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Clinical Trial Protocol

CLINICAL TRIAL PROTOCOL

Postoperative virtual reality for recovery after bariatric surgery: study protocol for a randomised clinical trial

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Abstract

Background: Enhanced Recovery After Surgery (ERAS) protocols for bariatric surgery improve clinical outcomes. However, the impact of ERAS protocols on patient satisfaction is unknown. Virtual reality has been implemented as an effective adjunct to standard analgesic regimens. This study seeks to find out if immersive virtual reality in the immediate postoperative period could improve the subjective quality of recovery and further reduce opioid requirements for bariatric surgery patients compared with ERAS care alone.

Methods: This is a single-centre, randomised clinical trial of patients recovering from laparoscopic bariatric surgery. Once in the post-anaesthesia care unit (PACU), participants will receive either an immersive virtual reality plus ERAS protocol or ERAS protocol alone. The primary outcome will be the Quality of Recovery-15 (QoR-15) score at PACU discharge. Secondary outcomes include PACU opioid requirements, length of PACU stay, PACU pain scores, QoR-15 score on postoperative day 1, hospital length of stay, opioid requirements, and opioid-related adverse effects until hospital discharge.

Conclusions: Positive findings from this study could introduce virtual reality as a non-pharmacological adjunct during PACU care that improves subjective recovery for patients undergoing bariatric surgery.

Clinical trial registration: NCT04754165.

Keywords: metabolic and bariatric surgery; opioid sparing; postoperative pain; subjective recovery; virtual reality

In 2018, >250 000 metabolic and bariatric procedures were performed in the United States, and the number of cases has been rising for the last decade.[1] Recently, significant efforts have been made to optimise perioperative management for bariatric surgery patients to reduce the risks of adverse events, the length of hospitalisation, and to decrease perioperative costs.

Opioid analgesics are undesirable for bariatric surgery patients during the postoperative period for several reasons including respiratory depression, ileus, nausea, and possible opioid dependence. Thus, current Enhanced Recovery After Surgery (ERAS) protocols for laparoscopic bariatric surgery emphasise multimodal analgesia to minimise perioperative opioid use.[2] The use of an ERAS protocol dramatically reduced the length of hospitalisation and the number of patients discharged home with an opioid prescription in a before/after study.[3] However, ERAS protocols emphasising opioid avoidance may be detrimental to patient satisfaction, especially in scenarios with limited effective alternative means of analgesia.

Immersive virtual reality (VR) can effectively distract patients experiencing acute pain and is superior to simpler distraction methods in reducing pain scores for hospitalised patients.[4] In preliminary studies, VR has been found to be a safe and effective adjunct to standard analgesic regimens for painful conditions such as dressing changes for burn patients,

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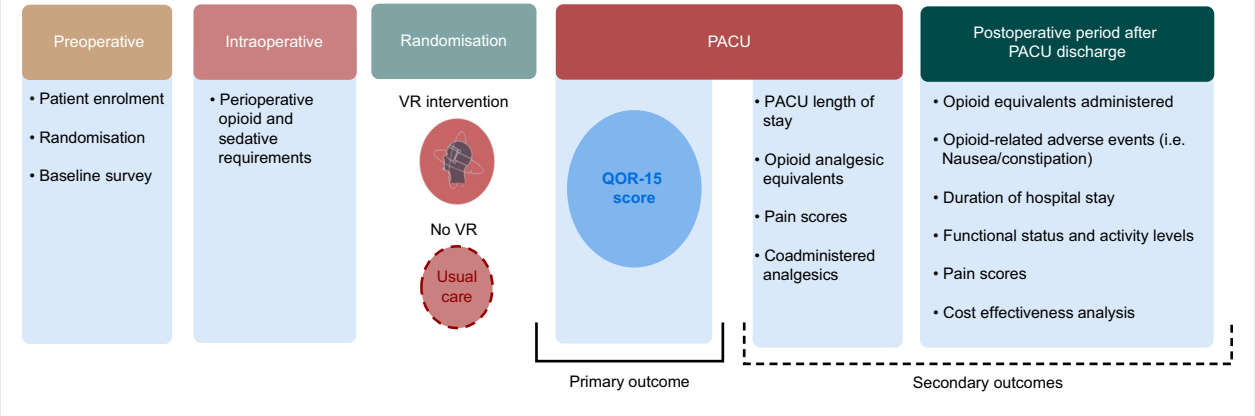

