# Non-pharmacological Pain Care using Virtual Reality Therapy or Music Therapy during complex wound care in adults

Published: 01-11-2022
Last updated: 21-12-2024

The main objectives of this study are to investigate to what extent:1) VRT and MT can contribute to pain reduction compared to patients who receive no VRT and MT intervention during complex wound care; and2) VRT can contribute to pain reduction...

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

## Summary

### ID

NL-OMON53602

**Source**
ToetsingOnline

**Brief title**
Non-pharmacological pain care during complex wound care procedures.

### 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, Music therapy, Pain, Virtual Reality

## 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

Wound-related pain is common and is usually experienced as both physically and emotionally unpleasant. Pain can cause stress which can negatively affect wound healing and the patient's quality of life. Opioids are mostly used for pain management. However, opioids have side effects, risk of dose tolerance and risk of drugs dependence. Therefore, it is important to be able to offer patients effective alternatives, such as non-pharmacological pain relief through distraction. Virtual Reality therapy and Music therapy are one of these non-pharmacological interventions. Previous research has shown that Virtual Reality therapy and Music therapy have a positive effect on pain, anxiety and opioid use.

This study investigates the extent to which Virtual Reality glasses and Music therapy can contribute to less pain, and less anxiety compared to patients who receive no intervention during complex wound care. And to investigate to what

extent VRT can contribute to pain reduction compared to patients receiving MT.
In addition, it is examined which of the two interventions is preferable.

## Study objective

The main objectives of this study are to investigate to what extent:

1) VRT and MT can contribute to pain reduction compared to patients who receive no VRT and MT intervention during complex wound care; and
2) VRT can contribute to pain reduction compared to patients receiving MT

In addition, it is examined which of the two interventions is preferable.

## Study design

Randomized Clinical Trial

After 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 Virtual Reality glasses during the wound care moment, where they can choose from a number of themes. This group wears the Virtual Reality glasses 10 minutes before the start of the wound care, until 1 minute after the wound care has ended.
- Group 2 (intervention group 2): The intervention group 2 wears a headphone with music, where they can choose their own music. This group wears the headphone with music 10 minutes before the start of the wound care, until 1 minute after the wound care has ended.
- Group 3 (control group): The control group receives neither Virtual Reality glasses nor Music Therapy during wound care.

Patients who have experienced at least 1 wound care moment, where they have indicated a VAS equal to 4 or higher, can participate in the study. After they have decided to participate, they are examined during 1 to 3 wound care moments. Before and after 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.
During the wound care moment, the mean heart rate, blood pressure, respiratory rate and saturation are recorded for both groups.
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

glasses during the wound care moment, where they can choose from a number of themes. This group wears the Virtual Reality glasses 10 minutes before the start of the wound care, until 1 minute after the wound care has ended.
Group 2 (intervention group 2): The intervention group 2 wears a headphone with music, where they can choose their own music. This group wears the headphone with music 10 minutes before the start of the wound care, until 1 minute after the wound care has ended.
Group 3 (control group): The control group receives neither Virtual Reality glasses nor Music Therapy during wound care.

**Study burden and risks**

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 questionnaires investigating anxiety (STAI-6) and satisfaction (patient satisfaction questionnaire). Blood pressure, heart rate, saturation and respiratory rate are measured 5 minutes before wound care. During wound care, heart rate, satiety and respiration 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.

# Contacts

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**Scientific**
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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 having wounds receiving wound care
- Individuals who will undergo minimum of 1 to a maximum of 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

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| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 17-11-2022 |
| Enrollment: | 72 |
| Type: | Actual |

### Medical products/devices used

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| Generic name: | SyncVR Relax & Distract; Virtual Reality application for reducing pain;anxiety and stress in healthc |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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| Date: | 01-11-2022 |
| Application type: | First submission |
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br><br>Kamer G4-214<br><br>Postbus 22660<br><br>1100 DD Amsterdam<br><br>020 566 7389<br><br>mecamc@amsterdamumc.nl |

Approved WMO

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|---|---|
| Date: | 16-11-2023 |
| Application type: | Amendment |

| | |
|---|---|
| Review commission: | MEC Academisch Medisch Centrum (Amsterdam)<br>Kamer G4-214<br>Postbus 22660<br>1100 DD Amsterdam<br>020 566 7389<br>mecamc@amsterdamumc.nl |

# 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 | NL82062.018.22 |