Virtual Reality Distraction for Reduction in Acute Postoperative Pain

NCT: NCT04416555

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1. INTRODUCTION

1.1 Background

A. Postoperative Pain Management

Despite more and more surgeries being moved to the outpatient realm, the scope of inpatient postoperative pain management remains large[1]. As the American population ages and life expectancy increases, major orthopedic hip arthroplasties are increasingly common. The American Academy of Orthopedic Surgeons projects that by 2030, primary total hip replacement will grow by 171%[2].

In this era of healthcare, opioids comprise the first line of treatment in acute postoperative pain yet in the interest of patient safety this reliance should shift. Depending on opioids alone can leave patients dissatisfied, still in pain and have the potential for abuse. A 2016 review of current management of postoperative pain revealed an unmet need for better therapy[3].

B. Opioid Analgesics and Side Effects

Opioids are effective yet a recent survey showed a majority of patients reported moderate to severe pain after adequate narcotic analgesics[4]. Most patients in this survey had at least one side effect with the most common being drowsiness, constipation, and nausea. Respiratory depression is a serious side effect and puts these patients at risk of harm. Receiving narcotic analgesics also places patients at risk for abuse: either misuse by family members, addiction or tolerance. Acute tolerance requires patients to increase opioid dose for comparable effect and, although controversial, there is even a concept of opiate-induced hyperalgesia[5] In opiate induced hyperalgesia, studies show a paradoxical response where patients treated with more opioids become more sensitive to pain and have higher opioid requirements. In this era of the opioid crisis, multiple advisory boards have issued education regarding proper opioid prescribing[6]. Current recommendations call for using opioids only when necessary and at the lowest possible dose.

C. Multimodal Analgesia

Multimodal treatment plans provide an advantage for acute postoperative pain based on the theory that the total narcotic dose will decrease and side effects be consequently reduced. A recent multi-society guideline defines multimodal analgesia as having three parts: (1) the pre-, intra- and post-operative use of pharmacological and interventional techniques with the primary aim of decreasing acute pain; (2) use of these same techniques to decrease postoperative opioid needs; and, (3) reducing the risk of persistent incisional pain[3]. As defined above, postoperative analgesia starts preoperatively. Planning for each patient may start with education about various interventions. One such intervention may be use of Virtual Reality (VR). This distraction technique has been shown to be a safe and effective adjunctive therapy for acute pain in multiple randomized controlled studies[7].

D. Virtual Reality

Virtual Reality (VR) is a technology that provides an immersive multisensory experience that simulates a user's physical presence in a software and hardware environment in a way that allows the user to interact with it. The VR enviroment studied here is interactive software and a goggle headset unit that gives users the sensation of being in a scenario and controlling certain actions with their body movements. Patients views the immersive environment through light-weight head-mounted goggles that gives feedback on certain movements including breathing exercises. The goggles provide a stereo visual image creating a sense of space and depth, and is thus three dimensional. A motion tracker in the goggles measures the position of the head and aligns the visual image accordingly. Although VR has been studied for more than 2 decades, recent factors have converged to make this intervention worth studying, namely the opioid crisis, decreasing cost of the device, and increasing quality and accessibility.

VR allows users to have an immersive experience that modifies their immediate environment and experience ”presence” in the simulated environment[8]. The external environmnet is excluded. The exact mechanism of action remains unknown, but VR is a distraction technique that fully engages patient’s auditory, visual, and propioception

senses[8]. The theory is that full engagement in a VR environment may restrict the mind's ability to simultaneously processing painful stimuli. There is so far limited understanding of possible biological and psychological mechanisms of action[9].

A 2017 study evaluated hospitalized patients who had both somatic and visceral pain, and identified several factors that may preclude safe and effective VR use[8]. Concerning conditions include active neurologic conditions, epilepsy, facial injuries, ventilator dependence, nausea or vomiting, and excessive frailty. Although the trial protocol limited treatments to 15-minute sessions, some patients nonetheless became dizzy or nauseated.

A recent feasibility study of immersive VR in hospitalized patients showed that although treatments were apparently analgesic and reduced anxiety, many patients were unwilling to use VR or ineligible[10]. Among eligible patients, the elderly were least likely to participate, possibly because they had difficulty adopting to the novel technology.

