The effectiveness of virtual reality-assisted hypnosis in reducing itch: a proof-of-concept study

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This study aims to assess the effectiveness of VRH in reducing itch along with its psychological burden in individuals with chronic itch.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON56407

Source
ToetsingOnline

Brief title
Reducing itch with hypnosis and virtual reality

Condition

- Epidermal and dermal conditions

Synonym
itch, Pruritus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Inverdiende gelden Prof. AWM Evers;bijv voor het geven van lezingen

Intervention

Keyword: hypnosis, Itch, virtual reality (VR)

Outcome measures

Primary outcome

The study will be conducted to assess whether a VRH intervention is a useful technique (compared to a waiting list control group) (with clinically relevant effect) for short-term (during and at end of treatment) and longer-term (approximately 6 weeks post-treatment) itch reduction in terms of clinical itch intensity (0-10 NRS) [various time points during and after treatment compared to baseline].

Secondary outcome

The study will furthermore be conducted to assess whether VRH intervention is a useful technique (compared to a waiting list control group) (with clinically relevant effect) in terms of (a) the impact of the itch and overall wellbeing (Impact of Skin Disease on Daily Life (ISDL) scales for skin status, physical symptoms, scratching, impact of illness, psychological functioning and illness cognitions; and the Hospital Anxiety and Depression Scale (HADS)), (b) medical treatment need (type of drug/treatment x quantification), and (c) itch sensitivity (upon application of cowhage) [end of treatment and follow-up compared to baseline].

Finally, the study will be conducted to assess the extent to which treatment confidence, hypnotic susceptibility, and perceived presence in the VR environment correlate with the difference in clinical itch intensity at the end

of treatment and at follow-up compared to with baseline.

Study description

Background summary

Chronic itch is a disabling condition with currently limited treatment options. Chronic itch can cause severe sleep disturbances and may even trigger depression and suicidal ideations. Virtual reality (VR) is a relatively new approach that provides immersion in another environment and has been shown to have a temporary itch mitigating potential. Hypnosis, which is a state of relaxation, has been successfully applied with more long-term treatment effects in the specific case of itch as a result of severe atopic dermatitis. However, hypnosis tends to depend on an individual*s susceptibility, or ease to come into a hypnotic state. A combination of VR and hypnosis (VRH) has been put forward since it may combine the longer lasting effects of hypnosis with VR making the hypnosis more accessible by facilitating imagination. Even though VRH is a promising avenue, it has never been investigated in the context of itch.

Study objective

This study aims to assess the effectiveness of VRH in reducing itch along with its psychological burden in individuals with chronic itch.

Study design

Randomised controlled trial investigating the effects of a VRH treatment from baseline to 6 sessions and at follow-up (ca. 6 weeks after the end of treatment) compared to a waiting list control group.

Intervention

The VRH group will receive 6 virtual reality hypnosis therapy sessions over the course of ca. 7-18 weeks, along with instructions to listen to a guided self-hypnosis recording daily. During this time, the waiting list control group will be asked to complete the same questionnaires concerning their itch intensity and overall wellbeing.

Study burden and risks

Participation in this study requires some time investment (±13h over ca. 7-18 weeks and one follow-up session of ±1h after ca. 6 weeks). Furthermore, VR can

cause motion sickness (hence severe susceptibility to motion sickness serves as an exclusion criterium), and both VR and hypnosis may evoke fear in a very small group of people. To this end, at all times someone is present to help, and potentially end the intervention. Lastly, cowhage is applied to the skin of the participants, which gives a short-term itch sensation only, and has - since the 1950s - been frequently administered worldwide - amongst others to people with chronic itch - to our knowledge without reports on (unexpected) side effects (see also section E9). Given the minimal risks and the itch-reducing potential of VRH expected from the literature, this study offers hope for people with chronic itch who are undertreated with their current therapies.

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

Adults (aged 18-80 years) with chronic itch of any origin for at least 1 year prior to inclusion in this study, who have been seen by a physician for the itch. Itch symptoms lead to psychological and/or functional impairment despite standard medical treatment. Patients should speak and understand Dutch and be able to complete questionnaires.

Exclusion criteria

(history of) severe psychiatric comorbidities irrelated to their itch condition such as psychosis or severe clinical depression or anxiety disorder (anxiety and depressive symptoms in itself are common in individuals with chronic symptoms and therefore no reason for exclusion); history of seizures; history of severe migraine; high susceptibility to motion sickness; balance problems; face, head, or neck injury; visual or audiological impairment; pacemaker, defibrillator or other electronic (implantable) device of vital importance; pregnancy or when lactating, and participation in another interventional itch study.

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:	Recruiting
Start date (anticipated):	24-01-2025
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Virtual Reality Set-up
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-12-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL83542.058.23