Physiotherapy through a different lens

Virtual reality in physiotherapy for people with chronic low back pain



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Chapter 1

General introduction

Pain

The International Association for the Study of Pain (IASP) defines pain as "*an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage*" and states that pain is always a personal experience.[1] Acute pain is an unpleasant process that possesses a survival value, functioning as a protective mechanism to prevent the body from potential harm.[2,3] Pain that persists for more than three months, which is usually beyond the required time for tissues to heal, is considered as chronic pain.[4] The biopsychosocial model (Figure 1.1) can be used to classify causing and maintaining factors that constitute the 'mosaic' of chronic pain. Factors include for example genetics (biological), coping mechanisms (psychological) and cultural beliefs about pain (social).[5] So far, it remains unclear why some patients with acute pain develop chronic pain, while others recover. Risk factors for developing chronic pain include lifestyle and the presence of psychosocial factors (e.g., catastrophizing).[6] The most common type of chronic pain is chronic musculoskeletal pain (CMP), defined as pain in muscles, bones and ligaments.[7] Chronic pain can be divided into primary chronic pain (in which no underlying condition adequately accounts for the pain, e.g., fibromyalgia) and secondary chronic pain (in which an underlying condition adequately accounts for the pain, e.g., chronic postsurgical pain).[8]

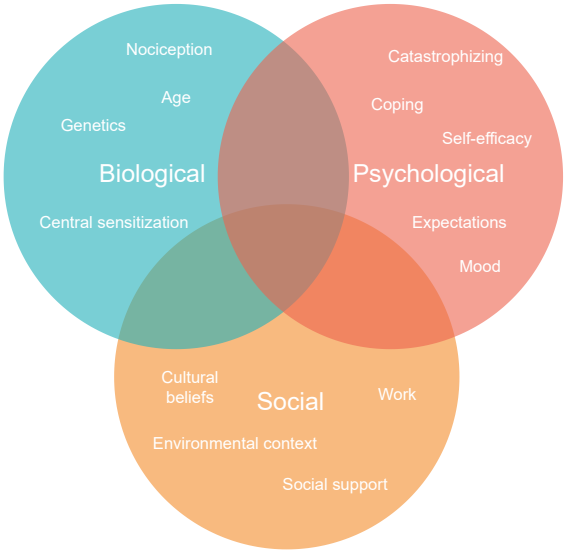


Figure 1.1. Biopsychosocial model of pain.

This is reflected in the International Classification of Diseases (ICD-11), which states that chronic pain could respectively be a disease or a symptom.[4] In addition, chronic pain is generally categorized in three phenotypes: nociceptive pain (associated with tissue injury or damage), nociplastic pain (associated with an altered function of sensory pathways) and neuropathic pain (associated with nerve tissue injury or damage).[2,9] Yet, the prevalence of each of these three chronic pain phenotypes remains unknown, in part because distinguishing between the types can be challenging and multiple types could co-occur.[10]

A key component in chronic pain is central sensitization, the amplification of neural signaling by the central nervous system that elicits pain hypersensitivity.[11] The increasing attention for central sensitization over the past years initiated a shift from primarily considering peripheral mechanisms in pain management to also including central mechanisms.[12] However, the culturally dominant paradigm is still that (chronic) pain signals tissue damage, which is often reinforced by health care professionals.[13] This view is problematic as it could confine reasoning and contribute to acting on a more biomedical perspective, which is related to for example more care that conflicts with guideline recommendations.[14,15] Estimations on the prevalence of chronic pain differ, but approximately 20% of adults suffer from chronic pain.[16,17] Having chronic pain is associated with for example diminished health-related quality of life, psychosocial complaints (e.g., anxiety and depression) and social problems.[18,19]

The most common chronic pain condition is chronic low back pain (CLBP), defined as chronic pain located from the 12th rib to the iliac crest,[6] see Figure 1.2. Globally, CLBP is a leading contributor to disability and disease burden.[20] Most patients with CLBP suffer from non-specific CLBP, meaning that there is no clear nociceptive-specific cause.[21,22] Risk factors for developing CLBP include a higher body weight, being female and depressive symptoms.[23,24] On the other hand, being physically active was found to be a protective factor against developing CLBP.24 The estimated societal costs for low back pain, largely stemming from patients with CLBP,[20] are estimated to be over three billion euros per year just in the Netherlands. Of the costs, 12% are direct (medical) costs and 88% are indirect costs (e.g., due to absence from work).[25] It is projected that because of demographic developments like an aging population and increased rates of obesity, the future global prevalence of CLBP will increase even further.[26]

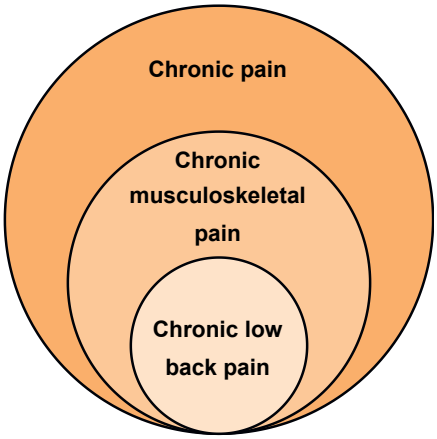


Figure 1.2. Diagram chronic pain, CMP and CLBP.

Treatments for chronic low back pain

Similar to other chronic pain conditions, patients suffering from CLBP have both pharmacological and non-pharmacological treatment possibilities. Treatment for patients with CLBP is generally advised to be individualized patient-centered care, and should be based on the biopsychosocial model.[2] Pharmacological treatment options for CLBP are for example non-steroid anti-inflammatory drugs (NSAIDs), antidepressants and opioids. However, the effectiveness of these pharmacological treatment options is usually modest at best and most therapies come with substantial side effects.[27–29]

Non-pharmacological treatment options for CLBP include physiotherapy, psychology and occupational therapy. These treatment options are usually considered primary care in the Dutch health care system, while secondary care (hospitals) and tertiary care (university hospitals) are other options.[30] In the Dutch system, the general practitioner (GP) is considered the gatekeeper and care coordinator, even though GPs' referrals are sometimes constrained by limited awareness of the full range of available treatment options.[31] In some international guidelines, stepped care is advised for patients with CLBP.[32] This means that patients should start with cheap and more conservative primary care, before advancing to more expensive and complex forms of secondary or tertiary care.[33] Lately, matched care is receiving more attention, in which patients with CLBP are directly matched to the primary, secondary or tertiary health care provider who seems most fitting.[34]

Physiotherapy is a common non-pharmacological primary care treatment option for patients with CLBP.[35,36] Most clinical physiotherapy guidelines, including the guideline from the Dutch Society for Physiotherapy (KNGF), recommend exercise therapy and pain education to treat CLBP.[37,38] Moreover, physiotherapy treatment should support patients' self-management. Passive physiotherapy treatment modalities (e.g., mobilizations or massage) could be considered as supplementary interventions when patients do not respond to initial treatment,[38,39] but should ideally not be used as singular interventions. It should be noted that passive treatments might signal to patients that the physiotherapist will treat the patient, while the patient should be encouraged to actively cope with their complaints.[40] Exercise therapy could alleviate CLBP complaints by improving muscle and joint strength, muscle function and range of motion.[41,42] Pain education aims to increase CLBP patients' understanding of pain, to enable them to best manage and treat it.[43] Additionally, it should be noted that combining multiple treatment modalities in physiotherapy for CLBP seems most effective.[44] This is reflected in two recently published trials, which showed promising results in holistic, multimodal physiotherapy treatments for CLBP, based on the biopsychosocial model.[45,46]

Limited effects of physiotherapy for chronic low back pain

Unfortunately, the effects of physiotherapy for CLBP are on average small and diminish over time,[42,44] which could be explained by a number of reasons. Given that CLBP is a complex problem caused and maintained by a combination of factors, a biopsychosocial treatment approach is recommended.[47] However, many physiotherapists struggle with providing treatment using the biopsychosocial model and prefer a more biomedical approach.[48,49] This is caused by for example a hesitating attitude, perceived lack of necessary skills and difficulty integrating a biopsychosocial perspective in clinical physiotherapeutic reasoning.[50] Another reason for the limited effect of physiotherapy for CLBP is that pain-related fears might hinder patients from performing their prescribed home exercises.[51] It is estimated that up to 70% of patients with CLBP do not adhere to the home exercises prescribed by physiotherapists.[52] This is in part due to patients' belief that certain movements could deteriorate complaints or patients perceiving home exercises as boring.[53] The lack of treatment adherence negatively impacts the overall treatment success of physiotherapy.[54] Methods to improve treatment adherence include

amongst others engagement through immersion and gamification,[55] partly because immersion might decrease pain-related fears.[56] A final reason for small effects of physiotherapy for CLBP is that pain-related fears and high initial levels of disability are known prognostic factors for an increased risk of poor long-term recovery.[57] Altogether, the explanations for the limited effects imply that the physiotherapeutic approach of CLBP should change and ideally include: 1) multimodal treatment (with exercise therapy and pain education as main treatment modalities), based on the biopsychosocial model and aimed to improve patients' self-management, 2) attention to treatment adherence, and 3) patient-centered and tailored care to suit complex patients.[58–60]

Digital health innovations in physiotherapy for chronic low back pain

Worldwide, more and more initiatives are launched to reform (primary) health care, for example by substituting secondary or tertiary care with primary care.[61] An emerging method to support the shift to primary care and improve physiotherapy for patients with CLBP is through the use of digital health. Digital health could be defined as "*proper use of technology for improving the health and wellbeing of people at individual and population levels, as well as enhancing the care of patients through intelligent processing of clinical and genetic data*".[62] The integration of digital health in physiotherapy is known as blended care. Various forms of blended care or digital health in physiotherapy for patients with CLBP have been studied. Smartphone or mobile health (mHealth) apps that support physiotherapists have been introduced as part of multimodal CLBP treatment. However, the effectiveness of mHealth apps is not yet entirely clear,[63–65] partly because not all patients manage to adhere to using the app. In addition, telerehabilitation has been introduced as a digital health innovation in CLBP physiotherapy care. Unfortunately, the effectiveness of telerehabilitation compared to usual care physiotherapy is not evident[66] and most telerehabilitation interventions have a unimodal (i.e., exercise therapy) focus. Another digital health innovation in physiotherapy for patients with CLBP, is the use of inertial measurement units (IMUs) or wearable sensors.[67] Sensors provide possibilities to improve diagnosis, prognosis and treatment of CLBP.[68,69] Nonetheless, wearable sensors are solely used in exercise therapy, but not in for example pain education.[69] Over the last decade, virtual reality (VR) was introduced in physiotherapy for patients with

CLBP as an innovative technology. VR "*leverages immersive technologies to simulate interactive virtual environments or virtual worlds with which users become subjectively involved and in which they feel physically present*".[70] Generally, VR is divided into sensory non-immersive, semi-immersive and immersive VR.[71] An example of sensory non-immersive VR is the Wii system (Nintendo, Kyoto, Japan). However, the Wii system is mainly used for exercise therapy and is relatively expensive compared to other digital health options. Similarly, semi-immersive VR systems like Cave Automatic Virtual Environment (CAVE) are generally considered very costly and are mainly used for complex exercise therapy.[72]

Immersive VR in physiotherapy for chronic low back pain

Current use of immersive VR in physiotherapy for chronic low back pain

Sensory immersive VR has several defining characteristics that make it a distinctive tool; the ability to sensory emerge users in the virtual environment (VE), the ability for users to interact within the VE and the ability to induce a sense of presence inside the VE.[73,74] The first characteristic, also known as sensory immersion,[75] is usually achieved through the use of a head-mounted display (HMD).

Due to the ability of VR to sensory immerse patients in the VE, VR has a strong distracting quality. Because of this, VR is an effective tool in for example acute pain management.[76] Several systematic reviews with meta-analyses on the effect of VR for CLBP showed that VR could alleviate pain intensity and improve functioning in patients.[77–79] However, it is unknown to what extent VR is currently used in physiotherapy practice to treat patients with CLBP and how this is perceived by physiotherapists.

Current evidence of immersive VR in physiotherapy for chronic low back pain

Due to the novelty of the field, there is little research on VR in physiotherapy for CLBP. VR research can be divided into the following three study types, according to the Virtual Reality Clinical Outcomes Research Experts (VR-CORE).[80] VR1 studies are focused on content development through co-creation, VR2 studies conduct pilot testing on for example feasibility and VR3 studies are randomized controlled trials (RCTs). Especially VR3 studies are warranted to examine to what extent VR is effective in physiotherapy for patients with CLBP. According to the literature, future

methodologically rigorous research should employ decent prospective, experimental study designs (e.g., RCTs) in an appropriate clinical setting to examine VR for specific types of chronic pain, like CLBP. Also, the studies should include follow-up periods with an adequate length.[80–82] Several psychosocial VR treatment modalities have been shown to be effective for patients with CLBP, such as relaxation,[83] graded exposure,[84] and behavioral pain-relief skill training.[85] These examples support the premise that VR could supplement physiotherapy treatment for CLBP by incorporating multimodal, psychosocial treatment modalities,[86] that could assist patients' self-management skills.[87] In addition, VR could be used to improve treatment adherence to motivate patients in for example doing gamified immersive home exercises.[88–90] Several of the previously mentioned RCTs provided stand-alone VR interventions, while integrating VR in physiotherapy care might be more effective.[91–93] This was shown in two recent RCTs that showed that physiotherapy with integrated VR for patients with chronic pain improved pain-related outcomes, compared to a usual care physiotherapy control group without VR.[94,95] Although, it must be noted that some of the aforementioned trials also included patients with other types of chronic pain. Further, the quality of some RCTs is questionable. As of yet no high-quality trials have been conducted incorporating VR in CLBP physiotherapy. The lack of high-quality research is also the case for research on prognostic factors that predict which patients would respond to VR treatment. For chronic pain patients in general, VR seems to be more effective in complex patients with more severe complaints.[96,97] Patients with CLBP who received therapeutic VR generally valued the intervention,[92,98] although most patients had limited knowledge about VR and its potential.[99] The lack of knowledge about VR could have affected patients' treatment expectations and credibility of therapeutic VR, which are factors associated with treatment outcomes.[100] Exploring methods to brief patients about VR seems necessary to optimize treatment expectations of patients with CLBP.

Summarizing, multimodal VR could increase the effectiveness of hands-off physiotherapy treatment for patients with CLBP, by incorporating psychosocial interventions that support self-management. Also, VR could improve home exercise adherence (e.g., through gamification and immersion) and provide patient-centered, tailored treatment for complex CLBP patients. Furthermore, treatment expectations of patients should be aligned with VR's potential, to optimize the treatment effect in CLBP patients.

Improving and standardizing virtual reality research

In the broader context, there is a call for more standardization in VR research (for chronic pain) to support purposeful progress.[82,101] Prior research on VR trials in health care described the current state of clinical VR research as the "*Wild West*", with a "*lack of clear guidelines and standards*".[80] This state is for example reflected in the large amount of questionnaires used to examine one specific aspect of VR (i.e. sense of presence).[102] Recently, first steps were taken to improve this, for example through the development of the manuscript reporting guidelines for the early-phase clinical evaluation of extended reality (XR) applications.[103] However, there remains an urgent need for guidelines and standardization in other phases of clinical VR research.

Aims and outline thesis

The **first aim** of this thesis is to provide an overview of the current state and perception of VR usage in physiotherapy for patients suffering from chronic (low back) pain, and to evaluate the effect of a briefing about VR on treatment expectations. **Chapter 2** reports the results of an online survey study among Dutch primary care physiotherapists on the use of and experiences with therapeutic VR in chronic pain treatment. Participants were recruited in two phases, respectively using random and purposive sampling. **Chapter 3** presents the results of an interview study to understand physiotherapists' perceptions and attitudes towards the added value of therapeutic VR in treating patients with CLBP. Participating physiotherapists were both current and past users with extensive experience working with VR for CLBP. **Chapter 4** details the results of two randomized controlled trials on the effect of a positive or neutral language briefing about VR for chronic pain, on treatment credibility and expectancy. The first randomized controlled trial included patients with chronic pain, and the second randomized controlled trial included healthy participants.

The **second aim** of this thesis is to develop a physiotherapeutic intervention with integrated VR through co-creation for patients with complex CLBP, and to examine the effectiveness of this combined intervention compared to usual (primary) care physiotherapy (VARIETY study). **Chapter 5** details the iterative, mixed-methods co-creation process with CLBP patients, physiotherapists and VR researchers to

develop this intervention. **Chapter 6** describes the study rationale and design for a pragmatic, multicenter, cluster-randomized controlled trial to examine the effectiveness of the physiotherapy with integrated VR intervention for patients with complex CLBP. The primary outcome measure was physical functioning and secondary outcome measures included pain intensity, pain-related fears and pain self-efficacy. **Chapter 7** presents the results of the pragmatic cluster-randomized controlled trial, investigating the 3-month effectiveness of the aforementioned intervention for patients with complex CLBP compared to usual care primary care physiotherapy.

The **third aim** of this thesis is to improve and standardize the reporting and evaluation of (therapeutic) VR interventions. **Chapter 8** reports the results of an international three-round online Delphi study with a validation round, to develop an intervention reporting guideline for therapeutic immersive HMD VR interventions. **Chapter 9** describes the results of a systematic scoping review identifying and appraising questionnaires to evaluate different aspects of VR, including presence and user experience. Analysis of the results culminated in a narrative synthesis on and recommendations to use specific VR questionnaires.

Chapter 10 concludes this thesis by summarizing and synthesizing the main outcomes from **Chapters 2** through **9**, and discusses their methodological considerations. Finally, practical and theoretical implications are considered and directions for future research are provided.

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Chapter 2

Limited use of virtual reality in primary care physiotherapy for patients with chronic pain

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Abstract

Background: Chronic pain is a disabling condition which is prevalent in about 20% of the adult population. Physiotherapy is the most common non-pharmacological treatment option for chronic pain, but often demonstrates unsatisfactory outcomes. Virtual Reality (VR) may offer the opportunity to complement physiotherapy treatment. As VR has only recently been introduced in physiotherapy care, it is unknown to what extent VR is used and how it is valued by physiotherapists. The aim of this study was to analyse physiotherapists' current usage of, experiences with and physiotherapist characteristics associated with applying therapeutic VR for chronic pain rehabilitation in Dutch primary care physiotherapy.

Methods: This online survey applied two rounds of recruitment: a random sampling round (873 physiotherapists invited, of which 245 (28%) were included) and a purposive sampling round (20 physiotherapists using VR included). Survey results were reported descriptively and physiotherapist characteristics associated with VR use were examined using multivariable logistic regression analysis.

Results: In total, 265 physiotherapists participated in this survey study. Approximately 7% of physiotherapists reported using therapeutic VR for patients with chronic pain. On average, physiotherapists rated their overall experience with therapeutic VR at 7.0 and "whether they would recommend it" at 7.2, both on a 0–10 scale. Most physiotherapists (71%) who use therapeutic VR started using it less than two years ago and use it for a small proportion of their patients with chronic pain. Physiotherapists use therapeutic VR for a variety of conditions, including generalized (55%), neck (45%) and lumbar (37%) chronic pain. Physiotherapists use therapeutic VR mostly to reduce pain (68%), improve coordination (50%) and increase physical mobility (45%). Use of therapeutic VR was associated with a larger physiotherapy practice (OR=2.38, 95% CI [1.14–4.98]). Unfamiliarity with VR seemed to be the primary reason for not using VR.

Discussion: Therapeutic VR for patients with chronic pain is in its infancy in Dutch primary care physiotherapy practice as only a small minority uses VR. Physiotherapists who use therapeutic VR are modestly positive about the technology, with large heterogeneity between treatment goals, methods of administering VR, proposed working mechanisms and chronic pain conditions to treat.

Introduction

Approximately one in five adults suffer from chronic pain,[1] which mostly occurs in the lower back.[2] Chronic pain is defined as pain lasting longer than three months and is often caused and sustained by a complex interplay of biological, psychological and social factors.[3] Patients with chronic pain report lower quality of life, more social problems, depression and other mental complaints[2,4] compared to people without chronic pain. Moreover, chronic pain is associated with high direct and indirect societal costs.[5]

Treatment options for patients with chronic pain are diverse and include both pharmacological and non-pharmacological possibilities, of which physiotherapy is the most common non-pharmacological treatment.[1,2] It is recommended to administer stepped care for patients with chronic pain, meaning that treatment modalities of more basic steps (e.g., education, resume normal activities) should be applied before advanced treatment modalities (e.g., physical or psychological therapy) can be considered.[6] During their patient journey, most patients with chronic pain visit a physiotherapist to receive exercises and patient education.[1,2] However, effects of this treatment are often small to moderate and diminish over time,[7,8] partly due to a lack of treatment adherence of patients.[9] Virtual Reality (VR) could offer a possibility to support physiotherapists in their treatment of patients with chronic pain, amongst other potential mechanisms by motivating patients to keep exercising.[10]

VR is an emerging technology in healthcare,[11] and is defined as an interactive, 3D computer-generated program in a multimedia environment.[12] VR can be categorized as either immersive or non-immersive, in which immersion usually evokes a greater sense of presence and feeling of being there in the virtual environment (VE). In immersive VR, the user wears equipment, like a head-mounted display (HMD), through which the VE is delivered. In non-immersive VR, the VE is usually delivered through a computer or television screen and controlled using a joystick or other device.[13,14] Besides motivating patients, proposed working mechanisms of VR for chronic pain include distraction,[15] graded exposure therapy,[16] relaxation[17] and neurophysiologic alterations.[18] VR has shown to be an effective therapeutic tool in several chronic pain conditions, including fibromyalgia,[19,20] complex regional pain syndrome[21] and chronic low back pain.[22,23] Besides this, VR in primary care physi-

otherapy offers possibilities including patient monitoring and at-home treatment, while also offering physiotherapy practices the opportunity to present themselves as innovative.[24,25] Given the rising healthcare costs, VR could be a useful tool in the treatment of the growing population of patients with chronic pain, by acting as a substitute for treatment or enhancing current treatments as a complementary treatment modality. Moreover, a recent publication by the Dutch Society for Physical Therapy (KNGF) stated that physiotherapy treatment of patients with chronic pain should focus on three core elements: education, self-management and promoting healthy activity behaviour.[26] VR could be of use to aid with each of these goals.

Despite the widespread attention for VR as a treatment tool in chronic pain science and physiotherapy practice, it is not clear to what extent therapeutic VR is being used in primary care physiotherapy in patients with chronic pain. Moreover, it is unclear what the reasons of physiotherapists are to use or not use therapeutic VR, how VR as a treatment modality is being perceived by physiotherapists, and which physiotherapist characteristics are related to VR usage. Results of this study could provide valuable insights for physiotherapists, researchers, policy makers and VR developers to further improve chronic pain treatment of physiotherapists. The aim of this study was to explore physiotherapists' current usage of, experiences with and characteristics associated with applying therapeutic VR for chronic pain rehabilitation in Dutch primary care physiotherapy.

Methods

Design and sample

This cross-sectional, survey study is part of the VARIETY project and funded by ZonMw (project number: 10270032021502), as described in the study protocol.[27] Approval of the ethical research committee of our institution was obtained for this study (HAN ECO: 347.04/22) in compliance with the Declaration of Helsinki. All participants signed online informed consent before participating (tick-box response). The survey data was collected between March and December 2022. This study is reported in line with the Checklist for Reporting Results of Internet E-Survey (CHERRIES).[28]

Survey

The online open survey was constructed using Google Forms (online Appendix 2.1). Survey questions were based on literature and refined and pilot tested by the research group, by asking four physiotherapists to complete and comment on the online survey before recruitment of participants started. The survey consisted of five demographic questions (i.e., gender, age, practice size, years' experience as a physiotherapist, physiotherapy specialization), 14 closed-ended questions for physiotherapists who use therapeutic VR (regarding overall experience with therapeutic VR, patients for which therapeutic VR is applied, method of offering therapeutic VR and working mechanisms regarding therapeutic VR) and eight closed-ended questions for physiotherapists who do not use therapeutic VR (regarding reasons not to use therapeutic VR, patients who could use therapeutic VR and possible working mechanisms of therapeutic VR). The order of the questions was constant, without alternation or randomization, adaptive questioning was used to prevent stating redundant questions, reviewing of questions was possible and all questions needed to be answered before completing the survey. The questions were shown on two screens, using a maximum of 13 questions per screen. The survey took physiotherapists approximately five minutes if they use therapeutic VR and two minutes if not.

Recruitment and sample

Data was collected using two consecutive rounds (see Figure 2.1). The first round used cluster simple random sampling[29] and included Dutch primary care physiotherapists who did and did not use therapeutic VR for patients with chronic pain. For both rounds, physiotherapists were eligible for participation if they were: (1) practicing primary care physiotherapists who were, (2) working in the Netherlands and, (3) accessible online through e-mail or a contact form. The second round followed a purposive sampling methodology,[29] aimed at Dutch primary care physiotherapists who applied therapeutic VR for patients with chronic pain.

First round

Participants of the first round of the study were recruited using cluster simple random sampling, in two different regions, namely 40 kms around Arnhem and around Almelo, both cities from the eastern part of the Netherlands. In these two regions, every physiotherapy practice that fulfilled the inclusion criteria was contacted online, regardless if they used therapeutic VR.

Second round

Participants in the second round of the study were recruited nationwide using purposive sampling and invited to participate if they provided therapeutic VR for patients with chronic pain.

Procedure

The initial contact with eligible participants in both rounds consisted of an information letter about the survey and an invitation to voluntarily participate. Two reminders were sent respectively one and two weeks after initial contact to non-responding participants in the first round,[30] to reach a minimal retention rate of 25%.[31] All participants voluntarily answered the survey and were not rewarded for participation.

Analysis

The survey results were downloaded and analysed using SPSS version 27 (IBM corporation, Armonk, NY). Demographic characteristics of physiotherapists were presented using means and standard deviations and frequencies. To examine the association between physiotherapist characteristics (i.e., age, gender, practice size, specialization and years of experience) and therapeutic VR use, a multivariable logistic regression analysis was conducted. For this analysis, the following physiotherapist characteristics were dichotomized: number of years working as a physiotherapist (≤9 or ≥10 years), specialization (yes/no) and size of physiotherapy practice (≤9 or ≥10 physiotherapists). The results to the closed-ended questions were analysed by calculating percentages and presented in tables and graphs using GraphPad Prism (GraphPad Inc., San Diego, CA). The surveys from the first round were analysed to gain insight in the prevalence of VR use and characteristics for (non)usage of VR. The survey results of only physiotherapists using therapeutic VR from the first round were combined with the survey results from the second round, to analyse experiences with VR.

Results

Inclusion

In total, 873 physiotherapists were invited in the first round. Of these physiotherapists 245 (28%) completed the survey, as shown in Figure 2.1. In the second round, 20 physiotherapists who use therapeutic VR completed the survey. All physiotherapists who started the survey completed it.

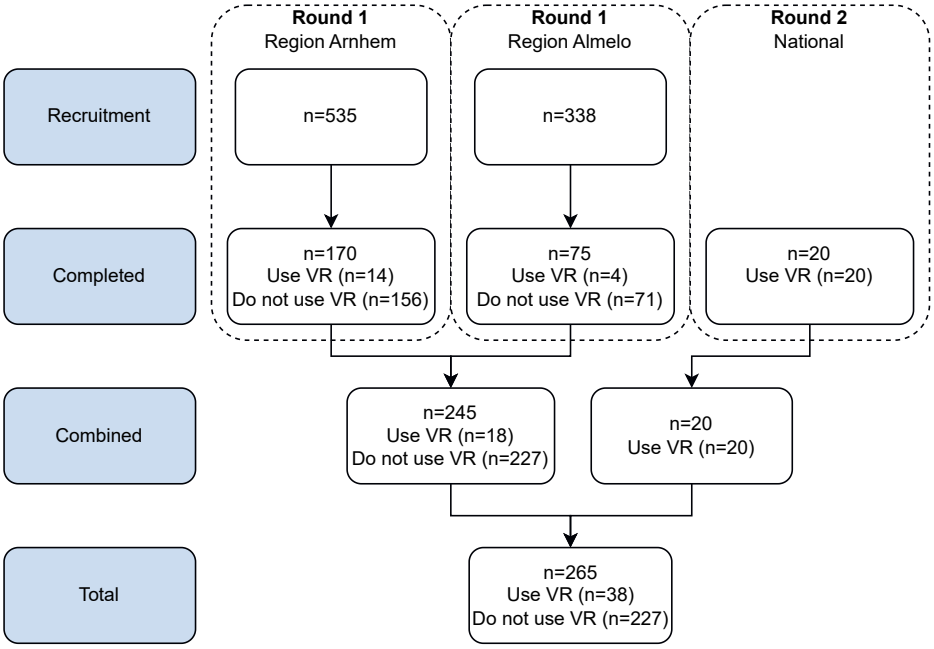


Figure 2.1. Flow of participating physiotherapists.

VR use in physiotherapy practice

From the total of 245 participating physiotherapists from the first round, 18 (7%) stated that they use therapeutic VR in their treatment of patients with chronic pain, as shown in Table 2.1. In combination with the 20 physiotherapists using VR from the second round, a total of 38 physiotherapists who use therapeutic VR were surveyed.

Table 2.1. Demographic characteristics of physiotherapists who use and do not use VR

	Round 1		Round 2	Total sample
	Physiotherapists using VR	Physiotherapists not using VR	Physiotherapists using VR	
N	18	227	20	265
Gender, n (%)				
Female	10 (55.6%)	115 (50.7)	7 (35)	132 (49.8)
Male	8 (44.4)	112 (49.3)	13 (65)	133 (50.2)
Age, mean (SD)	37.8 (14.5)	44.4 (13.9)	42.4 (11.4)	43.8 (14)
Number of years working as a physiotherapist, n (%)				
0–9 years	7 (38.9)	66 (29.1)	5 (25)	78 (29.4)
9+ years	11 (61.1)	161 (70.9)	15 (75)	187 (70.6)
Specialization, n (%)*				
No specialization	5 (27.8)	65 (28.6)	2 (10)	72 (27.2)
Manual physiotherapy	4 (22.2)	70 (30.8)	13 (65)	87 (32.8)
Sports physiotherapy	1 (5.6)	11 (4.8)	2 (10)	14 (5.3)
Psychosomatic physiotherapy	2 (11.1)	19 (8.4)	4 (20)	25 (9.4)
Paediatric physiotherapy	1 (5.6)	11 (4.8)	0 (0)	12 (4.5)
Pelvic physiotherapy	0 (0)	7 (3.1)	1 (5)	8 (3)
Geriatric physiotherapy	1 (5.6)	12 (5.3)	0 (0)	13 (4.9)
Other	5 (27.8)	53 (23.3)	4 (20)	62 (23.4)
Size of physiotherapy practice, n (%)				
1–9 physiotherapists	7 (38.9)	160 (70.5)	11 (55)	178 (67.2)
9+ physiotherapists	11 (61.1)	67 (29.5)	9 (45)	87 (32.8)

* More than one option possible.

