Statistical Analysis Plan

Virtual Reality Alternative to Pharmacological Sedation During Colonoscopy

Principal Investigator	Daniel C. Chung, MD
	Director, High-Risk GI Cancer Clinic
	Massachusetts General Hospital
	Boston, Massachusetts

Protocol Identification Number	2018P001618
ClinicalTrials.gov identifier	NCT04349150

Signature Page

Principal Investigator

Daniel C. Chung, MD

9-22-2021

Date

1. Introduction

Virtual reality (VR) technology has been previously explored to reduce pain perception during medical procedures through distraction. We sought to determine whether VR technology may be a feasible alternative to pharmacological sedation during colonoscopy procedures.

2. Study design

Individuals 18 years or older who are scheduled for a routine colonoscopy and who have had a prior colonoscopy will be recruited to participate. The recruitment goal for this pilot study is 30 participants. Study participants will prep for the colonoscopy according to standard practice and will be prepared for the colonoscopy according to the standard of care at Massachusetts General Hospital. All participants will undergo a VR experience through a head-mounted display (HMD) throughout the duration of the colonoscopy and the procedure will be initiated without the administration of IV sedatives or narcotics. However, standard pain medication will be available upon participant request.

All participants will be asked to complete a questionnaire about their experience. The endoscopist will also complete a questionnaire about their experience working with the participant using VR distraction.

3. Aims and objectives

The goal of the study is to assess whether VR is an acceptable alternative to using pharmacological sedation during colonoscopy procedures. Data will be collected on participant willingness, tolerability, experience, and desire to use VR during subsequent colonoscopies.

4. Outcomes

4.1 Primary Outcome 1: Proportion of Individuals Who Complete Colonoscopy Using Virtual Reality and no Pharmacological Rescue

This outcome will be measured as x/n, where x = number of participants who completed colonoscopy using virtual reality and no pharmacological rescue, and n = total number of participants who initiated colonoscopy using virtual reality. This data will be collected immediately following the colonoscopy.

4.2 Primary Outcome 2: Cecal Intubation Rate

This outcome will be defined as the cecal intubation rate of colonoscopies performed on participants using VR and no pharmacological sedation. It will be measured as x/n, where x = number of subjects in whom cecal intubation is achieved when subject is using virtual reality and no pharmacological sedation, and n = total number of participants who initiated colonoscopy using virtual reality. This data will be collected during the colonoscopy.

4.3 Secondary Outcome 1: Participant-reported Pain and Discomfort Levels

Participants will rate their pain and discomfort on a numeric rating scale of 1-10 (1 = no pain/discomfort, 10 = extreme pain/discomfort). This data will be collected immediately following the colonoscopy.

4.4 Secondary Outcome 2: Participant Satisfaction

Participants will rate their satisfaction with their experience using virtual reality during colonoscopy on a numeric rating scale of 1-10 (1 = not satisfied, 10 = extremely satisfied). This data will be collected immediately following the colonoscopy.

4.5 Secondary Outcome 3: Participant Willingness to Undergo Future Colonoscopies With Virtual Reality and no Pharmacological Sedation

Participants will rate their willingness to undergo future colonoscopies using virtual reality and no pharmacological sedation as "Yes," "Maybe," or "No." This data will be collected immediately following the colonoscopy.

4.6 Secondary Outcome 4: Endoscopist Satisfaction

Endoscopists will rate their satisfaction performing colonoscopy on participants using virtual reality instead of pharmacological sedation on a numeric rating scale of 1-10 (1 = not satisfied, 10 = extremely satisfied). This data will be collected immediately following the colonoscopy.

4.7 Secondary Outcome 5: Endoscopist Willingness to Incorporate Virtual Reality Into Regular Colonoscopy Practice

Endoscopists will indicate whether they would incorporate VR into their regular colonoscopy practice by selecting one of the following: "Yes" "No" or "Yes, but I would use virtual reality as an adjunct therapy rather than a standalone therapy." This data will be collected immediately following the colonoscopy.

5. Populations to be analyzed

The population analyzed will consist of all participants who initiate the study using the virtual reality technology.

6. Analyses

6.1 Primary Outcome 1: Proportion of Participants Who Complete Colonoscopy Using Virtual Reality and no Pharmacological Rescue

This outcome will be analyzed as a percent from the proportion of participants who complete colonoscopy using VR and no pharmacological rescue.

6.2 Primary Outcome 2: Cecal Intubation Rate

This outcome will be analyzed as a percent from the proportion of participants in whom cecal intubation is achieved.

6.3 Secondary Outcome 1: Participant-reported Pain and Discomfort Levels

The mean values for participants' pain and discomfort will be calculated, along with the standard deviation.

6.4 Secondary Outcome 2: Participant Satisfaction

The mean values for participant satisfaction will be calculated, along with the standard deviation. Correlation between satisfaction values and values for pain and discomfort will be assessed using the Pearson r correlation.

6.5 Secondary Outcome 3: Participant Willingness to Undergo Future Colonoscopies With Virtual Reality and no Pharmacological Sedation

Counts of participants selecting "Yes," "Maybe," and "No" will be analyzed as percentages.

6.6 Secondary Outcome 4: Endoscopist Satisfaction

The mean values for endoscopist satisfaction will be calculated, along with the standard deviation.

6.7 Secondary Outcome 5: Endoscopist Willingness to Incorporate Virtual Reality Into Regular Colonoscopy Practice

Counts of endoscopists selecting "Yes," "No," and "Yes, but I would use virtual reality as an adjunct therapy rather than a standalone therapy" will be analyzed as percentages.