CONSENT TO PARTICIPATE IN RESEARCH

Study Title: Enhanced Preoperative Pancreatoduodenectomy Patient Education Using Mixed Reality Technology: A Randomized Controlled Pilot Study

Principal Investigators: Rohan Jeyarajah, MD

Introduction

This research study wants to learn about the effects of mixed reality on patient understanding of surgical treatment. Patient participation will last one day. Patients will be given a survey before their HoloLens session to assess their understanding of the whipple procedure. After the HoloLens session, patients will be given a post-survey to see if their understanding improved.

Purpose

The investigators are conducting this study to investigate the effectiveness of mixed-reality technology for patient education around the time of surgery. Patients will be enrolled by Dr. Jeyarajah, a surgeon at Methodist Dallas Medical Center, and will be selected if they have undergone a pancreaticoduodenectomy, or whipple procedure.

Procedures

Patients who agree to participate in this study will be given a HoloLens and will be walked through a PowerPoint deck and 3D anatomy model that illustrates abdominal anatomy and concepts relevant to the whipple procedure. The medical student will also be wearing a HoloLens and will provide the patient with an introduction to the HoloLens system via an interactive 3D environment.

All participants who agree to participate will be provided with a HoloLens. Participation will take approximately 15 minutes and will occur at a single office visit. Before using the HoloLens, the patient will be provided with a survey to assess their understanding of the whipple procedure. After using the HoloLens, the patient will be given the same survey to assess whether their understanding of the whipple procedure has improved.

Risks

There are no anticipated risks associated with participation in this study except for those associated with the use of a mixed-reality device.

If you are injured or become ill as a direct result of using the Microsoft HoloLens, please contact the study team.

There is no extra compensation for costs such as lost wages, travel, or expenses, other than the medical treatment. Neither the Sponsor, your researcher, Methodist Health, or Texas Christian University agree to give compensation for any injury from being in this study.

Benefits

Participants will not be receiving any direct benefits from the study. The investigators hope to use protocols of this study to improve patient understanding of the whipple procedure.

Costs

There will not be additional costs to you if you participate in this study.

The HoloLens will be supplied by the Burnett School of Medicine at TCU at no cost to you. Insurance companies and other third-party payers will not be billed for research procedures.

The rest of the medical care that you will receive in this study is considered standard care for your situation and would be recommended whether or not you participate in this study. These costs will be billed to you or your insurance carrier.

Research-related injury

In the case of injury or illness resulting from your participation in this study, medical treatment is available to you at Methodist Health. You will be charged the usual and customary charges for any such treatment you receive.

The sponsor of this research is Texas Christian University.

Compensation

You will not be paid for participating in this study.

Voluntary Participation

Your participation is voluntary. If you decide not to participate in this study you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

Withdrawal

You may choose to stop your participation in this study at any time.

New Information

You will be told of any information we learn during your participation in this study that may affect your willingness to participate.

Confidentiality

Every effort will be made to keep the information we learn about you private. No data will be collected outside of the patient survey. Survey responses will be kept anonymous. Participant information will be anonymized when the study results are published.

Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: data provided on survey *(name, age, gender, rating of technology/whipple procedure).* By signing this consent document, you authorize Dr. Jeyarajah and his study staff to collect this information and use your records as necessary for this study. Dr. Jeyarajah (and research team) will use your de-identified information to report findings for purposes of publication.

The information collected for this study will be kept indefinitely and may be combined with information collected through other research studies or used in other studies, but no information will identify you.

Your medical information and records, once disclosed, may be re-disclosed and may no longer be protected by the Privacy Standards of the

Health Insurance Portability and Accountability Act (HIPAA), which is a federal regulation designed to protect medical information, including medical information and records created through research.

You have the right to cancel this authorization at any time by providing Dr. Jeyarajah with a written request to cancel the authorization. If you cancel this authorization medical information and records about you that were created before the authorization was cancelled will still be used and disclosed as needed to preserve the integrity of the study.

If you do not sign this consent document, you will not be allowed to participate in this study.

Number of Participants

This is a single site study at Methodist Dallas Medical Center with a goal study population of 20 participants for the study.

Questions

If you have questions about this study or need to report any problems, side effects, or injuries, please email Paul Murdock at paul.murdock@tcu.edu.

You may also choose to discuss your rights as a research participant with the Human Research Protections Program (HRPP) at Texas Christian University (TCU). They may be contacted by phone at 817-257-1708 or by email at research@tcu.edu. The HRPP ensures that the rights and welfare of human research participants are adequately protected and that such research complies with applicable laws and TCU institutional policies.

Participants will be given a copy of this consent document if requested.

Statement of Participation

***(PLEASE NOTE**: The Principal investigator is responsible for ensuring all participants enrolling in the study have given legally effective informed consent and/or assent.)*

I have been told about this study and the possible risks and benefits. My participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at Methodist Health.

By signing this form I am not giving up any legal rights *(I or my child, whichever is applicable)* may have.

_____ _____

Participant's Printed Name Participant's Signature

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

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Signature of Principal Investigator

_____

Date*

**Absent extenuating circumstances, the investigator's signature should be obtained within 72 hours of the participant's signature.*