Physiotherapists (n=38) who stated they use VR in their treatment of patients with chronic pain scored their overall experience with therapeutic VR at 7.0 (on a 0 (extremely bad) to 10 (extremely good) scale) and whether they would recommend using therapeutic VR at 7.2 (on a 0 (definitely not) tot 10 (definitely yes) scale). Most physiotherapists (71%) started using therapeutic VR less than two years ago and 82% of physiotherapists use VR for a small proportion (<10%) of their patients with chronic pain. Physiotherapists use VR at the physiotherapy practice only (39%) or both at practice and patient's home (61%). Multiple proposed working mechanisms of VR were stated, and educating the patient (58%), relaxation (53%) and activation (53%) were most frequently mentioned. The most commonly reported treatment goals when using VR were pain reduction (68%), coordination improvement (50%) and physical mobility improvement (45%). Regarding VR hardware,

nearly everybody (97%) uses HMDs, with a preference for Oculus (56%) and Pico (47%) headsets. Regarding VR software, Reducept (Reducept, Leeuwarden, The Netherlands) is the most used software (50%), followed by Corpus VR (inMotion VR, 's-Hertogenbosch, The Netherlands) (26%) and SyncVR (SyncVR, Utrecht, The Netherlands) applications (16%). Physiotherapists using therapeutic VR reported it is mostly used for chronic pain patients between 31–50 years old (90%) and 51–70 years old (82%). The main conditions of patients who receive therapeutic VR are musculoskeletal conditions (53%) and medically unexplained physical symptoms (53%). Within musculoskeletal conditions, VR is mostly applied in patients with generalized pain complaints (55%) and nonspecific cervical (45%) and lumbar (37%) pain (see Table 2.2).

Table 2.2. Characteristics of usage of therapeutic VR by physiotherapists (n=38)

	n (%)
Physiotherapists' experience with therapeutic VR (years)	
<1	10 (26.3)
1–2	17 (44.7)
3–5	10 (26.3)
5+	1 (2.6)
Percentage of physiotherapists' patients who receive therapeutic VR	
0–10%	31 (81.6)
11–25%	5 (13.2)
26–40%	2 (5.3)
Method of offering therapeutic VR	
Only at home	0 (0)
Only at practice	15 (39.4)
Both	23 (60.5)
Proposed working mechanisms VR*	
Education	22 (57.9)
Relaxation	20 (52.6)
Activation	20 (52.6)
Exposure	15 (29.5)
Other	8 (21.1)
Treatment goal of therapeutic VR*	
Reduce pain	26 (68.4)
Improve coordination	19 (50)
Improve physical mobility	17 (44.7)
Improve stability	14 (36.8)
Improve strength	9 (23.7)
Improve stamina	9 (23.7)
Other	6 (15.8)

Table 2.2 continues on next page.

Table 2.2. *Continued*

	n (%)
Therapeutic VR hardware used	
VR headset	37 (97.4)
Nintendo Wii	1 (2.6)
Type of VR headset used*	
Pico G2	14 (36.8)
Oculus Go	13 (34.2)
Oculus Quest	9 (23.7)
Pico Neo 3	4 (10.5)
Oculus Rift (S)	2 (5.3)
Samsung Gear	2 (5.3)
HTC Vive	2 (5.3)
Other/unknown	3 (7.9)
Type of VR software used*	
Reducept	19 (50)
Corpus VR	10 (26.3)
SyncVR Fit	6 (15.8)
SyncVR Relax & Distract	5 (13.2)
Kana	3 (7.9)
Koji's Quest	2 (5.3)
Other (commercial) software	3 (7.9)
Patients' age for therapeutic VR use*	
<18 years	6 (15.8)
18–30 years	28 (73.7)
31–50 years	34 (89.5)
51–70 years	31 (81.6)
70+ years	12 (31.6)
Patients' chronic pain conditions for therapeutic VR use*	
Musculoskeletal conditions	20 (52.6)
Medically unexplained physical symptoms	20 (52.6)
Neurological conditions	7 (18.4)
Geriatric conditions	5 (13.2)
Heart, arterial or lung conditions	2 (5.3)
Oncology	1 (2.6)
Paediatric conditions	0 (0)
Other	6 (15.8)
Patients' musculoskeletal conditions for therapeutic VR use*	
Generalized pain complaints	21 (55.3)
Nonspecific cervical complaints	17 (44.7)
Nonspecific (low) back pain	14 (36.8)
Fibromyalgia	12 (31.6)
Headache or dizziness	10 (26.3)
Arthritis	8 (21.1)
Shoulder or arm complaints	7 (18.4)
Pelvic or hip complaints	2 (5.3)
Other	4 (10.5)

* More than one option possible.

Physiotherapist and practice characteristics associated with therapeutic VR use

Results from the multivariable logistic regression analysis among physiotherapists from round one, showed that working at a larger physiotherapy practice (p=.02) was the only physiotherapy characteristic that was associated with therapeutic VR use, while other physiotherapist characteristics (i.e., age, gender, years working as physiotherapist and specialization) were not found to be associated with therapeutic VR use (see Table 2.3).

Table 2.3. Physiotherapist characteristics associated with therapeutic VR use

	OR	95% CI	p
Age	1.02	.99–1.06	.17
Gender			
Male	1.00 (reference)		
Female	.70	.34–1.44	.33
Years working as physiotherapists			
≤9 years	1.00 (reference)		
≥10 years	1.24	.46–3.32	.67
Specialization			
No	1.00 (reference)		
Yes	2.01	.78–5.19	.17
Size physiotherapy practice			
≤9 physiotherapists	1.00 (reference)		
≥10 physiotherapists	2.38	1.14–4.98	.02*

* Statistically significant for p<.05; OR = odds ratio.

Physiotherapists who do not use therapeutic VR

From a total of 227 physiotherapists not using therapeutic VR, only 2% has ever used therapeutic VR before and stopped using it, while 98% never used VR. The main reason for not using therapeutic VR is that physiotherapists were unfamiliar with VR as treatment modality (71%), while costs (20%) and lack of eligible patients for VR (18%) are much less reported as reasons (see Table 2.4).

Table 2.4. Characteristics of physiotherapists who do not use therapeutic VR (n=227)

	n (%)
Physiotherapists who have ever used therapeutic VR	
Yes, but not anymore	4 (1.8)
No	223 (98.2)
Reasons for not using therapeutic VR*	
Costs	46 (20.2)
No suitable patients	40 (17.6)
Unfamiliarity with therapeutic VR	162 (71.4)
Other	28 (12.3)

* More than one option possible.

Discussion

This survey among 265 physiotherapists across the Netherlands showed that a minority of approximately 7% of Dutch primary care physiotherapists of the sample population currently uses therapeutic VR in their treatment of patients with chronic pain. Unfamiliarity with VR is the primary reason for not using VR. Larger physiotherapy practices seem to be more likely to use VR compared to smaller practices. Physiotherapists are modestly positive about VR as a treatment modality and use VR for a variety of treatment goals.

The limited VR usage found in our large survey corresponds with that of other therapeutic eHealth technology studies in Dutch physiotherapy care.[32,33] Ehealth has been introduced in the past two decades amongst other reasons as a strategy to reduce health care costs. Despite the introduction of eHealth, costs of healthcare are still rising in the Netherlands. Studies indicate that many physiotherapists, at least in the Netherlands, are still hesitant to incorporate eHealth in their treatment. For example, one study found that only 1% of patients of physiotherapists in the Netherlands received some form of therapeutic eHealth.[34]

In this study, working in a larger physiotherapy practice was associated with using therapeutic VR. This is in line with a previous study that found that eHealth use was associated with physiotherapy practice size,[33] possibly due to more financial resources. In contrast to this potential facilitator, implementation of VR in healthcare might be hindered due to technical limitations of the device, lack of comparative research and perceived increased work pressure.[35–37] Some of these barriers were mentioned by the physiotherapists in this survey, but the main reason for

surveyed physiotherapists not using therapeutic VR was that they were unfamiliar with using therapeutic VR. This might be related to underexposure of eHealth in physiotherapy programs, as eHealth for example was not mentioned in a recent Delphi study on pain-related content in the Dutch physiotherapy curriculum.[38]

Several treatment goals of therapeutic VR were mentioned by physiotherapists, with reducing pain intensity as most commonly reported treatment goal (68%). Therapeutic VR has indeed been found to be effective in reducing acute pain,[39] but for chronic pain, the level of evidence for therapeutic VR is weaker and less available.[40,41] This is surprising since the survey was specifically about treatment of patients with chronic pain. Another treatment goal reported by 50% of the physiotherapists was improving coordination. This can be considered surprising as well, as not improving coordination, but muscle strength or aerobic capacity are more established treatment goals for chronic pain,[42] but reported less by the physiotherapists. On the other hand, it could be more difficult to target these established treatment goals by VR.

Another interesting finding in this survey is that therapeutic VR is used less often in older patients (>70 years old) compared to younger patients with chronic pain. This is in line with previous studies in which healthcare providers tend to not treat older patients with VR, because of existing ageist beliefs that this population for example does not understand VR technology.[43] However, recent studies found that elderly patients with chronic pain could benefit from treatment with VR[44,45] and find it an acceptable way to manage their pain.[46,47] This implies there might be possibilities to enhance treatment of older adults with chronic pain by adding therapeutic VR.

One of the strengths of this study was using two rounds of sampling, which made it possible to gain more insight in the reasons for using and not using VR, and in the experiences with VR. Also, by cluster random sampling in two areas in the Netherlands, it was possible to reach an adequate sample size of surveyed physiotherapists. On the other hand, this study had several limitations that should be noted. First, this study focused specifically on primary care physiotherapists and on patients with chronic pain. It is possible that VR use is different in other healthcare settings and for other patient populations. Another limitation is the small sample size of physiotherapists who use therapeutic VR (n=38), despite efforts to reach

this group of physiotherapists using professionals networks and social media. Also, most of these physiotherapists were not very experienced with therapeutic VR for patients with chronic pain. The combination of this sample size with lack of experience with therapeutic VR could impair the generalizability of results about VR usage in clinical practice. Moreover, even though probability sampling (i.e., cluster random sampling) was used to recruit physiotherapists in the first round, it is possible that sampling bias occurred to some extent. For example, because of an increased likelihood of physiotherapists who use VR to respond to the survey rather than physiotherapists who do not use VR. Finally, the survey only included close-ended questions, which might have hindered the collection of more in-depth qualitative information.[48] We chose this to minimize the time for physiotherapists to finish the survey.

Results of this study indicate that therapeutic VR use is still in its infancy in primary care physiotherapy. One possible reason for the low adoption of VR, next to the reported barriers such as costs, is a lack of high-quality evidence on the effectiveness of therapeutic VR for patients with chronic pain.[49] There were some explorative RCTs on therapeutic VR for patients with chronic pain in physiotherapy settings,[50–52] but the quality of some of these RCTs is insufficient and limitations to generalize these results include heterogeneity of patient populations and differences between dosage and diversity of used VR software and hardware.[53,54] Therefore, future research should provide more insights in the (cost-)effectiveness, possible working mechanisms and most suitable patient groups of therapeutic VR for patients with chronic pain, in order to be recommended in clinical guidelines and adopted in clinical practice.[49,55] Finally, given the novelty and possible increasing usage of therapeutic VR, future research may also focus on replicating the current explorative study after some years to see how therapeutic VR adoption advances in clinical physiotherapy practice.[56] Also, this future research could include open-ended questions to acquire more thorough information and incorporate topics including physiotherapists' attitudes towards VR, likelihood of VR use and (both physical and mental) symptoms, behaviours and conditions they treat with VR. Finally, for the implementation of VR in physiotherapy care, it would be interesting to gain more insight into values, attitudes and beliefs of physiotherapists who do not use therapeutic VR yet.

Results of this study showed that therapeutic VR for patients with chronic pain is still in its infancy in current Dutch primary care physiotherapy practice, with only 7% of physiotherapists using VR. Unfamiliarity with VR seems to be the primary reason for not using VR. Moreover, larger physiotherapy practices seem to be more likely to use VR compared to smaller practices. This survey also showed that physiotherapists are modestly positive about VR as a treatment modality and that physiotherapists report a large heterogeneity in treatment goals, methods of administering VR, proposed working mechanisms and chronic pain conditions to treat with VR.

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Appendices

Appendix 2.1: Survey

URL: https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-024-07285-5#appendices



Chapter 3

"A new tool for my toolbox": Physiotherapists' perceptions on therapeutic virtual reality for chronic low back pain – a qualitative descriptive study

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Abstract

Objective: Therapeutic virtual reality (VR) is an emerging intervention in physiotherapy for patients with chronic low back pain (CLBP). However, broad adoption of VR by physiotherapists (PTs) is slow. This is possibly due to PT's negative perceptions on and attitudes towards the added value of VR in physiotherapy for patients with CLBP. The aim of this study was to explore these perceptions and attitudes.

Methods: We performed a qualitative descriptive study using semi-structured interviews. The study sample included eleven primary care PTs with a median age of 35 years (range: 28–58). Participating PTs had at least one year of experience using VR for the treatment of patients with CLBP, after which they continued using VR or stopped using it. The interviews were transcribed verbatim and inductively analyzed using reflexive thematic analysis.

Results: Analysis of the interviews identified four overarching themes: (i) therapeutic VR is perceived as non-threatening to the PT's role; (ii) VR has distinctive qualities that complement the PT's toolbox; (iii) contrasting attitudes towards the added value of therapeutic VR for CLBP; and (iv) PTs need specific skills, positive attitudes and knowledge to administer therapeutic VR.

Conclusion: The study results showed that VR was perceived as a valuable and non-threatening innovation for physiotherapy in patients with CLBP, that fits the hands-off and coaching role of PTs. Therapeutic VR seems promising in physiotherapy for patients with CLBP, but further adoption depends on breaking practical and systemic barriers. Also, more education is needed to train PTs to effectively administer VR.

Introduction

Chronic low back pain (CLBP) is the leading chronic pain condition worldwide[1] and is associated with a high burden on patients and society.[2,3] Patients with CLBP often endure sleep disturbance, psychological complaints and poorer health-related quality of life.[4–6] Treatments for CLBP vary and include pharmacological and non-pharmacological options, of which physiotherapy is the most common non-pharmacological treatment.[7] Physiotherapy for CLBP usually consists of a combination of pain education and exercise,[8] possibly supplemented with other interventions. One of these interventions is virtual reality (VR), which is defined as "the interaction between a participant and a simulated three-dimensional, immersive world".[9]

VR has only recently started to be used in physiotherapy,[10] for various purposes such as relaxation,[11] graded exposure,[12] and pain education and management.[13] Previous, mostly small quantitative studies showed that providing physiotherapy with therapeutic VR to patients with CLBP seems to be of added value.[14,15] This is supported by systematic reviews with meta-analyses that show that VR, not specifically in physiotherapy, was effective in decreasing both pain intensity and disability in patients with CLBP.[16,17] However, qualitative studies on the perception and attitudes regarding VR for chronic musculoskeletal pain (CMP) are limited, and were mainly from the patient's point of view.[18] The healthcare provider perspective was provided in two qualitative studies, which examined physiotherapists' (PTs) experiences with VR for musculoskeletal shoulder pain.[19,20] The first study reported that PTs who administered VR during their treatment of patients with shoulder pain thought VR would be a novel and fun treatment modality for a variety of shoulder complaints (e.g., frozen shoulder).[19] However, some safety and adverse event (AE) issues were mentioned as well.[19] The second study corroborated most of these findings and additionally found that PTs were unsure about their new professional role when administering VR.[20] Another study among different health professionals (including PTs) studied opinions on VR-based pain education to develop health literacy in patients with chronic pain.[21] Their results showed that health care professionals perceived VR as an acceptable and feasible technology to improve health literacy in patients with chronic pain. They mainly value its immersive and entertaining qualities. Other, more comprehensive studies on

healthcare provider's experience with VR or telerehabilitation in general for CMP mentioned several benefits (e.g., VR stimulates self-management and patient satisfaction),[22,23] but also barriers such as higher costs and failing technology.[24,25] Also, a study from ourselves showed that PTs stated they should have sufficient affinity with VR for it to be effective.[25] We lack knowledge in more in-depth perceptions and attitudes like PTs' changing professional role when using VR, as this is an important factor for implementing telehealth in physiotherapy.[26]

To summarize, previous qualitative studies on PTs' perspective on VR for CMP focused mainly on topics like practical barriers and facilitators. Also, only one of these previous studies focused specifically on VR for CLBP, although this is the most common CMP condition in the Netherlands[7] and did not include PTs with extensive experience working with VR. Therefore, the aim of this study was to explore in-depth perceptions on and attitudes towards therapeutic VR for patients with CLBP of primary care PTs with extensive experience with VR. Specifically, the study aimed to explore how PTs perceive the role of VR in clinical practice and how using VR might alter the PT's professional role, for example regarding their responsibilities, therapeutic identity and patient-therapist alliance. Also, the study aimed to identify contextual factors that influence VR implementation and examine knowledge, skills, and beliefs PTs consider essential for the effective use of VR.

Methods

Design

In this qualitative descriptive study, semi-structured, in-depth interviews were conducted between April and September 2024. This study employed interpretive epistemology[27] and qualitative descriptive methodology.[28] This methodology fits an interpretive epistemology, which assumes reality is subjective and differs from person to person.[27] The qualitative descriptive methodology was chosen because it best fitted our research aim to obtain straightforward and comprehensive insights that stayed close to the participants' experience, without extensive theoretical context.[28,29] This study received approval of the ethics committee of the University of Twente (ID: 240074). The study was reported according to the consolidated criteria for reporting qualitative research (COREQ).[30]

Participants and recruitment

Study participants were recruited through purposive sampling using social media networks and physiotherapy practice websites, to include information-rich participants (i.e., PTs experienced in using therapeutic VR).[31] To adequately realize our research aim, we aimed to include both PTs who still administer therapeutic VR and PTs who stopped using VR. Including both groups captured a broader range of experiences and barriers (e.g., financial, technical, and clinical) and reduced positive bias that might occur if only active, potentially more enthusiastic VR users were interviewed. Participants were eligible if they 1) were employed as a PT in a Dutch, primary care practice; and 2) were currently using therapeutic VR for ≥1 year in the treatment of CLBP or had used therapeutic VR for ≥1 year in the treatment of CLBP. No more than two PTs per practice were included, to stimulate sample heterogeneity. Participants who met the inclusion criteria and expressed interest in study participation were contacted by the researcher and provided with more detailed information on the study procedures, using an information letter. Participants were able to ask questions regarding study procedures before the interview. All participants signed written informed consent and provided demographic information (i.e., gender, age, years of experience as a PT, physiotherapy master's degree, years of experience with VR and currently using VR). PTs did not receive any (financial) compensation for study participation.

Data collection

Semi-structured interviews were conducted online and recorded using Microsoft Teams (Microsoft, Redmond, USA). An interview guide with open-ended questions was constructed by the author consortium, partly based on literature and prior research.[19,20] The interview guide was pilot-tested before the study start with a physiotherapist. This physiotherapist (46-year-old man) holds a manual physiotherapy master's degree, had five years' experience working with VR and still used VR when the interview was conducted. The data of this pilot-test were not included in the final analysis and the interview guide was reduced to ensure study feasibility. The definitive interview guide had a total of five topics to discuss, for example "roles and habits of the PTs" and "social influence of patients and colleagues on VR use" (see online Appendix 3.1 for the full interview guide). The audio recordings of the interviews were transcribed verbatim using Amberscript (Amberscript, Amsterdam, the Netherlands) and then manually checked for accuracy and

corrected if needed. Participant anonymity and confidentiality were ensured by assigning unique identification codes to each transcript and removing any personal information that could reveal participants' identities. Interview recordings were deleted after transcribing and pseudonymized transcripts were stored in a secure institutional online environment. The individual interviews lasted a median of 44 minutes (range: 35–59 minutes). Data collection stopped when code data saturation was obtained (i.e., three interviews with ≤5% new codes after an interview).[32] Even though reflexive thematic analysis generally values interpretive depth over numerical threshold, we used this indicator to transparently support our decision that sufficient informational richness was reached.[33]

Data analysis

The transcripts were analyzed based on inductive, reflexive thematic analysis to code and interpret the data.[34] We first (re-)read the transcripts to familiarize ourselves with the data. Thereafter, the first three transcripts were coded independently by two researchers (S.S. & J.K.). These codes were discussed and integrated until consensus on the coding procedure and codes was reached. This was not done to achieve coder agreement, but to foster reflexive dialogue and broaden interpretive insight, in line with reflexive thematic analysis principles.[35] Differences in interpretation were discussed to deepen understanding of the data and refine the coding framework, rather than to for example calculate reliability. Next, the remaining transcripts were coded by S.S. After coding all transcripts, emerging themes were identified independently by S.S. and J.K. by collating codes into potential themes, and subsequently discussed until consensus was reached. Then, the potential themes were reviewed, refined, and checked against the coded data and subsequently discussed among all authors until agreement was reached on the final themes. Finally, the themes were described and illustrated with representative quotes. Data analysis was performed using Atlas.ti software version 24 (Atlas.ti, Berlin, Germany).

Study rigor

To enhance the credibility of the study findings, member-checking by e-mail was used directly after the interview and by providing the interviewed PTs the preliminary results to check for misinterpretations and omissions.[36] Seven PTs (64%) responded and none had major comments. Also, researcher triangulation

was used for the first part of the data analysis. Two researchers were involved in the initial coding of the first three transcripts and discussed their interpretations to refine the coding framework. During theme development and review, multiple authors examined the emerging themes, comparing perspectives and discussing alternative interpretations until a shared understanding was reached. The interview transcripts were analyzed using Atlas.ti, securing independent and transparent data analysis with an audit trail. Transferability was strived for by providing thick descriptions of context and study results.[37]

Research team qualifications

The interviews were conducted either by the first author (S.S.), or by a student (S.v.R.) under supervision of S.S. S.S. (Dutch man) has a background in physiotherapy and health psychology and is currently pursuing a PhD related to VR in physiotherapy for patients with CLBP. S.S. followed multiple courses on and previously conducted qualitative research and has comprehensive experience with VR. S.v.R. (Dutch woman) is an occupational therapist who received extensive training in therapeutic communication, and participated in this study to complete her master's degree in health sciences and had limited experience with VR. This (allied health) background facilitated both interviewers to build rapport with and better understand the interviewed PTs, as the PTs probably saw them as peers instead of outsiders. Reflexivity was practiced throughout the entire study process.[38] The researchers practiced reflexive writing, by keeping a journal during the data collection period. Both researchers had no prior relationships with any of the study participants.

Results

Participants

In total, fourteen PTs expressed interest in study participation of which eleven (six women, five men) participated, of whom eight (73%) held a physiotherapy master's degree (MSc) and three (27%) held a physiotherapy bachelor's degree (BSc). Participants were from different regions in the Netherlands and worked in both rural and urban areas. Of the 11 participants, seven were still using VR, while four stopped using it. All PTs who stopped using VR stated that the high costs were the primary reason for quitting, although other reasons were mentioned as

well, for example the language barrier. Eight PTs (73%) used Reducept (i.e., pain education and management techniques), other PTs used Corpus VR (i.e., exercise therapy) (18%), Kana VR (i.e., stress management) (9%) or various applications (9%). More detailed information on individual participant characteristics is provided in Table 3.1.

Table 3.1. Demographic information of interviewed PTs

ID	Age	Gender	Experience as PT (years)	Master's degree	Experience with VR (years)	Currently using VR
1	28	Man	7	-	5	Yes
2	35	Woman	13	-	2	Yes
3	58	Woman	35	PP	1	No
4	57	Man	35	MP	6	Yes
5	37	Woman	16	PP	3.5	No
6	35	Man	10	PP	5	Yes
7	32	Woman	9	PP	5	Yes
8	36	Man	7	-	3	Yes
9	31	Man	9	PP	3	No
10	55	Woman	25	MP	2	Yes
11	32	Woman	10	PP	1	No

MP = manual physiotherapy; PP = psychosomatic physiotherapy.

Analysis of the interviews resulted in the following four themes: 1) Therapeutic VR is perceived as non-threatening to the PT's role, 2) VR has distinctive qualities that complement the PT's toolbox, 3) Contrasting attitudes towards the added value of therapeutic VR for CLBP, and 4) PTs need specific skills, positive attitudes and knowledge to administer therapeutic VR. These themes will be further described below including illustrative quotes of participants. The map of codes can be found in online Appendix 3.2.

Therapeutic VR is perceived as non-threatening to the PT's role

Participants mentioned that they generally do not administer therapeutic VR as a stand-alone intervention but usually combine it with other interventions (e.g., manual therapy). Participants did not view VR as a substitute for their physiotherapy treatment, but as an additional intervention in their treatment of patients with CLBP. Participants stated that therefore they did not perceive VR as threatening to their profession.

> *"Imagine someone enters and I say this is the VR headset and this is how it works, good luck. Then they will probably come back next week and say, this is not working for me." (physiotherapist 8)*

> *"And it [therapeutic VR] does not replace, by far, a physiotherapist." (physiotherapist 1)*

Participants mentioned that the hands-off nature of therapeutic VR fits the coaching role the PTs take on for these patients. By applying this coaching role, PTs signal to the patients that they need to actively cope with their complaints, instead of passively receiving treatment from the PT. This role might facilitate patients to better self-manage their chronic condition (at-home) and prevents patients to get dependent on their PTs.

> *"It [therapeutic VR] warrants a different way of providing physiotherapy, I think… you clearly have a more coaching role, instead of a treating one." (physiotherapist 4)*

> *"Since I do not have to touch the person, I indicate that I won't heal this person and I think that's fundamentally different." (physiotherapist 1)*

Since most participants already adopted their role as a coach, they did not perceive VR to really change their professional role as a PT or for example influence the patient-therapist alliance significantly.

> *"But it did not really change the way I work, because I already worked like this, it [therapeutic VR] fits that. Yes." (physiotherapist 9)*

> *"In that sense, it doesn't change anything, because my relationship with the patient was good already and VR is just something that is added." (physiotherapist 6)*

Participants viewed therapeutic VR as a complementary tool rather than a replacement for physiotherapy, usually integrating it with other treatments modalities. They stated that VR supports their coaching role by promoting patients' self-management without altering their professional identity or the patient-therapist relationship.

VR has distinctive qualities that complement the PT's toolbox

Participants stated that they perceive therapeutic VR as a valuable tool in their toolbox to treat patients with CLBP.

> *"We have a large toolbox with a lot of possibilities, and another possibility was added. That's how I view therapeutic VR." (physiotherapist 10)*

Participants praised the unique qualities of VR, including its potential for creating an immersive and lived experience, using for example embodiment, interactivity, personalization and gamification. These VR qualities enable patients to enter an entirely new virtual world and offer PTs possibilities they do not have in their usual toolbox, like illusions.

> *"This is really beautiful, because yes, you really are in a completely different world." (physiotherapist 4)*

> *"…with a beautiful technology that actually sometimes tricks the brain." (physiotherapist 11)*

The participants valued the variety of unique methods of action VR offers to treat patients with CLBP, like distraction, changing the patient's pain perception and breaking the vicious circle. Participants mentioned that patients frequently reported improved clinical outcomes after using VR (e.g., improved health-related quality of life and physical functioning), and noticed other benefits, such as higher motivation for exercise therapy in patients and sometimes shorter treatment duration.

> *"People are no longer a victim of their pain, but become a person with pain, instead of pain shaping the person." (physiotherapist 8)*

> *"This [therapeutic VR] can be quite a stimulus, extra stimulus, for people to exercise, because it's fun." (physiotherapist 4)*

The innovative and novel nature of VR is another positive feature participants mentioned. Most patients with CLBP received different interventions for their chronic pain but still see a PT for enduring complaints. Patients generally appreciated the PT introducing new treatment modalities, as they get the chance to try something new. By administering innovative therapies, the PT shows dedication to improving patient outcomes.

> *"Actually, I'm always looking for new gadgets, to see what can further help our profession." (physiotherapist 7)*

> *"They're actually grateful that I'm constantly looking for something new, to optimize my treatment." (physiotherapist 4)*

Participants believed that VR is especially helpful for patients who learn better by seeing than by reading, because of VR's focus on the visual aspect. This was not always easy to assess, as participants were occasionally surprised that a patient they thought would not be interested, responded very well to VR.

> *"And the funny thing is, actually sometimes the patients I beforehand assume to be very hesitant to administer VR, say they really enjoy it." (physiotherapist 10)*

PTs regarded therapeutic VR as a unique, diverse and innovative tool in their CLBP toolbox. They emphasized its ability to for example alter pain perception, increase patients' motivation and personalize treatment.

Contrasting attitudes towards the added value of therapeutic VR for CLBP

Participants stated that therapeutic VR in physiotherapy is still in its infancy and is only used in a minority of patients with CLBP. According to the participants, this is due to different factors, including a lack of scientific evidence, frequent problems with the VR technology, no guidance in physiotherapy treatment guidelines and implementation barriers. However, participants noticed that the field is developing quickly and the technology is improving.

> *"I do not think we are very far yet. I think that in some time in the future, when it's [therapeutic VR] easier, more practically applicable and the healthcare insurer is included, it will go much quicker." (physiotherapist 5)*

Participants mentioned their colleagues also hold contrasting attitudes towards therapeutic VR. On the one hand, many of their colleagues were interested in the possibilities of VR and would like to try it out themselves. On the other hand, others remained skeptical or did not understand how VR could enhance physiotherapy treatment of patients with CLBP.

> *"Some know it and some are very curious to what it can bring. Yes, and other colleagues have lower technology literacy, so they find it hard to make that transition and wonder how this can change our job." (physiotherapist 9)*

As VR comes with certain costs for software and hardware, participants devised different constructs to finance VR, such as patients paying monthly subscription costs or the patient's employer paying for the VR intervention. Some were disappointed that health care insurers do not compensate them for VR interventions, while VR could potentially reduce their health care spendings. However, other participants considered VR as an extra service they offered and did not expect earnings in return.

> *"We bought VR headsets, as a physiotherapy practice, and we lend those to the patient. They pay a deposit and a small monthly fee, so they can use it for three months or per month." (physiotherapist 8)*

According to the participants, therapeutic VR unfortunately comes with possible downsides in some patients, including the risk of cybersickness (e.g., dizziness), possible overuse when using VR at home and contraindications for VR use (e.g., epilepsy).

> *"Occasionally, people feel uneasy after using VR and they think the images are overwhelming." (physiotherapist 10)*

Similarly to the participants, their patients also appeared to hold different attitudes towards therapeutic VR. According to the participants, some patients did not take VR seriously, while others were very enthusiastic about it. Also, participants believed that therapeutic VR should not be used for every patient and is only effective in a specific subgroup of patients, such as those who are open minded towards VR, having high expectations of VR and the required technical skills to use VR.

