Effect of Virtual Reality on treatment experience with carpal tunnel - & triggerfingerrelease: a randomized controlled trial

Gepubliceerd: 08-04-2020 Laatst bijgewerkt: 18-08-2022

Virtual reality goggles during wide awake local anesthetic surgery improves patient experience and reduces stress and anxiety

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24719

Bron
NTR

Verkorte titel
VR in hand Surgery

Aandoening

Triggerfinger syndrome, carpal tunnel syndrome

Ondersteuning

Primaire sponsor: No funding
Overige ondersteuning: No funding for this research was provided

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Multiple outcomes were measured, of which all were measured both peri-operatively, direct post-operatively as well as 2 weeks post-operatively. We divided the outcome measures in three groups: Patient reported outcomes (PROMS), Patient reported experience outcomes (PREMS) and objective outcomes. Below we will elaborate on these different sets of outcomes.
PROMS
We measured pain, fun, nausea and relaxation using a 0-10 Likert Scale during peri-operatively and direct post-operatively. In addition, we asked patients to fill in the PHQ-4 questionaire for anxiety peri-operatively and direct post-operatively.
Furthermore, patients were asked to fill in the Michigan hand questionnaire/DASH at 2 weeks post-operatively.
PREMS
CQ-index was asked to be filled in after two weeks post-operatively to assess what the overall experience was the given treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Patients undergoing wide awake local anesthetic surgery often experience pain and anxiety during the procedure. Due to the pain and anxiety, patients are often stressed and hesitant in undergoing wide awake surgery. The use of virtual reality (VR) has potential in various aspects in medicine as multiple studies showed promising results in terms of pain and anxiety.
Objective: the aim of our study is to investigate what the effect is of virtual reality use during wide awake local anesthetic tourniquet & non-tourniquet surgery on both patient reported experience outcome (PREMS), patient reported treatment outcomes (PROMS) as well as objective outcomes in patients treated for their Trigger Finger or Carpal tunnel syndrome.
Study design: Single blind Randomized Controlled Trial
Study population: All patients who visited the outpatient clinic and were diagnosed with either carpal tunnel syndrome or triggerfiger of a single digit and suitable for undergoing wide awake local anesthetic surgery were asked to participate in this study.
Intervention (if applicable): After allocation to either the VR group or the control group, the VR group received a VR goggle with headphones.
Main study parameters/endpoints: Multiple outcomes were measured, of which all were measured both peri-operatively, direct post-operatively as well as 2 weeks post-operatively. We divided the outcome measures in three groups: Patient reported outcomes (PROMS), Patient reported experience outcomes (PREMS) and objective outcomes.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risks: No risks are associated with participation. Patients may get nausea or sea sickness due to the VR goggles.
Burden: Patients are asked to fill in questionnaires direct after procedure and at follow-up appointment at 2 weeks.

Doel van het onderzoek

Virtual reality goggles during wide awake local anesthetic surgery improves patient experience and reduces stress and anxiety

Onderzoeksopzet

During operation, direct after operation and 2 weeks after operation

Onderzoeksproduct en/of interventie

After allocation to either the VR group or the control group, the VR group received a VR goggle with headphones. During the procedure, each patient had the option to select their own preferable VR movie clip. The options ranged from scenery in wild forests to historical cities. The control group received routine standard care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients who visited the outpatient clinic and were diagnosed with either carpal tunnel

syndrome or triggerfiger of a single digit and suitable for undergoing wide awake local anesthetic surgery were asked to participate in this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria were severe hand disorders in which local anesthesia would not be sufficient (i.e. wrist surgery), motion sickness, unwillingness to wear bands around the head, patients younger than 18 years old or patients with claustrofobia

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8515
Ander register	METC isala zwolle : 72717

Resultaten