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Visual distraction to reduce anxiety and pain during nerve block injection

Submission date	Recruitment status	[_] Prospectively registered
17/12/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/07/2021	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A visit to the hospital for a medical procedure increases tension and emotion in many people. This is very understandable, which is why we are now investigating whether we can make a person's stay in the hospital more pleasant by using video glasses during the treatment.
A nerve block is an injection of a local anaesthetic to numb the nerves supplying a particular part of the body, such as the hand, arm or leg.
How much fear/pain someone experiences during a nerve block differs per person. By using the video glasses, we hope to be able to provide sufficient distraction to experience less fear and/or pain during the treatment.

Who can participate?
Adults over 18 years, who are going to undergo a nerve block at the hospital

What does the study involve?
The video glasses are a kind of glasses with headphones that allow you to watch and listen to a video during the treatment.
Participants will be assigned at random (by the computer) to one of the three research groups.
Group 1 standard treatment, with video glasses on during the treatment and a maximum of 5 minutes before the treatment to get used to the glasses and headphones.
Group 2 standard treatment, with video glasses on during the treatment but also 15 minutes before the treatment to completely unwind and relax.
Group 3 standard treatment, without using the video glasses (this is the current treatment currently being given in the hospital).

What are the possible benefits and risks of participating?
Patients will not directly benefit from participating in this study, apart from a potential reduction in pain. Disadvantages to participation will be 10 mins taken to complete questionnaires and an additional 15 mins for one of the treatment groups before the start of the treatment.

Where is the study run from?
Spaarne Gasthuis (Netherlands)

When is the study starting and how long is it expected to run for?
From March 2018 to February 2019

Who is funding the study?
Spaarne Gasthuis (Netherlands)

Who is the main contact?
Dr Karlijn van Stralen
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2018.273

Study information

Scientific Title
Effectiveness of an audio-visual device for anxiety and pain reduction during a nerve block procedure – a randomized controlled trial

Study objectives
The audio-visual device will influence the amount of experienced anxiety and pain during a pain relief procedure. In addition, we expect that patients will benefit when the distraction starts prior to treatment; by attenuating anxiety beforehand, affecting the perceived procedural pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics review committee of the VU University Medical Center (OHRP - IRB00002991 /FWA00017598) judged on June 5, 2018, that the medical research involving human subjects ACT (WMO) does not apply to this study as the intervention was not considered medical, as all patients received standard care and the intervention was the use of video glasses. They stated that this study did not require official approval by the committee. (2018.273).

Approved 05/07/2018, institutional review board of the spaarne gasthuis (Spaarne Poort 1, Hoofddorp, Netherlands 2134 TM; +31 (023) 22 42842; no email contact available), ref: 2018.0055.

Study design
Parallel group non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Pain and anxiety before and during a nerve block procedure

Interventions
Patients were randomly assigned (block size three) to one of the three intervention groups by computer program Research Manager, Deventer, The Netherlands, 2018. General preoperative characteristics were provided by the participants at home or in the waiting area of the clinic.

In the holding area room, all the participants scored their levels of anxiety and pain for that particular moment in time (T1).

After that, instructions on how to use the video glasses were provided for group 1 and 2.

Group 1 underwent the medical procedure with the glasses on.
Group 2 had an extra 15 min in the holding area ‘to relax’ with the video glasses on while watching their video of preference and continued watching the video during the medical procedure.
Group 3 underwent the medical procedure as usual, without video glasses.

Normal duration of the medical procedure was 10-12 min. After the medical procedure, all patients were moved to the recovery room where T2 was scored.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Video glasses

Primary outcome(s)
Anxiety assessed with the Dutch State and Trait Anxiety Inventory (STAI) form before (T1) and after (T2) the medical procedure

Key secondary outcome(s))
1. The Numeric Rating Scale (NRS) was used for measuring pain on a 0 -10 scale at T1 and T2
2. Electrodermal activity (EDA) sensor PIP, Dublin, Ireland 2018, was placed during the medical treatment only, recording EDA in frames of 8 times per second to determine stress levels and stress events during the procedure
3. Experiences of the intervention measured using a novel questionnaire at T2
4. Side effects reported on the questionnaire by the patients or noted by the medical staff at T2

Completion date
02/02/2019

Eligibility

Key inclusion criteria
1. Adults 18 years and older
2. Conditions that require nerve block intervention
3. Written informed consent
4. We allow re-enrolment in the randomisation procedure, as some patients will return for repeated treatment during the randomisation period. A new written informed consent is needed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
99

Key exclusion criteria
1. Patients with difficulties in speaking and reading Dutch
2. Patients physically or mentally not able to consent
3. Patients with severe hearing loss or refraction errors making it impossible to wear the audiovisual device

4. Anxiety disorders, such as panic disorder, obsessive-compulsive disorder, posttraumatic stress disorder and others
5. ASA 4 - 5

Date of first enrolment
20/06/2018

Date of final enrolment
02/02/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Spaarne Gasthuis
Spaarnepoort 1
Hoofddorp
Netherlands
2300RC

Sponsor information

Organisation
Spaarne Gasthuis

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Spaarne Gasthuis science fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Karlijn van Stralen (wetenschapsbureau@spaarnegasthuis.nl). The R dataset

will be available until December 2032. Approval for use of dataset is required from the local review board of the Spaarne Gasthuis, as well as the legal department to check if the data request falls within the consent of the participants. This depends on the required data, the country of the request, and the location of the analyses.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		16/11/2020	08/07/2021	No	Yes
Protocol file		04/05/2018	08/07/2021	No	No