> *"Some patients are not really interested in VR, while other think it's interesting." (physiotherapist 4)*

> *"It's something new, and if there's something new, they have high expectations and because of that a high probability that it works." (physiotherapist 7)*

Participants noted that VR for CLBP is still in its early stages and used by a limited number of patients. Further adoption is partly hindered by technical, financial, and evidential barriers.

PTs need specific skills, positive attitudes and knowledge to administer therapeutic VR

Participants stated that, to effectively administer therapeutic VR, PTs should have a certain level of additional skills, attitudes and expertise. PTs should for example have an open, interested, and supportive attitude towards VR for it to be effective.

> *"It's not just putting on the headset and the patient will manage. You also have to know the subject and yes, you should also be able to do something with that knowledge." (physiotherapist 10)*

> *"So yes, you as a PT should support it [therapeutic VR], I think that's very important" (physiotherapist 3)*

The participants also emphasized the importance of being able to properly explain VR before providing it to the patient, for it to be effective in patients with CLBP. This explanation included both the reasoning why VR could be effective for people with chronic pain, as the more practical explanation of how the VR headset and software operate.

> *"If we explain it well, they'll [the patients] go along with it." (physiotherapist 2)*

Participants mentioned that personalizing and integrating the content of the VR intervention into daily life of the patient is a crucial factor in treatment effectiveness, as they believe this supports a more durable effect. They also sometimes did this by using VR as an instrument to start a conversation and then use that in their treatment.

> *"I feel you would miss something if you would only give pain education and don't reflect on it. That would be a shame, because things come up that sometimes awaken people or they never thought about to be involved [in their pain] or because they become very emotional. So, you really have to reflect on that." (physiotherapist 3)*

> *"After using VR, people often come back with very interesting, surprising things, which we then review together." (physiotherapist 8)*

Since an (extensive) course on using VR is lacking, many participants stated that they learned providing VR by doing it. Also, they wished there were more options for (further) in-depth education on this topic.

> *"If we only use the information from the basic VR course, I do not believe that you would help people with CLBP as you should help them." (physiotherapist 10)*

> *"Because I think that through my practical experience, I learned even more about it." (physiotherapist 7)*

PTs mentioned that effective use of therapeutic VR requires PTs to have specific (communication) skills, the right attitude, and technical knowledge, stressing the need for more in-depth education.

Discussion

The aim of this study was to explore Dutch primary care PTs' perceptions of and attitudes towards therapeutic VR for patients with CLBP. PTs stated that using therapeutic VR fits their hand-off and coaching role as PT. Most PTs perceived therapeutic VR as an additional and innovative tool with unique qualities to treat patients with CLBP. However, PTs had nuanced attitudes towards the implementation of VR in clinical physiotherapy practice. They also stated that PTs should have a certain level of additional skills, attitudes and expertise to effectively provide VR.

The study showed that PTs believed that providing VR did not change their professional role, and felt therefore not threatened by the introduction of VR. They felt that VR further encouraged the hands-off, coaching approach they already applied (e.g., giving pain science education or exercise therapy). Prior qualitative research among PTs' perceptions of therapeutic VR for shoulder pain reported that some PTs thought VR could alter their role as PTs.[20] This could be explained by the fact that for some shoulder complaints (e.g., subacromial shoulder pain), hands-on techniques are recommended in physiotherapy guidelines as addition to exercise therapy.[39] For these PTs, providing VR would thus indeed alter their professional

role. In contrast, in CMP and particularly in CLBP, the recommended physiotherapy treatment consists of exercise therapy and pain science education,[8,40] which better fits the hands-off approach. Nonetheless, some PTs still use hands-on techniques like mobilizations, manipulations and massage therapy in their treatment of patients with CLBP, partly because some patients expect this.[41] While some of these techniques hold merit for patients with CMP, they should ideally not be provided as singular interventions.[8] Also, it should be noted that providing hands-on therapy signals to patients that the PT will treat them, as the patient does not need to actively participate or move, which may give patients the impression that progress can be made without their own effort during treatment. Current physiotherapy for CMP is increasingly aimed at improving patients' self-management and active coping,[42,43] which could be supported by VR (e.g., by teaching pain management techniques or relaxation exercises). PTs in this study emphasized that VR should not substitute physiotherapy, as they believed it was only effective when combined with other physiotherapeutic treatment modalities and integrated in the complete physiotherapy treatment of their patients with CLBP. This corresponds with the findings that studied professionals' and patients' perceptions on the use of VR in interdisciplinary pain treatment.[44] However, the previously mentioned study by Dejaco et al.,[20] reported that some PTs did consider VR to be a stand-alone intervention. Multiple studies have shown that stand-alone VR could be an effective intervention in reducing complaints related to CLBP,[45,46] but other studies reported that integrating VR in physiotherapy could be even more effective than a stand-alone intervention.[25,47] This is illustrated in the VARIETY trial we are currently conducting.[48] In this trial, CLBP patients receive usual care physiotherapy with integrated therapeutic VR modules (including psychosocially oriented VR modules).[25] Many PTs struggle to provide treatment to patients with CMP based on the biopsychosocial model, as they seem to be more comfortable and confident with treatment using a biomedical emphasis.[49–51] Although boundaries of the traditional PTs' role are contested,[52] several barriers (e.g., time constraints and patients' expectations) hinder adoption of biopsychosocial interventions in physiotherapy.[53] VR could support PTs for example by including elements of effective psychological therapies (e.g., cognitive behavioral therapy) for CMP in their biopsychosocial treatment.

PTs regarded VR as an innovative tool for their toolbox that could help improve their treatment of patients with CLBP. This is supported by a recent review on

VR applied to physiotherapy, that reported numerous benefits of VR including improved treatment effectiveness and patient independence.[54] Moreover, VR has shown it could motivate and engage patients during exercise therapy,[55] and could for example be used for a variety of treatment goals like embodiment[56] and distraction.[57] Although VR in general was regarded as valuable, PTs struggled to identify which patients would benefit from VR in advance. PTs mentioned that they thought that VR would work best for patients who were open-minded and had adequate technical skills and realistic expectations. PTs stated that they believed VR would be most suitable for young patients in a prior study regarding PTs perception on therapeutic VR for shoulder rehabilitation.[19] Such belief is supported by a recent systematic review with meta-analysis demonstrating better effects of VR in younger subjects.[58] Although VR also showed to be effective in physiotherapy treatment of CLBP patients with a mean age of 75.[59] Further research is needed to predict which patient with CLBP will benefit from VR augmented physiotherapy.

Strengths and limitations

Strength of the study was the sample of PTs who all had extensive experience with VR and included both current users of therapeutic VR and PTs who stopped using VR for patients with CLBP, preventing a selection bias and possibly overstating the positive sides of VR. Methodological quality was guaranteed by attaining code data saturation, and integrating for example member checking, positionality and reflexive practices, improving the trustworthiness and credibility of the study findings. By using one-on-one interviews, the interviewers were able to explore the participants answers more in-depth. This lowered the risk of social desirability bias compared to focus groups.[60,61] Results of this study are not limited to physiotherapy only, and are relevant for other health care providers, such as occupational therapists, psychologists and physicians, who were included in similar qualitative studies.[24,44] Moreover, the results of this study are not limited to patients with CLBP, as many therapeutic goals PTs aimed to achieve with VR (e.g., promoting movement, relaxation, and self-management) are shared across different CMP conditions.[62]

Several limitations should be noted regarding this study. The interviews were conducted by two interviewers (S.S. and S.v.R.). Despite study procedure standardization, this could have led to differences in for example follow-up questions. Due to

practical reasons, only 27% of the interview transcripts were coded independently by two researchers, which could be used to diminish researcher bias.[63] This could have led to missed quotes and codes that could have enriched the identified themes. All PTs in this study worked in the Netherlands, which limits the transferability of results to other countries and health care systems. However, given the similarities in results from qualitative studies on the addition of VR in physiotherapy for patients with CMP in the Netherlands,[20] Ireland,[19] and Australia,[21] it seems that most results are generalizable to at least other Western countries.

Clinical implications

Therapeutic VR is an innovative tool that PTs could integrate in their treatment of patients with CLBP. VR fits the PT's role as hands-off coach that could support patients with CLBP to self-manage their condition. Based on the current transition in physiotherapy from passive therapies to 'passive' therapists,[64] VR may fit even more in the future physiotherapy practice. To further improve implementation of VR in physiotherapy care, training and education on therapeutic VR should be provided to guide PTs. This education should preferably be part of the bachelor's or master's physiotherapy curriculum, as currently there is minimal attention for eHealth in physiotherapy curricula, let alone VR.[65] Also, clinical guidelines with specific recommendations on e.g., VR treatment instruction, content, and dosage should be developed to help PTs administer VR optimally. PTs reported to learn providing VR mostly by themselves, which was also reported in a study on PTs' view on VR to promote health literacy in patients with CMP.[21] This probably leads to diverging methods and varying quality of using VR. By providing decent education and guidelines, better application of therapeutic VR in physiotherapy will be accomplished.

Future research

For successful further uptake of therapeutic VR in physiotherapy treatment of CLBP, more research is warranted on VR effectiveness and for whom it works (patient characteristics), how it works (working mechanisms) and when it works (ideal dosage). Views of all involved stakeholders in CLBP care should be incorporated for successful implementation of VR, according to the consolidated framework for implementation research.[66] This framework includes the following five domains: innovation, outer setting, inner setting, individuals and

implementation process. This study contributed to the innovation, inner setting and individuals domains. However, more research on especially the outer setting (e.g., policy makers, health care insurers and physiotherapy practice owners) is warranted as well, as this information is lacking currently.

Conclusion

This study examined PTs' perceptions on and attitudes towards therapeutic VR for patients with CLBP. The study results showed that using VR fits the hands-off role PTs take on for patients with CMP and it is a valuable and non-threatening innovation for current physiotherapy treatment of patients with CLBP. Therapeutic VR shows promise in physiotherapy care for patients with CLBP, although widespread implementation depends on removing practical, educational and systemic barriers.

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Chapter 4

The effect of physiotherapists' explanation of therapeutic virtual reality on treatment expectations in healthy people and people with chronic musculoskeletal pain: Two online RCTs

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Abstract

Objectives: Chronic musculoskeletal pain (CMP) is a disabling condition, for which physiotherapy is a common treatment. Therapeutic virtual reality (VR) is an emerging treatment modality in physiotherapy care for patients with CMP. Treatment expectations of patients regarding therapeutic VR influence its effectiveness and could possibly be enhanced by the therapist by using positive language about therapeutic VR. The aim of the current studies was to explore the effect of physiotherapists explaining VR using positive versus neutral language, on treatment expectations of healthy participants (study 1) and patients with CMP (study 2).

Methods: Two web-based, double-blinded RCTs were conducted with two groups (healthy participants and patients with CMP), that were randomly allocated to a video explaining therapeutic VR using positive language or neutral language. The primary outcome measures were treatment credibility and expectancy, assessed at baseline and post-intervention. Between-group differences and within-group changes were respectively analyzed using simple linear regression analyses and repeated measures ANOVAs. All analyses were performed separately for healthy participants and patients with CMP.

Results: In total, 127 healthy participants (study 1) and 115 patients with CMP (study 2) were included and randomized. We found no between-group difference in treatment expectations between positive versus neutral language videos, neither in healthy participants nor patients with CMP. We found significant within-group changes for treatment expectations in both conditions (positive and neutral language) in healthy participants, and in the positive language condition only in the CMP group.

Conclusions: The studies show that any explanation of therapeutic VR (both using positive or neutral language) seems to improve treatment expectations. Unexpectedly, using positive language was not superior to using neutral language. Future research should examine strategies for healthcare providers to set optimal treatment expectations on therapeutic VR in patients with CMP.

Introduction

Chronic musculoskeletal pain (CMP), defined as pain lasting longer than three months, affects approximately 20% of the adult population, leading to significant disability and burden in daily life.[1] CMP frequently impacts physical activities, social relations and occupation.[2] In general, treatment and management of CMP is challenging due to its complexity.[3] Pharmacological therapy often is ineffective[4] and can result in different side effects.[5] Non-pharmacological treatment options include amongst others, multidisciplinary rehabilitation, behavioral therapies (e.g. cognitive behavioral therapy (CBT)) and physiotherapy.[6,7] However, these treatments often only yield small and short-term results.[8,9] Recently, emerging technological treatment options were introduced as adjunct CMP treatments, including telehealth and virtual reality (VR).[10]

Therapeutic VR currently is in its infancy in physiotherapy care for patients with CMP and is mostly being used for patients with chronic neck pain, low back pain and generalized pain.[11] A recent meta-analysis showed that VR seems to be effective for patients with CMP.[12] However, patients with CMP generally lack knowledge about therapeutic VR,[13] which could diminish the intervention's effectiveness and implementation. Mistrust in VR has been shown to be a barrier in implementing VR in healthcare, while patients feeling encouraged by their therapist has been shown to be a facilitator in implementing VR.[14] Expectations of a treatment influence the outcome,[15,16] so it is important that physiotherapists explain the possibilities of therapeutic VR as a new treatment modality correctly and thoroughly in order to set right treatment expectations.[17,18] Previous studies showed that treatment expectations of patients can be altered by the communication style of therapists,[19] which is presumed to be driven by placebo and nocebo effects.[20] Placebo (Latin for "I shall please") and nocebo (Latin for "I shall harm") effects represent complex and distinct phenomena, that are respectively defined as positive psychoneurobiological effects of the patient's positive expectation and negative psychoneurobiological effects of the patient's negative expectation.[21] Positive language use (e.g. "a success rate of 40%" instead of "a failure rate of 60%") by the therapist could enhance the placebo effect.[22,23] Prior research estimated that in physiotherapy for patients with CMP, contextual factors like language use are responsible for at least 46% of the overall treatment effect for exercise therapy and up to 87% of the overall treatment

effect for mobilizations.[24] Physiotherapists' verbal language use and the patients' expectations toward therapy are among the most important contextual factors.[25] However, the effect of physiotherapists' VR related positive or neutral language use on patients' treatment expectations has not been studied yet.

The aim of these studies was to explore the effect of physiotherapists' VR related positive or neutral language use on treatment expectations in both healthy participants (study 1) and patients with CMP (study 2). Our hypothesis was that the physiotherapist's VR explanation video with positive language use would be more effective than the video with neutral language on improving treatment expectations, in both studies. It should be noted that we did not aim to compare the results of this experiment between healthy participants and patients with CMP, as this would warrant age- and gender-matched controls.

Methods

Design

Two online, parallel, double-blinded RCTs, were conducted among Dutch participants and including healthy participants (study 1) and patients with CMP (study 2). The studies were conducted and reported following the Consolidated Standards of Reporting Trials (CONSORT) statement.[26] Randomization (1:1 ratio) and concealed allocation of participants was done by Qualtrics (Provo, Utah, USA). Data were collected between November 2023 and June 2024. Study 1 among healthy participants was initially conducted as a pilot to ensure feasibility and safety of the procedures. In addition, these data provide insights into the general mechanisms of treatment expectations and their perception on therapeutic VR. Both participants and researchers were blinded to intervention allocation. The two intervention videos were standardized in length, presenter, and setting, differing only in wording.

Approval was provided for each study separately by the ethical research committee of the HAN University of Applied Sciences (study 1: HAN ECO: 503.11/23) and (study 2: HAN ECO: 525.02/24). The studies were conducted in compliance with the Declaration of Helsinki.[27] Study 1 was registered retrospectively at ClinicalTrials.gov (identifier: NCT06307912) and study 2 was registered prospectively (identifier: NCT06282757). All participants signed online informed consent before data collection.

Participants

Participants for both studies were recruited online using convenience sampling through social media (and patient organizations in the CMP study) and were asked to participate in a study on their expectations of therapeutic VR. Recruitment of participants was done using a neutral message, requesting participants for research on expectations about therapeutic VR. Participants were eligible if they (1) were aged ≥18, (2) had access to the internet and (3) provided informed consent. They were excluded if they (1) lacked comprehension of the Dutch language and (2) had experience with therapeutic VR. Moreover, for study 2 with patients with CMP, participants were excluded if they did not suffer from CMP, while in study 1 with healthy respondents, participants were excluded if they suffered from CMP.

Sample size was determined a priori using G*Power 3.1.[28] This analysis revealed a required total sample size of 102 participants per study (for both healthy participants and patients with CMP) to detect a medium effect (d=.5) with a power of .8 and one-sided .05 significance level. This effect size was based on the results of a comparable study regarding effects of an online video on low back pain education in people with low back pain.[29] With an expected drop-out of 10%, we aimed to include 113 participants per study.

Interventions

The development of the two explanatory scripts followed an iterative process combining evidence from literature and expert opinion. Content on the general principles of VR for chronic pain (e.g., immersion through 360° view and sound, and possible working mechanisms) was derived from prior research.[11,30] Evidence on therapeutic communication strategies (e.g., expectancy-enhancing text, and avoidance of nocebo-inducing phrasing) was informed by literature on placebo and nocebo communication.[29,31] Expert insights complemented the literature-based content, including input from an expert in therapeutic communication (WvL) and in placebo and nocebo communication (JW). One script included positive language, while the other included neutral language. Some general parts were similar in both scripts (e.g. "while using VR, you are immersed in a different world with 360° view and sound"), but the scripts differed on important aspects, as examples show in Table 4.1. These scripts were discussed and refined within the research group and with several VR and communication experts. The full scripts are

Table 4.1. Examples of positive and neutral language in intervention scripts

Positive language	Neutral language
"Virtual reality is a form of therapy that is increasingly being used."	*"Virtual reality is a relatively unknown technology that is used to a limited extent in physiotherapy practice, but increasingly in video games."*
"Promising results are found in previous research, which has shown that virtual reality can have a positive influence. Previous research showed that pain complaints decreased, patients became less anxious about their complaints and patients indicated that their quality of life improved."	*"Virtual reality shows effects on pain, frustrating symptoms such as mood, pain behavior, and also on quality of life. The virtual reality treatment has not yet been proven, but we can try it."*
"Your body may need some time to get used to using the VR headset, for example you may feel a bit disoriented. But fortunately the majority, namely 80%, does not suffer from this."	*"You may feel a little dizzy or nauseous from the virtual environment. About 20% of patients experience it as disorienting in the beginning"*



Figure 4.1. Still image from one of the VR explanation videos.

added as Appendix 4.1. Finally, the scripts were transformed into two pre-recorded videos explaining VR therapy, as shown in Figure 4.1. In both videos, participants saw a researcher (JK) addressing the camera directly, filmed in a neutral physiotherapy consultation setting with a plain background. Non-verbal communication (e.g., facial expression and eye contact) was similar in both videos to ensure comparability across conditions. Each video lasted approximately 1 minute and 30 seconds. Prior to using them in the studies, both videos were pilot tested by 10 healthy participants using the same procedure as described in the next paragraph.

Procedure

Participants received a link to the online questionnaire in Qualtrics. After providing informed consent, participants were asked to answer the baseline questionnaires. Next, participants were randomized to either watch the positive or neutral language explanation video. Healthy participants of study 1 were asked to read and empathize with a case describing a common patient with CMP and respond accordingly, to help participants set their treatment expectations of therapeutic VR from a patient's perspective. Prior research showed that this is a reliable and valid approach for naïve participants to take on the role of patient.[32] Finally, all participants completed the post-intervention questionnaires. After completing these post-intervention questionnaires, participants were debriefed and informed about the purpose of the trial. Participants in the neutral language video arm also watched the positive language video, to get a more complete view of therapeutic VR. Figure 4.2 provides an overview of the steps in the study procedure.

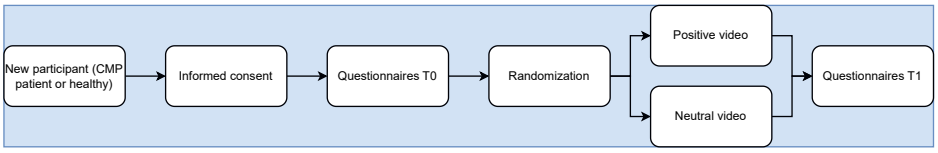


Figure 4.2. Study procedures.

Measurements

Demographics and potential confounders

The following demographic information was collected from all participants at baseline: age, gender and highest level of education, while only in study 2 with patients with CMP also pain duration and pain location were asked to report. Also

at baseline, one question was included on digital skills (i.e. "how good are your computer skills") on which patients scored themselves on a 1 (extremely bad) to 10 (extremely good) range, and one yes-no question was included on openness to therapeutic VR (i.e. "would you be open to treatment with therapeutic VR").

Outcomes

Before (at baseline) and after (post-intervention) the video, the Dutch version of the Credibility and Expectancy Questionnaire (CEQ)[33] was administered, as our primary outcome measure. The CEQ showed to be reliable and valid in measuring treatment credibility and expectancy.[34] This 11-item questionnaire was scored on a 9-point Likert scale and higher scores reflected better treatment credibility (possible range: 5–45) and expectancy (possible range: 6–54). Two subscales (i.e. attitude towards therapeutic VR and preference for therapeutic VR) of the Dutch version of the Attitudes Towards Virtual Reality Treatment (AVRT)[35] were administered at baseline and post-intervention, as secondary outcome measures. This questionnaire was only administered to patients with CMP, as the questionnaire was not yet publicly available when the study among healthy participants was conducted. The AVRT subscales included nine questionnaire items, that were scored on a 7-point Likert and higher scores reflected a more positive attitude towards VR treatment (possible range: 7–49) and preference for therapeutic VR (possible range: 2–14). The original English version of the AVRT showed sufficient reliability and validity,[35] and was translated to Dutch for these studies by a bilingual (Dutch/English) speaker. The translated questionnaire was then checked by the research group and approved for use in these studies.

Analysis

The results of the studies were downloaded from Qualtrics and analyzed using SPSS version 27 (IBM, Armonk, USA). Continuous data was described as mean and standard deviation (SD), categorical data was described as frequency and percentage. The primary analysis was to test for between-group differences (positive vs. neutral language) on all treatment expectation outcome measures, using simple linear regressions. Baseline characteristics were included in the models as covariates. The secondary analysis was to test for within-group changes on all treatment expectation outcome measures using repeated measures ANOVAs. For both between-group differences and within-group changes, outcomes were reported as

mean difference with 95% confidence intervals (CIs). Statistical significance was set a p<.05. All analyses were performed separately for study 1 (healthy participants) and study 2 (patients with CMP).

Results

In total, 247 participants completed the study procedures of this trial, of which 242 (98%) were included for data-analysis, as shown in Figures 4.3 and 4.4. The five participants excluded did not have CMP (n=4) or already received therapeutic VR (n=1).

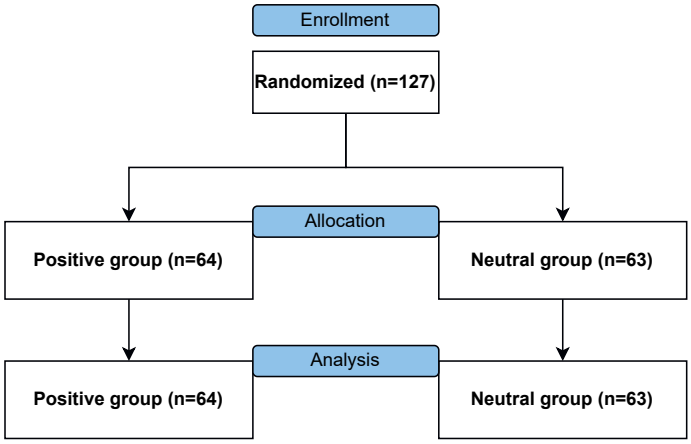


Figure 4.3. CONSORT diagram flow of healthy participants.

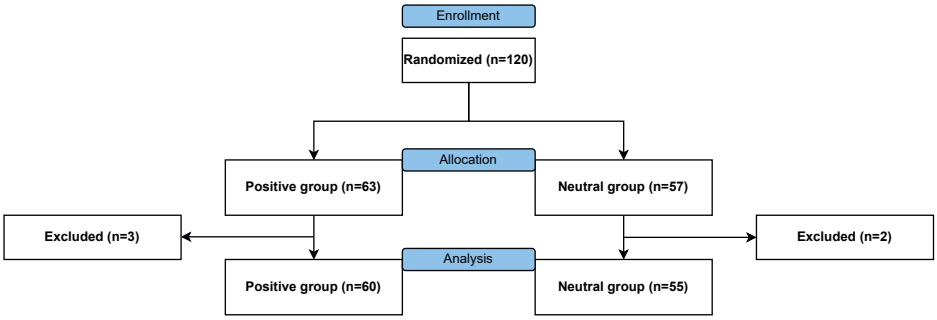


Figure 4.4. CONSORT diagram flow of patients with CMP.

All participants received the positive or neutral language explanation video as allocated. More information on participant demographics is provided in Table 4.2. At baseline, no significant differences were found between the positive and neutral language explanation video arm of healthy participants in study 1 and positive and neutral language explanation video arm of patients with CMP in study 2.

Table 4.2. Baseline characteristics

	Study 1: Healthy participants (n=127)		Study 2: Patients with CMP (n=115)	
	Positive video (n=64)	Neutral video (n=63)	Positive video (n=60)	Neutral video (n=55)
Age, n (%)				
18–30	31 (48)	23 (37)	11 (18)	12 (22)
31–40	6 (9)	4 (6)	3 (5)	3 (5)
41–50	2 (3)	10 (16)	6 (10)	14 (25)
51–60	9 (14)	13 (21)	11 (18)	12 (22)
60+	16 (25)	13 (21)	29 (48)	14 (25)
Gender, female, n (%)	33 (52)	42 (67)	53 (88)	47 (86)
Education level, n (%)				
Lower	10 (16)	10 (16)	11 (18)	6 (11)
Middle	46 (72)	39 (62)	38 (63)	41 (75)
Higher	8 (13)	14 (22)	11 (18)	8 (15)
Computer skills, mean (SD)	7.6 (1.3)	7.7 (1.0)	7.4 (1.3)	7.7 (1.5)
Open to VR, n (%)	57 (89)	60 (95)	52 (87)	49 (89)
Pain duration, n (%)	n/a	n/a		
3–6 months			6 (10)	4 (7)
7–12 months			7 (12)	5 (9)
1–5 years			18 (30)	15 (27)
6–10 years			10 (17)	15 (27)
11–20 years			14 (23)	13 (24)
20+ years			5 (8)	3 (5)
Pain location, n (%)	n/a	n/a		
Generalized pain			20 (33)	23 (42)
Cervical pain			3 (5)	4 (7)
Lumbar pain			23 (38)	12 (22)
Upper extremity pain			4 (7)	6 (11)
Lower extremity pain			10 (17)	10 (18)

CMP = chronic musculoskeletal pain; n/a = not available; SD = standard deviation; VR = virtual reality.

Between-group differences

No statistical significant between-group differences (positive vs. neutral language) were found for any of the outcome measures, both in study 1 (healthy participants) and study 2 (patients with CMP). More specifically, in both healthy participants, treatment credibility (mean difference (MD): -1.6, 95% CI: -4.9–1.6) and expec-

Table 4.3. Within- and between-group results of primary outcome measures

		Study 1: Healthy participants			Study 2: Patients with CMP		
		Positive video (n=64)	Neutral video (n=63)	Between-group difference	Positive video (n=60)	Neutral video (n=55)	Between-group difference
Treatment credibility, mean (SD)	Baseline	23.0 (9.5)	23.2 (13.0)		21.1 (7.8)	21.4 (9.8)	
	Post-intervention	28.4 (9.9)	26.7 (8.6)		24.2 (8.8)	22.6 (9.9)	
	Mean (within-group) change (95% CI)	5.4 (3.8–6.9)	3.5 (1.8–5.3)		3.1 (1.7–4.5)	1.2 (-.5–2.8)	
	Mean (between-group) difference (95% CI)			-1.6 (-4.9–1.6)			-1.6 (-5.1–1.9)
	p	<.001*	<.001*	.206	<.001*	.163	.371
Treatment expectancy, mean (SD)	Baseline	27.6 (12.1)	29.8 (11.5)		25.2 (10.7)	25.1 (11.6)	
	Post-intervention	32.9 (12.1)	32.5 (11.3)		27.2 (11.7)	26.0 (12.3)	
	Mean (within-group) change (95% CI)	5.4 (3.6–7.1)	2.7 (.5–5.0)		2.1 (.4–3.7)	.9 (-1.1–2.9)	
	Mean (between-group) difference (95% CI)			-.7 (-4.9–3.4)			-1.3 (-5.7–3.2)
	p	<.001*	.018*	.271	.018*	.382	.450

CI = confidence interval; CMP = chronic musculoskeletal pain; SD = standard deviation; VR = virtual reality.

tancy (MD: -.7, 95% CI: -4.9–3.4) and in patients with CMP, treatment credibility (MD: -1.6, 95% CI: -5.1–1.9) and expectancy (MD: -1.3, 95% CI: -5.7–3.2) showed no significant differences post-intervention. See Table 4.3 for all primary outcome measures within- and between-group results. In patients with CMP, no significant between-group differences were found on the AVRT questionnaire (Table 4.4).

Table 4.4. Within- and between-group results of secondary outcome measures in patients with CMP

		Positive video (n=60)	Neutral video (n=55)	Between-group difference
Attitude towards therapeutic VR, mean (SD)	Baseline	5.0 (.9)	5.1 (.9)	
	Post-intervention	5.2 (1.0)	5.1 (1.0)	
	Mean (within-group) change (95% CI)	.1 (-.1–.3)	-.1 (-.3–.1)	
	Mean (between-group) difference (95% CI)			-.1 (-.5–.2)
	p	.168	.387	.356
Preference for VR, mean (SD)	Baseline	3.3 (1.3)	3.2 (1.5)	
	Post-intervention	3.5 (1.3)	3.3 (1.4)	
	Mean (within-group) change (95% CI)	.2 (-.0–.4)	.2 (-.1–.5)	
	Mean (between-group) difference (95% CI)			-.1 (-.7–.4)
	p	.067	.171	.336

CI = confidence interval; CMP = chronic musculoskeletal pain; SD = standard deviation; VR = virtual reality.

Within-group changes

In study 1 (healthy participants) within-group changes were found for both treatment credibility and expectancy, for both the positive and neutral language explanation video. Within-group analyses of study 2 (patients with CMP) showed that the positive language explanation video improved both treatment credibility and expectancy, while the neutral language explanation video did not change either of these outcomes. However, no statistically significant changes were found for attitude towards VR and preference for VR in the positive and neutral language explanation arm of patients. Moreover, in patients with CMP, no significant within-group changes were found for the AVRT questionnaire.

Discussion and conclusion

Discussion

These studies aimed to explore the effect on VR treatment expectations of physiotherapists' therapeutic VR explanation using positive or neutral language in both healthy participants and patients with CMP. We found no between-group differences between the positive and neutral language videos on treatment expectations, neither for healthy participants and patients with CMP. On the other hand, we did find within-group changes in treatment expectations for both the positive and neutral language in healthy participants and for the positive language only in patients with CMP. Post hoc power to detect the observed effect (d=.17) was 23%, indicating a 77% probability of a Type II error.[36] Due to the low power, our sample size was likely insufficient to detect the smaller-than-anticipated effect, and conclusions regarding the absence of effect should be interpreted with caution.

Our finding that the positive language explanation video was not more effective in improving treatment expectations than the neutral language explanation video was not expected. Prior studies showed that positive language generally works better than neutral language in physiotherapy, partly due to the placebo effect.[20,37] There are several possible explanations for this unexpected finding in our study, besides the possibility of an underpowered trial. First of all, therapeutic VR is still a novel technology and relatively unknown among most people.[13] All new information about this technology might therefore improve treatment expectations, as treatment understanding can improve treatment expectations.[15,38] Furthermore, it is possible that the wording of the neutral explanation video was not perceived as neutral about VR by all participants, but also as a positive explanation about VR. Future studies could test this using for example a manipulation check[39] and should include sufficiently contrasting explanation videos. Finally, it can be hypothesized that neutral communication about VR might be perceived as an indication of a knowledgeable physiotherapist, and therefore improve treatment expectations.[40]

Another finding of these studies is that both healthy participants and patients with CMP seemed to have a positive attitude towards therapeutic VR, as for example in both groups around 90% of the participants were open to using VR at baseline. This is congruent with the results of a recent survey on the acceptability of therapeutic VR among patients with CMP.[41] However, prior research showed that a

therapist's perceived lack of open-minded patients is a barrier in VR implementation in healthcare.[14] This implies that it could be possible that physiotherapists hold misbeliefs about patients with CMP's openness to using new technological interventions like VR.

The strengths of these studies included the double-blinded, RCT study design, with sufficient participants to meet our a priori calculated sample size. Also, by including both healthy participants and patients with CMP, we managed to learn more about participants' perception on therapeutic VR, as this knowledge is limited for both healthy participants[35] and patients with CMP.[13]

The following limitations should be noted for these studies. First, the baseline questionnaires, intervention and post-test questionnaires were administered within the same session. This could have led to social-desirability bias as participants might remember their initial responses. Second, these studies did not mimic the natural physiotherapy setting, since the videos were shown online and participants for example were not able to ask questions regarding the intervention. Third, these studies did not include any follow-up measurements, which lacked the possibility to study longer-term effects of the videos. Fourth, participants were recruited with a text inviting them to a study on their expectations about therapeutic VR. This could have induced a sampling bias with participants who are more positive about therapeutic VR. Finally, this study did not include a no-intervention control group, so it is unclear whether the observed study results were solely due to the intervention or for example to participants' a priori expectation of using VR. Without a no-intervention control condition, these potential effects cannot be ruled out and interpretation of results should be done with caution.

Future studies should study treatment expectations for therapeutic VR in more detail, as much is still unknown about the context when administering digital therapeutics like VR.[42] These studies should examine the best communication strategies physiotherapists could employ to set the optimal therapeutic VR treatment expectations in patients with CMP. To better reflect clinical physiotherapy practice, they could for example include the possibility for patients to express doubts and ask questions, while also keeping non-verbal communication in mind[43] and include a try-out for patients, as a prior study showed that acceptance and attitudes towards VR improved in healthy participants after testing VR.[44] Future studies are needed

into real-world physiotherapy practices to understand how therapeutic VR is currently introduced and explained to patients. Qualitative studies could be incorporated to explore how patients perceive different communication strategies and whether these perceptions influence their motivation, engagement, or expectations regarding therapeutic VR.[45] These studies should incorporate follow-up measurements to study longer-term effects of altering treatment expectations. Finally, they could examine to what extent the results of this study are applicable to other emerging forms of digital health in CMP, like videoconferencing and mHealth.[10]

Practice implications

In spite of these limitations, these studies have several important implications. First of all, the studies underline the importance of information. A brief verbal explanation of a new therapeutic technology seems to alter treatment expectations in both healthy participants and patients with CMP. The effect of the positive language explanation video was similar to that of the neutral language explanation video, which underlines the importance of providing information on the intervention to modify and improve treatment expectations.[46,47] In providing this information, it seems that using both neutral or positive language is acceptable, while prior research showed that negative language use should preferably be avoided.[29,48] This will help patients with CMP, as treatment expectations have been shown to influence treatment satisfaction and clinical outcome measures.[49,50] Although it should also be stated that unrealistic treatment expectations might diminish treatment effects.[51] Therefore, it is important to use communication that raises positive but realistic expectations. To aid physiotherapists in doing this, it might be valuable to offer them communication training to improve treatment expectations.[29,52]

Conclusion

In conclusion, we found that effects on treatment expectations did not seem to differ between a physiotherapist's short explanation on therapeutic VR as a treatment modality for CMP using positive language versus neutral language. This was found consistently in both healthy participants and patients with CMP. Future research should examine physiotherapists' communication strategies, to optimally set CMP patients' treatment expectations regarding therapeutic VR.

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Appendices

Appendix 4.1: Script texts

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Chapter 5

Development of a multimodal, personalized intervention of virtual reality integrated within physiotherapy for patients with complex chronic low-back pain

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Abstract

Background: Chronic low-back pain (CLBP) is the leading cause of years lived with disability. Physiotherapy is the most common treatment option for CLBP, but effects are often unsatisfactory. Virtual reality (VR) offers possibilities to enhance the effectiveness of physiotherapy treatment. Primary aim was to develop and test a personalized VR intervention integrated within a physiotherapy treatment for patients with CLBP.

Methods: This study describes an intervention development process using mixed methods design that followed the Medical Research Council (MRC) framework. This involved a cocreation process with patients, physiotherapists, and researchers. A draft intervention was constructed based on a literature review and focus groups, and subsequently tested in a feasibility study and evaluated in focus groups. Focus group data was analyzed using thematic analysis. This intervention development process resulted in a final intervention.

Results: Focus group data showed that VR and physiotherapy can strengthen each other when they are well integrated, and that VR needs to be administered under the right conditions including flawless technology, physiotherapists with sufficient affinity and training, and the right expectations from patients. The draft intervention was considered feasible after evaluation by four patients and three physiotherapists and was further complemented by expanding the training for physiotherapists and improving the protocols for physiotherapists and patients. The final intervention consisted of a 12-week physiotherapy treatment with three integrated VR modules: pain education, physical exercise, and relaxation.

Conclusion: Using the MRC framework in cocreation with the end users, a personalized VR intervention integrated within a physiotherapy treatment for patients with CLBP was developed. This intervention was found to be feasible and will subsequently be evaluated for (cost-)effectiveness in a cluster randomized controlled trial.

Introduction

Chronic low-back pain (CLBP), defined as back pain that persists for 3 months or longer,[1] is the most frequent global chronic pain condition[2] and is a leading contributor to disability and disease burden.[3] CLBP is also associated with psychological complaints, social restrictions and high societal costs.[1] Like comparable chronic musculoskeletal pain (CMP) conditions, CLBP is a complex problem because of an interplay of biological, psychological and social factors.[4]

Current treatment options for patients with CLBP vary and include both pharmacological and non-pharmacological possibilities.[5] Physiotherapy is the most common non-pharmacological treatment, usually consisting of a combination of (home) physical exercises and pain education.[6,7] However, effects of physiotherapy seem to decrease or even disappear after stopping treatment.[8] Due to the frequent presence of psychosocial factors in patients with CLBP, an integrated biopsychosocial approach is recommended.[9,10] However, physiotherapists often struggle with providing psychosocial treatment elements to patients with CLBP,[11] due to for example, physiotherapists' skills and patient expectations.[12] Another limitation in CLBP physiotherapy treatment is that patients seem to be unable to keep performing their exercises at home.[13]

Virtual reality (VR) could support patients with CLBP in treatment adherence and guide physiotherapists in providing biopsychosocial treatment. This way VR potentially optimizes the effects of physiotherapy on both the short and long term. Specifically in CLBP, therapeutic VR provides multiple possibilities to support physiotherapists in optimizing their tailored treatment. In VR, a user interacts with a computer-simulated, immersive, three-dimensional world.[14] Therapeutic VR could be used for a variety of treatment goals, including relaxation,[15] graded exposure[16] and distraction.[17] For acute pain, VR seems to be an effective treatment modality,[18] while for chronic pain this is less apparent.[19] Prior studies mainly focused on stand-alone therapeutic VR, and showed that this could be an effective treatment option for patients with CLBP (e.g., [23,24]). However, it has been suggested that an integration of VR within the CLBP physiotherapy treatment could further enhance its effectiveness on clinical and adherence outcomes, in favor of VR as stand-alone treatment next to physiotherapy.[22,23] This integration comprises for example prescription of the VR exercises by the physiotherapist based on patients'

needs and preferences (i.e., personalization). Nevertheless, it should be noted that this integration of VR in the physiotherapy treatment was not empirically examined in clinical practice yet.

The aim of this study was therefore to develop a personalized VR intervention integrated within a physiotherapy treatment for patients with CLBP through a cocreation process. In the development of complex interventions, a cocreation process is advised to develop an intervention that fits differences in needs and interests of stakeholders.[24] Cocreation entails development in collaboration with the end users rather than development solely for the end users, actively involving stakeholders in the process of intervention development.[25] This intervention will subsequently be evaluated for (cost-)effectiveness in a cluster randomized controlled trial.[26]

Materials and methods

Design

This mixed-methods study is part of the VARIETY project, which aims to investigate the (cost-)effectiveness of a personalized VR intervention integrated within a physiotherapy treatment for patients with CLBP in a large cluster randomized controlled trial.[26] The current study, which was conducted following the Medical Research Council (MRC) framework[27] and the best practice framework developed by the VR-CORE international working group,[28] aimed at developing of our intervention in cocreation with the end-users. The MRC framework consists of core elements and four not necessarily consecutive stages, including the development, feasibility testing, evaluation, and implementation of an intervention. This study covered the stages development and feasibility, which are represented by phase 1–3 (development) and phase 4–5 (feasibility) in Figure 5.1. The stages evaluation and implementation will be described in a following study.[26]

The best practices framework of the VR-CORE group states three main phases with accompanying methodologies in the research of VR. This study is a combination of a VR1 and VR2 study, focusing on content development and early feasibility.

Ethical approval was obtained by the Research Ethics Committee of the HAN university of applied sciences (HAN ECO: 319.01/22) and was conducted according

to the principles of the Helsinki Declaration and in accordance with Dutch guidelines, regulations and Acts (Medical Research involving Human Subjects Act, WMO).

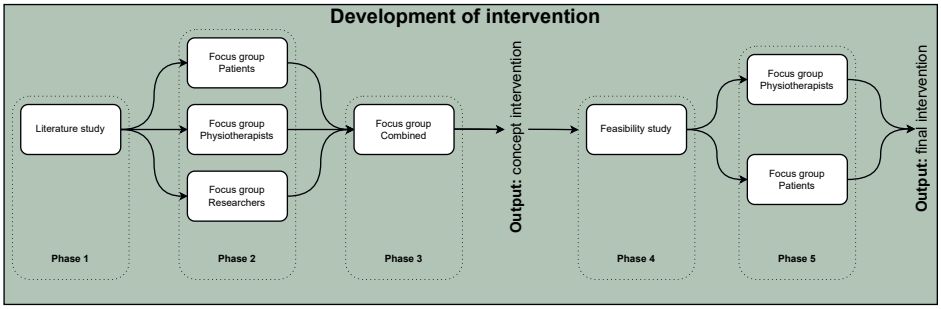


Figure 5.1. Development process of intervention.

Procedures

Literature review (phase 1)

The aim of this literature review was to examine current 'state of the art' CLBP care in primary care physiotherapy and identify recommendations regarding VR. A pragmatic literature review was conducted. We preferred this type over a systematic approach, because of its convenience and usefulness for the purpose of this study.[29] The review was carried out by utilizing and crosslinking the Dutch physiotherapy guideline for patients with LBP,[30] supplemented by a new literature search using PubMed to identify international research and clinical guidelines on VR interventions for patients with CLBP. Peer-reviewed studies from January 2010 up to March 2022 in English or Dutch were included. The search included combinations of the following keywords: "chronic low-back pain" or "CLBP", "virtual reality", and "physiotherapy" or "physical therapy". Based on information gathered in the literature search, supplemented with clinical knowledge and experience of the research team, a framework for the draft intervention was developed.

Focus groups (phase 2, 3 and 5)

Focus groups were used for data collection in phase 2, 3 and 5, to collect opinions and suggestions with regard to the draft intervention. For reporting, the consolidated criteria for reporting qualitative research (COREQ) checklist were used.[31]

The focus group sessions followed the divergence-convergence model,[32] in which the focus groups of phase 2 and 3 had an inductive structure and the focus group of phase 5 a deductive structure.

Semi-structured interview guides with open-ended questions were constructed, as shown in the moderator guide (Appendix 5.1).[33] All focus group sessions were conducted and audio-recorded online using Microsoft Teams (Microsoft Corporation, Redmond, WA) and were moderated by one of the researchers (S.S.). The moderator followed a semi-structured interview guide, ensured that all patients were actively involved in the discussion, and generated interaction between participants. The four sessions had a median duration of 66 (range: 45–82) minutes.

The final focus groups session was conducted similar to those in phase 2 and 3. A new semi-structured interview guide was constructed based on the focus groups in phase 2 and 3, the feasibility study in phase 4, and literature.[34]

Feasibility study (phase 4)

Before the start of the feasibility study, physiotherapists received a single two-hour group-training on the draft intervention, including the personalization of the intervention, integration of VR within physiotherapy treatment, and practical use of VR headsets. After this training, the physiotherapists could get familiar with the VR headset and go through the different VR modules during one week without patients.

Patients referred to a participating physiotherapist practice because of CLBP were screened for study participation by the physiotherapist during the patient's intake. The physiotherapist provided eligible patients with verbal and written information and obtained informed consent. Subsequently, patients were contacted by the coordinating researcher and instructed to complete questionnaires at baseline and directly after the intervention at 12 weeks.

Enrolled patients with CLBP received the draft intervention of VR integrated in physiotherapy.

Demographic information about the patients was gathered at baseline. The following Dutch questionnaires were administered at baseline (T0) and directly after the intervention (T1): physical functioning using the Oswestry Disability

Index (ODI),[35] pain intensity using the numeric rating scale (NPRS),[36] pain related fears using the fear avoidance beliefs questionnaire, physical activity subscale (FABQ-PA)[37] and pain catastrophizing scale (PCS),[38] general effect using global perceived effect (GPE),[39] problems with activities using the patient-specific complaints questionnaire (PSC)[40] and pain self-efficacy using the pain self-efficacy questionnaire (PSEQ).[41] Additionally, physiotherapists were instructed to report possible adverse events (AEs), treatment modalities, and duration of the physiotherapy treatment after each physiotherapy session. Last, used VR modalities and duration of VR usage per day were extracted from an online dashboard in which used VR treatment modalities and duration were registered.

Participants

Focus groups (phase 2, 3 and 5)

Purposive sampling was used to compose three homogeneous focus groups for phase 2. Patients were recruited through the newsletter of a low-back pain patient organization (de Wervelkolom; https://www.ruginfo.nl/) a previous study with a similar patient population, and physiotherapists who use therapeutic VR. Inclusion criteria for patients were: experience with therapeutic VR, and having CLBP. Physiotherapists were recruited through direct contact and social media posts. Inclusion criteria were: experience with therapeutic VR, and practicing as a physiotherapist. Researchers were recruited through direct contact using one inclusion criterion: participated before in VR studies. A heterogeneous focus group for phase 3 was created through inviting patients, physiotherapists, and researchers participating in phase 2.

All participating patients and physiotherapists in phase 4 were asked to participate in the focus groups of phase 5.

Feasibility study (phase 4)

Physiotherapists for the feasibility study were recruited using convenience sampling through directly contacting physiotherapy practices in the network of the researchers. The only inclusion criterion was practicing as a physiotherapist. Physiotherapists recruited patients for the feasibility study using the following inclusion criteria: age 18–80; CLBP >3 months as reason to visit the physiotherapist; absence of 'red flags' or signs of specific LBP;[30] combination of severe disability (ODI score

≥40)[35] and severe pain (NPRS ≥5)[36]. Participants were excluded if they had severe comorbidity that would substantially hinder the physiotherapy treatment, had a planned diagnostic or invasive treatment procedure (e.g., injection, nerve block or operation) for their CLBP in the next three months, lacked comprehension of Dutch language, were not able to use VR (e.g., because of epilepsy, open wounds on face, or severe visual impairment), and had no e-mail address and Wi-Fi connection at home.

Initially, the inclusion criterion of ODI score was set for 40 or higher, as this score singly is associated with severe disability.[35] However, during the feasibility study, physiotherapists stated that many patients underreported their disability and therefore they had to exclude many patients who they would consider eligible. Therefore, we decided to lower the ODI score to 30 or higher. Previous studies among patients with CLBP found that average ODI scores were around 23 (e.g., [44,45]) and the cut-off ODI score of 30 or higher was used in previous studies. It should be noted that an ODI score of 30 or higher combined with NPRS ≥5 is still expected to identify patients with complex CLBP in primary care physiotherapy.

Data analysis

Literature review (phase 1)

Studies found during the pragmatic literature review were screened by S.S. for usefulness regarding the development of a VR intervention integrated within physiotherapy. Studies (e.g., guidelines, reviews or RCTs) were deemed eligible for inclusion if they included information on VR treatment for CLBP, physiotherapy treatment for CLBP or the integration of VR in physiotherapy care. Relevant features regarding intervention content (VR and physiotherapy), intervention duration, integration of VR therapy within physiotherapy treatment, location of administration, and target population were extracted and considered for the development process.

Focus groups (phase 2, 3 and 5)

The content of the focus groups was transcribed using Amberscript (Amberscript, Amsterdam, the Netherlands). The transcripts were analyzed by two independent researchers (S.S. and T.G.) in Atlas.ti version 22 (Atlas.ti, Berlin, Germany) using

inductive thematic analysis.[46] The research question used was: "how can the intervention be improved?". For phase 5, the research question was somewhat specified: "what were strengths of the draft intervention used in the feasibility study and how can the intervention be improved?".

Both researchers independently coded the transcripts for meaningful improvements of the intervention. After each transcript the codes were discussed by the two researchers until consensus was reached, which was repeated for all transcripts. Subsequently, the identified codes were categorized into themes. The final codes and themes were discussed with all other researchers until consensus was reached.

Feasibility study (phase 4)

The feasibility of the intervention was reported descriptively using the physiotherapists' treatment registration, results on outcome variables on T0 and T1, and the VR data about used treatment modalities and duration. Moreover, possible improvements for the intervention and trial were registered during the feasibility study by the coordinating researcher (S.S).

Results

Phase 1: Literature review

The results of the pragmatic literature search yielded one relevant clinical guideline,[30] six RCTs,[15,21,22,47–49] three (systematic) reviews,[50–52] two other studies,[23,53] and one book[54] on VR and/or chronic (low-back) pain.

In summary, Swart et al.[30] describe in the Dutch physiotherapy guideline for patients with LBP that a treatment duration of approximately 12 week is most fitting for complex patients and this treatment duration showed the best results in VR interventions for CLBP.[51] Several types of VR programs in literature seem beneficial for patients with CLBP, including pain education,[21,48] activation,[53] relaxation,[15] and distraction.[49] Combination of these modules might offer a valuable contribution to usual physiotherapy.[48,51] There are various opinions on using either specifically designed VR applications or commercially available ones.[53] Specifically designed applications offer the possibility to target specific movements, pain sites, and with that a specific population. Whereas commercially available apps are more likely

to be applicable to people with a range of functional impairments and are more accessible. Several studies state that the integration of VR modules within physiotherapy could be more effective than stand-alone VR modules.[22,23] This is in line with the physiotherapy guideline that states that therapeutic eHealth could support physiotherapy treatment.[30] Regarding the location of VR therapy use, both use at the physiotherapy practice as use at home has been described.[21,53] Benefits of VR therapy at the physiotherapy practice are professional assistance of a physiotherapist and guidance in translating exercises to daily life. Possible benefits of at-home VR therapy are accessibility and taking exercises to the patients' own environment. Two studies describe the importance of exposure and opportunities of VR therapy to expose patients in a controlled and playful environment.[50,54] Within patients with CLBP, VR interventions seemed to be more effective in more complex patients.[47,52]

Draft intervention

Based on the results of the pragmatic literature review, a framework for the intervention was constructed. The draft intervention comprised a personalized, 12-week, intervention of VR therapy integrated in physiotherapy. The VR therapy contained three modules (pain education, physical exercise, and relaxation). The physiotherapy treatment contained of guideline-based usual care. An integrated, shared-decision making approach with home-based VR treatment combined with physiotherapy sessions was deemed most appropriate.

Phase 2 and 3: Focus groups

Demographics

Demographic information of the participants in the focus groups is described in Table 5.1. Physiotherapists who participated in the focus group held a master's degree for psychosomatic (n=3), manual (n=2) or occupational (n=1) physiotherapy. Researchers who participated in the focus group held functions including (associated) professor (n=3), senior researcher (n=3) or physiotherapy researcher (n=2). The combined focus group (n=5) of phase 3 comprised of patients (n=2), physiotherapists (n=2) and researchers (n=1) who participated in the focus groups of phase 2.

Table 5.1. Demographics of focus group participants of phase 2

	Focus group patients (n=4)	Focus group physiotherapists (n=5)	Focus group researchers (n=8)
Gender, female, n (%)	3 (75)	4 (80)	4 (50)
Age, median (range)	44 (29–73)	33 (29–46)	48 (27–64)
Duration of complaints (years), median (range)	14 (12–30)	-	-
Experience with VR (months), median (range)	2 (1.5–6)	28 (6–90)	-
Experience as physiotherapists (years), median (range)	-	11 (6–23)	-
Experience as researcher (years), median (range)	-	-	15 (1–30)

Thematic analysis

A total of three overarching themes with multiple subthemes as shown in Figure 5.2.

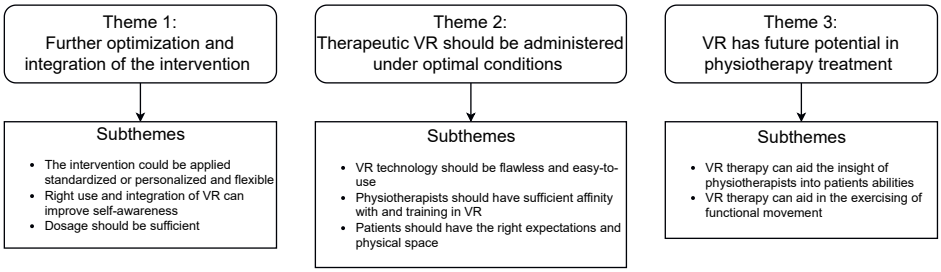


Figure 5.2. Identified themes and subthemes.

Theme 1: further optimization and integration of the intervention

Subtheme: the intervention could be applied standardized or personalized and flexible

An important topic regarding the optimization of the intervention design was the question to what extent the intervention should be standardized or leave room for personalization. Some participants advocated for a strict protocol for the physiotherapists to apply the intervention, to make sure physiotherapists exactly know how to administer the intervention:

> *"I would use a decision tree-like protocol, that allows you to choose one module using certain indications which are quite clear." (physiotherapist 3)*

Others had a different view and proposed a minimal protocol with room for physiotherapists to personalize the intervention:

> *"I don't even think you should use a standard set [of VR modules] that everyone should get, but you have a number of modules available and based on analysis of your physical examination, history taking, and other tests you make a choice." (researcher 5)*

One possible suggested way to personalize the intervention was through shared decision making:

> *"The best of course would be, if you want to imitate clinical physiotherapy practice as much as possible, to leave it to the therapist in consultation with the patient." (physiotherapist 5)*

The method of applying VR modules was discussed and a more parallel approach in which it is possible to alternate between VR modules was preferred:

> *"I would not like to first relax for a week, then exercise for a week and then receive pain education. I would like to use them mixed together." (patient 4)*

Subtheme: right use and integration of VR can improve self-awareness

Several methods to improve self-awareness of patients were discussed. Firstly, it was advised to have patients repeat learned skills and knowledge during the intervention:

> *"When thinking about pain education…you can't do that once. I think you need to repeat and repeat and repeat that." (researcher 8)*

Moreover, self-awareness could be improved by incorporating learned skills and knowledge from VR into daily life:

> *"And also look at how you can use that in daily life, in an exercise or in a psychological exercise or in a physical exercise." (physiotherapist 1)*

Finally, it was mentioned that self-awareness could be improved through feedback of the physiotherapist on experiences attained in VR.

> *"…that if people have an experience, you discuss it in a certain way, so a learning effect arises." (researcher 5)*

Subtheme: dosage should be sufficient

A total intervention duration from at least six to twelve weeks for the total intervention was considered sufficient by participants. The maximum duration of a single VR session was discussed to be around 30 minutes:

> *"We have also had people who practiced for hours, but they say that cybersickness increases after 30 minutes. So we do use 30 minutes as a maximum, also internationally." (researcher 1)*

> *"I also really think you should use it [VR] longer, so that's my main takeaway. That you can't really have a result in six weeks." (patient 1)*

Theme 2: therapeutic VR should be administered under optimal conditions

Different conditions were considered important in the context of the VR applications, the role of the physiotherapist, and the role of the patient.

Subtheme: VR technology should be flawless and easy-to-use

Participants stated that functioning technology was crucial in using therapeutic VR. Common technological obstacles that were mentioned included slow technology, limited battery life, and lack of explanation in VR applications. Participants mentioned that decent technological support was warranted.

Some potential beneficial elements of VR exercises were mentioned which might optimize the intervention. Patients said that a reward system in VR exercises might stimulate treatment adherence. Also, the possibility of using VR in different postures (e.g., sitting or lying down) and having variation within and between VR applications were mentioned as facilitators for VR use:

> *"So the variation yes, change something about the environment or make it more challenging, so you feel like you level up or something." (patient 4)*

Multiple participants stated that it is important to try to prevent side effects due to VR use.

> *"Your eyes receive the signal that you are on a road and you have to dodge cars, but the bike you are on is stationary. So, what you see and what your body is doing, if those are not corresponding, you could get sick." (patient 4)*

Subtheme: physiotherapists should have sufficient affinity with and training in VR

Participants mentioned that it was necessary for physiotherapists administering therapeutic VR to be skilled and trained in doing so (e.g., setting realistic expectations).

> *"The attitude, the knowledge and the skills in that area [VR] are important, because otherwise they [physiotherapists] might administer the VR intervention, but not in the best way possible." (researcher 5)*

Receiving sufficient preparatory information was considered important, including instructions about VR use and its side effects, but also about administering and communicating about the intervention in general. Having peer support groups for physiotherapists was thought to be helpful. To make sure the intervention is administered properly, physiotherapists should have sufficient time to do so.

Besides certain skills, physiotherapists should be motivated and enthusiastic to use VR in their physiotherapy treatment.

> *"We have had physiotherapists who could not handle VR themselves because they would get too dizzy. Patients complained a lot about this, since their physiotherapists did not understand what they were doing." (researcher 2)*

Subtheme: patients should have the right expectations and physical space

Managing expectations of patients was thought to be very important in optimizing conditions for patients to receive the intervention.

> *"What you have to take into account, is the fact that VR is a very hyped treatment. And a hyped treatment could induce a serious placebo effect, but also a nocebo effect." (researcher 1)*

Communication of physiotherapist to patient was deemed important. Patients should receive adequate information from their physiotherapist about the VR headset, VR modules, and intervention in general.

Patients could benefit more from the intervention in the right setting. This could be achieved by having a space to themselves or to use the VR modules in a quiet surrounding, possibly using headphones.

Theme 3: VR has future potential in physiotherapy treatment

Subtheme: VR therapy can aid the insight of physiotherapists into patients' abilities

To gain insight into the patients' performances, several new applications of VR technology were suggested, including the possibility to use biofeedback, measure range of motion (ROM), and examine a patient's load and capacity using VR.

> *"Motion sensors yes, to map movement and using biofeedback to visualize the load and loadability of a patient." (physiotherapist 4)*

Subtheme: VR therapy can aid in the exercising of functional movement

Several possibilities were advised to incorporate VR in the exposure module of the intervention, including the use of pain education and activating VR modules.

> *"When you have the exposure module and then integrate VR into it, for example by using Reducept in step two [education] and for example by using SyncVR Fit in step four [generalization], then you can integrate it." (physiotherapist 1)*

Also body region specific exercises in VR were thought to be of added value, like exercises for core stability or back muscles.

> *"…a little more for the spine, flexion and extension…I don't know if that exists in VR, perhaps like Pilates, a little bit of that learning to move, a little more focused on the spine specifically." (physiotherapist 3)*

Finally, it was suggested to incorporate a VR module to improve the quality of movement of patients.

> *"It would be nice if people start moving more nicely." (physiotherapist 3)*

Phase 4: Feasibility study

Demographics

The feasibility study was conducted by four physiotherapists (three women, one man) with the following physiotherapy specializations and master's degrees: manual therapy (n=2), psychosomatic physiotherapy (n=1) and none (n=1). One of the

physiotherapists had previous experience with therapeutic VR (2 years). During the feasibility study one of the physiotherapists started a new job and stopped participating.

A total of 23 patients were deemed eligible for participation in the feasibility study (Figure 5.3). In total, seven patients were enrolled of which four completed the 12-week intervention. These four patients (two females) had a median age of 56 years old and a duration of CLBP of 14 years (Table 5.2). The patients who completed the intervention showed improvements on all outcome measures except for physical activity (Table 5.3).

All values are reported as median (range) unless specified otherwise.

Patients received on average 6.3 usual physiotherapy treatments. Treatment modalities differed between physiotherapists and included manual therapy (48%), exercise therapy (48%), pain education (28%), and psychosomatic therapy (24%). Median VR use was 58.3 minutes per week (range: 30.3–126.8). Among the three VR modules in the intervention, SyncVR Relax & Distract was used most (67%), followed by Reducept (17%), and SyncVR Fit (16%). No AEs were reported.

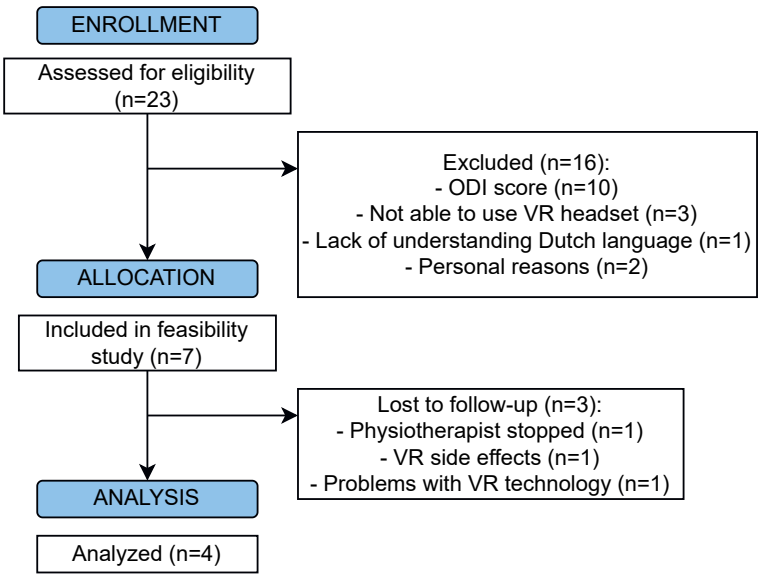


Figure 5.3. Flow of patients in feasibility study.