Several systematic reviews summarize available studies of clinical efficacy of virtual reality for pain reduction. Malloy and colleagues[9] evaluated controlled trials with either between-subjects or mixed model designs, in which VR analagesia was compared with at least one alternative intervention, placebo, standard care, or no-treatment. Using fairly strict criteria, the investigators identified 11 studies that point to the effectiveness of VR in reducing pain. VR was effective for experimental pain and for burn care, but results for sharp pain were less consistent. The authors point to a pattern in the literature suggesting that immersive VR technology is better than non-immersive technology for relief of pain. Recently Chan and her group did a systematic review and meta-analysis of randomized trials for clinical pain and although considerably heterogeneity in studies they found -0.49 (95%CI -0.83 to -0.41, p=0.006) standard mean reduction in pain score[11]. Another meta-analysis, by Kenney et al., also concluded that VR reduces clinical pain[12].

E. Rationale of the study

Previous VR studies have identified clinically meaningful reductions in pain scores; however, they did not evaluate opioid consumption which is a clinically meaningful

outcome. Opioid-related complications including respiratory depression and nausea and vomiting will also be assessed to include cost-effectiveness aspect.

Clinically, opioid-related complications are important from a patient safety perspective, and economically. One barrier to use VR in the perioperative period is that the units have been relatively expensive and cumbersome to use. Improvements in software, hardware and a reduction in cost have been developed that make VR a viable non-pharmacologic adjunct in the treatment of pain. Our trial will provide data for use in a future economic analysis of VR technology in postoperative patients.

2. Study Objectives

Using a randomized controlled design, our goal is to estimate the effect of VR on postoperative analgesia and opioid consumption.

Specifically, we propose to test the primary hypothesis that the use of Applied VR software in Pico G2 4K headsets decreases acute postoperative pain scores (with a 1 point difference considered clinically important) compared to sham treatment on a 0-10 scale 15 minutes after each use in the first 48 hours after surgery or hospital discharge, whoever comes first.

Our secondary hypotheses are that the use of VR over the initial two postoperative days or until hospital discharge:

1) reduces average pain scores (with 1 point being considered clinically important);
2) reduces postoperative opioid consumption (with a 25% reduction being considered clinically important).

On an exploratory basis, we will test the additional hypotheses that use of VR over the initial two postoperative days or until hospital discharge: 1) improves patient mobility; and, 2) reduces the need for nausea and vomiting treatments (ondansetron, dexamethasone, or metoclopramide).

3. Method and Study Design

A. Study Overview

The proposed trial will be conducted with IRB approval and registered at ClinicalTrials.gov before the first patient is enrolled. Written informed consent will be obtained from participating patients. The randomized, blinded, controlled trial will evaluate the effect of AppliedVR software on postoperative pain, opioid use, and opioid-related complications after elective primary total hip arthroplasty.

Participating patients will be randomly assigned to video headset analgesia (video headset featuring a relaxation program with three dimensional video experience and binaural audio) or sham video headset (identical video headset mimicking a void theater where a 2D content will be displayed on a " virtual screen" in front of the user). The headset will not be labeled with the terms "VR," "virtual reality," or "Pico." The study will be performed at two Cleveland Clinic hospitals.

Pico G2 4K VR googles (left) and a sample image of the video headset analgesia software displayed (right)

