Title: Virtual reality for outpatient management of cancer pain: a dosing study

BACKGROUND

Palliative care (PC) provides expert symptom management and communication skills for patients and families facing serious life-limiting illness. Many such patients experience negative quality of life (QOL) due to moderate-severe pain or other symptoms and require strong pharmacotherapies – often controlled substances such as opioids or benzodiazepines – to alleviate associated distress. A major tenet of quality supportive care is the combination of many types of therapy, both pharmacologic and non-pharmacologic. Patients with cancer are often interested in non-pharmacologic therapies to manage pain or other symptoms at home in addition to traditional pharmacologic therapies.[1,2,3] However, accessing non-pharmacologic therapies such as massage therapy or acupuncture can be

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[2]Ruano A, Garcia-Torres F, Galvez-Lara M, Moriana JA. Psychological and non-pharmacologic treatments for pain in cancer patients: a systematic review and meta analysis. J Pain Symptom Manag, 2021 Dec 22;S0885-3924(21)00680-1. Doi: 10.1015/j.jpainsymman.2021.12.021.

[3]Crawford C, Boyd C, Paat CF, Price A, Xenakis L, Yang E, Zhang W; Evidence for Massage Therapy (EMT) Working Group. The Impact of Massage Therapy on Function in Pain Populations-A Systematic Review and Meta-Analysis of Randomized Controlled Trials: Part I, Patients Experiencing Pain in the General Population. Pain Med. 2016 May 10. pii: pnw099. [Epub ahead of print]

challenging and are infrequently reimbursed by insurance.[4,5,6,7] Patients often request non-drug options, but medications remain the mainstay of treating pain and other symptoms for patients with cancer.

Virtual reality (VR) is a non-pharmacologic intervention that continues to demonstrate effectiveness in pain management. VR is a rapidly developing technology that temporarily immerses the subject in a calm, pleasant environment, providing distraction from pain and lowering pain sensation. To experience VR, subjects use a specially-designed headset (somewhat similar in size/structure to ski goggles) and equipment that introduces computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way by the user. Integration of interactive visual, auditory, and haptic stimuli creates a sense of "immersion" such that users feel they are present in the virtual environment. Early clinical research in patients undergoing painful procedures such as burn wound care or dental procedures shows that brief VR sessions (e.g. 3-30 minutes) can lower self-reported pain scores, lower opioid drug use, and improve satisfaction with pain management. [8,9] While the pathophysiology of pain is complex, such non-pharmacologic interventions

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[4] Griffin KH, Nate KC, Rivard RL, Christianson JB, Dusek JA. Referrals to integrative medicine in a tertiary hospital: findings from electronic health record data and qualitative interviews. BMJ Open. 2016 Jul 25;6(7):e012006. doi: 10.1136/bmjopen-2016-012006.

[5] Nahin RL, Barnes PM, Stussman BJ. Insurance coverage for complementary health approaches among adult users: United States, 2002 and 2012. NCHS data brief, no 235. Hyattsville, MD: National Center for Health Statistics. 2016.

[6]Fletcher CE, Mitchinson AR, Trumble EL, Hinshaw DB, Dusek JA. Perceptions of other integrative health therapies by Veterans with pain who are receiving massage. J Rehabil Res Dev. 2016;53(1):117-26. doi: 10.1682/JRRD.2015.01.0015.

[7] *Integrative Medicine in America: How Integrative Medicine Is Being Practiced in Clinical Centers Across the United States* (2012) from The Bravewell Collaborative Offers. ttp://www.bravewell.org/content/Downlaods/IMinAm.pdf)

[8] Keefe FJ, Huling DA, Coggins MJ, et al. Virtual reality for persistent pain: a new direction for behavioral pain management. Pain. 2012 Nov;153(11):2163-6

[9] Hoffman HG, Richards TL, Van Oostrom T, et al. The analgesic effects of opioids and immersive virtual reality distraction: evidence from subjective and functional brain imaging assessments. Anesth Analg. 2007 Dec;105(6):1776-83.

[10] McCaul KD, Malott JM. Distraction and coping with pain. Psychol Bull. 1984 May;95(3):516-33.

[11] Wickens CD. Multiple resources and mental workload. Hum Factors. 2008 Jun;50(3):449-55.

[12] McSherry T, Atterbury M, Gartner S, Helmold E, Searles DM, Schulman C. Randomized, Crossover Study of Immersive Virtual Reality to Decrease Opioid Use During Painful Wound Care Procedures in Adults. J Burn Care Res. 2017 May 26.

