Virtual Reality hypnosis during needle related procedures in children

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Virtual reality hypnosis is similarly effective in comparison to conventional medical hypnosis in reduction of pain and anxiety throughout needle related procedures in children in a clinical setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON23283

Source

NTR

Condition

• Therapeutic procedures and supportive care NEC

Synonym

Pediatric, virtual reality, hypnosis, pain, fear, randomized controlled trial

Health condition

Needle-related procedures can cause pain and fear in children and may lead to avoidance of future medical care. The aim of this study is to investigate whether virtual reality hypnosis (VRH) is non-inferior to medical hypnosis by a trained healthcare provider (MH) in reducing pain in children.

Research involving Human

Sponsors and support

Primary sponsor: OLVG, Amsterdam, The Netherlands Source(s) of monetary or material Support: No external funding.

1 - Virtual Reality hypnosis during needle related procedures in children 2-05-2025

Intervention

• Psychosocial intervention

Explanation

Outcome measures

Primary outcome

Patient-perceived pain before and after the procedure.

Secondary outcome

Anxiety scored before and after the procedure by child and health care worker. Pulse rate and blood pressure will be measured. Also, patient satisfaction, and possible adverse events nausea and dizziness will be recorded.

Study description

Background summary

Anxiety causes the brain to be more perceptive to painful stimuli, which can create an upward spiral of distress. Needle-related procedures are the most important cause of pain, anxiety and stress among children in a clinical setting. Research in children subjected to repetitive negative experiences, showed a slower post-surgical recovery and a persistent lower pain threshold. There is a growing body of evidence indicating that procedural distress is associated with various complications such as impaired wound healing. Therefore, it is hypothesized that by enhancing procedural comfort, the overall outcome can be improved. Non-pharmacological interventions are proven to be effective in reducing procedural distress. This includes distraction, breathing exercises, language-based "neutral signaling" and, most comprehensively, medical hypnosis. However, medical hypnosis is time-consuming and costly, which may pose a barrier to general implementation in a clinical setting. Recently, virtual reality (VR) has emerged as a new non-pharmacological treatment modality, which shows promising results in children undergoing medical procedures. Our aim is to compare VR hypnosis with conventional medical hypnosis by a health care worker in children undergoing needle-related procedures. This randomized controlled trial will assess the effect of VR hypnosis versus conventional medical hypnosis on pain and anxiety in children undergoing a needle-related procedure in a non-inferiority design.

Study objective

Virtual reality hypnosis is similarly effective in comparison to conventional medical hypnosis in reduction of pain and anxiety throughout needle related procedures in children in a clinical

setting.

Study design non-inferiority randomized controlled trial

Intervention

Virtual reality hypnosis, medical hypnosis.

Contacts

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Eligibility criteria

Age

Children (2-11 years) Adolescents (12-15 years) Adolescents (16-17 years)

Inclusion criteria

- Age between 6 and 18 years - Required needle related procedure (e.g. intravenous cannula insertion, venipuncture, injection and lumbar puncture)

Exclusion criteria

- - mental retardation
- - autism spectrum disorder
- - epileptic disorder
- - uncorrected visual and/or auditory impairment.
- · children with extreme needle phobia and/or fear

3 - Virtual Reality hypnosis during needle related procedures in children 2-05-2025

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NI

Recruitment stopped
17-04-2021
124
Actual

IPD sharing statement

Plan to share IPD: No

Plan description N/A

Ethics review

Approved WMODate:07-04-2021Application type:First submissionReview commission:Medical Research Ethics Committees United (MEC-U)Postbus 25003430 EM Nieuwegein088 320 8784info@mec-u.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 51145 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9385
ССМО	NL76118.100.20
OMON	NL-OMON51145

Study results

Results posted:	03-07-2023
Actual enrolment:	124

Summary results

We randomized 138 children to VRH or MH treatment and included 114 children in the analyses (VRH n=60, MH n=54). We found non-inferiority for VRH compared to MH on patient-reported pain (mean difference=-0.17, 95%Cl -1.01;0.66). Secondary outcomes were comparable between VRH and MH groups. Both treatments scored high on patient satisfaction (VRH median=9.0, MH median=10.0, p=0.512).

Adverse events

none