Table 5.2. Demographics of feasibility study patients (n=4)

Gender, female, n (%)	2 (50)
Age, median (range)	56 (20–70)
Duration of complaints (years), median (range)	14 (4–30)
Comorbidities, yes (%)	3 (75)
Occupation	
Yes, n (%)	1 (25)
No, n (%)	1 (25)
Retired, n (%)	2 (50)
Education level	
Higher, n (%)	1 (25)
Intermediate, n (%)	2 (50)
Lower, n (%)	1 (25)
Undergone diagnostic procedures past 6 months, yes (%)	3 (75)
Undergone therapeutic procedures past 6 months, yes (%)	4 (100)
Medication use, yes (%)	4 (100)
Experience with therapeutic VR, yes (%)	0 (0)
Experience with VR for entertainment, yes (%)	1 (25)

Table 5.3. Pre- and posttreatment outcome measures of feasibility study

	T0	T1
ODI	42.5 (32–50)	20 (0–56)
NPRS	8 (7–8.5)	6.5 (4–8)
FABQ-PA	13.5 (10–14)	13 (8–14)
PCS	28 (12–44)	21 (3–31)
Physical activity ↑ (minutes/week)	405 (70–900)	240 (210–840)
PSEQ	28 (19–34)	33.5 (30–47)
EQ-5D		
Quality of life (index value)	.80 (.73–.83)	.83 (.68–.86)
Health status	4 (3–5)	6.5 (4–7)
GPE		
Recovery	n/a	5.5 (5–6)
Satisfaction	n/a	6 (5–7)
CEQ		
Credibility	28.5 (0–32)	n/a
Expectancy	31 (0–33)	n/a

All values are reported as median (range) unless specified otherwise.

Phase 5: Focus groups

Demographics

The focus group of patients (n=2) included two men, aged 67 and 70, who were suffering from CLBP for 10 and 30 years and completed the draft intervention.

The focus group of physiotherapists comprised the three physiotherapists who administered the draft intervention during the feasibility study.

Focus group results phase 5

Thematic analysis of the two focus groups from phase 5 identified similar themes and subthemes as found the in focus groups of phase 2 and 3 confirming the importance of these recommendations. Some themes were supplemented with new insights. A specific recommendation from patients was to have a better explanation about the VR modules from their physiotherapists.

> *"Well, I might have misunderstood those, but I couldn't get them to function to be honest. I also tried to do the Sudoku game, but I don't know, I thought the manual and explanation were very brief and limited." (patient 1)*

Participants confirmed and further stressed the importance of the possibility to personalize VR modules to the needs and wishes of the patient and their therapist.

> *"I would like to have [VR] exercises that would fit with my abilities and inabilities to function…and I think maybe you can focus a bit more in the future, to see whether someone has physical problems or someone has mental problems, let's say memory problems, and say: this program will benefit you the most." (patient 1)*

Finally, it was suggested to further expand the VR modules towards for example motor imagery training.

> *"But I think, if you look at the applicability [of VR] to pain, there are many more possibilities in terms of content…visualization is different in people with chronic pain. And yes, I think those things could be even better in the future. And motor imagery training, you know what I mean right?" (physiotherapist 3)*

Final intervention

After evaluation of phase 4 and 5, several improvements for the final intervention were suggested. The training for physiotherapists was extended and split in two parts of approximately 90 minutes (i.e., VR soft- and hardware, and intervention

and research). The protocol for physiotherapists and explanation for patients was revised based on input from the participants and physiotherapists in the feasibility study (e.g., more extensive manual on VR use).

Intervention content

Based on the findings from the feasibility study and last focus groups, final adjustments were made to the draft intervention resulting in the final intervention (Figure 5.4). The final intervention consisted of a personalized intervention of VR therapy integrated in physiotherapy with a duration of twelve weeks. The final intervention is described in more detail below and schematically in Figure 5.4.

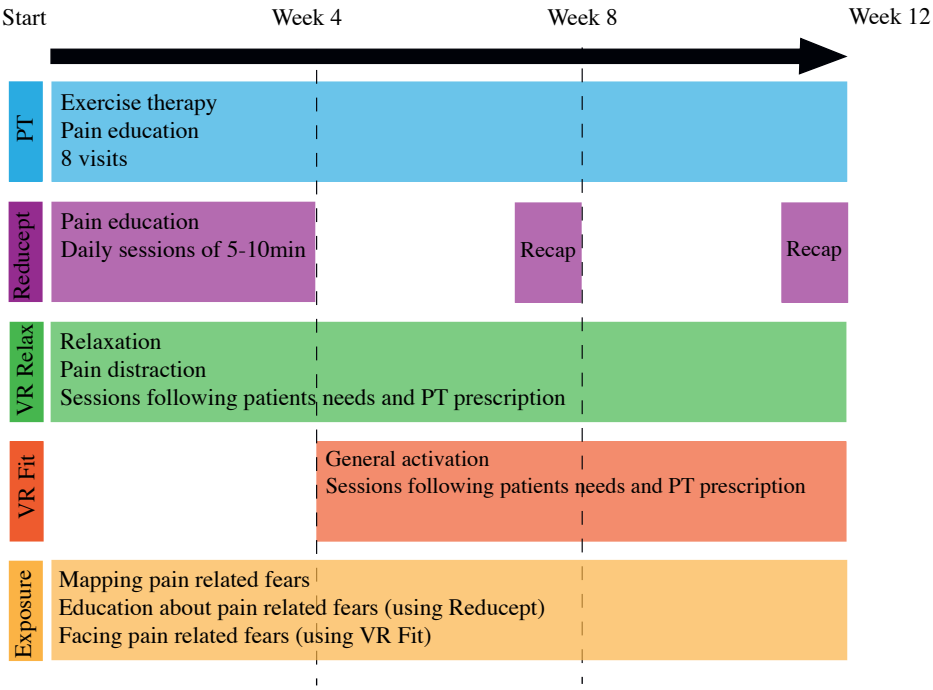


Figure 5.4. Schematic representation of final intervention.

Physiotherapy

The physiotherapy treatment was advised to consist of at least eight visits following usual physiotherapy care based on the Dutch physiotherapy guidelines for patients with LBP.[30]

VR

The VR therapy was applied using the Pico Neo 3 (Bytedance, Beijing, China). Patients were instructed to use the VR headset five times a week for 10–30 minutes at home. Three commercially available VR modules were incorporated in the draft intervention, because of the advantages regarding accessibility and wider applicability. First, Reducept (Reducept, Leeuwarden, The Netherlands; Reducept Game - Play-through Demonstration - YouTube) was used for pain education and practicing pain management techniques. This module contains consecutive sessions of approximately 10 minutes, in which a patient travels through the nervous system and gets exercises based on different psychological treatment principles and pain neuroscience education elements. Second, SyncVR Relax and Distract (SyncVR, Utrecht, The Netherlands; SyncVR Relax & Distract - YouTube) was used for relaxation and distraction. The module contains a wide variety of videos, games, and relaxation exercises with durations varying between 5–20 minutes. Third, SyncVR Fit (SyncVR, Utrecht, The Netherlands; SyncVR Fit - YouTube) was used for general activation. This module includes 11 movement and sports exercises (e.g., tennis and boxing) varying in duration between 5–10 minutes and with three intensity levels. Data security was attended to, by not using any personal data on the VR headset and only extracting pseudonymized usability data.

Physiotherapists and patients should select suitable VR modules through shared-decision making. Physiotherapists were instructed to start with the VR modules on pain education and relaxation in the first weeks and start using the VR module on activation in the fourth week. Physiotherapists were instructed to discuss the patient's VR use. Based on the patient's experience and preferences with VR, the physiotherapist could adapt (VR) treatment. Also, physiotherapists were advised to prescribe VR exercises for home exercises.

Specifically for those patients with a higher score on pain related fears (FABQ-PA ≥16 and/or PCS ≥30), physiotherapists were instructed to supplement usual care with exposure therapy. This exposure module was based on four steps: (1) mapping patient specific pain related fears, (2) education about these pain related fears (possibly using the VR module Reducept), (3) facing these pain related fears (possibly using the VR module SyncVR Fit), (4) facing these pain related fears in daily life.[55]

Discussion

Main findings

This study described the development of a physiotherapy treatment with integrated, multimodal, immersive VR for patients with complex CLBP. Unique for our final intervention is the strong integration of the VR modules in the usual physiotherapy treatment. Previously studied VR interventions were stand-alone interventions with no or minimal guidance of professional therapists.[20–22] Integration of VR into an existing treatment is challenging and has been reported as an important barrier to adoption.[56] Therefore, the development of our VR intervention is an important step towards better integrated therapeutic VR.

VR and physiotherapy can strengthen each other as suggested in previous studies[22,23] and explicitly mentioned in the focus groups in this study. Learned principles through VR education can be made explicit for daily situations in conversation with a trained (physio)therapist, thereby enhancing patients' self-awareness. Vice versa, VR can enhance adherence by making exercising more attractive, improve patient performance, and simultaneously provide possibilities to track patients' performances during exercises.[57,58] To accomplish this mutually beneficial relationship, VR needs to be administered under the right conditions, and therapists need guidance in the form of a protocol with sufficient freedom to further personalize the intervention through shared decision making. These right conditions were further specified in the focus groups in regard to the technology, physiotherapist, and patient. Firstly, easy-to-use and flawless technology was mentioned in the focus groups, which coincides with results from prior studies on barriers and facilitators to implement VR in physiotherapy.[59] Secondly, physiotherapists should have sufficient affinity with and training in therapeutic VR. Prior studies found that therapists administering therapeutic VR could benefit from a multi-stage training program[60] and mentioned it as a facilitator for implementing VR in physiotherapy care.[61,62] In our concept intervention, training of the therapists comprised of a single training. Based on the focus groups this training was extended to two separate 90-minute sessions; one specifically regarding VR soft- and hardware and the other regarding its integration in the physiotherapy treatment and specific research tasks. This is a one-time and relatively limited time investment and therefore regarded feasible and scalable. Thirdly, patients need the right expectations and physical

space. This corresponds with previous findings among patients with CMP, which showed that an individual's expectation critically influence the efficacy of pain treatment.[63]

To our knowledge, no previous VR interventions for CLBP were developed using a framework like the MRC framework. This framework provided a systematic approach to develop and test the intervention and the mixed-methods approach allowed us to include a broad range of perspectives from the different stakeholders on the content and design of the intervention while being able to practically test this in a feasibility study. Moreover, the framework includes multiple core elements that were considered during development of the final intervention, such as 'context'. This was taken into account and mentioned during the focus groups as identified in the subtheme that proposed that physiotherapists should have sufficient affinity with and training in VR. This coincides with the recommendation to consider the authentic context of use of digital therapeutics.[64] Also, intervention refinement is a core element that was included in the development of the final intervention, since multiple adjustments were made to the draft intervention.

In order to study the added effect of integrated VR in clinical primary care physiotherapy, participants of the focus groups suggested a more pragmatic intervention design. This pragmatic approach may include shared-decision making, alternating use of VR modules and flexibility in the intervention dose. Moreover, the possibility to personalize the intervention was mentioned. This is in line with patient-centred care, as advised for patients with CMP[65] and shown to improve effectiveness in VR studies.[61,66] Even though the choice for a more pragmatic approach might limit statements about efficacy and internal validity, the external validity will be higher.[67]

Strengths and limitations

A main strength of our study is the use of the MRC framework, providing a systematic approach to develop and test the intervention. A combination of homo- and heterogeneous focus groups enhanced the participant involvement and idea generation during the group discussions. The end-users (patients and physiotherapists) were closely involved in the development and testing of the intervention, which enhances the potential effectiveness and implementation in daily practice. Finally, by using commercially available VR software, implementation in physiotherapy practice is easier and programs are regularly updated.

This study might have benefitted from a larger sample size in the feasibility study. Because of the low sample size no conclusions can be made about the preliminary effectiveness of the developed intervention. Ideally, a larger pilot cluster-RCT would be performed to gain more insight in preliminary effectiveness. Second, the focus of this study was the development of a complex intervention and the examination of its feasibility, rather than comprehensively mapping all possible aspects concerning an integrated VR and physiotherapy intervention. Instead, we aimed to incorporate the most relevant aspects in the design of the intervention, requiring no data saturation.[68] Therefore, the iterative study design with five phases and the substantial sample of patients, physiotherapists and researchers that participated in the focus groups (n=22), was deemed sufficient to give a realistic view on the feasibility of the intervention. Third, we could have explored other topics than the integration of VR and physiotherapy, such as particular elements of the VR therapy in itself. This might have enriched the qualitative data with regards to the benefits and disadvantages of our new intervention.

Clinical and societal implications

There are many available treatments for CLBP patients. However, the complexity of the medical condition results in generally unsatisfactory outcomes of all of these treatments. Our new intervention, developed together with end-users, might be a new tool in the toolbox of healthcare providers to alleviate the complaints of patients with CLBP. This intervention could potentially support physiotherapists and other healthcare providers in administering integrated biopsychosocial treatment for patients with CLBP. Moreover, therapeutic VR might improve patients' treatment adherence and enable patients to self-manage their condition. Although specifically designed for patients with severe disability due to CLBP, it is plausible that this intervention is also applicable to patients with less severe disabilities or other CMP syndromes. However, it should be noted that this intervention is only applicable to patients that are willing and able to use VR. Besides the clinical effectiveness, the VR intervention developed in this study also offers opportunities to reduce healthcare costs and thereby the worldwide burden of CLBP.[69] By enabling therapy at home, it may reduce physical visits while enhancing multidisciplinary treatment. Such home treatment is becoming increasingly important with rising healthcare costs and additionally reduces the out of pocket costs (e.g., travel expenses or informal care arrangements) for patients,[70] while

also offering opportunities for CLBP patients in remote areas.[71] Fortunately, VR technology is dynamically evolving, with VR systems becoming more affordable and more common, making it increasingly accessible.[72]

Conclusion

This study described the development of a physiotherapy treatment with integrated, multimodal, personalized, immersive VR for patients with complex CLBP. The intervention development process followed the MRC framework in cocreation with the end-users, and resulted in an intervention indicated to be feasible in a small group of patients. Its clinical and (cost-)effectiveness will be further investigated in a separate cluster randomized controlled trial.

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Appendices

Appendix 5.1: Moderator guide focus groups

URL: https://www.liebertpub.com/doi/10.1089/jmxr.2023.0002#appendix



Chapter 6

Physiotherapy with integrated virtual reality for patients with complex chronic low back pain: Protocol for a pragmatic cluster randomized controlled trial (VARIETY study)

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Abstract

Background: Chronic low back pain (CLBP) is the most common chronic pain condition worldwide. Currently, primary care physiotherapy is one of the main treatment options, but effects of this treatment are small. Virtual Reality (VR) could be an adjunct to physiotherapy care, due to its multimodal features. The primary aim of this study is to assess the (cost-)effectiveness of physiotherapy with integrated multimodal VR for patients with complex CLBP, compared to usual primary physiotherapy care.

Methods: A multicenter, two-arm, cluster randomized controlled trial (RCT) including 120 patients with CLBP from 20 physiotherapists will be conducted. Patients in the control group will receive 12 weeks of usual primary physiotherapy care for CLBP. Patients in the experimental group will receive treatment consisting of 12 weeks of physiotherapy with integrated, immersive, multimodal, therapeutic VR. The therapeutic VR consists of the following modules: pain education, activation, relaxation and distraction. The primary outcome measure is physical functioning. Secondary outcome measures include pain intensity, pain-related fears, pain self-efficacy and economic measures. Effectiveness of the experimental intervention compared to the control intervention on primary and secondary outcome measures will be analyzed on an intention-to-treat principle, using linear mixed-model analyses.

Discussion: This pragmatic, multicenter cluster randomized controlled trial, will determine the clinical and cost-effectiveness of physiotherapy with integrated, personalized, multimodal, immersive VR in favor of usual physiotherapy care for patients with CLBP.

Trial registration: This study is prospectively registered at ClinicalTrials.gov (identifier: NCT05701891).

Background

Low back pain (LBP) is the principal cause of global disability and accompanied by high health care utilization and societal costs.[1,2] Chronic low back pain, defined as back pain that persists for 3 months or longer,[3] is the most common chronic pain condition worldwide.[4]

Primary care physiotherapy is currently one of the main treatment options for CLBP, mostly consisting of pain education and exercise therapy.[5] Unfortunately, the effectiveness of this treatment is small and diminishes over time.[6] Severe levels of pain intensity and disability have been identified as most prominent predictors for these disappointing results.[7,8] Moreover, compliance of patients with CLBP with advice and homework exercises from physiotherapists is low due to lack of patient's motivation.[9] Also, pain related fears, including catastrophizing and fear-avoidance beliefs, might hinder patients in performance of exercises and could lead to lower adherence.[8] In addition, pain related fears are related to an increase in bodily awareness, which in turn could increase pain and pain disability.[10] By tackling these issues, physiotherapy treatment for CLBP could potentially yield better results.

To aid the physiotherapist in providing more effective treatment for patients with CLBP, virtual reality (VR) could be of use as an addition to the current primary physiotherapy care.[11] VR is a relatively new technology that has been rapidly evolving over the past years.[12] VR is defined as "the interaction between a participant and a simulated three dimensional, immersive world".[13] Previous studies using VR as treatment modality have shown that VR could reduce pain and improve outcomes for conditions including fibromyalgia,[14,15] complex regional pain syndrome,[16] chronic headache,[17] and chronic neuropathic pain.[18] In regard to chronic pain, therapeutic VR has been used for several treatment goals, including distraction,[19] relaxation,[20] pain education,[21] exposure therapy,[22] activation,[23] and to increase treatment motivation.[24] To sum up, VR offers the opportunity to support physiotherapists in their treatment of patients with CLBP by integrating multiple treatment goals and tailoring treatment, which coincides with the shift towards precision medicine in chronic pain.[25]

Prior studies have shown that immersive VR can be successfully used in the treatment of patients with CLBP.[21,26] However, none of these studies specifically

focused on the complex group of patients with high pain intensity and disability, even though this group seems to benefit most from treatment with VR.[27] Also, most studies do not use immersive VR as part of blended care, lack sufficiently powered samples and do not compare to a suitable control condition.[28–30] Moreover, previous studies regarding VR and chronic pain recommend long-term follow-up periods,[31] an appropriate clinical setting (e.g., physiotherapy practice)[32] and possibilities to personalize the intervention.[33] These recommendations were included in the current study. Although prior studies on the effects of VR for patients with CLBP have been conducted, none of these studies deployed a pragmatic trial in which primary care physiotherapy with integrated multimodal VR was tested for patients with complex CLBP.

Aims

The primary aim of this study is to assess the effectiveness of physiotherapy with integrated multimodal VR for patients with complex CLBP compared to usual primary physiotherapy care on physical functioning. Secondary aims include the effectiveness on pain intensity, pain related fears, pain self-efficacy, physical activity level, global perceived effect, problems with activities and the cost-effectiveness of physiotherapy with integrated multimodal VR for patients with complex CLBP, compared to usual primary physiotherapy care. This protocol describes the warranted steps to accomplish the aims of this study.

Methods

Design

This study is part of the VARIETY project and funded by ZonMw (project number: 10270032021502). A pragmatic, multicenter, two-arm, parallel, superiority, cluster randomized controlled trial (RCT) including 120 patients with CLBP from approximately 20 physiotherapists will be conducted. Physiotherapy practices (with 2–3 participating physiotherapists per practice) will be randomly allocated on a 1:1 ratio to the experimental group that will administer blended care consisting of physiotherapy treatment with integrated, immersive, multimodal, therapeutic VR, or to the control group that will administer usual primary physiotherapy care for patients with CLBP. An online software program (www.sealedenvelope.com) will be used for cluster randomization. Cluster randomization was chosen above regular

randomization to prevent contamination due to physiotherapists providing both interventions. Patients will be allocated to the intervention or control group that their physiotherapy practice their physiotherapist was randomized in. The flow of participants is shown in the CONSORT flow diagram (Figure 6.1).[34]

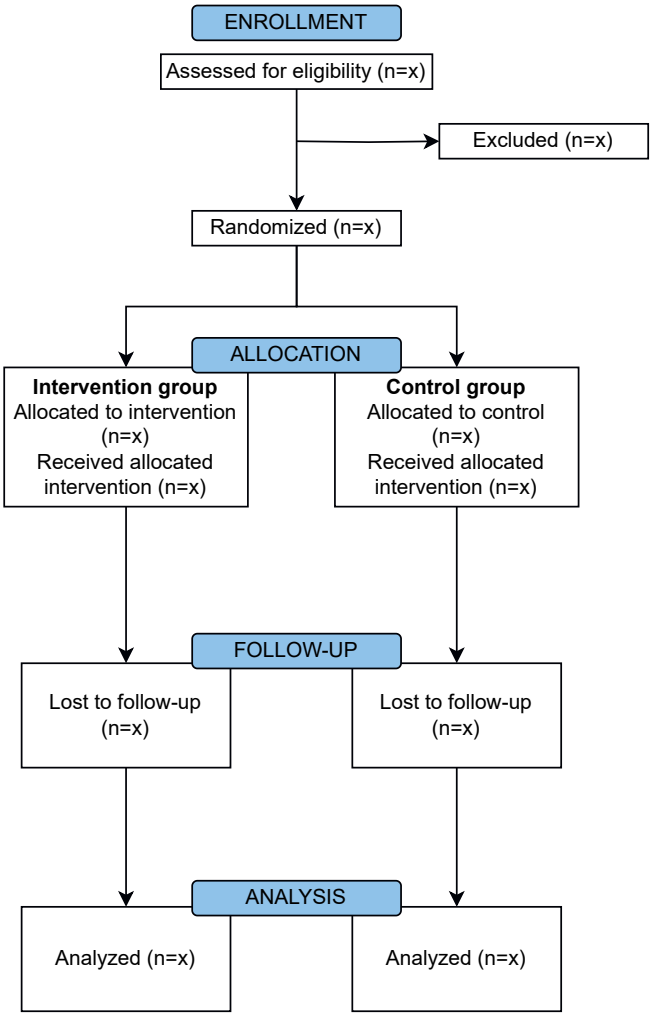


Figure 6.1. Flow of participants.

Patients and physiotherapists cannot be blinded for the treatment allocation due to the nature of this trial. On the other hand, patients will only be informed about their own intervention and will not be informed about the other arm, in line with the ethical recommendations for cluster RCTs. Physiotherapists of the control group

will not be informed about the content of the experimental intervention either. An independent statistician performing the primary analyses will be blinded for treatment allocation.

In order to support best practices in the methodology of VR trials, a best practices framework consisting of three phases was developed by the VR-CORE international working group. VR1 trials focus on content development, VR2 trials conduct early pilot testing and VR3 trials use a RCT design to determine effectiveness of an intervention.[32] Current study is a VR3 trial, studying an intervention that was developed using a VR1 and VR2 trial, reported in a separate article.

This study was approved by the medical ethical review board (METC Oost-Nederland, case number: 2022-15794) and is registered at ClinicalTrials.gov (identifier: NCT05701891).

Participants

Physiotherapists

Physiotherapists (n=20) will be recruited through their practices using convenience sampling through social networks (LinkedIn and Facebook) and physiotherapist networks (e.g., Dutch Society for Physical Therapy (KNGF) and local lower back pain networks). Of each responding physiotherapist practice a maximum of two physiotherapists will be included in the trial, to achieve a heterogenous sample. Physiotherapists are eligible for participation in this study if they: (1) work within 50 kilometers from Enschede or Nijmegen in the Netherlands, (2) have no prior experience using VR as a treatment modality in physiotherapy practice, (3) treat on average at least one new patient with CLBP per month and (4) are willing to cooperate with the study protocol.

Patients

Participants (n=120) will be newly admitted patients who visit the physiotherapist. Patients are considered to be eligible for participation if they meet the following inclusion criteria: (1) CLBP >3 months as reason to visit the physiotherapist, (2) absence of 'red flags' or signs of specific LBP,[5] (3) not having consulted a physiotherapist for CLBP in past six months, (4) combination of severe disability (Oswestry Disability Index (ODI) score ≥30)[35] and severe pain (Numeric Pain Rating Score

(NPRS) ≥5),[36] (5) aged 18–80 and (6) provides informed consent. Participants will be excluded if they: (1) have severe (physical or mental) comorbidity that will substantially hinder the physiotherapy treatment, (2) have a planned diagnostic or invasive treatment procedure (e.g., injection, nerve block or operation) for their CLBP in the next three months, (3) lack comprehension of Dutch language, (4) are not able to use VR (e.g., epilepsy, open wounds on face or severe visual impairment) and (5) have no email address or Wi-Fi connection at home.

Procedure

Patients visiting a participating physiotherapist practice because of CLBP are screened for study participation by the physiotherapist during the intake. If a patient is eligible, the physiotherapist provides a patient information letter and informed consent form, provides oral information about the study and asks the patient to decide within a few days to participate (and if so, provides an informed consent). In addition, the physiotherapist asks the patient's permission to send the patient's name and mail address to the researcher, and register this permission in their regular electronic patient file. If permitted, the physiotherapist provides the researcher the patient's name and mail address through a fully secured app (Siilo; www.siilo.com/nl/; frequently used by general practitioners (GPs), physiotherapists and other healthcare professionals) or by calling the researcher. Subsequently, the researcher will send the first online questionnaires to the patient. If the patient decides not to participate, no questionnaires will be sent (and if applicable, the first questionnaires can be ignored), and the patient will not be refused treatment by the physiotherapist.

Interventions

Both interventions in this trial will be 12-week physiotherapy treatments.

Control group

Patients in the control group will receive 8 to 24 usual physiotherapy sessions, based on the Dutch physiotherapy guidelines for CLBP.[5] The guidelines recommend pain education combined with exercise therapy, possibly complemented with behavior related treatment (e.g., graded activity, acceptance and commitment therapy (ACT) or relaxation) and non-exercise interventions (e.g., manipulations or massage).

Experimental group

Before the start of the trial, physiotherapists will receive a group-based training course on: (1) the developed intervention and methodology of personalizing the intervention, (2) integration of VR within physiotherapy treatment and (3) practical use of VR headsets.

The experimental intervention consists of (usual) physiotherapy with integrated VR.

Physiotherapy

The physiotherapy treatment will consist of 8 to 24 sessions of usual physiotherapy care as described for the control group, complemented with feedback and discussion on the patient's VR use. Based on the patient's experience and data on VR use, the physiotherapist can alter the treatment's intensity, frequency and modality of (VR) treatment. Additionally, physiotherapists are encouraged to use VR for any possible homework exercises.

VR

In addition to the usual physiotherapy, physiotherapists in the experimental condition will integrate therapeutic VR in their treatment. Patients will be instructed to use VR on Pico Neo 3 (PICO, San Francisco, CA) head-mounted displays (HMDs), five times a week for 10 to 30 minutes at home, during the 12-week treatment period. This dosage is based on a review of CLBP trials, which found that 8–12 week interventions with a minimal duration of 20 hours were most beneficial to pain and function[37] and is congruent with the Dutch norm for physical activity. Moreover, a maximal VR duration of 30 minutes per day is advised because the risk of vertigo increases notably after this. Patients will receive instructions for operating and using the VR headset from their physiotherapist. As discussed below, patients and their physiotherapists will tailor the VR modules to the patients' needs.

Physiotherapists and patients select which of the VR modules described below are most suited to the needs and wishes of the patient, using shared-decision making. It is advised to start the first three weeks of the intervention with the first two modules (Reducept and SyncVR Relax & Distract) and start with the third module (SyncVR Fit) in the fourth week. Moreover, to emphasize the importance of pain

education it is advised to repeat this module in week 8 and 12, as previous research has shown that repetition is crucial in pain education treatment.[38]

The following three VR modules will be used:

1. Reducept (Reducept, Leeuwarden, The Netherlands): Reducept contains five games, aiming to teach patients with CLBP that pain can be influenced and managed by changing their beliefs about chronic pain. This is done by a combination of pain education and different psychological therapies (e.g., cognitive behavioral therapy (CBT), mindfulness and visualization). Pain education has shown to be effective in the management of chronic pain, when incorporated within a multimodal therapy.[39] Psychological therapies, and mainly CBT, are also considered beneficial for patients with chronic pain.[40]

2. SyncVR Relax & Distract (SyncVR, Utrecht, The Netherlands): SyncVR Relax & Distract contains 50 videos (e.g., swimming with dolphins and city tour of Amsterdam), ten games (e.g., Sudoku and Memory) and five exercises (e.g., breathing and meditation exercises). Relaxation seems to be helpful as an added intervention for patients with CLBP, especially during regular practice.[41,42] On the other hand, distraction has great analgesic qualities, but usually works for shorter periods of time.[19]

3. SyncVR Fit (SyncVR, Utrecht, The Netherlands): SyncVR Fit contains 11 movement and sports exercises, including tennis, boxing and archery. Exercise therapy is a common treatment modality in CLBP and is recommended in clinical guidelines.[5,43] Also, patients with a higher score on pain related fears (Fear Avoidance Beliefs Questionnaire, physical activity subscale (FABQ-PA)[44] ≥16 or Pain Catastrophizing Scale (PCS)[45] ≥30) will receive additional exposure therapy by their physiotherapists, based on the following four steps: (1) mapping patient specific pain related fears, (2) education about these patients-specific pain related fears (3) facing these patients-specific fears (if possible using SyncVR Fit) and (4) facing patient-specific fears in daily life activities.[46]

Outcome measures

The time schedule of this study is shown in Table 6.1, following the SPIRIT recommendations.[47] The primary outcome measure is physical functioning, measured with the Oswestry disability index version 2.1a (ODI).[35] Secondary

outcome measures include pain intensity over the past week, measured using the single-item numeric rating scale (NRS),[36] pain related fears, measured using the fear avoidance beliefs questionnaire, physical activity subscale (FABQ-PA)[44] and pain catastrophizing scale (PCS),[45] general effect, measured using global perceived effect (GPE),[48] problems with activities, using the patient-specific complaints questionnaire (PSK),[49] pain self-efficacy, using the pain self-efficacy questionnaire (PSEQ),[50] intervention expectation, using the credibility and expectancy questionnaire (CEQ),[51] sense of presence, using the Igroup presence questionnaire (IPQ),[52] and physical activity, using an open-ended question. Economic measures include the quality-adjusted life years (QALYs), using the Euroqol five-dimensions (EQ-5D-5L)[53] and health-related and work-related costs, using a self-constructed questionnaire.