[13] Furman E, Jasinevicius TR, Bissada NF, Victoroff KZ, Skillicorn R, Buchner M. Virtual reality distraction for pain control during periodontal scaling and root planing procedures. J Am Dent Assoc. 2009 Dec;140(12):1508-16.

seem to modulate pain by reducing the level of attention paid to noxious stimuli, thereby suppressing transmission of painful sensations to the cerebral cortex. [10,11] When used in addition to usual care (opioid analgesics, with or without non-interactive distraction therapies), VR has been shown to provide clinically and statistically significant reduction in subjective pain score ratings. [12,13] The immersive nature of VR makes it a more engaging form of distraction therapy compared to playing a video game or listening to music (e.g. rather than watching a video of a beach, one visually and acoustically experiences being at the beach). Additionally, VR is becoming increasingly portable and affordable with growing availability of thematic content such that patients may select VR experiences that interest them.

Despite growing evidence to the benefit of VR for pain management, no research has yet elucidated its role in outpatients with cancer-related pain.

PURPOSE

The purpose of this research project is to evaluate the impact of virtual reality therapy on mitigating moderate to severe cancer pain in outpatients.

AIMS and HYPOTHESES

Specific Aim 1: To collect and compare pilot data on the impact of a VR intervention against standard care (pre-enrollment analgesic regimen) on pain management measures for outpatients with cancer who have a baseline pain self-rated at least 4/10 (0=no pain, 10=worst pain).

Hypothesis 1: Patients with cancer receiving a virtual reality (VR) intervention will have significantly larger improvements in self-reported pain scores, satisfaction with pain management, lower distress, greater well-being, and lower as-needed opioid use compared to their baseline.

Specific Aim 2: To evaluate frequency of utilization of a VR intervention in a real-world setting.

Hypothesis 2: Patients who use VR more in the setting of cancer-related pain will report lower self-reported numeric pain scores compared to baseline.

Specific Aim 3: To evaluate patient satisfaction with VR intervention and overall pain management, and end-user VR content preferences.

Hypothesis 3: Patients who engage in VR distraction therapy will report greater acceptance of the intervention and satisfaction with the impact on pain experience.

STUDY SETTING

Patients who are receiving outpatient cancer care at the Washington Cancer Institute at MedStar Washington Hospital Center (MWHC). This center serves one of the most culturally diverse areas of the United States, acting as a significant healthcare resource. This site's patient population is predominantly African American (>70%), with most living in low-income areas of the District and half of the patients with Medicaid or Medicare as their primary insurance. These populations traditionally have little to no access to integrative or non-pharmacologic analgesic strategies.

Community partners include the Participant Advisory Board of the Georgetown-Howard Universities Center for Clinical and Translational Science and the Smith Center for Healing and the Arts, the largest independent cancer support organization in the metro Washington, DC area. These partners will inform study design, recruitment strategy, and provide end-user feedback for future research.

STUDY DESIGN AND METHODS

Through ongoing collaborative work between the MedStar Washington Hospital Center Palliative Care team and the Washington Cancer Institute at MWHC, the research team will identify outpatients receiving cancer care at WCI.

The investigators and study coordinator will communicate weekly and meet at least twice monthly to discuss and address potential problems, ensure timely communication with the IRB if needed, and monitor study accrual. Two forms of recruitment materials will be generated: 1) patient-facing advertisement and recruitment material that are eye-catching and written to an 8th-grade reading level. Content will describe the study purpose, key eligibility criteria, and contact information for the study coordinator. Materials will be posted in WCI clinic and community areas where patients and caregivers are likely to be circulating; i.e., cafeteria, lobby, waiting areas and clinic rooms; 2) provider-targeted correspondence summarizing key study objectives and clearly outlining eligibility criteria, period of enrollment, study coordinator contact information, and highlighting the ongoing nature of the study. These materials will be distributed to WCI faculty and hematology/oncology medical fellows. The study coordinator will contact potentially eligible participants through participant self-referral or referral by the oncology team. The coordinator will screen the electronic health record to confirm eligibility, then schedule a time to meet with the participant. INCLUSION/EXCLUSION CRITERIA**:** Subjects will be considered for enrollment in this study if able to provide consent, at least 18 years old, and report moderate-severe pain (at least 4 out of 10 where pain is rated on a Likert scale between zero and 10) in the previous 7 days as a result of either cancer or cancer treatment. Palliative care consultation and/or referral to palliative care is not required for eligibility or participation. Additionally, participation will not be limited by whether subjects are receiving specific cancer-directed therapies at the time of enrollment. Subjects will be excluded if they already use VR for personal use, have intractable nausea/vomiting, history of motion sickness, history of seizures or epilepsy, have cranial structure abnormalities that prevent use of VR headset, or are currently enrolled in a palliative care or pain management study. Subjects will also be excluded if they have limited vision or vision defects that are not corrected with prescription eyeglasses, or if participants are unable or do not wish to wear required corrective eyeglasses with the VR headset. Informed consent will be conducted before enrolling each patient.

