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Can virtual reality help reduce pain during wound care? A pilot study at the Maimonides Geriatric Centre

Submission date 15/07/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/11/2025	**Overall study status** Ongoing	
Last Edited 07/11/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This pilot study addresses the problem of pain during wound care for pressure ulcers (PUs) in long-term care (LTC) residents, which in and of itself is a serious issue, but which can also lead to symptoms like agitation and depression. It proposes using immersive virtual reality (iVR), specifically the Rendever platform, as a non-pharmacologic pain reduction tool during wound care sessions

Who can participate?
Residents who have lived at the Donald Berman Maimonides Geriatric Centre (CHSLD) for at least 2 months who have received wound care for PUs

What does the study involve?
The study includes a baseline phase, a 2-week intervention phase with an iVR headset, and a washout phase. Pain and symptoms are assessed before, during, and after each wound care session. A future component may include physiological monitoring using a wearable device.

What are the possible benefits and risks of participating?
Possible benefits include reduced pain, agitation, and depression, and enjoyment of iVR as a novel experience. Possible risks include mild side effects like dizziness. If any signs of distress occur, the participant will be withdrawn. iVR sessions are limited to green-coded (low-stimulation, low-intensity) content to minimise adverse reactions.

Where is the study run from?
Donald Berman Maimonides Geriatric Centre (Canada)

When is the study starting and how long is it expected to run for?
January 2025 to August 2026

Who is funding the study?
The Maimonides Medical Research Foundation (Canada)

Who is the main contact?
Dr Machelle Wilchesky, machelle.wilchesky@mcgill.ca

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Machelle Wilchesky

ORCID ID
https://orcid.org/0000-0003-4138-009X

Contact details
5795 Avenue Caldwell
2D-02
Montreal
Canada
H4W 1W3
+1 (0)5144832121
machelle.wilchesky@mcgill.ca

Type(s)
Public

Contact name
Ms Stephanie Ballard

Contact details
5795 Avenue Caldwell
Montreal
Canada
H4W 1W3
+1 (0)5144832121
stephanie.ballard@ssss.gouv.qc.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The pain reduction using immersive virtual reality during wound care evaluation study at Maimonides (PRISM) – pilot study

Acronym
PRISM

Study objectives
Primary objectives:
1. To assess the use of immersive virtual reality (iVR) as a clinical tool for pain relief during wound care for pressure ulcers in the Donald Berman Maimonides Geriatric Centre (CHSLD) setting, as measured by behavioral tools (PACSLAC-II and PAINAD) and self-report (NPRS, where applicable).
2. To assess the feasibility and acceptability of using iVR as a clinical tool for pain relief during episodes of wound care for pressure ulcers in the CHSLD setting, based on feedback from staff involved in wound care.

Secondary objectives:
1. To assess whether the use of iVR in this context concurrently reduces agitation/aggression and depression/dysphoria, both neuropsychiatric symptoms that are prevalent among CHSLD residents, as measured by the NPI-NH.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 29/01/2025, Research Review Office of CIUSSS du Centre-Ouest-de-l'Île-de-Montréal (Jewish General Hospital, A-903 3755, Chemin de la Côte-Sainte-Catherine, Montreal, H3T 1E2, Canada; +1 (0)514 340 8222, local 22445; cer@jgh.mcgill.ca), ref: 2025-4494

Study design
Within-subject crossover study

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Pain, depression, agitation/aggression

Interventions
Data will be collected to understand the overall feasibility, acceptability, and efficacy of using iVR during wound care episodes at Donald Berman Maimonides Geriatric Centre. We will obtain informed consent from a sample of up to 20 residents (or their legal representatives) to pilot the use of iVR for pain management during episodes of wound care over a 6-week period. We will use a within-subject crossover design, where each resident will serve as their own control. Such designs eliminate confounding, given that each participant acts as their own unique control while also increasing statistical power.

Pain measurements will be conducted from the same participant during three time periods:
Phase I: 2 weeks of wound care without iVR exposure (the baseline period)
Phase II: 2 weeks of wound care with iVR exposure (the intervention period)
Phase III: 2 weeks of wound care but again without iVR exposure (the washout period)

During each time period, we will collect data pertaining to pain at three points in time:
Time Point 1: 1 hour before the commencement of a wound care episode
Time Point 2: During the care episode
Time Point 3: 1 hour after the wound care episode has been completed

Pain will be measured using the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC-II), the Pain Assessment in Advanced Dementia (PAINAD) validated pain scales, and the Numeric Pain Rating Scale (NPRS), all of which are validated pain scales. The NPRS will only be used with participants who are cognitively intact, and this measure will be obtained in addition to the PACSLAC-II and the PAINAD.

Given the association between pain and neuropsychiatric symptoms of dementia (NPS), we will also measure two common NPS domains (i.e., agitation/aggression and depression) using the Neuropsychiatric Inventory Nursing Home Version (NPI-NH), a validated tool used to assess these symptoms in LTC settings the NPI-NH requires caregiver respondents to provide information concerning the presence or absence of NPS over the span of a pre-specified period. As such, NPS data will be collected at 2-week intervals throughout the entire span of the study, with an additional data collection point occurring after the study has ended.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rendever immersive virtual reality

Primary outcome(s)
Pain measured using the Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC-II) at three points in time:
Time Point 1: 1 hour before the commencement of a wound care episode
Time Point 2: During the care episode
Time Point 3: 1 hour after the wound care episode has been completed

Key secondary outcome(s))
Pain measured using the Pain Assessment in Advanced Dementia (PAINAD) validated pain scales at three points in time:
Time Point 1: 1 hour before the commencement of a wound care episode
Time Point 2: During the care episode
Time Point 3: 1 hour after the wound care episode has been completed

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Living in the long-term care centre for at least 2 months prior to the start of the study
2. Receiving regular wound care for PUs, as per the recommendation of the wound care nurse, and reflected in the resident's nursing care plan
3. Able to tolerate iVR, based on consultations with the Recreation Technology team and the research team's preliminary study visit with the resident

Participant type(s)
Resident

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
110 years

Sex
All

Key exclusion criteria
1. Diagnosis of blindness, severe cataracts or glaucoma
2. Having allergies to synthetic plastic
3. Having skin conditions or wounds on both wrists, or on the head/ears, which impact the wearability of the headset
4. Diagnosis of neuropathy
5. Exhibiting behavior within the past 30 days that has endangered or posed a significant safety risk to regular care staff during routine care activities (e.g., wound care or personal hygiene assistance)
6. Must be able to understand English or French

Date of first enrolment
17/11/2025

Date of final enrolment
30/08/2026

Locations

Countries of recruitment
Canada

Study participating centre

Donald Berman Maimonides Geriatric Centre
5795 Avenue Caldwell
Montreal
Canada
H4W 1W3

Sponsor information

Organisation
The Integrated Health and Social Services University Network for West-Central Montreal (CIUSSS West-Central Montreal)

Funder(s)

Funder type
Charity

Funder Name
The Donald Berman Maimonides Medical Research Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes