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Two virtual reality apps for pain during venous leg ulcer dressing changes: randomized clinical trial

Submission date
12/01/2026

Recruitment status
Recruiting

Registration date
13/01/2026

Overall study status
Ongoing

Last Edited
13/01/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Venous leg ulcers are chronic wounds that often require regular dressing changes, which can be painful and distressing. Immersive virtual reality (VR) may reduce procedural pain by providing distraction and relaxation during the procedure. The aim of this study is to compare two immersive VR applications — Guided Meditation VR (passive viewing of scenes) and Nature Treks VR (interactive, allowing modification of the virtual environment) — for reducing pain during venous leg ulcer dressing changes.

Who can participate?
Adults aged 18 years and over with a venous leg ulcer who require dressing changes

What does the study involve?
Participants will be randomly allocated to one of two groups:
Group 1: Guided Meditation VR (passive viewing of calming virtual scenes).
Group 2: Nature Treks VR (interactive VR with the ability to modify the virtual world).
Before the dressing change, participants will wear the VR headset for 5 minutes to acclimatize then continue using VR throughout the dressing change. Standard wound care will be provided as usual. Pain will be recorded immediately before VR and immediately after completion of the dressing change with VR. Any VR-related discomfort will be recorded.

What are the possible benefits and risks of participating?
Possible benefits include reduced pain and anxiety during dressing changes and a more comfortable experience. There may be no direct benefit for every participant.
Possible risks include temporary VR-related side effects such as dizziness, nausea, eye strain, headache, or discomfort from wearing the headset. If a participant feels unwell, VR can be stopped at any time and standard care will continue.

Where is the study run from?
Surgical Outpatient Clinic and Healthcare Centre of Jan Paweł II District Hospital in Włoszczowa (Poland)

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

Who is funding the study?
Jan Dlugosz University in Czestochowa (Uniwersytet Jana Długosza w Częstochowie) (Poland)

Who is the main contact?
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Study information

Scientific Title
Procedural pain during dressing changes in adults with venous leg ulcers: a prospective, parallel-group randomized clinical trial comparing two immersive virtual reality interventions (Guided Meditation VR vs Nature Treks VR)

Acronym
VLU-VR

Study objectives
The primary objective of this randomized, parallel-group clinical trial is to compare the effect of two immersive virtual reality (VR) applications (Guided Meditation VR versus Nature Treks VR) on procedural pain intensity during venous leg ulcer dressing changes, measured using a numeric rating scale (NRS, 0–10).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/05/2023, Research Ethics Committee of the Jan Dlugosz University in Czestochowa (Jerzego Waszyngtona 4/8, Częstochowa, 42-217, Poland; +48 (0)34 3784 100; kancelaria@ujd.edu.pl), ref: KE-U/6/2023

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Venous leg ulcers

Interventions
Participants will be randomized 1:1 using a computer-generated random sequence. Allocation will be concealed using sequentially numbered, opaque, sealed envelopes, which will be opened only after participant enrolment.

VR acclimatization (both groups):
Before the dressing change starts, participants will wear the VR headset for 5 minutes to acclimatize to the virtual environment. The dressing change will then be performed while the participant continues using VR.

Group 1 (n = 25): Guided Meditation VR (passive immersive VR)
Participants will use Guided Meditation VR, in which they can passively view and experience different virtual sceneries/environments during the procedure, without interactive modification of the virtual world.

Group 2 (n = 25): Nature Treks VR (interactive immersive VR)
Participants will use Nature Treks VR, in which they can view virtual natural environments and additionally interact with and modify elements of the virtual world (interactive features) during the procedure.

Pain assessment (both groups):
Procedural pain intensity will be assessed using a numeric rating scale (NRS, 0–10) immediately before VR exposure and immediately after completion of the dressing change/VR exposure.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not applicable

Primary outcome(s)
1. Pain intensity measured using Numeric Rating Scale (NRS, 0–10) at immediately before VR exposure (baseline) and immediately after completion of the dressing change/VR exposure

Key secondary outcome(s))

Completion date
19/06/2026

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years
2. Diagnosis of venous leg ulcer (VLU) requiring wound dressing changes
3. Able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

50 years

Upper age limit
75 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Inability to provide informed consent (e.g., significant cognitive impairment)
2 .Non-venous aetiology of the leg ulcer (e.g., primarily arterial, diabetic/neuropathic, vasculitic) or mixed aetiology where venous ulcer is not the primary diagnosis
3. Contraindications to immersive VR use, including a history of epilepsy/seizures or other conditions where VR is not recommended
4. Severe motion sickness/known intolerance to VR (e.g., severe dizziness, nausea)
5. Severe visual or hearing impairment preventing effective use of the VR intervention
6. Acute medical instability or clinical condition during the dressing change that makes participation unsafe (as judged by the clinician)

Date of first enrolment
19/01/2026

Date of final enrolment
19/06/2026

Locations

Countries of recruitment
Poland

Sponsor information

Organisation
Jan Długosz University

ROR
https://ror.org/0566yhn94

Funder(s)

Funder type

Funder Name
Uniwersytet Humanistyczno-Przyrodniczy im. Jana Długosza w Częstochowie

Alternative Name(s)
Jan-Długosz-Universität Częstochowa, Uniwersytet Humanistyczno-Przyrodniczy im. Jana Długosza, Jana Długosza w Częstochowie, Jan Dlugosz University in Czestochowa, Jan Długosz University, UJD, JDU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available