This is a non-randomized, unblinded dose-titration study. After consenting to participate, in addition to usual pharmacologic pain management, participants will receive 1 week of VR daily for 10 minutes per session, then 1 week of VR twice a day for 10 minutes per session, then 1 week of VR use as desired by the participants.

VR sessions will be administered using the Facebook (Facebook Inc., Menlo Park, CA) Meta Quest 2 VR and Touch controllers. This equipment was selected because it is portable, has built in audio, and has clear graphics at a lower price than VR setups that require a computer to generate graphics. The headset has an optional eyeglass spacer to allow participants to wear corrective eyeglasses during the

VR session if appropriate. The hand controllers facilitate immersive, interactive VR experiences. Of note, we considered using smartphone-based VR technology for this study; however, although technology continues to evolve, smartphone-based VR technology has not yet evolved enough to provide an adequately immersive VR experience to assure accurate results. The VR software, Nature Treks VR application (https://naturetreksvr.com) that features ten non-violent, nature-based experiences in peaceful environments (e.g. forest, river, beach, etc.) that can be played in a seated or fixed position. A Facebook/Meta account is currently required to login to the Quest 2 device; to protect patient privacy and ensure access to the Nature Treks application, the research team will activate the device with a dummy Meta account that does not contain any patient-specific information or payment information prior to distribution to participants. Participants will be provided with information on resetting the device to factory settings at the end of the study period if they wish to remove the dummy account and access the device using a personal Meta account for future, personal use of the device. Participants will not be prevented from searching for or downloading other VR programs onto the device during the study period, but will not be able to purchase software while logged into the dummy account.

Because of the nature of the compared interventions, subjects and researchers cannot be blinded to intervention. Our primary outcome measure will determine the impact of VR on self-reported pain score in the last week (numeric rating scale, collected weekly). Self-reported pain experience remains the standard for clinical pain research. Secondary outcomes will measure pain interference (PROMIS Pain Interference Short Form, collected weekly), as-needed opioid use for patients taking opioid analgesics at the time of enrollment (self-reported using medication administration form), satisfaction with VR intervention and overall pain management (collected weekly), and survey of preferences for VR thematic content (collected after Week 4).

Following consent, subjects will complete baseline outcome assessments including self-reported pain score in the last week, the PROMIS Pain Interference Short Form, as-needed opioid use in the last week if applicable, and satisfaction with overall pain management. Subjects will then be provided with a VR headset and paired Touch controllers to bring home for the duration of the study and instructions on the frequency of use for each week. A member of the research will educate the patient on the technology and assure comfort with use. The research study coordinator will contact patients by phone at the end of each week to confirm dates and duration of use as specified by the study protocol, collect self-reported pain score in the last week, the PROMIS Pain Interference Short Form, as-needed opioid use in the last week if applicable, and satisfaction with the VR intervention and overall pain management. Additionally, participants will be surveyed on preferences for VR thematic content at the end of Week 3.

Participants will be monitored for adverse effects and harm for the duration of the study. Although well tolerated in previous studies of patients with cancer and advanced heart failure, potential risks may include dizziness, nausea, eye strain, and loss of confidentiality if data security is breached. Participants are instructed to only utilize the VR device while in a seated or reclined position and to never use the device when standing or ambulating due to the risk of potentially serious injury from falling.

Participants will be compensated for their time and participation in this research; participants may keep the VR headset assigned to them for the study, and will receive a $50 gift card upon completing the final survey at the end of Week 3. Participants will not be responsible for replacing or repairing the VR device if it is lost or damaged during the study period; a replacement device will be provided by the research team. Participants who wish to return the device may do so at their next scheduled appointment for usual care at MedStar Washington Hospital Center, where a member of the research team will collect it. Participants will not be required to schedule an appointment or return to MWHC for the purpose of returning the device. Participants who wish to return the device and are

unable or unwilling to return to MWHC for any reason will be provided with a prepaid shipping label by mail to return the device to the research team.

