The effect of Virtual Reality on pain in patients undergoing lumbar puncture. A randomized controlled trial

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The aim of this study is to determine whether VR used during lumbar puncture will significantly reduce pain and anxiety perception.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51820

Source
ToetsingOnline

Brief title
ViRe LP

Condition

- Other condition
- Administration site reactions
- Nervous system, skull and spine therapeutic procedures

Synonym
Pain in lumbar punctures / spinal tap

Health condition

Pijn en angst gerelateerd aan diagnostische ingreep (lumbaalpunctie)

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Zuyderland medical center

Intervention

Keyword: Lumbar puncture, Pain, Reality, Virtual

Outcome measures

Primary outcome

The primary outcome is experienced pain measured by the 11-point NRS. Scores will be analysed by means with standard deviations.

Secondary outcome

Anxiety: Anxiety will be measured with the 11-point NRS. This is a validated and reliable scale for measuring state anxiety. This will be measured before and after the procedure. In patients with VR the measurement of NRS will take place before starting the VR.

Complications: Complications will be assessed in a telephone call 3-5 days after the puncture.

Side-effect: Side effects of VR will be assessed after the procedure.

Study description

Background summary

Lumbar puncture (LP) is considered safe with a low risk of complications. However, LP are often experienced as painful, unpleasant and distressing, which is associated with more pain and anxiety. There is increasing evidence that virtual reality is effective in the reduction of acute pain during medical procedures and treatments. [9] Furthermore it has been proven to reduce pre-operative anxiety, mainly in children. [15] There is a tendency of pain reduction with the use of VR in adolescents undergoing LP [8]. VR has not been

studied in adults undergoing LP.

Study objective

The aim of this study is to determine whether VR used during lumbar puncture will significantly reduce pain and anxiety perception.

Study design

A single center, non-blinded, randomized controlled trail.

Intervention

Patients in the intervention group will have additional VR-experience before and during LP.

Study burden and risks

Patients included in this study will have a negligible medical risk when participating in this study, since VR has minimal and non-threatening side-effects (e.g. dizziness). The burden to participate in the study is also low considering that only an extra telephone call, which will take maximum of 15 minutes, is done on top of normal LP procedure.

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

- At least 18 years
- Indication for lumbar puncture
- Outpatient setting

Exclusion criteria

- Any contraindication for lumbar puncture:
o Suspicion of increased intracranial pressure in decreased consciousness, papilledema, focal loss or suspected increased intracranial pressure based on imaging
o Space occupying lesions with mass effect
o Space occupying lesions in posterior fossa of any kind such as tumor, hemorrhage or recent cerebellar infarction
o Spinal mass
o Infection at puncture site
o Thrombocytopenia <40x10*
o Use of blood-thinning medication (with the exception of acetylsalicylic acid)
- Patients who have epilepsy
- Patients who have had lumbar puncture before
- Patients who are completely deaf or blind

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-02-2023
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	13-01-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	28-03-2022
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	31-07-2023
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL79216.096.21