The (cost-)effectiveness of an innovative, personalised intervention of therapeutic VirtuAl Reality IntEgrated within physioTherapY for a subgroup of complex chronic low back pain patients

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

Summary

ID

NL-OMON53675

Source
ToetsingOnline

Brief title
VARIETY

Condition

- Joint disorders

Synonym
Chronic low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Arnhem Nijmegen (HAN)
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Chronic low back pain, Physiotherapy, Randomized controlled trial, Virtual Reality

Outcome measures

Primary outcome

Physical functioning (primary outcome), in addition to pain and a minimal set

of other secondary clinical, adherence-related, psychological and economic

measures, at baseline and 1, 3 and 12 months follow-up.

Secondary outcome

See protocol 6.1.2

Study description

Background summary

Physiotherapy, mainly consisting of exercise therapy and patient education, is a first-choice primary care treatment for patients with chronic low back pain (LBP), but unfortunately, especially patients with severe disability and pain demonstrate poor outcomes. Therapeutic VR is considered a potential breakthrough for LBP patients in general and for our complex group of patients with severe disability and pain in particular, as it specifically targets the identified limitations of usual physiotherapy. Therefore, a personalised, VR-integrated physiotherapy intervention, tailored to specific patient characteristics, is expected to result in larger improvements in physical functioning and pain, and more favourable cost-effectiveness, compared to usual physiotherapy.

Study objective

Our primary objective is to investigate whether a personalised, physiotherapy intervention with integrated therapeutic virtual reality (VR) is (cost-)effective at 3 months and 12 months follow-up, compared to usual

physiotherapy, in a subgroup of patients with complex chronic low back pain (LBP) and severe disability and pain.

Study design

Cluster randomised controlled trial.

Intervention

The experimental intervention will be a personalised, VR-integrated physiotherapy intervention in which a selection of existing VR modules developed by our partners (i.e. Reducept and SyncVR) will be integrated into physiotherapy based on the recommendations of the LBP guidelines. The control intervention will be physiotherapy as usual.

Study burden and risks

Participants from the control arm will be treated as usual by their physiotherapist, whereas participants from the experimental arm will receive the experimental, VR-integrated intervention by a trained physiotherapist, with no extra risks as compared to the regular delivery of primary care physiotherapy. The burden of the participants will be minimized to the time necessary for completing the questionnaires (approximately 1.5 hours in total) and the visits with the physiotherapist. Furthermore, for participants with a sufficient supplementary health insurance, the costs of the treatments from the physiotherapist will be compensated. Patients without or with an insufficient supplementary health insurance shall pay for the treatments themselves (approximately 30 euros per treatment). Measurements are limited to self-reported questionnaires, therefore not having any risk either.

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

- LBP > 3 months as reason to visit physiotherapist
- absence of *red flags* or signs of specific LBP
- combination of severe disability (Oswestry Disability Index (ODI) score >= 40) and severe pain (numeric rating score (NRS) >= 5)
- age 18-80 years
- provides informed consent

Exclusion criteria

- severe (physical or mental) comorbidity that will substantially hinder the physiotherapy
- planned diagnostic or invasive therapeutic procedure (e.g. injection, nerve block or operation) for LBP in next three months
- no comprehension of Dutch language
- inability to use VR (e.g. epilepsy, open wounds on face or severe visual impairment)
- no supplementary health insurance
- no email-address and Wi-Fi

Study design

Design

Study phase: 2

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-03-2023
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	17-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-12-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL82072.091.22