Fig 1. Study schema. Participants will be enrolled during the preoperative period and assessed using a baseline survey. They will then be randomised into one of two groups for the intervention (1:1 allocation), either the immersive VR plus ERAS protocol group or the control group of ERAS protocol alone. Assessments will be administered at PACU discharge and up until postoperative day 1. ERAS, Enhanced Recovery After Surgery; PACU, post-anaesthesia care unit; QOR-15, Quality of Recovery-15; VR, virtual reality.

the first stage of labour, and upper extremity surgery under regional anaesthesia.[5–7] However, no studies to date have assessed if VR immersion can be beneficial for bariatric surgery patients. To address this gap, we will investigate whether the addition of immersive VR to the standard of care of bariatric surgery patients in the immediate postoperative period could improve the subjective quality of recovery compared with an established ERAS protocol standard of care. We will also determine whether the use of VR can lead to reductions in postoperative opioid requirements and differences in important outcomes such as post-anaesthesia care unit (PACU) length of stay, and complications such as nausea and ileus. We hypothesise that the addition of immersive VR will improve the subjective quality of recovery scores at the time of PACU discharge compared with using standard care ERAS protocols alone.

Methods

Ethics approval and informed consent

This study was approved by the Committee on Clinical Investigations at Beth Israel Deaconess Medical Center (BIDMC), Boston, United States (IRB Protocol No. 2020P001149) on 21 December 2020. Enrolment began in March 2022, and as of the submission of this manuscript, recruitment is still ongoing. Written informed consent will be obtained from all study participants by the principal investigator or members of the research team who completed consent training. An explanation of the purpose, methods, anticipated benefits, and risks will be provided during the appointment with potential participants. Patients are free to withdraw consent at any time during the study.

Study design

This is a single-centre, randomised clinical trial of patients recovering from laparoscopic bariatric surgery at BIDMC, including laparoscopic sleeve gastrectomy, gastric banding, and gastric bypass. A run-in, non-randomised phase consisting of the first six enrolled patients will be used to gain experience with the VR intervention and to identify areas that need improvement before the trial begins. After informed consent, study participants will be allocated into one of two groups (1:1 allocation), either the immersive VR plus ERAS protocol group or the control group of ERAS protocol alone (Fig. 1).

Participant eligibility criteria

Eligible patients must be scheduled to undergo laparoscopic bariatric surgery at BIDMC under general anaesthesia. Exclusion criteria are as follows: age <18 yr, open wounds or active infection of the face, history of seizures or epilepsy, patients with hearing aids unable to tolerate the VR headset, those with complete or partial blindness who are unable to tolerate the VR headset while wearing corrective aids, patients with a pacemaker or other implanted electronic device that may be affected by the VR headset, patients on droplet or airborne precautions, those who are non-English or non-Spanish speaking, and patients with chronic opioid dependence as defined by an existing oral opioid prescription >3 months. In addition, patients whose surgery is converted to a laparotomy will drop out from the study because they are likely to have increased pain and analgesia requirements compared with laparoscopic surgical patients.

Recruitment and screening

Eligible patients will be identified by study staff before their pre-admission testing clinic date. Study staff will approach potential participants during their clinic appointments or remotely over the phone, and informed consent will be obtained from patients interested in participating. Before their surgery, the patient will be notified of their randomisation group over the phone.

Study setting

This single-centre study takes place at Beth Israel Deaconess Medical Center, a 740-bed academic teaching hospital in Boston, MA, USA.