Results of this study will be used to determine the effect size, variance and variability to estimate sample size for a larger study. For this pilot study, a sample size of 60 is sufficient to provide accurate estimates of the information needed to calculate sample size for a future study. In the unanticipated circumstance that we are not able to accrue 60 participants during the study period, we will still be able to perform the desired analysis and calculate sample size for a future study if accrual is as low as 30 participants.

Funding for this study has been obtained through the Palliative Care Research Collaborative investigator Development Pilot Award (https://palliativecareresearch.org). The grant award is $67,031 to support execution of the study over a 1-year period, beginning July 1 of 2022 and ending June 30, 2023.

DATA COLLECTION

Subjects will record daily use of the VR headset and duration of use for each session on a paper calendar provided to them at the time of enrollment. Subject survey data will be collected and entered by the research study coordinator using an online survey system accessible only to the research team (Tonic Health). Subjects will be assigned a de-identified code for survey entry. All data will be password protected and de-identified prior to analysis. Results will be reported in aggregate.

DATA SAFETY MONITORING PLAN

Given the low-risk nature of this study, the PI and Co-PI will jointly ensure that the trial is conducted according to the approved protocols and report the incidence of any adverse events to other study team members, the designated Independent Safety Monitor (ISM), the Institutional Review Board (IRB), and the Georgetown-Howard Universities Center for Clinical and Translational Science Volunteer Participant Advisory Board (VPAB). The ISM will be experienced in clinical trials and familiar with the study intervention, will be appointed by the PI, and will not be involved in the study design, planning, or execution, or affiliated with the study sponsor. The PI will be responsible for submitting reports to PCRC and NINR. At any time, the PCRC and/or NINR may inspect summaries presented to/reviewed by the ISM.

The PI and Co-PI will compose regular data safety monitoring reports for review by the study Independent Safety Monitor (ISM) and the Georgetown-Howard Universities Center for Clinical and Translational Science Participant Advisory Board (VPAB). Content of report and frequency of review summarized in the following table.

Data type	Frequency of review	Reviewer
Subject accrual (including compliance with protocol enrollment criteria)	Quarterly	PI, ISM, VPAB

Data type	Frequency of review	Reviewer
Status of all enrolled subjects, as of date of reporting	Quarterly	PI, ISM, VPAB
Adherence data regarding study visits and intervention	Quarterly	PI, ISM, VPAB
AEs and rates	Quarterly	PI, ISM, VPAB
SAEs	Per occurrence	PI, ISM, VPAB, NINR/PCRC

Study progress and safety will be reviewed every other week by the PI/Co-PI (more frequently if needed). Progress reports, including patient recruitment, retention/attrition, and AEs, will be provided to the Independent Monitor following each scheduled review, held quarterly at minimum. We will audit one complete case (informed consent through final survey collection) per quarter to assure compliance with IRB documents and include in the quarterly report for review. This quarterly report will also include a list and summary of AEs. In addition, the quarterly report will address (1) whether AE rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The quarterly report will be sent to the Independent Monitor and forwarded to the IRB and, if indicated, to the PCRC and/or NINR designated Program Officer.
The PCRC will receive notification of IRB approval prior to initiating any participant engagement. After study initiation, if any modifications are made to the IRB proposal and/or participant consent, the PI will alert the designated Program Officer for PCRC and NINR within 7 days.

To minimize risk associated with the study, we will take measures noted above to promote safety and independent monitoring of protocol adherence, data integrity, and AE reporting. Through the consent process, we will provide education to participants about potential risks associated with participation, as well as contact information for any additional questions, concerns, or reporting of AEs. The PI and Co-PI will continually monitor evolving literature related to VR interventions and relevant safety and/or ethical issues applicable to this study

During the funding of this study, any action by one of the study investigators, the IRB, or the VPAB that results in a temporary or permanent suspension of the study will be reported to the designated PCRC Program Official and the designated NINR Program Official within 1 business day of suspension.

DATA ANALYSIS

Descriptive analyses will be performed to summarize baseline characteristics, including initial pain measures from self-report pain rating scale and PROMIS Pain survey. Preferences for VR thematic content and satisfaction with VR intervention will also be summarized. Summary statistics include frequency (%) for categorical variables and mean, standard deviations, median and IQR (1st and 3rd quartile) for continuous variables. Paired t-test or Wilcoxon sign rank test will be used to compare each

time point (end of weeks 1, 2, and 3) to the baseline (beginning of week 1) regarding pain score and PROMIS survey outcomes. Linear mixed-effects model will be used to assess the trend of pain score over the study period controlling for pain medication usage and other covariates (e.g., age, sex).

