HappyMed in the Hospital; Will the use of the HappyMed (a portable multimedia system) during an orthopedic operation with local anaesthesia lead to reduced stress for the patient?

Published: 02-05-2016
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To assess if the use of videoglasses can lead to more anxiety reduction than hearing preferred audio in patients undergoing surgical procedures under local anesthesia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50193

Source
ToetsingOnline

Brief title
HappyMed in the Hospital, use of videoglasses for anxiety reduction

Condition

- Bone and joint therapeutic procedures

Synonym
Anxiety and Stress

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anxiety, Stress reduction, Video

Outcome measures

Primary outcome

-Stress level measured with the STAI 6 questionnaire

-Bloodpressure

-Heart rate

- Painscore measured with the VAS-score

Secondary outcome

N/A

Study description

Background summary

Patients experience different levels of anxiety before, during and after a surgical operation. The perception of a certain operation will depend on the procedure itself but also on the levels of stress and anxiety a patient go through. To positively affect the experience of an operation we need to reduce the stress and anxiety a patient encounter during the process of an operation.

The 'HappyMed' video glasses is an innovative portable multimedia system which can be used during an operation to try to reduce the stress and anxiety levels of the patient. This could be achieved by watching and listening to a movie with the 'HappyMed' video glasses.

This research addresses the potential benefits of use of the *HappyMed* videoglasses in terms of lowering anxiety and perceived pain in the outpatient setting during selected orthopedic procedures with an deemed operation time of at least 30 minutes.

The pilotstudy will be conducted in the OK-daycare of the Academic medical centre in Amsterdam

Study objective

To assess if the use of videoglasses can lead to more anxiety reduction than hearing preferred audio in patients undergoing surgical procedures under local anesthesia.

Study design

Randomized Clinical Trial

the patients are divided in two groups at random. The intervention group is offered the videoglasses with a scenic and relaxing wildlife/nature movie, the control group is offered preferred type of relaxing audio.

Both groups have to complete the validated questionaire about stress(STAI6) and score their pain with the VAS before and after surgery

During the operation the mean blood pressure and mean heart rate are measured by both groups

Intervention

The intervention group is offered the videoglasses with a scenic and relaxing wildlife/nature movie.
The control group will be hearing their preferred type of relaxing audio.

Study burden and risks

Patients are asked to complete questoinnaires investigating anxiety / stress (the STAI 6) and pain (VAS score analogue scale). This wil take about 30-60 minutes. The bloodpressure and heart ratings will be measured troughout the operation and recovery period, as is customary procedure (no extra burden of discomfort for the patient).

Contacts

Public
Selecteer

Hasnerstraße 123
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NL
Scientific
Selecteer

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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 to be scheduled for the following operations with a deemed surgical operation time of at least 30 minutes, under regional anesthetics :
- All procedures of the lower extrimities including: Anterior ankle arthroscopy(including cartilage and impingement procedures), Posterior ankle arthroscopy, Knee arthroscopy (including cartilage, meniscus lesions and anterior cruciate ligament procedures)
* Aged 18 years or older

Exclusion criteria

* Individuals with a known history of panic attacks, phobias, anxiety or borderline disorders as reported by patient in history taking or from patient files
* Individuals not being able to understand Dutch language at primary school level
* Individuals not being able to read or write Dutch
* Individuals with a known history of known hyper- or hypotensia
* Individuals with a history of loss of central or pheripheric field of vision on either eye

* Individuals with a history of either conductive, sensorineural or mixed hearing loss
* Individuals with refraction anomaly on either eye or both eyes, wearing glasses
* Individuals wearing hearing devices on either ear
* Individuals on any kind of antihypertensic medication
* Individuals using any kind of prescribed or non-prescribed pain medication
* Individuals on any kind of anti-arrhythmic medication
* Individuals with a known history of alcohol, drug, and/or psychiatric problems
* Individuals who are unable to sign informed consent owing to mental disorder or formally stated to be incompentent to decide
* Individuals not willing or being able to sign informed consent for the proposed study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	02-05-2016

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2017
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: 19928
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56379.018.16
OMON	NL-OMON19928