Effectiveness of Virtual Reality for chronic pain in patients with inflammatory arthritis; a randomized controlled pragmatic clinical trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON56861

Source
ToetsingOnline

Brief title
VIRTUAL trial

Condition

- Autoimmune disorders

Synonym
Inflammatory arthritis; Rheumatoid arthritis, Psoriatic arthritis, Spondyloarthritis; Rheumatism

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Bedrijven,Galapagos

Intervention

Keyword: Arthritis, Fatigue, Pain, Virtual Reality

Outcome measures

Primary outcome

Pain intensity (NRS score)

- In the VR group this is measured immediately before and immediately after

using Reducept, and always twice a day.

- In the control group this is measured once a week.

Secondary outcome

Before the start of the study, the following parameters are measured:

- Baseline variables (e.g. age, gender, occupation, comorbidities, etc.)

- Treatment Expectancy (ETS)

- VR disease (VRSQ)

- Qualitative Pain Assessment (GPQ)

During the study, the following parameters are measured in the intervention

group:

- Type of painkillers, dosage and frequency since last requested: measured

daily between 3:00 PM and 8:00 PM

- Fatigue (NRS score): measured twice a day

- Number of steps per day, measured during the entire study via the integrated

pedometer in the Avicenna app

During the study, the following parameters are measured in the control group:

- Type of painkillers, dosage and frequency for 1 week

- Fatigue (NRS score): once a week.

The following parameters are measured before the start and after the end of the study:

- Pain catastrophizing (PCS)

- Disease activity (DAS28, DAPSA, ASDAS)

- Quality of life (SF-36)

- Physical functioning (HAQ-DI)

- Self-efficacy (ASES)

After completion of the study, the following parameters are measured:

- Evaluation of VR

Study description

Background summary

Inflammatory rheumatic diseases are often associated with factors that limit patients' quality of life and sense of health, with pain being the most important factor. Conditions such as rheumatoid arthritis, psoriatic arthritis, and spondyloarthritis are associated not only with pain during joint inflammation, but sometimes with chronic pain even in inactive disease and in the absence of damage. Painkillers and anti-inflammatory drugs play a crucial role in the treatment of inflammatory arthritis, but a subgroup of patients still suffer from chronic pain despite taking medications, which often leads to

opioid overuse. Various alternative treatments have been investigated, such as pain education, relaxation techniques and cognitive behavioral therapy. However, most are time-consuming and dependent on the availability of expert healthcare providers. Therefore, there is a need for innovative methods to self-administer such treatments on demand. An example of such an innovative method is Virtual Reality (VR). VR is an artificial construction of a 3D environment created by computer technology. An immersive VR system consists of a 3D headset with environmental sensors combined with headphones, allowing users to fully engage and move within the VR environment. VR is increasingly used in the multidisciplinary treatment of pain. Using VR, the perception of pain can be reduced by educating about its cause, providing a distracting stimulus, regulating nociceptive neural signals, and increasing the sense of control over pain. One of these VR programs is Reducept, which aims to relieve chronic pain through pain education and psychotherapy. Previous pilot studies have demonstrated the applicability of the Reducept VR program in arthritis patients, as well as a reduction in pain intensity in a small sample. These pilot studies warrant a formal investigation into the efficacy of the Reducept VR program in patients with inflammatory arthritis who experience chronic pain despite low disease activity.

Study objective

The primary objective of this study is:
- to measure the effect of the VR program Reducept on the NRS pain score in patients with inflammatory arthritis with chronic pain despite low disease activity.

The secondary objectives are:
- to measure the direct effect of the VR program Reducept on the NRS pain score (before and after use of VR).
- to measure the effect of the VR program Reducept on the NRS pain score during the day.
- to measure the effect of the VR program Reducept on fatigue and the use of painkillers.
- to measure the effect of the Reducept VR program on quality of life, physical functioning and pain catastrophizing.
- to measure the effect of the expected outcomes of the VR program Reducept on the actual outcome after using Reducept.
- to measure the effect of the VR program Reducept on self-efficacy.
- to investigate the association between continuous measurement of mobility and patient-reported data on pain, fatigue and physical functioning.
- to measure the usability and acceptance of the ESM technique and VR among rheumatic patients.

Study design

This study is a randomized, controlled, pragmatic clinical trial. Patients will be randomized 1:1 into the VR intervention or the usual care group, with an emphasis on assessing the immediate and longer-term effects of the VR program Reducept on pain, fatigue and the use of pain medication. Patients in the intervention group use the VR headset with the Reducept application for 8 weeks; the first 4 weeks at least three times a week for 15 - 20 minutes and the last 4 weeks patients can use it 'on-demand'. The primary outcome measure NRS pain score and the secondary outcome measure fatigue and medication use are measured using the Experience Sampling Method (ESM), implemented via the mobile health smartphone application Avicenna. Using ESM, self-reported data can be collected regularly. In the VR group, pain is measured both around the use of Reducept and during the day. The patient can self-report the NRS pain score at any time via the app, with instructions to do this immediately before and after using the VR program Reducept. The control group is asked weekly to complete a digital questionnaire about their pain, fatigue and medication use. Eight questionnaires are also completed during a first appointment and at an appointment after 8 weeks.

Intervention

For this study, the Pico G2 4K VR headset will be used in combination with the VR training app Reducept. The Pico G2 is an all-in-one VR headset with an ergonomic design and a simple remote control to start the app. The Reducept training app focuses on training the brain and learning to improve the control over one*s body, thereby gaining more control over pain symptoms. It provides an explanation of pain, followed by a virtual journey through one*s own body, spinal cord, nerve pathways, and brain to deactivate pain signals. Reducept incorporates pain education with psychotherapies like cognitive behavioural therapy, acceptance commitment therapy and eye movement desensization and reprocessing.

Study burden and risks

Patients participating in this study will be required to visit the hospital twice for approximately 60 minutes. The control group must complete a short questionnaire of 3-5 minutes every week. The VR group must complete a short questionnaire of 3-5 minutes at least twice a day for eight weeks. In addition, these participants are asked to use the VR program for 8 weeks. There may also be a chance that the participants will experience cybersickness. However, this is considered unlikely as previous pilot studies have shown that a majority of participants reported no cybersickness symptoms.

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

- Diagnosis of rheumatoid arthritis, psoriatic arthritis or spondyloarthritis
- Disease duration >= 2 years
- Chronic pain symptoms (NRS pain >= 4 at >= 2 moments with >= 6 months between or NRS pain >= 4 at one moment + treating rheumatologist*s opinion about chronic pain) despite low disease activity (DAS28/DAPSA/ASDAS low disease activity at 2 moments >= 6 months between or DAS28/DAPSA/ASDAS low disease activity at one moment + treating rheumatologist*s opinion about low disease activity in the past 6 months)
- Home access to WIFI

Exclusion criteria

- Active disease
- Severe audio-visual impairments

- Any of the following comorbidities: dizziness, limited cognition, balance disorders, claustrophobia, fear of heights (if it makes the use of the VR headset impossible)
-Diagnosed with psychotic disorders, dementia or other disorders that preclude adherence to study procedures

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):	16-07-2024
Enrollment:	128
Type:	Actual

Medical products/devices used

Generic name:	Reducept
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-05-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86439.100.24