ISRCTN16621834 https://doi.org/10.1186/ISRCTN16621834

Virtual Reality for pain and fear relief in wound care

Submission date
15/03/2021

Recruitment status
No longer recruiting

Registration date
01/04/2021

Overall study status
Completed

Last Edited
06/04/2021

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Virtual Reality (VR) assisted wound care procedures may reduce pain and fear in patients undergoing these procedures. Additionally the use of VR technology may mean that patients need less pain relief and anxiety reducing medication than conventional wound care without VR. This has been shown in several focused studies with a small patient sample size (less than 50 participants). Use of VR is limited by the availability of resources in daily clinical care and therefore the number of patients who have the potential to be treated with VR remains unknown.

This study will assess children and adults admitted to theUZLeuven Intensive Care and Burn Unit for good candidates for successful VR application, where clinical care, human resources, and logistics to provide VR technology will be available for the study period. This study will identify the clinical and psychological characteristics of the best candidate-patients for VR during wound care, and will compare patient anxiety, fear, and drug requirements during VR-assisted wound care procedures to conventional wound care procedures. This will allow the study team to estimate the potential effect size of the intervention and to model the potential health economic impact of generalized implementation in Belgian Burn centers.

The study team also hope to will broaden the study to evaluate the maximum range of motion (ROM) during passive joint movement by a research physiotherapist with and without VR assistance. Furthermore, the study team may extend the study to evaluate the long-term medical and psychological outcome of this study cohort.

Who can participate?
Child and adult patients admitted to the UZLeuven Intensive Care and Burn Unit or patients selected in Pediatric Intensive Care Unit, Outpatient Burn Care, or Emergency Department who require wound care

What does the study involve?
All selected participants will receive Virtual Reality (VR) which can provide simple distraction through a film or game or VR-assisted hypnosis. The VR-technology will be explained and applied by trained study collaborators on the day before the planned wound care procedure.

Participants will be evaluated for their anxiety, fear, and drug requirements during the wound care procedure and asked if they would choose VR assistance again during (hypothetical) subsequent wound care sessions.

What are the possible benefits and risks of participating?
Potential benefits of participating are a reduction in the experience of pain and fear and reduced requirements for pain relief and sedation before wound care procedures. VR may also help with movement of the affected limb. There is a limit risk that VR may induce nausea.

Where is the study run from?
The UZLeuven Intensive Care and Burn Unit (Belgium)

When is the study starting and how long is it expected to run for?
From January 2020 to December 2022

Who is funding the study?
The Flemish Government, Department of Innovation (Belgium) and the Leuven University Hospitals (Belgium)

Who is the main contact?
Prof. Dr. Michael Casaer, michael.casaer@uzleuven.be

Contact information

Type(s)
Scientific

Contact name
Prof Michael Casaer

ORCID ID
https://orcid.org/0000-0002-7087-0795

Contact details
University Hospitals (UZLeuven/KULeuven)
Catholic University Leuven
Herestraat 49
Leuven
Belgium
3000
+32 16348786
Michael.Casaer@UZLeuven.be

Additional identifiers

Protocol serial number
S63103

Study information

Scientific Title
Determination of size and characteristics of the target population for the successful application of Virtual Reality during painful (wound) procedures: a prospective non-randomized interventional study

Acronym
VR-BWC-I

Study objectives
1. To quantify and characterize (clinically and psychologically) the proportion of patients admitted to the Burn Center eligible for successful VR therapy during wound care. Successful VR defined as the patient accepting VR and completing the entire wound care procedure under VR assistance and would choose again for VR assistance during (hypothetical) subsequent wound care session(s).
2. Non-randomized estimation of the potential magnitude of the impact of VR-assisted wound care procedures on pain, fear, analgesic and anxiolytic drug needs based on patients who underwent both VR-assisted and (for logistical reasons) “conventional” procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/12/2019, Ethical Committee UZ/KULeuven (Herestraat 49, B-3000 Leuven, Belgium; +32 16348600; ec@uzleuven.be), ref: s63103 B322201941190

Primary study design
Interventional

Study design
Prospective non-randomized interventional study within a project of improvement of quality of clinical care

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Burns and other traumatic, infectious, or immune-mediated skin and soft tissue lesions

Interventions
All participants will receive Virtual Reality (VR) aimed at inducing distraction and/or dissociation and reducing procedural pain and fear. VR-technology will be explained and applied by trained study collaborators on the day before the planned wound care procedure.