Data Collection Plan:

Time of Data Collection	Method of Data Collection+	Data Elements Collected
Beginning of Week 1 (Time of Enrollment)	Patient Survey (all patients)	1) Self-reported pain score 2) PROMIS Pain Interference Short Form 3) As-needed opioid use* 4) Satisfaction with overall pain management
End of Week 1	Patient Survey (all patients)	1) Self-reported pain score 2) PROMIS Pain Interference Short Form 3) As-needed opioid use* 4) Satisfaction with VR intervention and overall pain management
End of Week 2	Patient Survey (all patients)	1) Self-reported pain score 2) PROMIS Pain Interference Short Form 3) As-needed opioid use* 4) Satisfaction with VR intervention and overall pain management
End of Week 3	Patient Survey (all patients)	1) Self-reported pain score 2) PROMIS Pain Interference Short Form 3) As-needed opioid use* 4) Satisfaction with VR intervention and overall pain management 5) Preferences for VR thematic content

* Data collected for patients receiving as-needed opioid analgesics at the time study enrollment
+ Patient survey administered by Research Coordinator by phone, data entered into Tonic Health

DATA SHARING

Data collected over the course will include summary findings of *N* = 60 enrolled participants. Per MHRI policy and in full alignment with NIH policy, all data compiled from this and future projects related to data collected in this study will be available upon request by any academic or government researcher, with data shared via existing pathways built to ensure transparency but protect participants. As part of the NIH data sharing directive, de-identified data from this study will be transferred to the PCRC De-Identified Data Repositories.

RECORD RETENTION

- Any study records (including DCTs, etc.) will be retained in the site's research record for 10 years after the study is completed in accordance with Good Clinical Practice guidelines. At that time the research information will be destroyed by each site's research document destruction rules/regulations.
- Any research information already included in medical records will be kept indefinitely.
- The de-identified data that are collected and entered will remain in the PCRC Data Repositories indefinitely. These data could be used for future research studies or distributed to another investigator for future research studies without obtaining additional informed consent from you or your legally authorized representative.

DATA SHARING:

- De-identified study data from this study will be transferred to the PCRC Data Repositories. The PCRC fully supports the Final NIH Statement on Sharing Research Data, and will assist all investigators and study personnel to ensure their compliance. Consistent with OMB Circular A-110 and subsequent NIH Grants Policy Statements, the PCRC will provide access to all de-identified data collected as part of PCRC-supported investigations, insofar as access is consistent with IRB/CHR rules, local, state, and Federal laws and regulations, and the HIPAA Privacy Rule.
- The Palliative Care Research Cooperative Group (PCRC) will use or share your information in compliance with the PCRC Data Sharing Policy.
- De-identified **quantitative** data from this study will be transferred and stored on a server maintained by the PCRC at the University of Colorado (U of CO), which are maintained and monitored by U of CO's Office of Information Technology (OIT) Department to comply with good data storage and security practices.
- De-identified **qualitative** data from this study will be stored in the PCRC Collection at the Qualitative Data Repository (PCRC-QDR EOLPC) at Syracuse University.
- All de-identified data that are collected and entered will remain in the PCRC Data Repositories indefinitely. This de-identified information could be used for future research studies or distributed to other investigators for future research studies without obtaining additional informed consent from you or your legally authorized representative. All future data analysis will be performed on de-identified data in the PCRC Data Repositories. When information and data resulting from this study is presented at scientific meetings or published in a scientific journal, your identity will not be revealed. Quantitative and qualitative data will be presented in aggregate reports and only anonymous excerpts from qualitative data will be used.

