The effect of audio-visual immersion on pain, anxiety and satisfaction in patients undergoing wrist-fracture reduction in the Emergency Department, a randomized controlled trial

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

Summary

ID

NL-OMON49868

Source
ToetsingOnline

Brief title
Audiovisual Immersion in the Emergency Department (eMOVIE)

Condition

- Other condition
- Fractures
- Bone and joint therapeutic procedures

Synonym
pain during reposition of wrist fracture under local anesthesia

Health condition

pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anxiety, Audiovisual, Emergency Department, Immersion, pain, satisfaction, wrist fracture

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 an 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

Background summary

Patients undergoing surgical procedures in the Emergency Department often experience pain and anxiety. These procedures include reduction of fractures and reduction of dislocated joints. To ensure the comfort of these patients pharmacological options a.i. local anesthesia, analgesic medication and sedatives are usually given. However with pharmacological intervention there is always a risk of side effects and potential adverse events.

Distraction is an old technique that appears to be safe, inexpensive and effective in reducing anxiety and pain in short painful procedures. Recently this has been re-introduced by means of high-tech audio and visual applications for patients undergoing surgical procedures.

With this study we specifically evaluate the effect of distraction by audiovisual immersion in patients who receive a local anesthetic and reduction of a broken wrist in the Emergency Department.

Study objective

The primary objective of this study is to assess the effect of audio-visual immersion on pain perception in patients undergoing a short surgical procedure (a.i. wrist fracture reduction) under local anesthesia in the Emergency Department (ED). Furthermore, we aim to assess the effect of audio-visual immersion on anxiety and patient satisfaction.

Study design

Randomized controlled trial with 2 groups.

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.

Study burden and risks

Benefits for the patients
During the clinical intervention, we anticipate a potential benefit for the patients as they will be distracted from any unpleasant anxiety and/or pain inducing visual and audible inputs (a.i. needles (local anesthesia), counterweights and manipulation). It is anticipated that the patient may need less sedatives and/or analgesic medication. This may in turn lead to less side effects/ adverse events. We will also monitor first time success rate of the procedure, as this may increase when the patient is more relaxed. The subjective treatment time may be perceived as being reduced to actual time. All together this may result in improved patient satisfaction scores.

Benefits for the hospital
Gentle and non-pharmaceutical distraction of the patient may support ease of procedure and success rate of the procedure. This may in turn facilitate faster throughput times in the ED. It may also economize the use of sedatives and pain medication

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

- 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)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2019
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	28-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-05-2019
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

ID: 20686
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67837.018.18
OMON	NL-OMON20686