Interventions

Immersive VR group

Patients in this group will experience VR immersion as an adjunct to BIDMC's current ERAS protocol (Table 1, Supplementary Table S1). The intervention will begin at an initial recovery period of roughly 45 min after PACU admission, or when the patient has regained a sufficient level of consciousness to participate in the intervention. Participants will wear noise-cancelling headphones connected to a VR headset that will play preselected content displayed in a 360-degree immersive environment with paired audio. Available content includes guided meditation, underwater scenes with dolphins, and a narrated hike of Mount Everest, among other options. Study staff will be present in the PACU to monitor and manage the VR content via an external control software programme on a tablet. They will also be able to mirror the patient's screen and send direct messages throughout the intervention to minimise disruption.

The VR programming will run for as long as the patient desires before PACU discharge, with the goal of achieving a minimum of 30 min. A fully charged backup VR headset will be readily available to ensure continuity of programming in the event that the battery of the initial VR headset runs out. At the time of PACU discharge, the VR headset will be removed, and standard postoperative care will commence for the remainder of the hospital stay.

Control group

Study participants randomised to the control group will not wear a VR headset or headphones and will receive standard ERAS care according to BIDMC protocol.

Outcomes

The primary outcome is the Quality of Recovery-15 (QoR-15) score at PACU discharge. This 15-item questionnaire measures patient-centred outcomes that evaluate the quality of recovery from general anaesthesia, with higher scores indicating greater patient satisfaction.[8] The QoR-15 assesses five dimensions: pain, physical comfort, physical independence, psychological support, and emotional state and takes <3 min to complete. Secondary outcomes include the total dose of opioids administered in the PACU, length of PACU stay, PACU pain scores using the numeric rating scale, QoR-15 score on postoperative day 1 (POD1), hospital length of stay, total opioid dose per day, and opioid-related adverse events throughout the hospital stay. Opioid doses will be normalised to morphine equivalents in the event that multiple types of opioids are administered.

Table 1 BIDMC ERAS protocol in the postoperative period.[3] BIDMC, Beth Israel Deaconess Medical Center; CPAP, continuous positive airway pressure; ERAS, Enhanced Recovery After Surgery; OSA, obstructive sleep apnoea; PACU, post-anaesthesia care unit.

Respiratory
The anaesthesia team will notify PACU for postoperative respiratory patients with OSA, and patients with OSA will use their CPAP equipment if they have one
PACU nursing will utilise incentive spirometry as soon as possible
The head of the bed will be elevated to ≥30 degrees
Antiemetics
Ondansetron 4 mg i.v. (1st line)
Promethazine 6.25 mg i.v. (2nd line)
Haloperidol 0.5 mg i.v. (3rd line)
Analgesic
Hydromorphone 0.5–1 mg i.v. bolus every hour as needed for pain not responding to acetaminophen
Benzodiazepine use will be limited to severe anxiety, agitation, or nausea

Randomisation

Participants will be randomly assigned to immersive VR plus ERAS protocol or ERAS protocol alone (1:1) by block randomisation schemas with constant block sizes using the plan seed procedure in SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

A study team member will be designated from the beginning of the study to access the Research Electronic Data Capture (REDCap) database, which assigns a unique patient research identification number and executes the randomisation schema to allocate the patient into one of the two groups. An unblinded team member will contact the patient 2 days before surgery to inform them of their group allocation.

Blinding

The study staff responsible for randomisation will be unblinded to all participants' study group allocations. A different unblinded member of the study team will be responsible for notifying the participants of their assigned groups and performing the VR intervention on the day of the surgery. Blinded study team members will be responsible for obtaining all post-intervention assessments. However, if it becomes medically necessary to disclose the patient's group assignment to protect their safety or health, we will unblind the assessor, and the patient's group assignment will be revealed. If a blinded team member becomes unblinded, he or she will not perform any further assessments, and a blinded team member will take his or her place.

Data collection and monitoring

Primary and secondary outcomes will be assessed through data collection from the patient's electronic medical records and pre- and postoperative assessments. The Beck Anxiety Inventory (BAI) assessment will be obtained at baseline. Once the patient is deemed clinically ready for PACU discharge by the nursing staff, the patient will be assessed with the QoR-15 questionnaire. On POD1, the patient will also be evaluated with the QoR-15. Evaluation of opioids and other medications administered, pain scores, length of stay, and opioid-related adverse events will be conducted via chart review. Patients who discontinue their enrolment before all outcomes have been assessed will be asked if they will permit analysis of their data that has been collected up until the point they have decided to withdraw, and analysis will proceed according to their preferences. Missing data for outcomes will not be imputed for patients who do not complete the study.