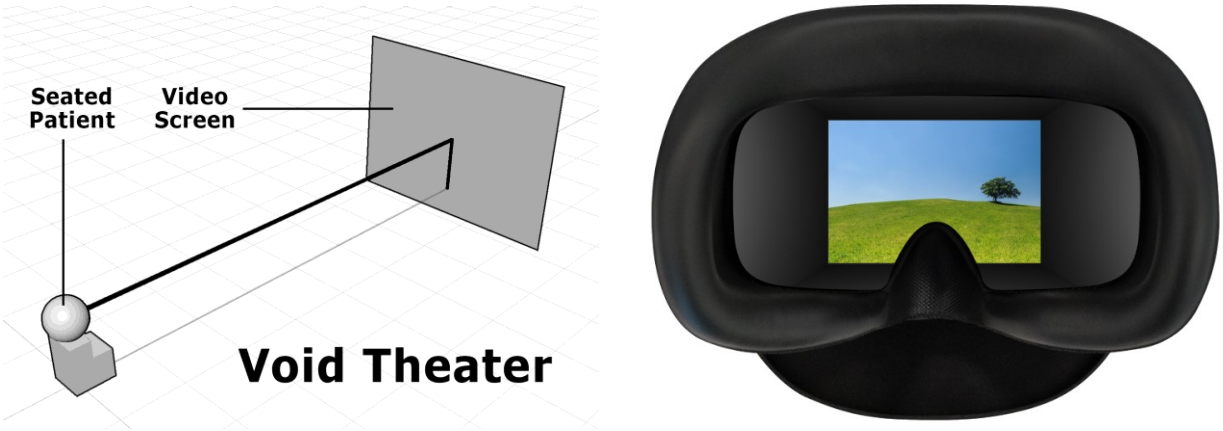

Diagram of the sham video mimicking a void theater with a screen showing 2D content (left) and a sample image of the sham video headset displayed (right)

B. Setting and Population

Inclusion criteria:

(1) Written informed consent;

(2) Men or women 18-85 years old;

(3) American Society of Anesthesiology Physical Status 1-3;

(4) Scheduled for elective, primary total hip arthroplasty;

(5) Anticipated hospitalization of at least 1 night;

(6) Expected to require parenteral opioids for postoperative pain;

(7) Able to use IV PCA systems.

Exclusion criteria:

(1) Use of more than 30 mg/day of oral oxycodone (or equivalent);

(2) Greater than 12 weeks of current and continued opioid use;

(3) History of seizures, epilepsy, motion sickness, stroke, dementia;

(4) Non-English speaking;

(5) Women who are pregnant or breastfeeding;

(6) History of illicit substance use disorder.

C. Withdrawal Criteria

Patients are free to withdraw from study at any time. Patients will also be removed from

study at any time for adverse events or if deemed necessary for their safety. Patients should be asked if they want to fully withdraw from the study, or only stop the intervention and answer the surveys and allow collect other data that may apply.

D. Protocol

Patients will be randomized to either sham video headset group or video headset analgesia group. Study coordinators will be assigned to either randomize and program headsets, or to assess patients' during sessions. All enrolled patients will receive education by research team who will demonstrate how to adjust the headset strap, activate the device, and adjust the volume following a predetermined script with the goal of making patients feel comfortable using the device on their own. Patients will be assured they will receive the routine pain control in addition to video headset experience.

Anesthetic management will follow pre-established clinical and institutional guidelines. Anesthesia will be at attending anesthesiologist's discretion; usually that will be spinal anesthesia without intrathecal opioids. Intraoperative and postoperative opioids will also be given at the discretion of the attending anesthesiologist. Prophylactic antibiotics will be given per surgical routine. Other intraoperative and postoperative medications may be used and include anti-inflammatory medications, gabapentin, pregabalin, ketamine, or lidocaine patches. Clinicians will be encouraged to give a single dose of dexamethasone (4-8 mg) for PONV prophylaxis. Inhaled steroids will be permitted as necessary to treat reactive airway disease.

Patients will be randomized in a 1:1 ratio to either relaxation program the morning of the first postoperative day, before start the intervention. Randomization will be based on computer-generated codes with random blocking and no stratification. Allocation will be concealed by a web-based system. The use of the video headset will be offered postoperatively while patients are awake between 8 AM to 4 PM. **Each session will have a maximum duration of 8 minutes. We will target 3 session per day, with at least one hour separating each treatments.** Treatments will continue for two postoperative days or until hospital discharge, whichever comes first.

The study device is a Pico G2 4K headset, but all labels will be masked to reduce

the risk of unblinding. A member of the research team will program the headsets to either one of the two different relaxation programs and will explain to patient how to set up and use the device. The sham video group will watch a 2D conventional video projected in a virtual screen mimicking a void theater in the same headset, whereas the treatment group will have a full immersive experience with three-dimensional video and binaural audio. Other research team members and healthcare providers will be blinded to intervention assignment and pain assessment will be done by the blinded study coordinator. Patients will not use the video headset device during physical therapy or while ambulating and use of the headset will be restricted to the hospital.

