety and depression and increased well-being. We hope the information learned from this study will provide more information about intervention strategies to improve the quality of life for patients facing life-limiting illnesses.

### **COSTS**

There is no additional cost for you to participate in this study. The study will take place during your scheduled appointment.

### **ALTERNATIVE**

An alternative is for you to choose not to participate in this study. If you decide not to enter this study, you can receive the usual care that you would receive even if you were not in the study.

### **CONFIDENTIALITY**

VCU and VCUHealth have established secure databases to help with monitoring and oversight of clinical research. Your information may be maintained in these databases but is only accessible to individuals working on this study or VCU/VCUHealth officials who have access for specific research related tasks. Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. The research data consists of data collected in questionnaires completed by you. We will not share any information about you with anyone; however, information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University, the research sponsor, or officials of Department of Health and Human Services.

Post intervention interviews will be audio-recorded for qualitative purposes and to help identify any technical barriers. Audio-recording will be destroyed after transcription and will not be shared with any member outside the research team.

What we find from this study will be presented at meetings or published in papers, but your name or identifiable personal information will not ever be used in these presentations or papers.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

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 Website will include a summary of the results. You can search this Web site at any time.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

### **HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?**

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" that is protected by federal law.

### **What type of health information will be used or shared with others during this research?**

The following types of information may be used for the conduct of this research:

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Complete health record                                 | <input checked="" type="checkbox"/> Diagnosis & treatment codes          | <input type="checkbox"/> Discharge summary    |
| <input type="checkbox"/> History and physical exam                              | <input type="checkbox"/> Consultation reports                            | <input type="checkbox"/> Progress notes       |
| <input type="checkbox"/> Laboratory test results                                | <input type="checkbox"/> X-ray reports                                   | <input type="checkbox"/> X-ray films / images |
| <input checked="" type="checkbox"/> Photographs, videotapes                     | <input type="checkbox"/> Complete billing record                         | <input type="checkbox"/> Itemized bill        |
| <input type="checkbox"/> Information about drug or alcohol abuse                | <input type="checkbox"/> Information about Hepatitis B or C tests        |   |
| <input checked="" type="checkbox"/> Information about mental health             | <input type="checkbox"/> Information about sexually transmitted diseases |   |
| <input type="checkbox"/> Other physical or mental health information (specify): |  |   |

### **Who will use or share protected health information about me?**

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

**Statement of Privacy Rights**

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at:

1101 E. Marshall St.  
Sanger Hall 6-030J  
P.O. Box 980230  
Richmond, VA 23298-0230

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to with draw will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation in this study may be stopped at any time by the study staff without your consent. The reasons might include:

- you have not followed study instructions; or
- administrative reasons require your withdrawal

**QUESTIONS**

If you have any questions, complaints, or concerns about your participation in this research, contact:

Egidio Del Fabbro, MD  
Palliative Care Endowed Chair and Program Director  
Department of Internal Medicine  
Division of Hematology, Oncology & Palliative Care  
Office: (804) 828-9909

If you have general questions about your rights as a participant in this or any other research, you may contact:

Office of Research  
Virginia Commonwealth University  
800 East Leigh Street, Suite 3000; P.O. Box 980568 Richmond, VA 23298  
Telephone: (804) 827-2157

Contact this number for general questions, concerns, or complaints about this research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in this research study can also be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

#### **WHERE CAN I GET MORE INFORMATION?**

You may visit the NCI website at <http://cancer.gov/> for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER ([1-800-422-6237](http://1-800-422-6237)).

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all your questions.

**STATEMENT OF CONSENT**

I have been provided with an opportunity to read this consent form carefully. All the questions that I wish to raise concerning this study have been answered.

By signing this consent form, I have not waived any of the legal rights or benefits, to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

---

\_\_\_\_\_  
**Participant Name printed**

\_\_\_\_\_  
**Participant Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Name of Person Conducting Informed Consent Discussion / Witness (Printed)**

\_\_\_\_\_  
**Signature of Person Conducting Informed Consent Discussion / Witness**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Principal Investigator Signature (if different from above)**

\_\_\_\_\_  
**Date**