Onderzoeksprotocol

(voor aanvraag niet-WMO verklaring)

Algemene gegevens

Titel	Effectiveness of an audio-visual device for anxiety and pain reduction during a nerve block procedure – RCT
Datum	4-05-2018
Versienummer	4-05-2018
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Onderzoekgegevens

Rationale	Because procedural anxiety and pain often cannot adequately be treated by pharmaceuticals alone, other possibilities of modern technology have been exploited. Recent publications on audio visual distraction show positive effects on the reduction of anxiety and or pain.
Doel	The aim of this randomised study is to find out whether an audio-visual device used as a distraction intervention during a nerve block procedure, can reduce the subject perceptions of perioprocedural anxiety and pain in adults.
Studie design	Randomized controlled trial Single centre trial, Group: Parallel, Type: 3 arms, randomised Blinding: no
Studie populatie	Eligible ambulant patients aged 18 years and older scheduled for an outpatient nerve block intervention at the Spaarne Gasthuis

Inclusiecriteria	• Adults 18 years and older • Conditions that require nerve block intervention • Written informed consent • 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
Exclusiecriteria	• Patients with difficulties in speaking and reading Dutch • Patients physically or mentally not able to consent • Patients with severe hearing loss or refraction errors making it impossible to wear the audio visual device • Anxiety disorders, such as panic disorder, obsessive-compulsive disorder, posttraumatic stress disorder and others • ASA 4-5
Aantal proefpersonen/ sample grootte	To our knowledge the mean and standard deviations for preoperative anxiety for nerveblocks have never been published. The magnitude of cohen's d=0,5 (f2 medium= 0,15) was chosen in order to ascertain a minimal important clinical change corresponding to a moderate effect size (Cohen J. Statistical power analysis for the behavioural sciences. London: Academic Press; 1969). Assuming a 0.05 significance level with 90% power, 153 patients are needed. Taking drop-outs in account, the total number of patients is set at 65 patients per group. Total of 195.
Werving proefpersonen	After acquiring a non-WMO approval from the ethics committees (Medical ethics committee of the VUmc, Amsterdam, The Netherlands, Approval No.:……, dated……. 2018). All patients requiring a nerve block intervention at the pain clinic Spaarne Gasthuis will be asked to join the study. The standard care for patients with a referral for a nerve block is that they receive prior to their first consultation questionnaires about the medical condition. We will send our information about the study and informed consent along with this information. At the first consult, the informed consent of patients willing to participate will be collected by their specialist. When informed consent is received, the patient will be randomised (research manager) and an appointment for their medical treatment will be scheduled.
Interventie	Regardless of allocation all patients will receive standard medical care.

	Patient randomly allocated to one of the three intervention groups; procedure. I Active Comparator: max. 5 min video glasses prior to procedure and during intervention. Regular care plus video glasses instruction in the recovery room plus max. 5 minutes (only adjust settings and adapt to the device on head) prior to the procedure and wearing the device during the whole pain procedure. II. Active Comparator: 15 min video glasses prior to procedure and during intervention. Regular care plus video glasses instruction in the recovery, plus 15 minutes to adapt to the device prior to the procedure and wearing the device during the whole pain procedure. III. No intervention: treatment as usual. After the procedure the patient is transported to the recovery room and will stay there for as long as needed. Patients are free to choose out of a variety of relaxation/ documentary/ concerts videos. Moments of measurement: (T0)The baseline measurement will be taken after their first consultation. Patients will receive a questionnaire at home digital or on paper if they prefer. The questionnaires covered questions regarding there demographic status, location of the procedure and medical history (previous nerve blocks, recent pain/anxiety/depression medication use) plus STAI-T and NRS. (T1)Prior to the medical treatment all patients have a moment in the recovery room were care providers check if the patients are fit for the procedure and patients will be asked to fill in the questionnaire STAI-S and NRS(pain) on a tablet. During medical treatment stress levels heartrate (HR) and galvanic skin response (EDA) will be monitored for all patients. (T2) When the patient is recovered from the pain procedure, the STAI-S, NRS and additional questions about the use of the video-glasses will be taken. After this the patient can go home.

Standaardzorg / Standaardbehandeling	dna
Studie parameters	Gender, age, location-/ and previous surgical procedures, medication use, anxiety (State and Trait), pain (NRS), heartrate (HR), electrodermal activity also known as galvanic skin response (EDA).
Studie eindpunten	Change in anxiety levels measured using STAI- S score pre (T1) and post treatment (T2) between groups. And change in pain score NRS (difference between T1 and T2) between the groups Stress parameters; (HR) and (EDA). Willingness of participants to use the device in the future and unanticipated effects
Statistische analyses	The difference in STAI and NRS scores between the groups will be analysed with a general linear mixed model. Residuals will be checked for normality (plotting, histogram and Shapiro-Wilk. test). Sub analysis will be conducted to compare the effects on location-/ and previous surgical procedures, medication use and the baseline STAI (T) score. And stress levels; HR and EDA. Outcome will be reported; median/IQR, SE (CI 95%) and ES. The data were analysed using Rstudio, www.rstudio.com. 'Intention to treat' and 'per protocol' analysis will be both performed. Intention to treat as main analysis to keep the randomisation intact and the 'per protocol' for the maximal effect. The significance level was set at $P < 0.05$ in all cases and power at 90. Missing values were imputed, according to the STAI manual. We allow re-enrolment in the randomisation procedure, as some patients will return for repeated treatment during the randomisation period. Adjustments for the correlation between the observations of the same patient is accounted for using multilevel analysis
Belasting voor de proefpersoon	Time: 3x10 minutes maximum for answering self-reported questionnaires. Group II additional extra 15 min distraction with video glasses prior to medical treatment.
Risico voor de proefpersoon	No risks involved

Voordelen deelname aan het onderzoek	None. Possible positive distraction effects for those wearing the video glasses.
Nadelen deelname aan het onderzoek	Apart from extra time, none
Vergoeding voor de proefpersoon	Participation is voluntary and reimbursement for study participation is not provided. An exit card for the hospital car park will be offered to compensate for additional time participants need to answer the questionnaires.
Administratieve aspecten	Handling and storage of data and documents are done research manager according to hospital regulations for clinical research and kept for 15 years. Patient data will be coded and will be made anonymous for statistical analysis.
Publicatiebeleid en amendementen	The Spaarne Gasthuis is sponsor and owner of the data and is entitled to publication of the results obtained from this clinical trial.
Overige punten van belang voor de METc	The audio visual device, is CE certified for hospital use. No additional regulations apply for participants. Intervention groups and control group receive same regular medical treatment as when they would not participate in the research study. Wearing the devices for distraction or not does not interfere with the medical outcome of the pain procedure itself. The device is 'only' a tool to apply to raise the patients sense of well-being and satisfaction.