Effect of Virtual Reality on treatment experience during surgical treatment of Carpal tunnel and trigger finger syndrome: a randomized controlled trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON49045

Source
ToetsingOnline

Brief title
Virtual Reality during hand surgery

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Carpal Tunnel Syndrome, Triggerfinger

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Het onderzoek wordt niet gefinancierd.

Intervention

Keyword: Experience, Hand surgery, Outcome, Virtual reality

Outcome measures

Primary outcome

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

Secondary outcome

Heartrate, blood pressure right before, during and direct post-operatively

Study description

Background summary

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.1 Furthermore, a systematic review studying the use of VR as a psychological intervention for pain management showed that VR based interventions lead to a pain reduction in patients undergoing medical procedures.2 Moreover, a systematic review by Zeng et al. studying the use of VR in symptom reduction in cancer patients showed significant positive results in regard to depression, cognitive function, pain and anxiety.3
Despite the growing evidence that VR has positive effects in patients, there are to date no publications demonstrating the use of virtual reality in hand surgery. As a result, it is unknown what the effect of VR-interventions is in patients undergoing wide awake local hand surgery with or without tourniquet. VR interventions during wide awake hand surgery might have the potential of reducing pain, anxiety and as a result better patient experience. In addition, the often applied tourniquet in local hand surgery is usually regarded as very unpleasant, sometimes even the most uncomfortable part of the procedure.

Study objective

Since Triggerfinger and Carpal tunnel syndrome are hand disorders most commonly presented at the outpatient clinic, 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

The study will be conducted as a randomized controlled trial following the CONSORT guideline and performed at the outpatient clinic for plastic, reconstructive and hand surgery in Isala hospital, located in Zwolle, the Netherlands

Intervention

After written informed consent, patients were randomly allocated in either the group that received VR experience (VR group) or in the group that does not

receive VR experience (control group). After allocation, 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.

Study burden and risks

Not applicable

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

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.

Exclusion criteria

Exclusion criteria was motion sickness, unwillingness to wear bands around the head, patients younger than 18 years old or patients with claustrofobia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2020
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	14-01-2021
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL72717.075.20
Other	NL8515