Data/Survey Instruments to be Collected

Baseline/Time of Enrollment

1. In the last week, how would you report your average level of pain with 0 being no pain and 10 being the worst possible pain
2. Do you currently take opioid pain medications on an "As Needed" basis as prescribed by your doctor to help manage your pain?
3. In the last week, how satisfied have you been with your overall pain management (0 being extremely dissatisfied and 10 being extremely satisfied)
4. PROMIS Pain Interference Short Form (see below)

At the end of Weeks 1 and 2

1. In the last week, how would you report your average level of pain with 0 being no pain and 10 being the worst possible pain
2. If you currently take opioid pain medications on an "As Needed" basis as prescribed by your doctor to help manage your pain, how many doses have you taken in the last week?
3. In the last week, how satisfied have you been with your overall pain management, including use of the virtual reality headset (0 being extremely dissatisfied and 10 being extremely satisfied)
4. PROMIS Pain Interference Short Form (see below)

At the end of Week 3

1. In the last week, how would you report your average level of pain with 0 being no pain and 10 being the worst possible pain
2. If you currently take opioid pain medications on an "As Needed" basis as prescribed by your doctor to help manage your pain, how many doses have you taken in the last week?
3. In the last week, how satisfied have you been with your overall pain management, including use of the virtual reality headset (0 being extremely dissatisfied and 10 being extremely satisfied)
4. PROMIS Pain Interference Short Form (see below)
5. In the last week, how would you report your average level of pain with 0 being no pain and 10 being the worst possible pain
6. If you currently take opioid pain medications on an "As Needed" basis as prescribed by your doctor to help manage your pain, how many doses have you taken in the last week?
7. In the last week, how satisfied have you been with your overall pain management, including use of the virtual reality headset (0 being extremely dissatisfied and 10 being extremely satisfied)
8. PROMIS Pain Interference Short Form (see below)
9. Did you find the VR program easy to use (yes/no)?
10. How much did you enjoy the VR program (0 being not at all and 10 being very much)?
11. While you were using the VR headset, how immersed did you feel in the virtual environment. Alternatively, to what extent did you feel like you "went into" the virtual environment (0 being not at all and 10 being very much)?

12. Do you prefer a virtual environment in which you are mostly observing the world around you, or in which you can participate, move around, or engage in activities (active or passive)?
13. Do you prefer a virtual environment that is realistic, such as a video of a real location, or simulated, such as computer-generated graphics (realistic or simulated)?

Data collected from electronic health records:

1. Participant demographics
    a. Age
    b. Sex
    c. Race
    d. Ethnicity
2. Medical history
    a. Cancer type
    b. Time since diagnosis
    c. Analgesic use (on opioids at baseline (Y/N); if yes, if taking short-acting, long-acting, or both; average daily oral morphine equivalents used at the time of enrollment (accounting for the week prior to enrollment) and for the duration of the study period. Daily OMEs will be reported as weekly averages.

Pain Interference – Short Form 6b

Please respond to each item by marking one box per row.

In the past 7 days…

		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAININ3	How much did pain interfere with your enjoyment of life?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ8	How much did pain interfere with your ability to concentrate?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ9	How much did pain interfere with your day to day activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ10	How much did pain interfere with your enjoyment of recreational activities?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAININ14	How much did pain interfere with doing your tasks away from home (e.g., getting groceries, running errands)?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
PAININ26	How often did pain keep you from socializing with others?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Phone Script for Weekly Follow-Up Calls

Hello, my name is _____. I would like to speak with [*participant name].* To ensure I am speaking with the correct individual, would you mind confirming your date of birth and zip code? *Confirm identity using two identifiers, i.e. date of birth and zip code.* Thank you! I am the research coordinator for the Virtual Reality Study you are participating in through the Washington Cancer Institute at MedStar Washington Hospital Center. We had scheduled a call at this time to collect information about your experience with the virtual reality headset and experience with pain in the last week; is this alright time to speak? *If patient says yes, proceed with survey tool. If patient says no, coordinate a time to follow up.*

- *If Yes:* Thank you! I will go through the survey questions with you now. The questions should take approximately 5 to 10 minutes to complete. Please stop me at any time if you need more time or have questions about the survey. *Administer survey tools*.
- *If No:* Thank you for letting me know, what would be a better time to give you a call? The questions should take approximately 5 to 10 minutes to complete. Is this still the best number to reach you at?

At the end of the survey. Thank you for your responses! Do you have any questions or concerns you would like to discuss with me? Please note that you can contact us at any time if issues arise later on. You have completed Week *X* of the study and have *X* week(s) remaining. We would like to remind you that for Week *X,* you will be using the VR headset for 10 minutes (*once a day/twice a day/as often as you wish)*. We will give you another call at the end of the week to review the survey questions. What would be a good time for me to call you at the end of the week? *Confirm day 7 and follow-up time as well as best contact information*.

Thank you! That concludes our follow-up call for Week *X*. We will contact you again at *scheduled date and time*, however you may reach out to us at any point if you have questions or concerns. *Confirm participant has contact information for research team*. Have a good *morning/afternoon/evening.*