The VR-material in this project is the Oncomfort Sedokit, it is designed and approved for medical sedation. The Sedokit can provide simple distraction through a film or game or VR-assisted hypnosis.

Successful VR defined as the patient accepting VR and completing the entire wound care procedure under VR assistance and would choose again for VR assistance during (hypothetical) subsequent wound care session(s).

Non-responders include patients in whom VR “is technically possible, but is not accepted by the patient (and/or proxies) or in whom the entire wound care procedure cannot be completed under VR assistance.”

Upon inclusion in the study the following baseline clinical data will be collected:
1. Demographics
2. Wound specific parameters, including Laser Doppler Scan Imaging (LDI) assessment (if available) of wound surface and healing potential, clinician-estimated Burned Surface Area (BSA) in % of total body surface area (TBSA), location and mechanism of burn, trauma or disease provoking the lesion, and the number of days since the initial wound occurred and since burn center admission will be registered.
2. Self-control assessed in a standardized manner by a short, age-adapted introduction, question, and answers on a Likert scale. The result will be registered directly in the eCRF.
3. Socio economic status (SES) will be addressed through the KWS Clinical Work Station social module , including highest educational degree, salary or other income , living together or not, and feeling supported by cohabitants or not
4. Psychological variables assessing anxiety, traumatic stress, and depression will be collected. For these variables, validated questionnaires will be presented to patients and stored in My Nexus (clinical file) as primary source and the appropriate summary data will be manually or automatically transferred to the eCRF:
4.1. The Mini Mental State Examination (MMSE) will evaluate cognitive problems among patients >18 years
4.2. Post Traumatic Stress Disorder (PTSD) will be assessed with the Impact of Event Scale (IES)
4.3. Common mental disorders will be assessed with the Composite International Diagnostic Interview- Screening Scales (CIDI-SC) that assesses DSM-5 criteria for common mental disorders such as major depressive disorder, panic disorder, or generalized anxiety disorder
4.4. The Alcohol Use Disorders Identification Test (AUDIT) will be used to identify patients engaging in “risky or hazardous drinking” and to identify patients with “risk for alcohol dependence”
4.5. Among minors, the Strength and Difficulties Questionnaire (SDQ) will be administered in order to assess emotional problems
4.6. The Child Trauma Screening Questionnaire (CTSQ) will be used for participants aged 6-16 years old.

Participants will be assessed using self-reported questionnaires administered via My Nexus. In case of patient difficulties with filling out these questionnaires, a research collabroator will assist patients administering the questionnaires and obtaining self-reported data. Answering the surveys will take each patient around 20 mins. The automatic data collection for psychological variables will be implemented into the NEXUS framework of UZLeuven and will be following the same process as the one in the Leuven College Surveys for which approval of the ethical committee was granted in the past. If the My Nexus platform is not be ready at the initiation of the study, the answers to the questions will be stored on standardized forms that will be securely stored and entered a posteriori into the platform. Applicable scores and components will be transferred from NEXUS to the eCRF.

Intervention Type
Device

Phase
Phase IV

Primary outcome(s)

1. Proportion of patients successfully completing procedures with VR within all patients admitted measured from eCRF records collected at the end of the study
2. Fraction of wound care procedures successfully conducted with VR within all procedures measured from eCRF records collected at the end of the study
3. Predictability of successful VR based on psychological variables and baseline clinical characteristics measured using scored in real time by the study psychologist or study nurse in the eCRF after the procedure

Key secondary outcome(s)

