

The effect of watching a movie with videoglasses and a headset on pain, anxiety and satisfaction of patients who need a wrist fracture reduction in the Emergency Department

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20686

Source

Nationaal Trial Register

Brief title

eMOVIE

Health condition

wrist fracture, distal radius fracture, audiovisual, immersion, pain, anxiety, satisfaction, emergency department

Sponsors and support

Primary sponsor: University Medical Center Amsterdam, location AMC

Source(s) of monetary or material Support: University Medical Center Amsterdam, location AMC

Intervention

Outcome measures

Primary outcome

Pain perception is measured using the VAS. The VAS-P is an 11 point scale ranging up from 0 to 10. With 0 indicating “no pain” and 10 indicating “the worst pain possible”. Pain perception is measured at two intervals. The first measurement will be just before putting on the glasses, last one immediately after the procedure. During the last measurement the patients will be asked to grade the maximum pain score of the local anaesthetic placement and of the procedure (fracture reduction) that took place.

Secondary outcome

Anxiety is measured using the VAS-A, an 11 point scale. With 0 indicating “no anxiety” and 10 indicating “severe anxiety”.

Anxiety is measured prior to putting on the video glasses and immediately after taking the video glasses off.

The patient satisfaction VAS-S will be scored prior to patient discharge. The VAS for the measurement of satisfaction is an 11 point scale ranging up from 0 to 10. With 0 indicating “not satisfied at all with the total procedure” and 10 indicating “completely satisfied with the total procedure”.

The patient will also be asked to rate the quality of the audio and visual effects on an 11-point scale and if he/she would consider using the device again under similar circumstances.

Study description

Study objective

We hypothesize that audio-visual immersion by using high-quality video glasses with surround sound headphones can reduce pain and anxiety scores. Furthermore, we anticipate that patient satisfaction in these patients will increase.

Study design

right before and right after the intervention

Intervention

The intervention group will be provided with the audiovisual headset device as soon as the patient is placed in the room where the procedure will take place. The device will be worn during the placement of the local anaesthetic and continued to be worn during the short surgical procedure. At all times the device can be removed if the patient feels uncomfortable or if the treating physician deems it necessary.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Dislocated wrist fracture with an indication for repositioning in the ED under local anaesthesia with lidocaine
- Age >18 years old

Exclusion criteria

- Individuals not being able to understand Dutch language at primary school level
- Individuals not being able to read or write Dutch
- Individuals who are unable to sign informed consent owing to mental/psychiatric disorder or formally stated to be incompetent to decide
- Individuals not willing or able to sign informed consent for the proposed study
- Individuals with a history of loss of central or peripheral field of vision on either eye
- Individuals with a history of either conductive, sensorineural or mixed hearing loss

- Individuals wearing hearing devices on either ear
- Individuals with a known history of anxiety disorder
- Individuals with an alcohol, drug dependency problem or intoxication
- Individuals using chronic opioid pain medication
- Individuals with a fracture or dislocated joint that requires immediate surgery in the operating theatre or a fracture which is > 24 hours old
- Individuals with a known allergy or other contra-indication for the use of lidocaine
- Individuals with a multi-trauma (excluding superficial wounds and minor contusions)
- Second reduction attempt (after cast immobilization) of same fracture

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2019
Enrollment:	36
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49868

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7473
NTR-old	NTR7715
CCMO	NL67837.018.18
OMON	NL-OMON49868

Study results