Patients will be allowed to receive prophylactic anti-emetics during intraoperative time based on the risk assessment for nausea and vomiting. Postoperative anti-emetics for symptomatic treatment will also be allowed; ondansetron will be the first choice.

Patients will be followed-up by phone call one week after hospital discharge to ask them the Pain Outcomes Questionnaire Short Form (POQ-SF). No more than 3 attempts should be accomplished to contact the patients for the one-week post-discharge follow-up.

E. Measurements

Demographic and Background Information

Demographic data to be obtained includes height (cm), weight (kg), age (years), sex, ASA physical status classification, and self-declared ethnicity. Patients will be questioned for social history (tobacco) and medical history (pulmonary disease, kidney disease, diabetes mellitus, neurological disease, chronic pain conditions, illegal drug usage, alcohol abuse, myocardial infarction, previous surgery or stent placement and medications usage). Available preoperative laboratory tests and medication list will be recorded.

Standard anesthesia monitoring will be used. Data obtained from electronic medical records for intraoperative variables will include: duration of surgery, intraoperative opioid consumption and antiemetic medications.

Data for variables for the day of surgery as a baseline will be obtained from

electronic medical records for opioid consumption in PACU and ward; pain scores before surgery, in PACU and ward; requirement of oxygen in PACU and ward; nausea and vomiting, requirement of antiemetics, requirement of naloxone, and adverse events. Patient interaction with presented video content will be characterized using eye-tracking metrics.

Outcomes

All postoperative assessment will be made by an investigator who is strictly blinded to treatment allocation, and actual treatment (e.g., full immersion or sham distraction).

Primary Outcome

1. **Pain Scores**. We will assess pain using NRS scores (0-10, with 10 being worst) immediately before and 15 minutes after each intervention with the device, starting on postoperative day one (POD1) and until end of postoperative day two (POD2) or hospital discharge, whichever occurs first.

Secondary Outcomes

1. **Total opioid consumption**. We will measure total opioid consumption, converted to morphine milligram equivalents (MME), starting at the first pre-intervention pain score measurement, postoperative day one (POD1), and until the end of postoperative day 2 (POD2) or hospital discharge, whichever occurs first.
2. **Pain scores.** We will capture all pain score measurements done every 4 hours by standard of care starting at the first pre-intervention pain score measurement, POD1, and end of postoperative day two or hospital discharge, whichever occurs first, using NRS scores (0-10, with 10 being worst). Only the pain scores from routine nurse assessments will be used here (pain scores measured as a part of the primary outcome won't be included).
3. **Perception of video system usability.** Patient's perception of video system

usability will be assessed using a validated questionnaire (System Usability Scale[13]) once after the last intervention with the device and before hospital discharge. The System Usability Scale is scored from 0 to 100 and higher scores are related with devices that are easier to use.

4. **Post discharge pain outcomes**. Patients will be called one week after hospital discharge to assess post discharge pain outcomes using a validated questionnaire (Pain Outcomes Questionnaire Short Form[14]) which evaluates five domains (pain, mobility, activities of daily living, vitality, negative affect and fear). The Pain Outcomes Questionnaire Short Form is scored from 0 to 190 and higher scores are related with worst pain outcomes.

Tertiary Outcomes

1. **Anti-emetic medications**. We will record use of anti-emetic medications, and the outcome variable will be calculated as the number of anti-emetic medications administered starting at the first pre-intervention pain score measurement, POD1, until end of postoperative day two or hospital discharge, whichever occurs first.
2. **Patient mobility score**. We will measure patient mobility using physical therapy daily postoperative assessment ("6 Clicks" Basic Mobility Inpatient Short Form questionnaire[15]) starting at the first pre-intervention pain score measurement, POD1, until end of postoperative two or hospital discharge, whichever occurs first. The "6 Clicks" Basic Mobility Inpatient Short Form questionnaire is scored from 6 to 24 and higher scores are related with lower levels of functional impairment.