Table 6.1. SPIRIT flowchart: time schedule of study

		STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Follow-up	
Timepoint	-T1	T0	T1	T3	T6	T12
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Experimental intervention (n=60)		X	●———	——●		
Control intervention (n=60)		X	●———	——●		
ASSESSMENTS:						
Demographic information	X	X				
Primary outcome measure		X	X	X		X
Secondary outcome measures		X	X	X		X
Economic outcome measures		X		X	X	X
Treatment parameters		X	X	X		
VR parameters		X	X	X		

All questionnaires used will be in Dutch and have sufficient reliability and validity. Participants will complete questionnaires at baseline (T0), one month after the start of the intervention (T1), directly after finishing the intervention (T3), and follow-up after 6 months (T6) and 12 months (T12). All questionnaires will be provided to the patients using an online data management system.

Additionally, patients will be asked to report the following demographics at baseline: age, sex, BMI, tobacco use, duration of complaints, comorbidities, occupation, education level, diagnostic and therapeutic procedures in past 6 months, medication use, experience with VR for treatment and entertainment. After the intervention, patients are asked to report other treatments than physiotherapy for their CLBP in the past 12 weeks.

Physiotherapists will be asked to report their age, gender, years' experience as a physiotherapist and specialization before the start of the trial.

The following treatment parameters will be reported by all physiotherapists after each physiotherapy treatment: modalities and duration of treatment. Additionally, physiotherapists in the experimental group will report adverse events (AEs) if necessary. These measures will give an insight in the administered physiotherapy treatment.

In the experimental group, the following VR parameters will be extracted from the online dashboard: treatment modality and duration (i.e., number of days a week and minutes per day, patients performed the modality) and VAS (before and after use of Reducept).

Sample size

A clinically relevant between-group difference of at least 10 points on the ODI[35] at 3-months follow-up is expected, which seems plausible based on recent pilot studies with VR from our research group[33,54] and others.[27,55–57] For this expected and clinically relevant difference of 10 and a standard deviation of 15 (based on previous studies from our group,[58] 60 patients are needed per group (a=0.05; power=90%; ICC for clusters 0.05; 15% drop-out). We expect to include 1 patient every 2 months per physiotherapist. A total of 20 participating physiotherapists will result in a total of 120 patients after 12 months.

Statistical analysis

All statistical analyses will be done using SPSS version 27 (IBM Inc., San Diego, CA) and StataSE version 17 (Stata Corporation, College Station, TX). The statistical analysis plan (SAP) is registered at ClinicalTrials.gov (identifier: NCT05701891). The two study arms will be compared on baseline using descriptive statistics.

Means and standard deviations will be presented for continuous variables (or medians and interquartile ranges in case of a skewed distribution), and frequencies and percentages for categorical variables. We will check for outliers by inspecting histograms and boxplots, the effect of any outliers will be assessed by comparing a 5% trimmed mean to the total mean. Results will be considered statistically significant if $p<.05$ (two-sided testing).

Effectiveness

Effectiveness of the experimental intervention compared to the control intervention will be analyzed on the primary outcome physical functioning. Data will be analyzed using an intention-to-treat, linear mixed-model analysis with maximum likelihood estimation (MLE), comparing both groups on clinical effectiveness at 3 months (primary end-point) and 12 months follow-up, with all follow-up time points included in the analysis. The analysis will be adjusted for major prognostic characteristics that could confound the treatment effects (e.g., pain severity), in addition to important baseline patient (e.g., age) or physiotherapist (e.g., specialization) characteristics that differ considerably between the two arms. Additionally, per protocol analyses will be carried out as described in the SAP.

Similar analyses will be performed for the secondary outcome measures pain intensity, pain related fears, pain self-efficacy, physical activity level and problems with activities. GPE will be analyzed as a dichotomous variable (i.e., completely and much recovered vs. all other responses), using logistic multilevel analysis.

Cost-effectiveness

Besides intervention-related costs, primary and secondary healthcare costs and medication costs will be measured. Also, costs related to presenteeism, absenteeism, unpaid productivity and informal care will be measured. Cost-effectiveness of the experimental intervention compared to the control intervention will be analyzed for the 12-months follow-up period on physical functioning and pain intensity. Cost-utility of the experimental intervention compared to the control intervention will be analyzed for the 12-months follow-up period on quality of life. All patients included in the study will be analyzed, with missing data handled by using Multivariate Imputation by Chained Equations (MICE). Costs and effect differences will be estimated using Seemingly Unrelated Regression (SUR) analyses,

in which their possible correlation can be accounted for. The 95% confidence intervals surrounding the cost differences will be estimated using Bias-Corrected and accelerated (BCa) bootstrapping. Subsequently, Incremental Cost-Effectiveness Ratios (ICERs) will be estimated by dividing the differences in costs by the differences in effects. Uncertainty surrounding the incremental cost-effectiveness ratios will be graphically illustrated by plotting BCa-bootstrapped cost-effect pairs on cost-effectiveness planes. Also, cost-effectiveness acceptability curves will be constructed to provide an indication of the probability of physiotherapy with integrated multimodal VR therapy being cost-effective with usual care at different values of willingness to pay.[59]

Discussion

This protocol describes the rationale and design of a large, pragmatic, multicenter cluster randomized controlled trial, aiming to determine the clinical and cost-effectiveness of physiotherapy with integrated, personalized, multimodal, immersive VR compared to regular physiotherapy for patients with CLBP.

Opposed to most VR studies, this VR study will be a pragmatic trial in which physiotherapists will integrate VR in their treatment of patients with CLBP, instead of providing VR as standalone treatment. Another strength of this study is the thorough monitoring of patients and their treatment, including five measurement moments for patients with a maximal follow-up of 12 months. Moreover, the VR modules in this intervention are multimodal and will be personalized to the patients' needs.

The preference for a pragmatic trial increases the external validity of the study results. However, this might to some extent compromise the internal validity,[60] due to a possible range of variations in the applied interventions (e.g., duration and content of VR modules and physiotherapy sessions and expertise of physiotherapist) and a relatively small number (n=10) of physiotherapists applying the experimental intervention. Moreover, due to the absence of a sham VR group, we cannot rule out a placebo effect in the experimental group.

The results of this study will contribute to the mounting literature on the effect of VR for patients with chronic musculoskeletal pain. Also, the results are interesting

for practicing physiotherapists treating patients with CLBP and could aid in the discussion to add eHealth in Dutch physiotherapy care to contest the rising health-care costs. Last and most important, the complex subgroup of CLBP patients with severe pain and severe disability might receive more effective treatment, when the VR integrated physiotherapy treatment will demonstrate superior effects.

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Chapter 7

Physiotherapy with integrated virtual reality for patients with severe chronic low back pain: Cluster-randomized controlled trial (VARIETY)

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Abstract

Introduction: Chronic low back pain (CLBP) is a leading cause of disability worldwide. Physiotherapy is a common treatment, but its effect on physical functioning is generally modest, particularly for patients with severe complaints. Virtual Reality (VR) may complement physiotherapy, yet evidence for its effectiveness remains limited. The aim of this study was to assess the effectiveness and feasibility of a VR intervention integrated within physiotherapy for people with severe CLBP.

Methods: A cluster-RCT across Dutch physiotherapy practices was conducted. Patients in the control group received 12 weeks of usual care following physiotherapy guidelines. Patients in the intervention group received similar usual care, enhanced with integrated, home-based VR consisting of pain education, exercise therapy, and relaxation modules. The primary outcome was physical functioning at three months. Secondary outcomes included feasibility, pain intensity, and catastrophizing. Analyses were conducted according to the statistical analysis plan, using linear mixed models.

Results: Twenty-five patients participated in the intervention group and seven in the VARIETY control group, instead of the planned sample size of 120 participants due to recruitment challenges. The VARIETY control group was therefore supplemented with 18 controls from comparable trials, forming the total control group (n=25). The intervention group showed greater improvements from baseline in physical functioning (42%), compared to the VARIETY control group (26%). Between-group differences were neither statistically significant nor clinically relevant for all outcome measures, compared to the VARIETY control group (e.g., ODI mean difference at three months: -4.80, 95% CI: -17.78–8.18), or the total control group (-8.80, 95% CI: -2.57–20.17). The intervention was considered feasible and safe to use in practice.

Discussion: This study found limited support for the use of VR as an adjunct to physiotherapy for people with severe CLBP. Further well-powered trials should reconsider study procedures to optimize patient recruitment and corroborate VR's clinical effectiveness in physiotherapy.

Introduction

Chronic pain, defined as pain lasting longer than three months, is a major health condition. Chronic low back pain (CLBP) is the most common chronic pain condition.[1] CLBP is associated with diminished quality of life, occupational problems and psychosocial complaints.[2,3] Similar to other chronic pain conditions, CLBP is caused and maintained due to a combination of biological, psychological and social factors.[4]

Physiotherapy is a frequently used non-pharmacological treatment for people with CLBP.[2] It typically includes exercise therapy and pain education and may be supplemented with psychosocial interventions such as relaxation techniques.[5] However, similar to other treatment options for CLBP, the overall effectiveness of physiotherapy in improving physical function and reducing pain is limited.[6] This limited effectiveness is partly attributed to patients' poor adherence to home exercise programs and physiotherapists' difficulties in integrating psychosocial treatment components into their practice.[7,8]

Severe CLBP patients (i.e., with a higher initial level of disability, fear-avoidance behavior and pain intensity) have an even worse prognosis.[9] Recently, virtual reality (VR) has been introduced as a novel treatment option to support physiotherapists in CLBP treatment. VR "*leverages immersive technologies to simulate interactive virtual environments or virtual worlds with which users become subjectively involved and in which they feel physically present*".[10] VR is generally provided through a head-mounted display (HMD) to sensory immerse the user in a virtual environment.[11] VR could potentially support physiotherapists in their CLBP treatment, by providing patients with more engaging home exercises and supplement their treatment by offering psychosocial treatment modalities.[12] For example, prior VR research for CLBP used relaxation exercises,[13] graded exposure,[14] and behavioral therapy.[15] Currently VR is only being used by a minority of physiotherapists.[16,17]

So far, limited research has been conducted on the effect of VR combined with physiotherapy to treat CLBP. The effectiveness of VR for CLBP is inconclusive, as some reviews suggests VR is effective to for example improve disability and alleviate pain,[18,19] while others remain cautious and warrant more high-quality research.[20] It should be noted that most of the reviews include trials that are not

always comparable in terms of study design and VR intervention.[21] Prior research showed that VR is more effective in chronic pain patients with severe complaints.[22,23] Also, it has been suggested that VR integrated within physiotherapy seems to be more effective than stand-alone VR.[24]

The primary aim of this pragmatic trial was to assess the effectiveness of physiotherapy with an integrated VR intervention for patients with severe CLBP (i.e., combination of severe disability and severe pain), compared to usual care physiotherapy on physical functioning. Secondary aims included to examine this intervention's effectiveness on pain intensity, pain related fears, and pain self-efficacy. Also, we examined the intervention's feasibility in a process evaluation, based on the actual use of the intervention.[25]

Methods

Design

This study employed a multicenter, two-arm, pragmatic, cluster-RCT. The protocol with information about the study's rationale and design was published previously[26] and the study was prospectively registered with ClinicalTrials.gov (reference number: NCT05701891). The study was approved by the medical ethics committee 'METC Oost-Nederland' (reference number: 2022–15794) and conducted in compliance with the Declaration of Helsinki. Participants were recruited from March 2023 until March 2025. The trial was reported in line with the Consolidated Standards of Reporting Trials (CONSORT) statement extension to cluster randomized trials[27] and RATE-XR reporting guideline[28] for extended reality (XR) studies.

Participants

Physiotherapists

Primary care physiotherapists were recruited using convenience sampling (e.g., through social media and physiotherapy networks). Physiotherapists were eligible for study participation if they: (1) had no prior experience using VR as a treatment modality in physiotherapy, (2) treated on average at least one new patient with CLBP per month, and (3) were willing to cooperate with the study protocol. Physiotherapists were cluster-randomized on practice level.

Patients

Patients were screened by their physiotherapist using the following inclusion criteria: (1) patients with CLBP ≥3 months as the reason for visiting a physiotherapist, (2) absence of 'red flags' or signs of specific CLBP, (3) no physiotherapy consultation for CLBP in the past six months, (4) combination of severe disability (ODI score ≥30) and pain (NPRS ≥5), (5) aged 18–80 years, (6) provided informed consent. Exclusion criteria comprised: (1) severe comorbidity that would substantially hinder physiotherapy treatment, (2) planned diagnostic or invasive treatment for CLBP in the next three months, (3) lack of comprehension of the Dutch language, (4) inability to use VR, (5) absence of an email address or Wi-Fi connection at home.

Based on the sample size calculation, we aimed to include 120 participants in total.[26] The calculation was based on a clinically relevant between-group difference of 10 points (SD: 15) on the ODI at three months, with a = .05, beta = .1, ICC for clusters = .05 (which resulted in a sample size of 104, 52 per group) and an expected drop-out of 15%.

Procedure

Patients visiting a participating physiotherapist were screened for study participation by the physiotherapist during intake. Eligible patients were informed about the study by the physiotherapist using a patient information letter and informed consent form. If patients had any questions regarding the study, they could ask their physiotherapist or the coordinating researcher. After signing the informed consent form, participants were enrolled in the study and allocated to the group their physiotherapist was allocated to. Next, the coordinating researcher would send the first online questionnaires to the participant and the participant would start with their physiotherapy treatment. Participants in the intervention group received the VR headset from their physiotherapist to temporarily use at home during the 12-week intervention period.

Interventions

Control group

Participants in the control group received physiotherapy care based on the Dutch clinical physiotherapy guidelines for CLBP.[5]

Intervention group

Patients in the intervention group received the same guideline-based physiotherapy treatment as the participants in the control group, but enhanced with VR. The intervention was developed in co-creation with patients, physiotherapists and researchers and showed to be feasible in practice.[29]

Physiotherapists received a two-hour training to be able to provide the VR intervention to patients. The physiotherapists instructed the VR to the patients using a written manual. Patients were asked to use the plug-and-play VR HMD headset (Pico Neo 3 (Bytedance, Beijing, China)) five times a week for 10–30 minutes unsupervised at home. The headset included the following three off-the-shelf VR modules:

(1) Reducept (Reducept, Leeuwarden, the Netherlands) contains five consecutive games lasting approximately ten minutes each, that aim to educate patients about their (chronic) pain and provide pain management techniques. Patients play and interact within these serious games through for example visualization exercises, where they have to shoot at insects in the body that represent pain signals. Reducept is based on the principles of 'Explain Pain'[30] and uses metaphors to explain pain.[31] By increasing patients' understanding of pain and addressing pain-related cognitions, the games aim to foster a sense of control over chronic pain. This may contribute to a reduction in the pain experience, in line with mechanisms also targeted in cognitive behavioral therapy.[32]

(2) SyncVR Relax & Distract (SyncVR, Utrecht, the Netherlands) contains over 50 360° videos (e.g., swimming with dolphins), ten games (e.g., Sudoku) and five exercises (e.g., breathing exercises) with a varying duration between five and 20 minutes. Prior research showed that relaxation is helpful for patients with CLBP,[33] while distraction also has known analgesic qualities.[34]

(3) SyncVR Fit (SyncVR, Utrecht, the Netherlands) consists of eleven general exercise and movement games, such as boxing, goal keeping and tennis. Each game had an approximate duration of ten minutes and three difficulty levels. Exercise therapy is the most common treatment for CLBP.[35] For patients with higher scores on pain-related fears (FABQ-PA ≥16 and/or PCS ≥30), physiotherapists were advised to complement their treatment with graded exposure treatment. The exposure module was based on these steps: (1)

mapping patient-specific fears, (2) education about these fears (if possible using Reducept), (3) facing these fears (if possible using SyncVR Fit), (4) facing these fears in daily life.

Participant and physiotherapist decided through shared decision making which modules the participant should use. The VR interventions were integrated into usual care physiotherapy, intended as an adjunct rather than a replacement. All three VR modules have been examined in research before[36–38] and are among the most used VR applications in Dutch physiotherapy for chronic pain.[17]

Outcome measures

The primary outcome measure was physical functioning, measured using the Oswestry Disability Index (ODI) version 2.1a.[39] Secondary outcome measures included pain intensity measured using the Numeric Pain Rating Scale (NPRS),[40] pain related fears measured using the physical activity subscale of the Fear Avoidance Beliefs Questionnaire (FABQ-PA)[41] and Pain Catastrophizing Scale (PCS),[42] general effect measured using Global Perceived Effect (GPE),[43] pain self-efficacy using the Pain Self-Efficacy Questionnaire (PSEQ),[44] intervention expectation using the Credibility and Expectancy Questionnaire (CEQ),[45] sense of presence using the Igroup Presence Questionnaire (IPQ)[46] and physical activity using an open-ended question. The Dutch version of all questionnaires was used all of which have shown sufficient reliability and validity. Participants completed the questionnaires at baseline, after 1 month (T1), and after 3 months (T3). At baseline participants completed the following demographics: age, gender, occupational status, education level (based on Verhage, 1964),[47] BMI, tobacco use, complaint duration, comorbidities, medication use, diagnostic and therapeutic procedures in past 6 months, and experience with VR for treatment and entertainment.

Physiotherapists completed the following information before the study started: age, gender, years' experience as a physiotherapist, physiotherapy master's degree, member of a back network, interest in VR (scale of 0 to 10), and technological skills (scale of 0 to 10). Also, they completed the Pain Attitudes and Beliefs Scale for Physiotherapists (PABS-PT).[48]

Process evaluation

Physiotherapists reported the following treatment information after each included participant: treatment modalities and duration. Also, physiotherapists reported participants' VR intervention related adverse events (AEs), such as cybersickness.

The following VR parameters were extracted from the online dashboard: applied VR modality and duration of application.

Protocol deviations

Recruitment of patients was more troublesome than initially expected, especially in the control group. Therefore, already in the first phase of the trial, multiple activities were undertaken to improve patient recruitment, including longer trial duration (i.e., one year longer than anticipated), the addition of more physiotherapists in the trial (from 20 to 57 participating physiotherapists), and payment of compensation fees to patients and physiotherapists. After extensive discussions within the research group and consultation with the funding body, it was ultimately decided to terminate the trial because completing the trial with the anticipated sample size was not realistic.

Also in contrast to our study protocol, the long-term results (i.e., 6- and 12-month follow-up) and cost-effectiveness analyses will be published in a separate scientific article due to practical reasons related to the extended participant recruitment period.

Additional control group

To complement the small number of participants in the VARIETY control group, control group data from two comparable trials with the same primary end point (i.e., 3 months), the same setting (i.e., primary care physiotherapy in the Netherlands), the same control intervention (i.e., usual care physiotherapy) and the same study group (i.e., people with CLBP) were retrieved to form a larger control group (i.e., additional control group). We only included severe participants who met the aforementioned in- and exclusion criteria of the VARIETY trial. The first trial is the Back2Action trial,[49] the second trial is the e-Exercise trial.[50] From participants of these trials, the following demographic information was provided: age, gender, education level, comorbidities and occupational status from the e-Exercise trial and the following outcome measures pre and post intervention: ODI, NPRS and PCS,

and FABQ-PA from the e-Exercise trial. This additional control group combined with the VARIETY control group is the total control group.

Statistical analysis

All statistical analyses were conducted using SPSS v. 27 (IBM, San Diego, USA), based on the a priori published statistical analysis plan registered with ClinicalTrials.gov (reference number: NCT05701891) and study protocol.[26] The study arms were compared at baseline using descriptive statistics (i.e., observed means with standard deviation (SD) or frequencies with percentages). Clinical effectiveness was examined using linear mixed model (LMM) analyses, based on the intention-to-treat principle, comparing the intervention group to the VARIETY control group at the primary end-point (3 months) with the 1-month time point included in the analysis. Based on the one in ten rule (i.e., one predictor per 10 participants), three dominant covariates (i.e., age, education level and comorbidities) were included in the model.[51] Similar methodology was repeated in an analysis with the total control group (i.e., VARIETY control group and additional control group), for the outcome measures ODI, NPRS and PCS at 3 months. Similar intention-to-treat analyses were also conducted for all secondary outcome measures. Analyses were conducted using both imputed and complete-cases datasets. Results were considered statistically significant if $p<.05$ (two-sided testing). Clinical relevance was explored by calculating the number of participants who reached the minimal important change (MIC) thresholds of the ODI (i.e., 10 points).[52] Feasibility outcomes were examined using descriptive statistics.

Results

In total, 81 participants were screened for eligibility of which 33 were randomized and 32 started treatment. The intervention group consisted of 25 patients and the VARIETY control group consisted of seven patients. This VARIETY control group and the additional control group (n=18) together formed the total control group of 25 participants.

See Figure 7.1 for the flow of participating physiotherapy practices and patients, and Table 7.1 for the patients' demographic information. More detailed demographic information about the participants of the other two control groups is reported in online Appendix 7.A.

Table 7.1. Demographics of participants VARIETY trial and combined controls

		Control group		
	Intervention group (n=25)	VARIETY control group (n=7)	Additional control group (n=18)	Total control group* (n=25)
Age, mean (SD)	51.5 (14.1)	44.3 (20.2)	49.2 (11.6)	47.9 (14.5)
Gender, female, n (%)	17 (68)	7 (100)	13 (72)	20 (80)
Occupational status, n (%)			n/a	n/a
Working	18 (72)	5 (71)		
Retired	3 (12)	1 (14)		
Incapacitated for work	4 (16)	1 (14)		
Education level, n (%)				
Lower	8 (32)	2 (29)	3 (17)	5 (20)
Middle	10 (40)	4 (57)	10 (56)	14 (56)
Higher	7 (28)	1 (14)	5 (28)	6 (24)
BMI, mean (SD)	27.4 (5.1)	25.1 (3.6)	n/a	n/a
Tobacco use, yes, n (%)	3 (12)	3 (43)	n/a	n/a
Complaint duration, mean years (SD)	11.9 (9.1)	13.5 (14.3)	n/a	n/a
Comorbidities, yes, n (%)	14 (56)	1 (14)	8 (44)	9 (36)
Medication use, yes, n (%)	14 (56)	2 (29)	n/a	n/a
Procedures in past 6 months, yes, n (%)			n/a	n/a
Diagnostic	22 (88)	2 (29)		
Therapeutic	19 (76)	4 (57)		
Experience with VR, yes, n (%)			n/a	n/a
Treatment	0 (0)	0 (0)		
Entertainment	5 (20)	1 (14)		

BMI = body mass index; N/a = not available; SD = standard deviation; VR = virtual reality.
* Total control group is the VARIETY control group combined with the additional control group.

Flow of participating physiotherapists VARIETY trial

The VARIETY trial started with 21 physiotherapists from 10 practices. In a second recruitment wave, 12 physiotherapists of 6 new practices and 4 physiotherapists from participating practices were enrolled. In a third recruitment wave, 20 physiotherapists of 9 new practices were enrolled in a 2:1 ratio (control:intervention group). During the two-year patient recruitment period, four physiotherapists stopped participating in the trial (new job (n=2) and lack of time (n=2)), and two were temporarily absent due to parental leave. Participating physiotherapists reported similar demographic characteristics, as shown in online Appendix 7.B.

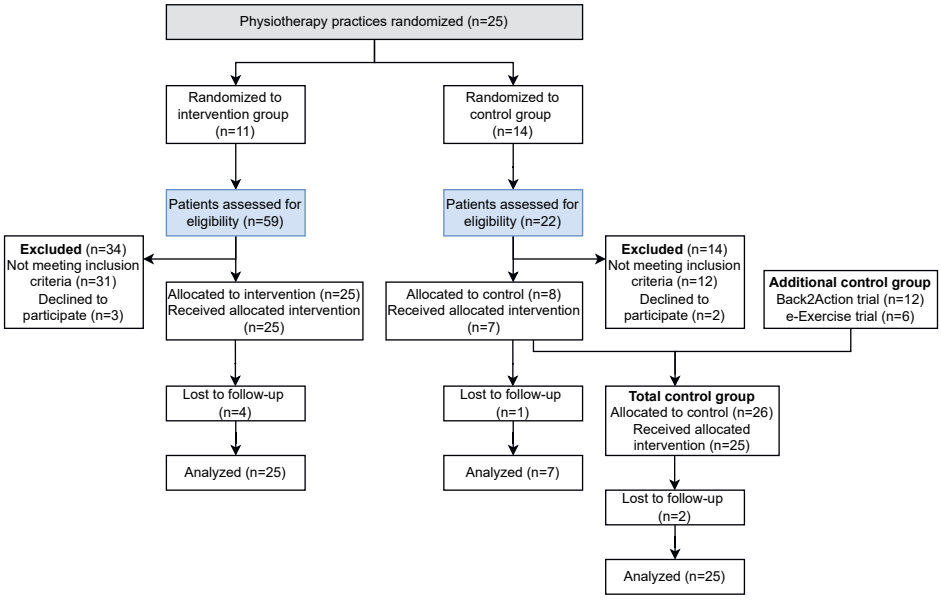


Figure 7.1. CONSORT flow of physiotherapy practices and patients.

Process evaluation

Patients in the VARIETY intervention and control group, respectively received an average number of 10.5 (SD: 3.2) and 9.3 (3.8) physiotherapy sessions. Table 7.2 shows the average number of sessions in which each specific type of treatment modality was provided.

Table 7.2. Average number and percentage of physiotherapy treatment modalities

Applied treatment modality, n (%)	Intervention group (n=25)	VARIETY control group (n=7)	Total (n=32)
Education	5.4 (51)	4.6 (49)	5.2 (51)
Exercise therapy	8.0 (76)	6.4 (69)	7.6 (74)
Manual therapy	4.8 (46)	3.2 (34)	4.4 (43)
Behavioral therapy	3.4 (32)	4.3 (46)	3.6 (35)
Other	.7 (7)	1.0 (11)	.8 (8)

Note: multiple options were possible per treatment.

Participants who received the VR intervention used this for an average of 427 minutes (SD: 155.6, range: 230–818). The advised intervention usage duration was 600 minutes (50 minutes per week), but it should be noted that a VR intervention

usage duration of 600 minutes is long compared to other VR trials.[18] The most used application was SyncVR Relax & Distract (44%), followed by SyncVR Fit (34%) and Reducept (22%). Figure 7.2 presents the VR modalities used per week, highlighting the gradual decline in VR usage over the 12-week intervention period. Participants who received the VR intervention scored high on sense of presence, as they scored a mean (SD) IPQ score of .8 (SD: .6).[53] No treatment related AEs were reported after using the VR intervention.

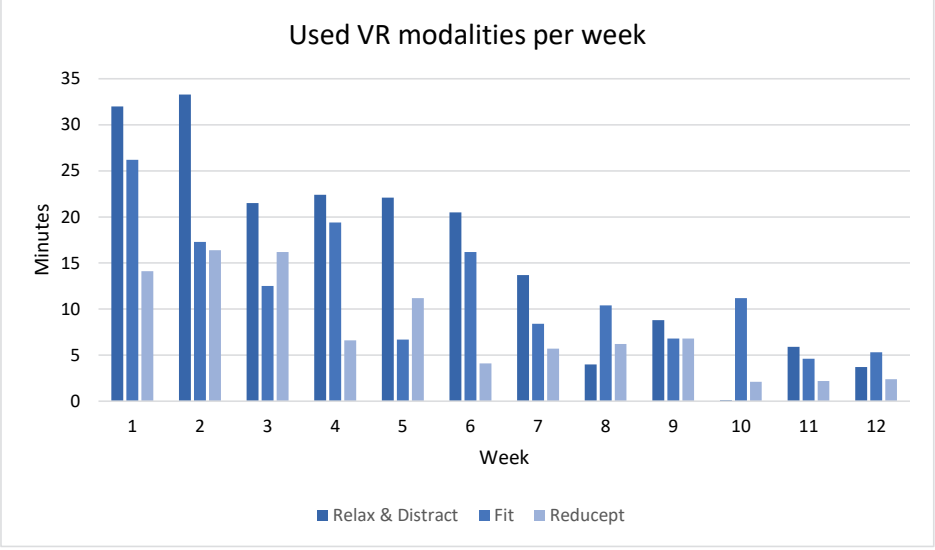


Figure 7.2. Used VR modalities per week.

Outcome measures

Table 7.3 provides the outcomes on the primary and secondary outcome measures of the VARIETY trial and combined controls. The separated outcomes of the intervention, VARIETY control, Back2Action, e-Exercise and total control groups are reported in online Appendix 7.C.

Effectiveness analyses

Intervention group compared to VARIETY control group

The intervention group improved 16.7 points (42%) on the ODI, compared to 9.7 points (26%) in the VARIETY control group at 3 months. The adjusted mean difference between the VARIETY intervention and VARIETY control for the primary

outcome (i.e., physical functioning) at 3 months was -4.80 (95% CI: -17.78–8.18). Similarly, no statistically significant differences were found for any of the other secondary outcome measures between the VARIETY intervention and VARIETY control group, as shown in Table 7.3.

Intervention group compared to total control group

The mean difference between the VARIETY intervention and total control group for the primary outcome at 3 months was -8.80 (95% CI: -2.57–20.17). As shown in Table 7.3, none of the primary or secondary outcome show a significant difference between the VARIETY intervention and combined control groups. Similar results were reported for complete case and crude intention-to-treat analyses.

Regarding clinical relevance, 12 (57%) participants of the intervention group reached the MIC threshold on physical functioning, compared to four (67%) in the VARIETY control group, and 10 (43%) in the total control group. The results show similar numbers of participants who reached the MIC threshold between intervention and VARIETY control group. Comparing the intervention group with the total control group, the intervention group seemed to improve somewhat more.

Discussion

Principal findings

The aim of this study was to evaluate the effect of physiotherapy with integrated VR for patients with CLBP with severe disability and pain, compared to patients receiving usual care physiotherapy. Due to problems with patients' enrollment, the trial was terminated prematurely which made it impossible to draw strong conclusions on the effect of VR integrated in physiotherapy.

Results of this study showed no statistically significant differences between the two groups on all primary and secondary outcome measures. On the other hand, the intervention group improved 42% on physical functioning, compared to 26% in the VARIETY control group and 22% in the total control group.

