The role of executive functions in the efficacy of VR as pain relief during experimental pain

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The primary objective is investigating the influence of Virtual Reality distraction on pain. The secondary objectives were, investigating if (1) the executive functions and catastrophizing thoughts influence the effect of VR as pain relief; (2) the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43440

Source
ToetsingOnline

Brief title
VR during experimental pain

Condition

- Other condition

Synonym
distraction, pain

Health condition

experimentele pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Catastrophizing, Executive functions, Experimental pain, Virtual Reality

Outcome measures

Primary outcome

The primary parameters are (1) the distraction technique is significantly associated with the VAS pain score and (2) the distraction technique is significantly associated with the tolerance time.

Secondary outcome

The secondary parameters were (3) the executives functions and catastrophizing thoughts (continue variables) have a moderating role in the expected relation of the distraction technique and VAS pain scores; (4) the VAS-score for presence predicts the VAS-score for pain; (5) the VAS-score for presence predicts the tolerance time; (6) the executive functions (continue variable) predict the degree of presence in the virtual world (continue variable); (7) the distraction technique (categorical variable) predicts the degree of presence (continue variable).

Study description

Background summary

Virtual Reality is promising as pain relief and considered as distraction technique. The extent to which VR is effective in relieving pain depends on the extent of presence in the virtual world. This study investigates if the quality

of the different executive functions (inhibition, divided attention and working memory) and the degree of catastrophizing influences the presence in the virtual world and herewith the effect on pain. This question is also included in our current study to VR as pain relief during colonoscopies (RTPO-53709).

Study objective

The primary objective is investigating the influence of Virtual Reality distraction on pain.
The secondary objectives were, investigating if (1) the executive functions and catastrophizing thoughts influence the effect of VR as pain relief; (2) the degree of presence in the virtual world influences the effect of VR as pain relief; (3) the executive functions are associated with the presence in the virtual world; (4) the degree of presence in the virtual world is greater during playing a game than watching a video.

Study design

This concerns a randomized study with stratification for age. There are two age groups (<50 jaar en >=50 jaar) with three research groups each: 1) VR game, 2) VR video and personal associations. In total 78 (2x(3*13) subjects are needed. The duration of this study is from the first of March 2016 until the first of March 2017.

Intervention

Group 1 is undergoing the cold pressor task with VR game, group 2 with VR video, group 3 without VR glasses and with the task to think about something distracting. Preliminary, all subjects carry out four executive tasks and fill in one questionnaire.

Study burden and risks

This study attemts to clarify the efficacy of VR as pain relief. A few studies describe nausea as possible side effect of the use of VR. Subjects recover directly by putting off the VR glasses.

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

Healthy adults between 18 and 75 years old.

Exclusion criteria

- Limited vision or hearing
- Limited communication skills
- Acute or chronic pain
- Phenomenon of Raynaud
- Cardiovascular disorders
- Hypertension
- Endocrine, metabolic, neurologic disorders
- Musculoskeletal disorders like rheumatism or muscular disorders
- epilepsy
- psychiatric diagnoses, like depression or anxiety
- current injuries to the hands
- use of medication
- pregnancy
- use of alcohol or drugs 24 hours before the start of participation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2016
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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: 20465
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL56224.099.15
OMON	NL-OMON20465