1. Extent to which the patient has the experience to be present in “another world” due to diverted attention (potentially related to analgesic and anxiolytic effect) measured using the question "To what extent did you feel you ‘went into” the virtual world?" (not at all/not really /undecided/somewhat/very much) after each procedure
2. Persistence of the analgesic and anxiolytic effect and patient satisfaction in patients undergoing multiple VR sessions measured using the questions "To what extent did you feel the VR equipment was easy to use?" (not at all/not really/undecided/somewhat/very much), "Have you enjoyed the VR session?" (not at all/not really/undecided/somewhat/very much), "How satisfied were you with the virtual reality system during your dressing change?" (not at all/not really/undecided/somewhat/very much), and "If you would need wound care tomorrow would you like to have VR assistance again?” (yes/no, if no participants will be asked to provide the reason why not) after each procedure; participants will also be asked for their overall satisfaction with the VR equipment (not at all/not really/undecided/somewhat/very much) at the end of the study
3. Healthcare provider satisfaction with VR measured using the following at the end of the study:
3.1. Nurse satisfaction measured using the questions "To what extent did you feel the VR equipment was easy to use?" (not at all/not really/undecided/somewhat/very much) and "To what extent did you feel the VR equipment interfered with clinical care?" (not at all/not really /undecided/somewhat/very much)
3.2. Physiotherapists’ satisfaction (only for procedures with research physiotherapists available) measured using the questions "To what extent did you feel the VR equipment was easy to use?" (not at all/not really/undecided/somewhat/very much) and "To what extent did you feel the VR equipment interfered with clinical care?" (not at all/not really/undecided/somewhat/very much)
4. Detailed Patient and Caregiver satisfaction with VR measured in a convenience sample at the end of the study
5. In patients who undergo repeated procedures with and without VR-assistance the following will be measured:
5.1. Difference in drug requirements recorded in the Patient Data Management System (PDMS) during the procedure
5.2. Observed and self-reported pain and anxiety measured using:
5.2.1. The numeric rating scale for anxiety (NRS-A) and numeric rating scale for pain (NRS-P) during the procedure, the FLACC (Face, Legs, Activity, Cry, Consolability) scale will be used before, during, and after the procedure
5.2.2. For children, the Faces Pain Scale, and fear thermometer during the procedure
5.3. Heart Rate and Respiratory Rate monitored in the Patient Data Management System (PDMS) from the bedside/procedure room monitor and minimal and maximal levels recorded throughout the procedure
6. Potential Health Economy impact based on differences in drug requirements and on the material and HR-related costs for providing VR to all eligible patients

On condition that a research physiotherapist is financed:
1. Difference in obtained Range Of Motion (ROM) measured by the study physiotherapist during passive joint mobilization in a selected subgroup of patients

On condition of additional funding:
1. Patient physical recovery, emotional well-being, residual pain and discomfort, presence of PTSD, and feeling of self-control measured using a short survey at 6 months

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Mental age ≥6 years
2. Need for wound care
3. Admitted to E519 (Burn center unit) or ad-hoc patients selected in Pediatric Intensive Care Unit, Outpatient Burn Care, or Emergency Department
4. Able to communicate in Dutch, English, French language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Deaf
2. Blind
3. Schizophrenia, advanced dementia, dissociative disorder, or serious claustrophobia
3. Lesions exclusively in the facial area, precluding VR application during wound care
4. Permanent hypoesthesia in the affected area
5. No informed consent given

Date of first enrolment
06/01/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Belgium

Study participating centre
UZLeuven
University Hospitals Catholic University Leuven
Herestraat 49
Leuven
Belgium
3000

Sponsor information

Organisation
Universitair Ziekenhuis Leuven

ROR
https://ror.org/0424bsv16

Funder(s)

Funder type
Government

Funder Name
Vlaamse regering

Alternative Name(s)
Flanders, Flemish Government, Flandre, Flandern, Vlaanderen

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Belgium

Funder Name
Universitaire Ziekenhuizen Leuven, KU Leuven

Alternative Name(s)

University Hospital Leuven, KU Leuven, UZ Leuven

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository The research database (eCRF) will be hosted on the University Hospitals Leuven servers. This closed network is only accessible for employees and affiliated persons which have to use a personal login and password to log into the system. Equipment can only have access to the network after registration/installation by the central ICT service. The hospital network is protected by a firewall but authorized research staff can access the network over the internet using a secure SSL-solution with one-time passwords (using a Vasco Digipass or Google Authenticator).
The firewall and external access procedure has been audited and approved by Ubizen and Deloitte.

The research database resides on the central servers with mirrored or RAID5 system disks and has hourly backups. The database is written in FilemakerPro and is login/password protected. An access log and audit trail are available.

For reasons of data integrity and internal control name and hospital number are stored in a separate table linked to the eCRF, but these data will be only accessible for the concerned Research staff and the principal database manager on a login/password base. When the database is finalized, those data will be detached from the eCFR and stored at the local site

No data will be made available unconditionally in the public space. The participant level data of this clinical study will not be publicly available. This would be a potential source of erroneous findings due to inadequate interpretation of the study design and would not be covered by the consent given by the patients. The data will be stored in the research database of the Clinical Department and Laboratory of Intensive Care Medicine and request for post-hoc analyses with a clearly defined research question and methodology can be sent to the investigators. Email Michael.casaer@uzleuven.be This approach to avoid misinterpretation of complex data and databases has been proposed in a recent summit on data sharing organized by the NEJM in April 2017 where Prof. Dr. Greet Van den Berghe Chair of the Clinical Department and Laboratory of Intensive Care Medicine contributed.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/04/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes