Virtual Pain Care; The effectiveness of Virtual Reality Therapy on reducing pain, and anxiety during complex wound care procedures in adults

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To assess whether the use of Virtual Reality Therapy can reduce pain, and anxiety than without Virtual Reality Therapy in patients undergoing complex wound care procedures.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON56062

Source
ToetsingOnline

Brief title
Virtual Pain Care

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Pain and Anxiety

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Pain, Virtual Reality, Wound care

Outcome measures

Primary outcome

Pain score measured with the VAS-score

Secondary outcome

- Level of anxiety, measured with the STAI-6 questionnaire

- Length of hospital stay

- Patient and provider satisfaction, measured with questionnaires

- Blood pressure

- Heart rate

- Saturation

- Respiratory rate

Study description

Background summary

Pain is the most common clinical symptom of tissue damage. Wound-related pain is usually experienced as physically and emotionally unpleasant and is unique to each individual, which can cause stress and lead to adverse effects on wound healing and the patient's anxiety. Therefore, adequate pain and anxiety management during wound care is important. The use of (more) pain medication, such as opioids, has side effects. It is therefore important to be able to offer patients effective alternatives.

Virtual Reality system generate an immersive virtual environment, which can lead to audiovisual distractions.

This research addresses the potential benefits of use of the Virtual Reality system in terms of pain reduction, and reduction of anxiety, during complex

wound care procedures.

Study objective

To assess whether the use of Virtual Reality Therapy can reduce pain, and anxiety than without Virtual Reality Therapy in patients undergoing complex wound care procedures.

Study design

Randomized Clinical Trial.

Alter the patient has decided to participate in the study, it is randomly determined to which group the patient belongs:

- Group 1 (Intervention group 1): The intervention group 1 wears the Virtual Reality system (glasses + headphone) during the wound care moment, where they can choose from a number of themes/videos. This group wears the Virtual Reality system 10 minutes before the start of the wound care, until 1 minute after the wound care has ended.

- Group 2 (control group): The control group receives no Virtual Reality Therapy.

Patients who have experienced at least 1 wound care moment, where they have indicated a VAS equal to 4 or higher, or patients reporting a VAS >= 4 before initiating the wound care procedure, can participate in the study. After they have decided to participate, they are examined during 1 to 3 wound care moments.

Before and alter the wound care moment, both groups are asked to indicate the pain score according to the VAS score, to complete the validated questionnaire about anxiety (STAI-6) and the satisfaction questionnaire. A maximum of 7 questionnaires will be administered in total.
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Heart rate, respiratory rate and saturation are measured every 5 minutes during wound care in both groups (intervention- and control group). Blood pressure, heart rate, respiratory rate and saturation are also measured 5 minutes before, and 5 minutes after the wound care procedure.

Patients are prescribed the basic pain medication according to the WHO pain ladder as standard: paracetamol and/or NSAIDs. At the request of the patient, patients can receive escape pain medication.

Intervention

Group 1 (intervention group 1): The intervention group 1 wears Virtual Reality system during the wound care moment, where they can choose from a number of themes. This group wears the Virtual Reality system 10 minutes before the start of the wound care, until 1 minute alter the wound care has ended.

Group 2 (control group): The control group receives no Virtual Reality Therapy during wound care.

Study burden and risks

All patients who decide to participate in the study will be asked to indicate their pain score (VAS) before and after wound care, and asked to complete questionnaire investigating anxiety (STAI-6). In both groups, blood pressure, heart rate, saturation and respiratory rate are measured 5 minutes before wound care. During wound care, heart rate, saturation and respiration rate are measured every 5 minutes. These vital signs are measured again 5 minutes after wound care has ended. In total, a minimum of 1 to a maximum of 3 wound care procedures will be included in the study. After the third wound care procedure all participants are requested to fill out the patient satisfaction questionnaire. A maximum of 7 questionnaires will be administered in total. In total, this study will take approximately 180 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Individuals aged 18 or older with wounds receiving wound care
- Individuals who will undergo minimum of 1 to 3 sequential complex wound care* procedures
- At least 1 prior painful wound care procedure, where they have indicated a VAS >= 4, or patients reporting a VAS >= 4 before initiating the wound care procedure.

*Complex wound care: Wound care deemed fit for conservative wound care (based on wound properties, such as: cause, location, size, the necessary intervention), including necrosectomy at the hospital ward as per regular wound care protocol

Exclusion criteria

- Individuals not being able to understand Dutch language at primary school level
- Individuals not being able to read or write Dutch
- Individuals diagnosed with dementia and/or cognitive impairment
- Individuals diagnosed with epilepsy
- Individuals diagnosed with migraine
- Individuals with severe dizziness and/or nausea
- Individuals with a known history of claustrophobia
- Individuals who are unable to sign informed consent owing to mental disorder or formally stated to be incompetent to decide
- Individuals who have no feeling in the wound care area
- Individuals with physical (and/or cognitive) disabilities on the face, eye, ear, nose and neck that prevent the use of the VR headgear and/or headphones

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2023
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	VRelax
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-01-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82360.029.22