Table 7.3. Clinical effectiveness analyses primary and secondary outcome measures

	Intervention group (n=25)	VARIETY control group (n=7)	Est. diff. between intervention and control VARIETY (95% CI); p-value	Total control group (n=25)	Est. diff. between intervention and total control group (95% CI); p-value
Primary clinical outcomes					
Physical function (ODI), adjusted mean ± SD					
Baseline	39.6±6.8	37.4±5.4		40.7±9.3	-
1 month follow-up	22.6±9.2	28.0±17.5	-5.40 (-16.36–5.56); p=.32)		
3 months follow-up	22.9±13.8	27.7±14.1	-4.80 (-17.78–8.18); p=.44)	31.7±24.5	-8.80 (-2.57–20.17; p=.13)
Overall			-5.18 (-13.69–3.33); p=.24)		
Secondary clinical outcomes					
Pain intensity (NPRS), adjusted mean ± SD					
Baseline	7.0±1.0	6.3±1.1		7.0±1.1	-
1 month follow-up	5.0±2.2	4.8±1.7	.17 (-1.84–2.18; p=.87)		
3 months follow-up	4.2±2.3	4.9±2.3	-.43 (-2.68–1.82; p=.70)	5.3±2.0	-.35 (-1.94–1.25; p=.67)
Overall			-.13 (-2.27–2.01; p=.90)		
Pain related fears (FABQ-PA), adjusted mean ± SD					
Baseline	13.8±3.9	13.5±6.3			
1 month follow-up	11.5±3.9	14.0±5.2	-2.50 (-6.54–1.54; p=.21)		
3 months follow-up	11.1±4.5	11.7±6.2	-.52 (-5.19–4.15; p=.82)		
Overall			-1.51 (-5.86–2.84; p=.50)		
Pain related fears total (PCS), adjusted mean ± SD					
Baseline	22.8±11.2	21.7±9.9		24.3±10.4	-
1 month follow-up	18.5±11.2	18.0±8.8	.50 (-9.80–10.80; p=.92)		
3 months follow-up	14.2±12.9	18.1±11.7	-4.65 (-16.89–7.60; p=.44)	19.6±13.8	-2.39 (-11.05–6.27; p=.59)
Overall			-2.08 (-13.41–9.25; p=.72)		

Pain related fears rumination (PCS), adjusted mean ± SD			
Baseline	8.2±4.4	6.5±2.1	
1 month follow-up	6.8±4.2	6.8±3.4	-.09 (-3.99–3.82; p=.97)
3 months follow-up	5.0±4.7	6.7±4.5	-1.67 (-6.15–2.82; p=.45)
Overall			-.88 (-5.09–3.33; p=.68)
Pain related fears magnification (PCS), adjusted mean ± SD			
Baseline	3.9±2.4	4.2±2.5	
1 month follow-up	3.6±2.6	2.5±1.6	1.05 (-1.29–3.39; p=.36)
3 months follow-up	2.8±3.2	3.0±2.0	-.19 (-3.04–2.66; p=.89)
Overall			.43 (-2.18–3.04; p=.75)
Pain related fears helplessness (PCS), adjusted mean ± SD			
Baseline	10.7±5.5	9.8±6.7	
1 month follow-up	8.2±5.4	8.7±4.9	-.47 (-5.58–4.64; p=.85)
3 months follow-up	6.4±5.9	9.2±6.6	-2.79 (-8.51–2.94; p=.33)
Overall			-1.63 (-7.06–3.80; p=.55)
Physical activity, adjusted mean ± SD			
Baseline	352.9±527.7	257.5±224.7	
1 month follow-up	679.5±790.5	155.8±189.3	523.67 (-157.09–1204. 42; p=.13)
3 months follow-up	767.4±977.9	323.3±299.2	444.05 (-399.58–1287.67; p=.29)
Overall			483.86 (-282.52–1250.24; p=.21)
Pain self-efficacy (PSEQ), adjusted mean ± SD			
Baseline	39.8±12.1	41.3±14.6	
1 month follow-up	43.5±9.9	40.3±13.4	3.12 (-7.17–13.4; p=.54)
3 months follow-up	46.2±11.8	41.7±11.6	4.57 (-6.64–15.78; p= 41)
Overall			3.85 (-6.91–14.61; p=.48)

95% CI = 95% confidence interval; FABQ-PA = fear-avoidance beliefs questionnaire – physical activity; N/a = not available; NPRS = numeric pain rating scale; ODI = oswestry disability index; PCS = pain catastrophizing scale; PSEQ = pain self-efficacy questionnaire; SD = standard deviation.

Comparison to literature – added value of VR

Regarding the effectiveness results of the study, we found no statistically significant differences between the intervention and control groups. In contrast, participants in the intervention group seemed to improve considerably more than participants in the VARIETY control group. Given that intervention effects of CLBP treatment are generally small, large sample sizes are warranted to detect these effects.[54] Therefore, the results of the trial should not be interpreted as clear evidence for the lack of effectiveness of adding VR to physiotherapy for patients with CLBP, as "*the absence of evidence is not evidence of absence*".[55]

Studies on HMD VR integrated in physiotherapy for patients with CLBP are scarce. To our knowledge, only one prior study examined the effect of an integrated 12-session, pain education, HMD VR intervention in physiotherapy for patients with CLBP.[56] This study was comparable to our study regarding design and (control) intervention, and also struggled to enroll sufficient participants. Similarly, no significant differences were reported between the intervention and usual care control groups, although they report that VR in physiotherapy for patients with CLBP seems feasible and acceptable. Given that so far not many trials were conducted that examined the effect of VR in physiotherapy for patients with CLBP, our results were also compared to trials studying the effect of VR in physiotherapy for other types of chronic pain. One study evaluated the effectiveness of an HMD VR intervention in physiotherapy for patients with chronic neck pain.[57] The results of this RCT showed that the intervention group improved significantly more than the usual care physiotherapy control group. Another study examined the added value of VR in physiotherapy for patients with chronic musculoskeletal pain to manage fear of movement.[58] This study reported that the intervention group of physiotherapy with integrated VR significantly reduced their pain-related fear of movement. Aforementioned studies suggest that HMD VR could effectively improve physiotherapy for patients with chronic pain when studied with an adequate sample size. Nonetheless, these studies were not conducted in Western countries, but respectively in China and Japan, and also included treatment modalities that are not common in Dutch physiotherapy (e.g., TENS). In summary, although integrating VR into physiotherapy appears to be feasible and potentially of added value, current evidence is limited and ambiguous.

Comparison to literature – patient enrollment

Similar to some other studies among CLBP patients in Dutch physiotherapy, this study was terminated due to insufficient patient enrollment. One of the reasons for the lack of patient inclusion were the strict in- and exclusion criteria used, especially the combination of severe disability and severe pain. A total of 81 patients were assessed for study eligibility, of whom only 33 (41%) were randomized. Among the 48 participants who were excluded, 43 (90%) did not meet the inclusion criteria, suggesting that a subset of the broader patient group was included in this study. This corresponds with results from the e-Exercise trial that studied blended physiotherapy for patients with CLBP in the Netherlands. In this study, 52% of the participants who were assessed for eligibility were excluded.[59] The limited patient enrollment highlights potential challenges in implementing digital health interventions in physiotherapy practice, as strict eligibility requirements may limit the intervention's reach. Another reason for the limited patient enrollment was the additional administrative load on physiotherapists. Research on barriers to conduct scientific research among physiotherapists showed that lack of time and resources were among the most mentioned obstacles.[60] Future studies should carefully consider which patient population is most representative for primary care physiotherapy, and apply inclusion and exclusion criteria accordingly, while also minimizing the administrative burden for physiotherapists (e.g., by using questionnaires that physiotherapists already use in practice). To deal with the lack of patients in the VARIETY control group, we combined this group with historical control data from two comparable prior studies. In theory, combining randomized and historical controls could increase the sample size and statistical power, and reduce type I error.[61,62] There is however a risk of bias when patients of the historical control group are enrolled based on different inclusion criteria, and different outcome measures and time points that were used, as was the case in our study.

Strengths and limitations

Our study had the following strengths. First, the pragmatic trial was conducted in a real-world clinical physiotherapy setting using a pragmatic study design, which enhanced external validity. Second, rich data was collected, including information on the treating physiotherapists' characteristics, and details regarding the VR and usual care physiotherapy treatment. Third, the intervention tested in this trial was developed in a co-creation process with patients, physiotherapists and researchers.

Our results should be interpreted with caution due to the following limitations. First, obviously, the limited sample size was the main disadvantage of this study. Despite efforts (e.g., more than doubling the number of participating physiotherapists) to improve the recruitment rate of participants, we failed to reach our intended sample size (i.e., n=52 per group). In response, we included data from participants of two comparable trials to supplement our control group to reach n=25 per group. The baseline data of these participants were comparable to the data in our control group, but the results of the total control group should be interpreted with caution because participants were from different trials (e.g., different methods of recruitment and in- and exclusion criteria). Nevertheless, this approach aligns with the FAIR principles (findable, accessible, interoperable, reusable).[63] Second, because participant recruitment in the trial was slow, physiotherapists were not able to gain experience in providing the VR-integrated treatment, which could have limited the effectiveness of the intervention. Third, instead of the small feasibility study we did during the intervention development process,[29] we could have conducted a pilot-RCT that might have allowed us to identify and tackle these problems.

Clinical implications and future research

Due to the low sample size, our results do not provide a clear conclusion on the added value of VR-integrated physiotherapy compared to usual physiotherapy for patients with severe CLBP. However, the results of the trial showed that the integration of VR within the CLBP physiotherapy treatment is feasible and safe. No statistically significant differences were observed between groups, but the somewhat better outcomes in the intervention group may indicate limited potential that warrants further investigation.

This study could be replicated with a well-powered sample. Future research should incorporate methods to improve patient recruitment, for example by reducing administrative burden and involving CLBP patients and physiotherapists from the start.[64] To specifically improve severe CLBP patient recruitment, the trial should reconsider how to recruit severe patients, as this inclusion criterion (i.e., a combination of severe disability and severe pain) was one of the main reasons for slow patient enrollment. Instead of using this criterion, multiple ways have been proposed to define severe pain patients. As an example, 'high impact chronic pain'

is defined as "*pain present on most days for six months or more that is associated with substantial restriction of participation in work, social, and self-care activities*"[65] and can be measured using the Graded Chronic Pain Scale Revised.[66] Another option would be to include a broad group of CLBP patients and subsequently conduct subgroup analyses on the patients who are considered severe.[67] Future studies should investigate how stratification based on patient characteristics can be used to tailor specific VR intervention components, for example through single-case experimental design studies. Moreover, future studies should also consider including more process-related outcomes such as treatment adherence, and therapeutic alliance, because it could be expected that improving this would indirectly enhance intervention effectiveness.

Conclusion

This pragmatic RCT found limited support for the use of VR integrated into physiotherapy care for patients with CLBP and that it is feasible to use in practice, although not statistically superior to usual physiotherapy in this underpowered study. While results are insightful, further research is needed to evaluate the intervention's effectiveness and explore longer-term outcomes.

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Chapter 8

Reporting guideline for therapeutic immersive virtual reality interventions: International eDelphi study (INVIRTUE)

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Abstract

Introduction: With the rising adoption of virtual reality (VR) in healthcare, research publications on the topic are increasing rapidly. Guidance on reporting VR interventions is limited, which risks misinterpretation of findings, inappropriate data synthesis in reviews and meta-analyses, and reduced reproducibility. This could also result in possible misuse of VR interventions and might hinder further implementation in clinical practice. The aim of this study was to develop a reporting guideline for therapeutic, immersive VR interventions using head-mounted displays in scientific publications. To reach this aim we intended to achieve expert consensus on key items and categories for reporting these interventions.

Methods: We conducted a three-round, modified, online Delphi study with a validation meeting to develop a VR intervention reporting guideline. Participants were international experts in therapeutic VR research, working as academic or industrial researchers. Convenience, purposive, and snowball sampling were used to recruit participants. Consensus was a priori defined as ≥75% agreement on each reporting item and category.

Results: Of the 280 invited experts, 61 participants (22%) completed all three rounds of this Delphi study. Participants (32 females (52%)) had an average of six years' experience with VR research and diverse backgrounds in VR research settings and disciplines. The final consensus-based VR intervention reporting guideline consists of 16 reporting items divided into six categories (i.e., theory, content, deployment, development, safety, and context).

Discussion: The INVIRTUE intervention reporting guideline provides a framework for describing therapeutic, immersive VR interventions. Using this tool may enhance the uniformity and completeness of VR intervention reporting and support study replicability and scientific progress. The reporting guideline will also facilitate efficient empirical comparison across existing VR interventions and ultimately contribute to the appropriate use and effective implementation of therapeutic VR in clinical practice.

Introduction

Extended reality (XR) is increasingly used in health care as an (adjunct) intervention.[1] XR is an umbrella term that encompasses virtual reality (VR), mixed reality (MR), and augmented reality (AR). VR can be defined as a "*computer-generated digital environment that can be experienced and interacted with as if that environment was real*"[2] and is usually provided through a head-mounted display (HMD). By using a HMD, the user generally is sensory immersed in the virtual environment.[3] Therapeutic immersive VR is used for a variety of conditions, including (chronic) pain,[4] phobias,[5] and stress.[6]

Recently, a cross-sectional study reviewed the quality of reporting XR interventions in health care publications and showed that current intervention reporting is very poor.[7] This corresponds with a recent review on XR interventions in pain management research, which showed that only 23% of the examined scientific papers included a substantial content description of the VR intervention and only 46% included a substantial hardware description.[8] This lack of detail and completeness in VR intervention reporting can lead to, for example, inappropriate interpretation, as well as comparisons and pooling of heterogeneous interventions in reviews and meta-analyses.[9,10] This is a potential factor that hinders the adoption of therapeutic VR in health care settings and replication of VR effectiveness studies.[11] Recent literature on the current state of clinical VR research described it as "*the Wild West*", with a lack of clear guidelines, standards, or substantial progress.[12,13] Multiple sources suggest that the current state of VR scientific inquiry is underpinned by the absence of consensus on an intervention reporting guideline. This was mentioned as a limitation of recent VR research in different health care settings, including psychology,[14] chronic pain,[15] and physical rehabilitation research.[16]

Several intervention reporting guidelines of therapeutic interventions exist; the Template for Intervention Description and Replication (TIDieR) checklist is one of the most commonly used in health care.[17] This checklist includes items delineating why, how, and where the intervention was delivered. More specific intervention reporting guidelines were developed for exercise interventions such as the Consensus on Exercise Reporting Template (CERT),[18] but not yet for therapeutic VR. Given the multiple specific technical, content, and user-interactive elements involved in immersive VR applications, existing therapeutic reporting guidelines

are limited in the ability to capture the essential components of therapeutic VR interventions.[7]

The aim of this study was to develop an internationally accepted reporting guideline on how to describe therapeutic, immersive HMD VR interventions in scientific papers. In this study, therapeutic VR is considered to be sensory immersive and provided through a HMD. We chose to focus specifically on VR rather than other forms of XR because it is the most extensively researched area within the XR domain.[8,19] To reach this objective, we aimed to achieve consensus on key items and categories for reporting therapeutic immersive, HMD VR interventions.

Methods

Design

The three-round, modified, electronic Delphi (eDelphi) survey and additional validation meeting was conducted among international VR research experts. Delphi techniques are often used to identify consensus or develop standards by collecting knowledge from domain-specific experts.[20,21] Traditional Delphi studies use open-ended questions to identify responses for future Delphi rounds, while modified Delphi studies provide a set of initial statements that are developed a priori.[22] Consequently, in modified Delphi studies the coordinating researchers have an active role in generating consensus and generally two to three Delphi rounds suffice, rather than at least four rounds required in traditional Delphi studies.[21] We chose a modified Delphi design to facilitate timely study completion, diminish burden on study participants, and permit tailoring of the process to study needs. In addition, existing intervention reporting guidelines served as a useful foundation for determining key items and categories. This Delphi study included three rounds: round one (demographic information, rating, and proposing (new) items and categories), round two (rating and testing stability of items and categories), and round three (rating and testing stability of items and categories). The reporting guideline was finalized during a validation meeting.

The study was based on the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network recommendations for developing reporting guidelines[23] and reported according to the guidance on Conducting and REporting DElphi Studies (CREDES) guidelines.[24]

Approval to conduct the study was granted by the ethics committee of the HAN University of Applied Sciences (HAN ECO: 564.06/24). All participants provided electronic informed consent before participating in the study. The study was registered prospectively on the Open Science Framework (OSF) (doi: 10.17605/osf.io/hfp4m) and with the EQUATOR network. The Delphi rounds were conducted between June 2024 and March 2025, and the validation meeting was conducted in June 2025.

Contributors

The study was primarily conducted by a day-to-day committee, supported by an international steering committee. Members of both committees were all researchers studying the application of therapeutic immersive VR in health care interventions.

Day-to-day committee

The day-to-day committee of the Delphi study consisted of SS, MH, HvG, RO, JBS, and JK. The committee conceptualized, designed, coordinated, and co-authored this scientific paper on the Delphi study.

Steering committee

The international steering committee of this Delphi study consisted of DH, LB, BD, TG, PAvdH, MK, JBS, ZT, and DU. The committee supported the day-to-day committee in providing feedback and co-authored this scientific paper.

INVIRTUE expert panel

Potential candidates of the expert panel were identified by the day-to-day committee. Expert panel members studied VR interventions in different health care areas and were included if they: 1) (co-)authored a scientific paper on therapeutic VR in a peer-reviewed journal and 2) were employed as researcher in an academic institution or industry. Participants were recruited through convenience sampling (e.g., by inviting colleagues of committee members), purposive sampling (e.g., by searching scientific databases for specific researchers), and snowball sampling (e.g., by asking participants to propose other participants in the first Delphi round). We strived to include at least 40 experts in the final round of the Delphi study, which is considered to be sufficient.[25] Participants in the expert panel who completed all three Delphi

rounds were mentioned as final author of this paper as part of the "VR intervention reporting international consensus (INVIRTUE) group" (see acknowledgements).

Procedure and analysis

Preparation

Before the first round, a list of reporting items and categories was developed. The list was based on thematic analysis of >100 scientific papers that reported on the effectiveness of a therapeutic HMD VR intervention (derived from Trost et al.[26]), other intervention reporting guidelines (i.e., TIDieR[17] and RATE-XR[27] checklist), and group-discussions with the day-to-day and steering committees. Relevant features describing the therapeutic VR intervention of the aforementioned sources were systematically reviewed and inductively coded by one researcher (MH), and subsequently discussed with two additional researchers (SS and JK). Next, these three researchers categorized the codes into themes through iterative comparison and discussion.[28] The a priori constructed list consisted of 26 intervention reporting items divided into five categories (i.e., theory, dose, content, preparation and additional).

Before conducting the Delphi rounds, pilot-tests were conducted to ensure study procedure feasibility. Results of the pilot tests were included in the final analysis, as no major issues were identified. Participation in the study was confidential, but not anonymous, because the coordinating researcher could identify participants based on their e-mail address. Participant identification was necessary to be able to invite participants who completed a Delphi round for the next round. Personal data were stored on a secure server.

Round 1

All potential candidates of the expert panel were invited by the day-to-day committee through email to participate in round 1 of the study. The email contained general information about the Delphi study and a link to the survey on web platform Qualtrics (Qualtrics, Provo, USA).

This first round included three parts. The first part contained the information letter and accompanied informed consent (see Appendix 8.1). After agreeing to participate in the study, participants continued to the actual survey. The second part requested the following (demographic) information about the participants: e-mail address,

age, sex, country of residence, VR research context, primary VR research area, and number of years' experience in VR research. The third part comprised the a priori constructed list of 26 intervention reporting items with explanation per item and five categories (see Appendix 8.2), which were rated on a 9-point Likert scale per item (1=of no importance to 9=extremely important). The rating was based on the following question: "how important do you think this topic is for a therapeutic, immersive VR intervention reporting guideline?". Besides rating, there were two types of free-text boxes, one to comment on individual reporting items and suggest new items, and one to comment on the categories suggested in the a priori constructed list.

Participants received an email reminder to participate in the study after 7 and 14 days. Three weeks after study start, this first round was closed. Items were proposed in the next round for inclusion in the reporting guideline when 75% of the participants rated an item 7 or higher and less than 15% of the participants rated the item 3 or lower. Items were proposed in the next round to be excluded from the reporting guideline when 75% of the participants rated an item 3 or lower and less than 15% of the participants rated the item 7 or higher.[29] Item and category clarifications or modifications and new items proposed by participants were screened and analyzed inductively by the day-to-day committee, and if deemed of added value, included in the second round. This ensured that expert input, not just quantitative consensus, played a central role in shaping the subsequent rounds.

Round 2

The second round provided controlled feedback in the form of an anonymized summary of results from round 1. This round had three parts. First, to study item stability, items from round 1 that scored as sufficient to be included or excluded were presented with the question of whether the intervention reporting item should indeed be included or excluded in the reporting guideline.[21] An item was deemed stable if 85% of the participants agreed that an item should be included or excluded.[30] Second, items and categories without consensus were presented again with the median and interquartile range (IQR) scores that the item scored in round 1.[31] Third, new items proposed during round 1 were presented. Both items without consensus and new items were again rated based on the procedure presented for round 1. There was no option to suggest new items in this or subsequent rounds, but participants had the option to suggest minor revisions for both the items and their descriptions.

Round 3

The procedure of round 3 was similar to the survey procedure of round 2 and based on the results from round 2. In addition, participants were asked to classify all proposed intervention reporting items in the following categories: 'essential in reporting guideline', 'nice to have in reporting guideline' or 'not necessary in reporting guideline', based on Duncan et al.[32] Intervention reporting items were considered as included in the final reporting guideline if they scored a median rating of 7–9[33] and/or if >50% of participants categorized an item in the 'essential in reporting guideline' category. Similarly, intervention reporting items were considered excluded from the final reporting guideline if they scored a median rating of 1–3 and/or if >50% categorized an item in the 'not necessary in reporting guideline' category. Finally, participants had the option to suggest minor revisions for the items and their descriptions.

Validation meeting

Results of round 3 were discussed with members of the day-to-day and steering committees during an online consensus meeting. In this meeting, each individual reporting item and associated category was discussed, and the members were asked to improve as necessary the information regarding the suggested reporting items (i.e., reporting item title, category, description, and example). The results of the consensus meeting formed the validated version of the VR intervention reporting guideline.

Results

280 international VR research experts were invited for the first Delphi round, 61 (22%) completed all three Delphi rounds (see Table 8.1).

The 61 participants who completed the third round had a mean age (SD) of 39 (9.7) and an average of six years' experience with VR research. They were located in 13 countries from four continents and studied VR in a variety of disciplines and settings. For more information on participant demographic information see Table 8.2. Comparison between the participants who completed all three rounds and non-completers showed no large differences in demographic information (see Appendix 8.3)

The flow of the included, excluded, new and merged reporting guideline items throughout the three Delphi rounds and validation meeting is shown in Figure 8.1.

Table 8.1. Flow of participants

	1st round	2nd round	3rd round
Invited	280	104	77
Responded as unavailable	29	4	4
Started survey	128	86	65
Completed survey	104	77	61

Table 8.2. Participant characteristics

	Expert panel (n=61)
Sex, female, n (%)	32 (52)
Age, mean (SD)	38.6 (9.7)
Country of origin, n (%)	
Netherlands	26 (43)
United Kingdom	7 (11)
USA	5 (8)
Germany	4 (7)
Belgium	4 (7)
Australia	3 (5)
Switzerland	3 (5)
Denmark	2 (3)
Ireland	2 (3)
Italy	2 (3)
Canada	1 (2)
Chile	1 (2)
Poland	1 (2)
VR research primary area, n (%)*	
Pain management	24 (39)
Physical rehabilitation	20 (33)
Mental health therapy	15 (25)
Other**	24 (39)
VR research setting, n (%)*	
Out-hospital	42 (69)
In-hospital	32 (52)
Fundamental	19 (31)
Years' VR experience, mean (SD)	6.0 (4.3)

* Multiple options possible.
** For example cognitive rehabilitation.

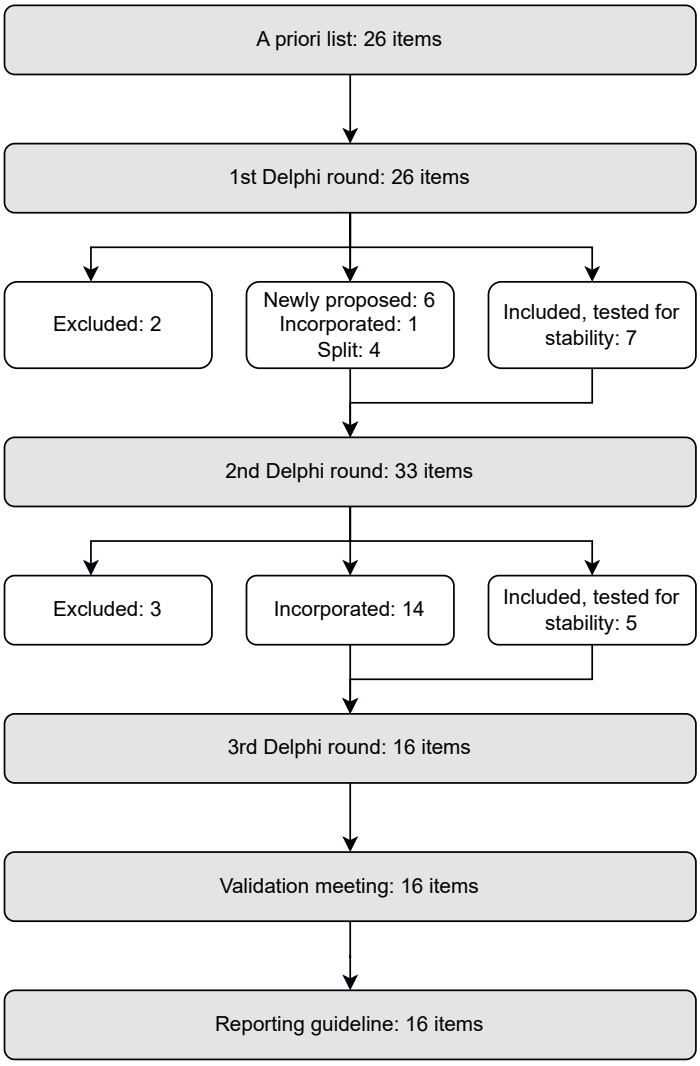


Figure 8.1. Flowchart of reporting items.

In the first round, the 26 items (divided into five categories) from the a priori constructed list of intervention reporting items were rated. After this round, seven items (i.e., *clinical aim*, *time per session*, *intervention duration*, *frequency*, *intervention set-up*, *application/game*, and *interactivity*) were rated sufficiently important to include in the reporting guideline, six new items were proposed (i.e., *purpose of VR intervention*, *scientific evidence*, *participant involvement*, *availability/accessibility*, *professional training*, and *data security*), and two items were excluded (i.e., *intensity* and *software for development*). *Intervention procedure* was incorporated into the

existing reporting item *application/game*, and four items were split (i.e., *proposed working mechanism* was split into *clinical aim* and *proposed working mechanism*, *hardware* was split into *technical requirements* and *hardware*, *intervention instruction* was split into *preparation time* and *intervention instruction*, and *intervention time session* was split into *time per session* and *VR time*).

In the second round, 33 items (divided into six categories) were rated based on the results of the first round. Three new categories (i.e., usability, population, and safety) were added, and two categories (i.e., preparation and additional) were removed. The 33 items of the second round included the seven items that were included after the first round, to test their stability. After this round, five items were rated sufficiently important to include in the reporting guideline (i.e., *clinical aim*, *application/game*, *interactivity and feedback*, *dosage*, and *setting and supervision*) and three items were excluded (i.e., *costs*, *presence*, and *embodiment*). 14 items were incorporated into existing reporting items (i.e., *purpose of VR intervention* was incorporated into *clinical aim*, *scientific evidence* was incorporated into *proposed working mechanism*, *feedback mechanism* was incorporated into *interactivity and feedback*, *intervention modification* was incorporated into *modification*, *personalization and tailoring*, *motion tracking*, *audio* and *technical requirements* were incorporated into *hardware*, *time per session*, *intervention duration*, and *frequency* were incorporated into *dosage*, *intervention set-up*, *body position*, *safety measures* were incorporated into *setting and supervision*, and *provision/delivery* was incorporated into *instruction*).

In the third round, 16 items (divided into six categories) were rated based on the results of the prior rounds and included in the reporting guideline. One category was added (i.e., deployment) and one category was removed (i.e., dose).

In the validation meeting, these 16 items were discussed and their descriptions were improved if necessary (e.g., including for example more extensive examples per reporting item).

The final consensus INVIRTUE reporting guideline on how to describe therapeutic, immersive HMD VR interventions contains 16 items divided among six categories: theory, content, deployment, development, safety, and context. The full version of the reporting guideline is shown in Table 8.3, and Appendix 8.4 provides a customizable version of the guideline. Appendix 8.2 gives a full overview of the reporting items and categories per round.

Table 8.3. Final INVIRTUE reporting guideline

	Item		Description	Example
Theory	1.	Clinical aim	Description of the clinical aim of the VR intervention	The aim of the VR intervention was to increase the range of motion of the user's shoulder
	2.	Proposed working mechanism	Description of the proposed underpinning neuro/psycho/biological working mechanism of the VR intervention	The proposed working mechanism of the VR intervention was distraction
	3.	Proposed user group	Description of whether the VR intervention was developed for a particular user group or body region	The provided VR intervention was originally developed for users with chronic low back pain
Content	4.	Application/game	Description, illustration and name of the VR intervention	The VR intervention 'Beatsaber' was used (see figure). In this intervention users use VR controllers to slice through flying colorful blocks in sync with music
	5.	Interactivity and feedback	Description of whether and how the VR intervention was interactive and provided (audio-visual, tactile or vestibular) task feedback	The VR intervention included interaction with avatars and provided audio-visual feedback
	6.	Tailoring	Description of whether and how the VR intervention had the option to be tailored (e.g., using different levels or personalization) to the specific user	VR intervention tailoring was possible through automatic progression in difficulty based on the performance of the user
	7.	Availability	Description of whether the VR intervention is available for the public (open source or not)	The VR intervention used was an available off-the-shelf intervention

Deployment	8. Hardware	Description of the hardware and services (e.g., Wi-Fi) used, including HMD, audio and motion tracking equipment	The VR intervention was provided using the standalone Oculus Quest 3 HMD VR headset with built-in spatial audio
	9. Dosage	Description of the VR intervention duration, frequency and time per session	The VR intervention had a duration of four weeks, three times per week for 15 minutes per session
	10. Setting and supervision	Description of the location the VR intervention took place and whether this was supervised	The VR intervention was provided in a hospital room supervised by a physiotherapist
	11. Instruction	Description of what kind of instruction was given to the user about the use of the VR intervention, by whom and the time needed for the instruction	Users who received the VR intervention were given a 10-minute verbal instruction by a nurse
	12. Preparation time	Description of how much time the set-up of the system took before the VR intervention could start	Set-up of the VR intervention took approximately 15 minutes
	13. Professional training	Description of the training given to the professional providing the VR intervention	Physiotherapists who provided the VR intervention received a one-hour online training
Development	14. End-user involvement	Description of whether the end-user (e.g., user or provider) was involved in the development of the VR intervention and in which way they contributed	Users with agoraphobia contributed to the intervention content description
Safety	15. Anticipated adverse events	Description of issues that may be encountered during the VR intervention and utilized safety considerations	To diminish the risk of falling during the VR intervention, a safety harness was used
Context	16. Co-interventions	Description of other interventions provided during the VR intervention period	The users who received the VR intervention simultaneously received weekly psychotherapy

Discussion

This Delphi study reached agreement on reporting items and associated categories that resulted in the consensus INVIRTUE intervention reporting guideline, which could improve uniformity and completeness of therapeutic, immersive HMD VR intervention reporting in scientific papers. The consensus reporting guideline consists of 16 items divided in six categories.