F. Data Analysis

We will assess the balance between randomized groups on baseline variables using the standardized difference (i.e., difference in means or proportions divided by the pooled standard deviation). For all analyses we will adjust for baseline variables having absolute standardized difference <0.10[16]. The analyses will be carried out using a modified Intention-to-Treat approach. More specifically, all patients who receive the treatment for

any duration of time will be included in the analysis. For example, if a patient chose to withdraw on POD 2, their measurements from POD1 would still be used in the analysis. We'll only exclude patients who didn't receive any treatment at all either due to refusal or because they chose to withdraw.

Primary outcome. We will assess the effect of VR on NRS pain score after each study treatment over postoperative days one and two using a linear mixed effects model on the series of post-VR pains scores while adjusting for the corresponding pre-VR pain score, with time and randomized group as fixed effect categorical variables. We will adjust for within-subject correlation across the pains scores using either an autoregressive AR (1) or unstructured correlation matrix, whichever has better fit (lower AIC, BIC). We will assess the group-by-time interaction, but even if significant (P<0.15) the primary result will be made collapsing over time.

Secondary Outcomes

1. **Total opioid consumption**. We will assess the effect of VR on log-transformed total opioid consumption starting at the first pre-intervention pain score measurement, POD1, and until end of postoperative day 2 or hospital discharge, whichever occurs first, using a linear regression model.
2. **Pain scores.** We will assess the effect of VR on pain score over time starting at the first pre-intervention pain score measurement, POD1, and until end of postoperative day 2 or hospital discharge, whichever occurs first, using a linear mixed effects regression to account for within-subject correlation. Only the pain scores from routine nurse assessments will be used here (pain scores from Aim 1 won't be used).
3. **Perception of video system usability.** We will assess the effect of VR on perception of video system usability as measured by the System Usability Scale using a Wilcoxon rank-sum test and report the median difference (along with the 95% CI) estimated using the Hodges-Lehmann approach.
4. **Post discharge analgesia**. We will assess the effect of VR on analgesia scores one week after discharge using a Wilcoxon rank-sum test and report the median

difference (along with the 95% CI) estimated using the Hodges-Lehmann approach.

Tertiary Outcomes

5. **Anti-emetic medications**. We will assess the effects of VR on the number of times a patient required anti-emetic medication within starting at the first pre-intervention pain score measurement, POD1, and until postoperative day 2 or hospital discharge, whichever occurs first, using a Wilcoxon rank-sum test, and report the median difference (along with the 95% CI) estimated using the Hodges-Lehmann approach.
6. **Patient mobility score**. We will assess the effect of VR on patient mobility scores(s) during the postoperative day one (POD1), and until end of postoperative day 2 or hospital discharge, whichever occurs first, using a Wilcoxon rank-sum test, and report the median difference (along with the 95% CI) estimated using the Hodges-Lehmann approach.

Interim analyses. We will use a group sequential design to conduct interim analyses at each 25% of the planned enrollment to assess efficacy and futility of the intervention using a gamma spending function. Specifically, we will maintain the overall alpha level (monitoring efficacy) at 0.05 using gamma parameter of -4 [similar to O'Brien Fleming], and power at 90% (monitoring beta, type II error) using gamma parameter of -1 [more aggressive]. Under the alternative hypothesis (assuming a true difference of 1 point) the cumulative probability of crossing an efficacy (and futility in parentheses) boundary at the 1st through 4th analyses will be 0.08 (0.017), 0.36 (0.038), 0.71 (0.065) and 0.90 (0.10).

Sample Size Considerations. We base the sample size to have 90% power at the 0.05 significance level to detect a difference of 1 point or more between VR and placebo on the serial post-intervention NRS measurements in our linear mixed effects model. If we

assume a SD of 1.5 points (taking into account the within-subject correlation in the repeated measures design), a total of 98 patients (49 per group) would be needed, and after adjusting for interim analyses, a total of 113. This sample size will also be sufficient for detecting moderate effect sizes in most of the other outcome variables.

Interim Pilot Study to Re-Assess variability.

We plan to re-estimate the sample size at the first interim analysis. For the outcome, the variance (σ^2) and ICC (ρ) will be estimated from the enrolled patients. Further, the correlation coefficient (r) between pre-intervention and post-intervention pain scores was also estimated. The variance for the outcome (σ^2) will be estimated for each of the pain score measurements separately and the most conservative (i.e., highest variance) option will be selected. Correlation coefficient was calculated in a similar manner and the lowest one was selected. For estimating ICC (ρ) a linear mixed effects model will be set up. We'll obtain estimates of between subject variance (σ_b^2) and total variance (σ_t^2) from the model and estimated ICC as σ_b^2/σ_t^2.

Such a re-assessment "nuisance" parameters, does not affect the statistical properties of the design (i.e, does not increase type I error or decrease power). Keeping everything else the same as initially planned (90% power at the 0.05 significance level to detect a difference (Δ) of 1 point or more, 4 total analyses), we will calculate the new sample size using the equation below[17,18], where n is the number of observations required per group and m is the average cluster size. The total variance will be estimated by calculated by estimating the total variance for each observation separately and selecting the most conservative (i.e., highest variance) option. Correlation coefficient will be calculated in a similar manner. The number of patients required per group (N) would then be n/m.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 2\sigma^2}{\Delta^2} \times (1 - r^2) \times (1 + (m-1)\rho)$$

If an increase in the total sample size is deemed necessary, the primary analysis will be carried out using the efficacy/futility boundaries for the new sample size.

Addendum.

A. Pain Outcomes Questionnaire Short Form[14] (POQ-SF)

01. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst possible pain, how would you rate your pain on AVERAGE on the LAST WEEK?

← **No pain** 0 1 2 3 4 5 6 7 8 9 10 → **Worst possible pain**

02. Does pain interfere with your ability to walk?

← **Not at all** 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

03. Does your pain interfere with your ability to carry/handle everyday objects such as a bag of groceries or books?

← **Not at all** 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

04. Does your pain interfere with your ability to climb stairs?

← **Not at all** 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

05. Does your pain require you to use a cane, walker, wheelchair or other devices?

← **Not at all** 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

06. Does your pain interfere with your ability to bathe yourself?

← **Not at all** 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

07. Does your pain interfere with your ability to dress yourself?

← **Not at all** 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

08. Does your pain interfere with your ability to use the bathroom?

←	0	1	2	3	4	5	6	7	8	9	10	→
Not at all												**All the time**

09. Does your pain interfere with your ability to manage your personal grooming (for example: combing hair, brushing teeth, etc.)?

←	0	1	2	3	4	5	6	7	8	9	10	→
Not at all												**All the time**

10. Does your pain affect your self-esteem or self-worth?

←	0	1	2	3	4	5	6	7	8	9	10	→
Not at all												**All the time**

11. How would you rate your physical activity?

←	0	1	2	3	4	5	6	7	8	9	10	→
Significant limitation in basic activities												**Can perform vigorous activities without limitations**

12. How would you rate your overall energy?

←	0	1	2	3	4	5	6	7	8	9	10	→
Totally worn out												**Most energy ever**

13. How would you rate your strength and endurance today?

←	0	1	2	3	4	5	6	7	8	9	10	→
Very poor												**Very high**

14. How would you rate your feeling of depression TODAY?

←	0	1	2	3	4	5	6	7	8	9	10	→
Not at all depressed												**Extremely depressed**

