Virtual Reality therapy for pain management at the Emergency Department

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53184

Source
ToetsingOnline

Brief title
VRxOPUS-2

Condition

- Other condition

Synonym
acute pain

Health condition

acute pijn door enige oorzaak

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute pain, Emergency Department, Pain management, Virtual Reality

Outcome measures

Primary outcome

NRS scores of pain at rest, repeated

Secondary outcome

Anxiety

- NRS anxiety scores, repeated

Analgesics

- Oral Morphine Equivalent (OME)

- Administered analgesics at the ED and type

- Administered non-pharmacological analgesia (eg. casting, reduction of

fracture)

Patient reported outcome measures

- Acceptability of pain at discharge (yes/no)

- Patients desire for analgesics upon admittance and at discharge (yes/no)

- NRS immersion score

- Satisfaction with pain management (NRS-scale)

Process indicators

- Duration ED visit

Follow-up (diary)

- Analgesic prescriptions by emergency physician

Safety outcomes

- Reasons for withdrawal

- Adverse events during VR therapy

Barriers to implementation

- Technical problems

- Feedback on apps

Study description

Background summary

Analgesics prescriptions, especially opioids, have doubled in the Emergency department (ED) over the past decades to control for frequently reported undertreatment of pain in ED patients. Consequently, there is a shift towards reduced used of opioids at the ED. However, there are still few non-pharmacological alternatives.
Virtual Reality (VR) is a relatively new and promising technique in non-pharmacologic pain reduction and anxiolysis. VR based on distraction (VRD) is the most widely described form of VR therapy and shows positive results on pain relief and reduces opioids use. VR based on focussed attention (VRF) is a relatively new modality based on the principles of therapeutic communication, which differs itself from distraction by the involved focussed attention and is well described for pain management. We hypothesize that both VR is effective for reducing pain scores and analgesics use at the ED.

Study objective

Primary objective is to investigate the effect of VR on patient-reported pain outcomes in the ED. Secondary objectives are to investigate the effect of VR on analgesics use, patient-reported outcomes, and process indicators and to identify barriers to implementation.

Study design

Randomized controlled trial

Intervention

One group will receive usual care, the intervention group will receive VR, being VR based on distraction or VR based on focussed attention.

Study burden and risks

Participants in the intervention groups may benefit in the form of improved pain management and reduced anxiety, and they might need less pharmacologic analgesia reducing the risk of side-effect from analgesics. The results from this study will provide new insight in possible use of new non-pharmacological pain management options in the ED. The risks for participants are negligible. We expect no or only minimal adverse effects from the VR intervention. Participants in the intervention group will not be withheld *usual* analgesia. The burden of the participants associated with this study is related to the measurement of endpoints, which will include every hour a few short questions about pain experience and anxiety, and upon admittance and at discharge some additional questions about patient characteristics, satisfaction, and experience with the intervention.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient >=16 years admitted to ED
- NRS pain at rest score >=4
- Pain not acceptable for patient
- Patient is willing and able to comply with the study protocol

Exclusion criteria

- Patients initially treated by another physician than the EP.
- EMV < 14
- History of dementia, seizures
- Severe hearing/visual impairment not corrected
- Headwounds or damaged skin with which comfortable and hygienic use is not possible.
- Presentation to ED because of chronic pain (>=3 months) exacerbation
- Chronic opioid use (>=3 months)
- Psychiatric disorders interfering with patients* understanding of the study protocol and informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2023
Enrollment:	124
Type:	Actual

Medical products/devices used

Generic name:	Virtual reality headset;software of syncVR medical and HypnoVR
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-09-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL84480.091.23