Data monitoring will be performed by the project manager and statistician, with oversight from the principal investigator. The reviewing institutional review board (IRB)

determined that an external committee was not required for this study.

Statistical analysis

Sample size

The primary outcome of this study will be differences between groups in the QoR-15 score at PACU discharge. Based on a standard deviation of 19 points, 90% power, and an α significance level of 0.05, using the two-sample *t*-test we estimate that 41 patients per group will be required to detect a difference of 12 points (1.5 times the minimal clinically significant difference [MCID] in the QOR-15).[9] To account for dropouts, the sample size will be increased to 50 per group for a total of 100 patients. Additionally, we will enrol six patients during the run-in phase. Data collected from run-in patients will not contribute to the primary outcome analysis. Thus, 106 participants are the total expected enrolment.

Analysis plan

Analyses will be conducted using IBM SPSS Statistics Version 25 (IBM, Armonk, NY, USA), considering a two-sided *P*-value <0.05 to be statistically significant. Continuous data will be represented using mean (standard deviation) or median (interquartile range) for variables with skewed distributions and compared using a *t*-test or Wilcoxon rank sum test depending on normality. Categorical data will be presented using proportions and compared using a χ^2 or Fisher's exact test.

Primary outcome

The primary outcome of this study is the QoR-15 score at PACU discharge. A *t*-test or Wilcoxon rank sum test will be used to assess differences in scores between groups. If necessary, univariate and multiple linear regression modelling will be used to adjust for significant differences in baseline characteristics that remain after randomisation. Our primary analysis will be conducted according to the intention-to-treat principle.

Secondary outcomes

Secondary outcomes include total PACU opioid dose, length of PACU stay, PACU pain scores using the numeric rating scale, QOR-15 score on POD1, hospital length of stay, total opioid dose per day, and opioid-related adverse effects throughout the hospital stay. For all secondary analyses, parametric or non-parametric tests will be used in an analogous fashion to our baseline characteristics between groups.

Dissemination plans

During the course of the study, important protocol modifications (e.g. changes to eligibility criteria, outcomes, analyses) will be communicated to the IRB, posted in the ClinicalTrials.gov registry, and disclosed to study participants as appropriate. Upon completion of this clinical trial, data acquired from this research will be made available to the scientific community and the general public in a timely manner. The publication will be prepared by study staff involved in the design and implementation of the study, which will then be submitted to a widely accessible scientific journal. Authorship on publications or any other written work will be determined by active participation in the study's design, implementation, analysis, and writing.

Adverse event monitoring

The scope of adverse event monitoring and reporting will be limited to adverse events related to the study procedures, such as equipment malfunction, nausea during or immediately after VR use, or seizure. Participants will be observed for adverse events until the time of PACU discharge.

Confidentiality

Data will be stored on password-protected computers behind the BIDMC firewall and entered into REDCap. Computers and data collected on paper will be stored in locked study offices. For all analyses, subjects will be identified only by their unique coded study ID number assigned for the study. Limited information will be retained on patients who are pre-screened and do not qualify or who are approached and decline participation for the purpose of generating a CONSORT diagram for the trial. At the completion of the study, final, aggregated and de-identified data may be shared with XRHealth.

Auditing

Auditing is performed by the BIDMC's Human Subject Protection Office and the Center for Anesthesia Research Excellence.

Authors' contributions

Study protocol design: JPEL, RM, MJ, TS, VG, BPOG
Drafting of paper: JPEL, RM, ERH, TR, VG, BPOG
Subsequent revising and final approval of paper: all authors

Declarations of interest

BPOG is part of the scientific advisory board for Sedana Medical. All other authors declare that they have no conflicts of interest.

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Protocol version

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Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT in order to improve readability. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bjao.2024.100258.

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