15. How would you rate your feelings of anxiety TODAY?

←	0	1	2	3	4	5	6	7	8	9	10	→
Not at all anxious												**Extremely anxious**

16. How much do you worry about re-injuring yourself if you are more active?

←	0	1	2	3	4	5	6	7	8	9	10	→
Not at all												**All the time**

17. How safe do you think it is for you to exercise?

Not safe at all ← 0 1 2 3 4 5 6 7 8 9 10 → **Extremely safe**

18. Do you have problems concentrating on things TODAY?

Not at all ← 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

19. How often do you feel tense?

Not at all ← 0 1 2 3 4 5 6 7 8 9 10 → **All the time**

Pain Outcomes Questionnaire Short Form14 (POQ-SF) scoring template

Pain Self-report of pain intensity	Item 1
Mobility Self-report of pain-related impairment in mobility	Item 2 + item 3 + Item 4 + Item 5
Activities of Daily Living (ADL) Self-report of pain-related impairment in completing ADL	Item 6 + Item 7 + Item 8 + Item 9
Vitality Subjective sense of impairment in activity and energy levels	30 – (Item 11 + Item 12 + Item 13)
Negative Affect Self-report of dysphoric affect and associated symptoms	Item 10 + Item 14 +Item 15 + Item 18 + Item 19
Fear Pain-related fear and avoidance	(10 – Item 17) + Item 16
TOTAL SCORE:	0 (best score) to 190 (worst score)

B. Boston University AM-PAC "6 Clicks" Basic Mobility Inpatient Short Form[15]

How much difficulty does the patient currently have…	Unable	A lot	A little	None
1. Turning over in bed (including adjusting bedclothes, sheets and blankets)?	☐	☐	☐	☐
2. Sitting down on and standing up from a chair with arms (e.g. wheelchair, bedside commode, etc.)	☐	☐	☐	☐
3. Moving from lying back to sitting on the side of the bed?	☐	☐	☐	☐
How much help from another person does the patient currently need…	**Total**	**A lot**	**A little**	**None**
4. Moving to and from a bed to a chair (including a wheelchair)?	☐	☐	☐	☐
5. Need to walk in hospital room?	☐	☐	☐	☐
6. Climbing 3-5 steps with a railing?	☐	☐	☐	☐

Boston University AM-PAC "6 Clicks" Basic Mobility Inpatient Short Form scoring

How much difficulty does the patient currently have…	Unable	A lot	A little	None
1. Turning over in bed?	1	2	3	4
2. Sitting down on and standing up from a chair with arms?	1	2	3	4
3. Moving from lying back to sitting on the side of the bed?	1	2	3	4
How much help from another person does the patient currently need…	**Total**	**A lot**	**A little**	**None**
4. Moving to and from a bed to a chair?	1	2	3	4
5. Need to walk in hospital room?	1	2	3	4
6. Climbing 3-5 steps with a railing?	1	2	3	4
TOTAL SCORE: Sum of the scores for each of six questions above 6 (worst outcome) to 24 (best outcome)	06: ±100% of functional impairment 10: ±77% of functional impairment 15: ±58% of functional impairment 19: ±42% of functional impairment 24: ±0% of functional impairment			

C. System Usability Scale assessment[13]

01. I think that I would like to use this product frequently				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
02. I found the product unnecessarily complex				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
03. I though the product was easy to use				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
04. I think that I would need the support of a technical person to be able to use this product				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
05. I found that the various functions in this product were well integrated				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
06. I thought that there was too much inconsistency in this product				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
07. I would imagine that most people would learn to use this product very quickly				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
08. I found the product very awkward to use				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
09. I felt very confident using the product				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐
10. I need to learn a lot of things before I could get going with this product				
Strongly disagree	Disagree	Neutral	Agree	Strongly agree
☐	☐	☐	☐	☐

System Usability Scale assessment scoring

	Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly agree**	**SCORE**
I think that I would like to use this product frequently	1	2	3	4	5	(score) – 1
I found the product unnecessarily complex	1	2	3	4	5	5 – (score)
I though the product was easy to use	1	2	3	4	5	(score) – 1
I think that I would need the support of a technical person to be able to use this product	1	2	3	4	5	5 – (score)
I found that the various functions in this product were well integrated	1	2	3	4	5	(score) – 1
I thought that there was too much inconsistency in this product	1	2	3	4	5	5 – (score)
I would imagine that most people would learn to use this product very quickly	1	2	3	4	5	(score) – 1
I found the product very awkward to use	1	2	3	4	5	5 – (score)
I felt very confident using the product	1	2	3	4	5	(score) – 1
I need to learn a lot of things before I could get going with this product	1	2	3	4	5	5 – (score)
TOTAL SCORE: 0 (worst outcome) to 100 (best outcome)	Sum of the scores for each statement and multiply by 22.5 55 raw score: P25%, 68 raw score: P50%, 75 raw score: P75%					

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