Discussion of intervention reporting guideline content

The Delphi rounds facilitated important discussions and revealed challenges in defining the final reporting guideline. One unexpected challenge was orienting all participants to discussion of intervention reporting rather than traditional manuscript reporting. This is reflected, for example, in participants suggesting including an item on adverse events, even though this would be more suitable for manuscript results instead of the intervention description. The final reporting guideline includes an item on anticipated adverse events and safety considerations to prevent these (item 15). Another topic where consensus proved difficult was how detailed the reporting guideline should be. Some participants suggested including detailed technical reporting (e.g., utilized HMD refresh rate). This level of technical detail, while essential for hardware and software design, was generally considered less relevant for reporting of applied therapeutic VR research. After the three rounds, this item was excluded from the reporting guideline, but we urge authors to include this if they think it is appropriate. Further, the a priori list of reporting items included 26 reporting items and after the first Delphi round only six new items were proposed. This suggests that the initial list already was quite comprehensive and captured substantial relevant content. There was likewise some debate on using the term *tailoring* or *personalization* to describe reporting for item 6. In line with the TIDieR checklist and a recent review on the concepts of personalization and tailoring in eHealth interventions, we chose the term *tailoring* as we think this best reflects the description of the reporting item.[34] Finally, although participants struggled to reach consensus on certain reporting items in the first and second rounds although, consensus was reached on all items after the third Delphi round. This could be due to the novelty of the field and broad range of therapeutic VR applications, which is reflected in other current debates in VR research, including the struggle to define (immersive) VR in general.[35–37]

Comparison to other reporting guidelines

This is the first guideline specifically for VR intervention reporting, whereas more general manuscript and intervention reporting guidelines already exist. Comparing our reporting guideline to the established TIDieR reporting checklist for interventions in general, it seems our reporting guideline is comprehensive.[17] Most items of the TIDieR checklist are reflected in our reporting guideline, i.e.: *brief name* (item 4 of our reporting guideline), *why* (items 1 and 2), *what* (items 4–8, and 11), *who provided* (items 10 and 13), *how* (item 10), *where* (item 10), *when and how much* (item 9), *tailoring* (item 6), *modifications* (item 6). The only item not reflected in our reporting guideline is the final item of the TIDieR checklist (i.e., *how well*), that describes the planned and actual intervention adherence and fidelity. This is possibly due to the fact that this item is not strictly about describing the intervention itself, but rather about the correct deployment of the intervention. Our reporting guideline is specifically designed for therapeutic VR interventions, providing more specific guidance. This is for example illustrated in the *why* reporting item of the TIDieR checklist (i.e., describe any rationale, theory, or goal of the elements essential to the intervention). Our reporting guideline divides this item into multiple items that ask for a therapeutic VR specific clinical aim (item 1) and proposed working mechanism (item 2). Similarly, the intervention items of the RATE-XR checklist[27] are reflected in our reporting guideline, i.e.: *4 - setting and location* (item 10), *5b - providers and training* (item 10 and 13), *6 - application description* (item 4–12), *7 - intervention development* (item 14), and *8 - participant timeline* (item 16). The RATE-XR manuscript reporting guideline aims to improve reporting of XR evaluation studies and includes items from title to statements. However, the RATE-XR focus was not specifically on the in-depth description of immersive, therapeutic VR interventions.

Intervention reporting guideline use

Sole use of this reporting guideline may not suffice for uniform and complete VR intervention reporting and possible study replication. It should be noted that this reporting guideline is not exhaustive and additional details are warranted to ensure in-depth and comprehensive intervention description for individual VR interventions. However, not all suggested reporting items are always necessary to report in a scientific paper, for example when a VR intervention is described in-depth in a separate paper. In such cases, it is crucial that authors explain why

they omitted this reportable information or where more information can be found. Unfortunately, it is not possible to establish a single, definitive reporting guideline that fits all VR interventions given the considerable breadth of the therapeutic VR research field, which spans amongst others physical, psychological, and cognitive rehabilitation applications. Moreover, it should be stressed that this reporting guideline focuses specifically on VR intervention description in a scientific paper. Other guidelines were developed to provide general guidance across a variety of scientific reporting, for example the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline for randomized trials[38] and Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) reporting guideline for systematic reviews and meta-analyses.[39] Also, the RATE-XR manuscript reporting guideline was recently published to report early-phase clinical evaluation of XR applications.[27,40] Therefore, we suggest combining the INVIRTUE intervention reporting guideline with a fitting manuscript reporting guideline.

Strengths and limitations

This study has several strengths. First, the study employed a comprehensive methodological approach including a literature review, multiple Delphi rounds, and a validation meeting, resulting in rich qualitative and quantitative data. Also, the international EQUATOR network recommendations to develop intervention reporting guidelines were adopted, which aims to advance high quality reporting of health research studies.[41] Further, the study was a priori registered on OSF and the EQUATOR network. Second, the included expert sample was larger than anticipated and sufficient for a Delphi study.[25] Also, no considerable differences in characteristics were observed between responders and non-responders, suggesting decent external validity. The sample further included experienced VR experts with a large heterogeneity in locations, expertise and backgrounds, which ensured comprehensive and trustworthy study results.

This study has the following limitations. First, participants were mostly from Western countries and especially from the Netherlands, since most members of the day-to-day and steering committee where from the Netherlands. In addition, the study lacked input from lower- and middle-income countries even though experts from these countries were invited. Consequently, the guideline may not reflect a global perspective on a VR intervention reporting guideline and for

example miss important topics like availability of therapeutic VR interventions in different languages. Moreover, differences across countries in for example healthcare infrastructure and access to VR may limit the generalizability and global applicability of the reporting guideline. Second, since participants were invited through convenience, purposive, and snowball sampling, selection bias might have influenced the results. Also, using the a priori constructed list of reporting items may have introduced confirmation bias, which we mitigated by incorporating open-ended feedback and revising items across rounds. Third, we limited participants to those that (co-)authored a scientific paper on therapeutic VR in a peer-reviewed journal, which may have overlooked variability in research expertise. Accordingly, the consensus achieved might not represent all expert perspectives, and certain guideline details could differ with a different participant group. Fourth, the reporting guideline was developed for scientists and therefore only researchers who published VR-related scientific papers were invited. Although several participating researchers also work as clinicians, the lack of variety in stakeholders may have affected the generalizability of the results.

Fourth, the reporting guideline was developed for scientists and therefore only researchers who published VR-related scientific papers were invited. Although several participating researchers also work as clinicians, the lack of variety in stakeholders may have affected the generalizability of the results.

Future research

Future research could address several topics based on the results of this study. First, studies could increase the scope of this research and, for instance, extend these results to XR or digital health in general. Although the current version of the reporting guideline is likely already well suited for describing XR interventions. Also, while our results are limited to therapeutic VR, VR is increasingly being used in diagnostics[42] and it might be worthwhile to study this in detail. Second, this study is a small step in advancing research on therapeutic VR, but more steps are needed to mature this relatively new area of research. One of these steps could be the development of a research agenda with the most urgent topics to study in the field of therapeutic VR, to which the current guideline can be applied. The fast-paced evolution of VR warrants continuous updating of this study's outcomes, including input from lower- and middle-income countries and different VR stakeholders

(e.g., clinicians, users and developers). In addition, new technological advancements, including the use of haptics and eye tracking, are likely to improve and be integrated into therapeutic VR interventions of the future, necessitating further expansion or modification for optimal VR intervention reporting. To ensure continuous relevance, the INVIRTUE group will update the reporting guideline every five years, taking into account significant developments within the field.

Impact

Implementation of this reporting guideline could be achieved in multiple ways. We will notify academic journals and researchers (including Delphi participants) about completion of the guideline. Further, this reporting guideline is freely available and we will continue cooperating with EQUATOR to disseminate this reporting guideline. Implementation of this guideline is expected to have an impact on different stakeholders in research on therapeutic VR. Researchers could use the reporting guideline for transparent and comprehensive intervention reporting. This way, the reporting guideline would support appropriate interpretation, comparison, and pooling of VR interventions. Clinicians could use the reporting guideline to extract essential VR interventions elements (e.g., dosage) required for accurate intervention application, which would ultimately support intervention adoption and effectiveness in clinical practice. Finally, the reporting guideline may also inform other stakeholders including funding bodies and industry, by improving the clarity and consistency of intervention reporting and facilitating the translation of research findings into real-world applications.

Conclusion

To conclude, this study reached consensus on key items and categories to report therapeutic, immersive HMD VR interventions in scientific papers. These results culminated in the new consensus INVIRTUE VR intervention reporting guideline, which provides the scientific community with a meaningful tool for uniform, detailed and comprehensive VR intervention description. Utilizing this tool could support researchers in study interpretation, comparison, and replicability, ultimately building a stronger empirical foundation for VR utility, and supporting clinical practice in the appropriate application and effective implementation of therapeutic VR in health care.

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Chapter 9

Questionnaires for evaluating virtual reality: A systematic scoping review

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Abstract

Introduction: Virtual reality (VR) is an emerging technology in fields including education and healthcare. A challenge for VR researchers is knowing which VR evaluation instruments exist, and which best align with their research objectives. Therefore, a systematic scoping review was conducted to identify and appraise questionnaires that evaluate VR.

Methods: A scoping review across five scientific databases identified articles that described the development of questionnaires that evaluated VR. All identified articles were screened and data about the measured constructs, (psychometric) properties, and availability were extracted.

Results: The initial search identified 4,461 articles, 151 were full text screened, and 56 were included in the review. In total, seven constructs were measured to evaluate VR, of which presence (n=26), user experience (n=15) and motion sickness (n=6) were most commonly used. However, these constructs were not always clearly defined, and measures of the same construct often differed in their content. Reliability was reported for 34 (59%) questionnaires, evaluations of validity were found in 42 (72%) questionnaires. Moreover, recommendations per construct on most optimal VR questionnaires were proposed.

Discussion: A wide range of questionnaires used to evaluate VR were identified. Further, VR-related constructs were reviewed by comparing definitions, exploring questionnaire items, and examining their differences. Where relevant, constructs were divided (e.g., presence was divided into social, self, and spatial), and suitable definitions for each (sub-)construct were given. We provide recommendations for a structured approach of the development of measures to evaluate VR alongside priority areas where new measures are most sorely needed.

Introduction

Virtual reality (VR) is a technology already used and defined as a "real or simulated environment in which a perceiver experiences telepresence"[1] over 30 years ago. Although the technology has changed drastically throughout the years, the similarities in definitions remain in current literature "VR is a three-dimensional computer-generated simulated environment, which attempts to replicate real world or imaginary environments and interactions".[2] VR possesses multiple defining characteristics that make it a distinctive technology:[3] a key element of VR is its ability to induce a sense of presence,[4] which can be described as a sense of 'being there' in the virtual environment (VE).[5] Moreover, interaction is possible in VR and often achieved using hand-held controllers, 3D tracked data gloves, or motion suits.[6–8] These characteristics make VR a unique realistic technology, by combining user control and 360° immersion within a simulated environment.[9]

Despite the rapid development of VR hardware, the same questionnaires to evaluate VR are still used in current research (e.g., Slater Usoh Steed Presence Questionnaire).[10] Previously the focus was on creating realistic VEs, nowadays it has extended beyond visual input (e.g., inclusion of haptics).[11] It remains unclear whether these new technological advances impact the suitability or validity of existing evaluation measures and whether differences exist between different fields.[12] For example, in VR crisis negotiation social and co-presence are of great importance for the added value of VR,[13] while using VR for surgical education haptic feedback and sensitivity of controls might be more important,[14] and when applying VR for relaxation sensory immersion might in turn be a more crucial feature.[15,16]

To evaluate VR, both explicit and implicit techniques could be used. Explicit methods, such as questionnaires and/or interviews require active participation from the participant, while implicit methods are based on automatic responses and do not require the participant to actively report their experiences, such methods include heart rate variability (HRV), electroencephalogram (EEG), functional magnetic resonance imaging (fMRI).[17] Explicit methods, especially questionnaires, are most commonly used in VR evaluation due to their ease-of-use and versatility in topics[18] and enable evaluation of subjective lived experiences.[12] Therefore, the focus of this review lies on questionnaires specifically. A large variety of questionnaires are used in research, however, guidance on which questionnaires to

choose is lacking.[19] This suggests that a thorough investigation into VR evaluation questionnaires is needed to address different types of questionnaires and assess whether new questionnaires are required.

Since scoping reviews provide an opportunity to develop clarified conceptual frameworks and theory generation through a narrative synthesis of the extant literature,[20] systematic scoping review was found to be the most fitting for the study's broad research aims[21] and because it is particularly useful for topics with emerging evidence (like VR) in both published and grey literature.[22] Our review identified what questionnaires have been developed to evaluate VR. We distinguished for which constructs the questionnaires were created, what psychometric evaluations have been performed during scale construction, whether users can access the identified scales, found available translations and/or adaptations, and provided suggestions for suitable VR questionnaires.

Methods

Search strategy and selection of studies

This systematic scoping review was reported in accordance with Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR).[23] The initial literature search was conducted on August 10, 2023 and updated on August 13, 2024 using five scientific databases, namely: Google Scholar, Scopus, Web of Science, IEEE Xplore, ACM Digital Library. Considering that Google Scholar provides a vast number of results (including grey literature), only the first 300 hits in each search were considered, as suggested previously.[24] It was also clear that the probability of retrieving additional relevant sources beyond the initial 300 marker was low in our specific case. We tested our search string against selected key references of commonly used VR questionnaires to ensure our search string was identifying these known resources (see Appendix 9.1 for the list of selected key references).[25]

The search string consisted of three main parts. The first targeted studies that directly address VR. The second limited the search to articles that primarily addressed questionnaires and their development. The third identified constructs that have been used to evaluate VR. The search string and the adapted search strings for each database can be found in Appendix 9.2 and 9.3 respectively.

Inclusion and exclusion criteria

To ensure we captured as many articles that developed a new measure of VR performance as possible, we adopted broad inclusion criteria with more specific exclusions.

Inclusion criteria targeted any study which includes a new or reconstructed questionnaire which is used to evaluate the VR environment used within the study. Exclusion criteria led to the exclusion of all papers not written in English or Dutch, translations and/or validations of pre-existing scales, and single-use questionnaires (questionnaires made for a specific case without a future line). It also excluded articles that did not present new empirical data (e.g., short abstracts or review papers), articles that only presented objective measures/observations/anything other than questionnaires without also using questionnaire evaluations, articles that did not assess/evaluate VR technology, and articles that could not be accessed despite our best efforts. For example, by contacting study authors, and searching the websites of individual academics and institutional repositories.

Data extraction

To assess eligibility, two researchers (LB and SS) independently screened all titles and abstracts and subsequently reviewed all full text articles. The web-based screening tool Covidence was used for its ability to facilitate the collaboration process.[26] The machine learning function, which identifies relevant papers based on previous choices and places them at the top of the unscreened articles list was used to help identify relevant articles faster. Discrepancies were discussed until consensus was reached. The interrater reliability of included studies was calculated using Cohen's Kappa and in the first round for the title and abstract screening was moderate (.5).[27] The inter-rater reliability was not ideal due to the large number of results not specifying whether they have developed a new or one-time use questionnaire and therefore, several exclusion criteria were iteratively added in the second round of screening. Cohen's Kappa was substantial (.7) for the full text screening.

Questionnaires were grouped based on the constructs they were targeting. To describe included questionnaires, the following characteristics were included: authors, publication year, name of questionnaire, construct measure (e.g., immersion, presence), number of items and domains, psychometric information, number of citations. Reported psychometric properties were extracted from

the articles. Cronbach's alpha is a commonly used measure to report reliability, therefore, we used it to report reliability per scale, subscale, or item based on availability and interpreted it as unacceptable ($\alpha<0.5$), poor ($\alpha>0.5$), questionable ($\alpha>0.6$), acceptable ($\alpha>0.7$), good ($\alpha>0.8$), and excellent ($\alpha>0.9$).[28] Validity was divided into four types:[29] face, content, construct (including convergent and discriminant), and criterion validity.

A narrative synthesis comparing and contrasting the different questionnaires, subscales, and items used to measure VR-related constructs (e.g., presence, immersion) was performed. This narrative synthesis allowed for an analysis of the extent to which the different scales indicated agreement upon the boundaries or facets of specific constructs. For example, which aspects of user experience (UX) determine presence, embodiment or immersion, and to what extent do these potentially related constructs differ from one another according to how they are measured.

Results

The systematic literature search identified 4,461 articles next to the 26 selected key references (see Appendix 9.1). After title and abstract screening, the full text of 151 articles were screened and 56 that met all criteria were included in the final review. Figure 9.1 shows a summary of the article selection process.

Overview of included studies

A total of 56 articles (including 58 questionnaires) met the inclusion criteria. Studies included in the review primarily measured the following constructs: presence (n=26), UX (n=14), simulator- /motion- /cyber-sickness (n=6), simulator realism (n=4), immersion (n=3), embodiment (n=3), and virtual therapist alliance (n=1). It is important to note that some questionnaires had multiple constructs in one questionnaire, for example interactivity, presence and flow.[30] The number of items in the questionnaires varied remarkably from one item[31] to 100.[32] Almost all questionnaires used a Likert-scale response format (n=52), some had extra open questions (n=4), yes/no questions and/or a sliding scale (n=5). Other answer formats were a verbal rating scale,[31] a picture-based scale,[33] a scale from 0 to 100,[34] and three did not specify their response format.[35–37] The included questionnaires differed considerably in the number of times they were cited in Google Scholar,

ranging from 034 to 7,568.[38] The included articles were published between 1993[39] and 2024.[35,40,41] Out of 56 articles, eight were not available or (fully) provided in the original papers and two were provided upon request. Furthermore, according to a manual search on Google Scholar, for 25 questionnaires there are translations to other languages provided either by the original authors or by follow-up papers and for 13 questionnaires there are modifications created (for their availability see Appendix 9.4).

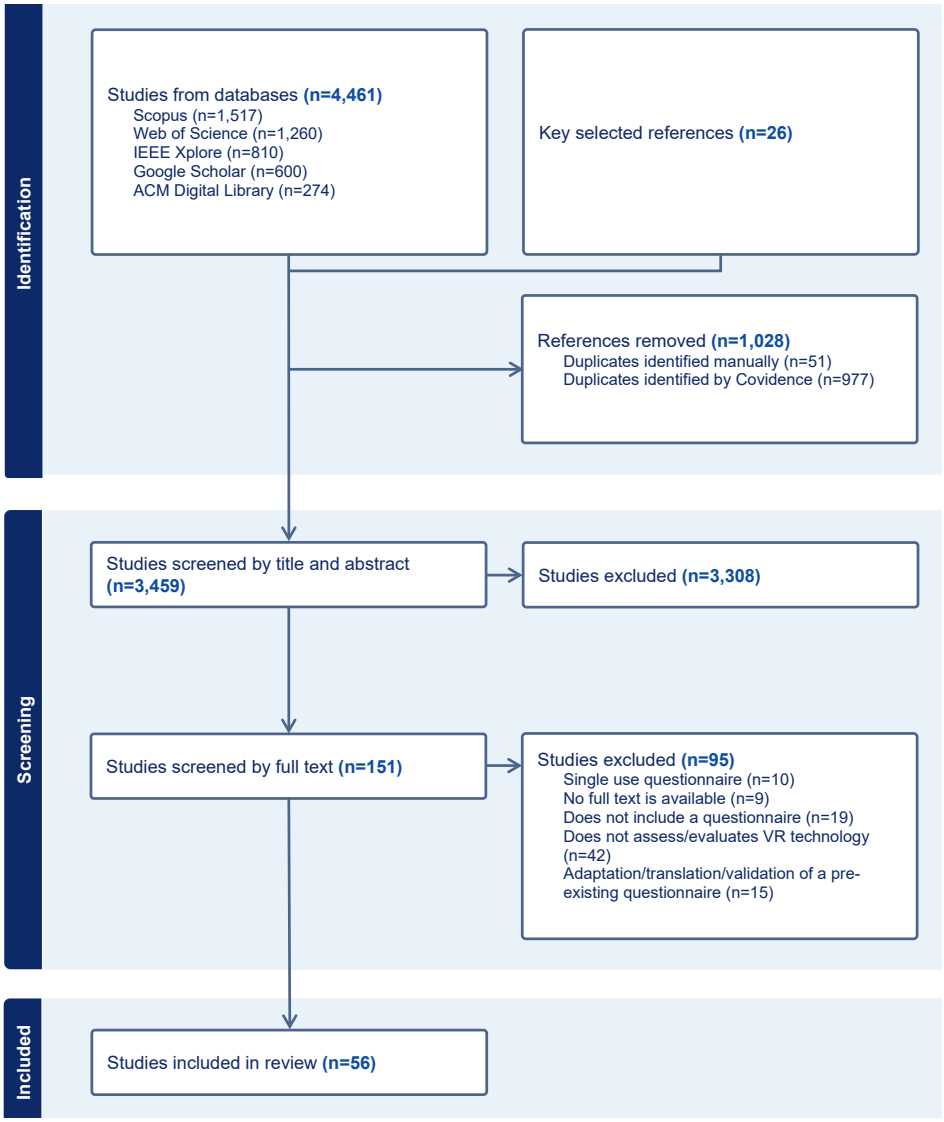


Figure 9.1. PRISMA figure of articles included in the scoping review.

Constructs measured

The different constructs that were found contained presence, UX, simulator-/motion-/cyber-sickness, immersion, simulator realism, embodiment, and virtual therapist alliance. Each construct is discussed in-depth below.

Presence

Presence can be defined as "the extent to which something (environment, person, object, or any other stimulus) appears to exist in the same physical world as the observer".[42] This term was chosen because the available questionnaires found in this scoping review categorized as measuring the construct presence showed a lot of variation on how presence was defined (see Appendix 9.6). For example, sense of presence, spatial presence and mental immersion were found in different questionnaires with the aim to measure a similar construct. Most questionnaires (14/20, 70%) included one or multiple questions on "the sense of being in the VE". This sensation of arrival or being in the VE, was complemented by departure or being out of the VE in two questionnaires.[43,44] Other topics that often were part of the questionnaire were the possibility to interact with one's environment (70%), realism (or a sense of congruency between the real world and VE) (65%), and feelings of agency or embodiment of the virtual avatar (45%). Also, several questionnaires included or only aimed to measure social or co-presence (30%). While some questionnaires were developed for very specific purposes (e.g., measuring social and co-presence for people with fear of public speaking),[36] other questionnaires were developed as a more general measure of presence (e.g., multimodal presence scale).[45] Two questionnaires (and the immersive tendencies part of the presence and immersive tendency questionnaire),[46] were developed to examine immersive tendencies before using VR.[38,47]

UX

UX is a broad concept covering not only instrumental but also subjective needs of a user.[48] Its definition covers three distinct parts: "user's internal state (predispositions, expectations, needs, motivation, mood, etc.), the characteristics of the designed system (e.g., complexity, purpose, usability, functionality, etc.) and the context (or the environment) within which the interaction occurs (e.g., organizational/social setting, meaningfulness of the activity, voluntariness of use, etc.)".[48] An in-depth analysis of the questionnaires categorized as measuring UX showed

that they included a combination of different constructs, ranging from three[49] to 14 constructs,[50] as shown in Appendix 9.7. The most common constructs included in UX questionnaires were presence (8/15, 53%), enjoyment (40%) and hardware (33%). Also, some questionnaires included more specific constructs (e.g., disruptions,[51] storytelling,[52] or continuance intention).[35] A distinction can be made between questionnaires that focus more on the technical hardware side of UX,[53] while other questionnaires focus more on the subjective side of UX[49] or learning experience.[50,54] Furthermore, two questionnaires focused solely on UX in the metaverse. The metaverse is a new virtual world that can be used both in and outside of VR, its users interact by embodying virtual characters.[55] Due to metaverse's rapid development and spread among users it was decided to include questionnaires dedicated to it and not consider them as one time use. Both UX questionnaires, Metaverse Learning Experiences Scale (MLES)[54] and Metaverse characteristics[35] cover previously mentioned aspects typical for UX user's needs, system characteristics, and context, yet the questions in the MLES do not specifically mention the metaverse. Finally, all questionnaires were meant to be administered after VR use and as discussed in prior results, many UX questionnaires state to measure similar constructs (e.g., immersion) but use different definitions for the same construct (e.g., technical immersion).

Motion sickness

Motion sickness is an overarching term to describe the negative feelings that occur after experiencing real or virtual stimuli.[56] Therefore, all questionnaires measuring negative sensations before or after VR use were placed in this category. From the found questionnaires two (2/6, 33%) focused on cybersickness,[57] one (17%) on motion sickness,[31] one (17%) on simulator sickness,[39] and two (33%) were phrased as neuroscience[58] and HMD VR symptoms[59] questionnaires (see Appendix 9.8). After further investigation into each questionnaire, it can be concluded that most motion sickness questionnaires are based on, inspired by, or compared to the Simulator Sickness Questionnaire (SSQ) (including the Virtual Reality Sickness Questionnaire (VRSQ); Cybersickness Susceptibility Questionnaire (CSSQ); Cybersickness in VR Questionnaire (CSQ-VR); Fast Motion Sickness Scale (FMS)). That is explained by the SSQ being the earliest and most cited (5,777 citations) questionnaire addressing simulator sickness. It has proposed three subscales: oculomotor – focusing on eye-strain, headache; disorientation – including

dizziness, vertigo; nausea – addressing symptoms of stomach awareness, burping,[39] which were later adapted to fit other ideas e.g., ocular ("eye-strain", "tired eyes") and non-ocular ("nausea", "dizziness", "fatigue") in VRSQ.[59] Such or similar items can be found in all questionnaires in this category. Motion sickness questionnaires are flexible with their application, since they can be done before, after, and sometimes even during[31] the virtual experience. Also, an addition of predictive factors (such as age, gender, vision)[60] and software features of VR[58] in cyber sickness questionnaires gives researchers a lot of freedom to choose the most fitting approach (e.g., working with sensitive groups, using a questionnaire before a VE, could prevent some people from using a VE and experiencing motion sickness effects).

Immersion

Similarly to presence, there is no one concrete shared definition stating what immersion is.[61] Immersion is oftentimes mixed up, used interchangeably,[49] or as a predictor of presence.[38] Of the few immersion questionnaires found, Witmer & Singer[38] proposed the Immersive Tendencies Questionnaire (ITQ), which was meant to be used to assess one's ability to feel immersed or "present" in an environment. Meaning that the ITQ would be a predictor, contributing to presence and not an evaluation of the quality of a VE. Immersion as a predictor is often also called immersive tendencies and it overlaps with feelings of presence since parts of the ITQ are used for presence assessment.[46] Contrary to immersive tendencies, Jennett et al.[62] argued that immersion should be defined as a distinct construct, not related to presence. They proposed that one experiences immersion as a loss of awareness of time, real world involvement, and sense of being in the task as a consequence of a good gaming experience. This becomes clear in their formulation of questions (see Appendix 9.9). Questions from the Immersive Experience Questionnaire (IEQ) focus on one's experiences within a game[62] rather than general experiences and abilities to feel involved or switch between tasks as in the ITQ.[38]

Simulator realism

Simulator realism measures the effectiveness of training simulations after their use.[34] Simulator realism questionnaires cover specific questions regarding responsiveness and quality of visuals and interactions of training environments (see Appendix 9.10). Differences in focus are that the VR Training Questionnaire

(VRTQ) focuses more on control, sensory, distraction, and realism factors,[34] the Simulation Task Load Index (SIM-TLX) on measuring workload and includes both questions about the simulation and more personal and subjective experiences,[63] Visual Realism Classification Scale (VRCS) on concrete visual elements of the simulation such as shadows and textures,[64] while the Colonoscopy Simulator Realism Questionnaire (CSRQ) assesses topic specific questions regarding the realism of the simulator and its feel.[65] In general, the inclusion of CSRQ[65] stands out considering how specific it is. Yet it has made past the screening criteria, since there is a variety of colonoscopy simulators in VR, making it not a one-time measuring tool.

Embodiment

Virtual body ownership and embodiment were combined into the same category, since they both cover one's experiences in the body of a virtual avatar (see Appendix 9.11). According to Kilteni, Groten, and Slater[66] sense of embodiment is comprised out of sense of self-location, sense of agency, and sense of body ownership. Illusion of Virtual Body Ownership (IVBO) explores the proposed categories but also additional subscales (e.g., enjoyment, anthropomorphism) and includes more general questions about one's experience.[67] The Virtual Embodiment Questionnaire (VEQ) by Roth & Latoschik[68] builds on IVBO and other embodiment questionnaires yet keeps the three categories proposed in the definition to measure embodiment. Only a sense of self-location is renamed to change. Similarly to VEQ, the Embodiment Questionnaire (EQ) also uses categories such as ownership and agency and uses very similar or almost identical items (e.g., VEQ: "It felt like the virtual body was my body"[68] and EQ: "I felt as if the virtual body was my body"[40]). However, the EQ proposes a new category called disembodiment which refers to reduced sense or awareness of user's physical limbs.[40,69] It is the opposite of embodiment, yet embodiment can be induced without simultaneous movement of the user's body, thus making embodiment and disembodiment opposite, yet not exclusive.[69]

Virtual therapist alliance

Alliance between a client and a therapist consists of three processes: the goodness of fit between a client and a therapist, consensus on tasks, and goals.[70] For this final part, only one questionnaire focusing on virtual therapist alliance[71] was

identified (see Appendix 9.12). There were no other similar VR questionnaires found for it to be grouped with. The Virtual Therapist Alliance Scale (VTAS) is a scale based on a Working Alliance Inventory,[72,73] but adapted specifically for VEs. VTAS is meant to assess one's relationship with a virtual therapist since positive interactions with a virtual therapist show significant improvements in treatment outcomes.[71]

Psychometric evaluation

Questionnaire reliability was provided in 34 of the original papers and eight were found with an additional search. Reliability included calculating the internal consistency of a measure either for the whole scale (n=17), per subscale (n=14), or both whole scale and subscale (n=11). Most questionnaires showed good to exceptional reliability for the whole scale (n=23). Forty-two of the original and three additional papers have provided one or multiple scores for validity. Types of validity reported were face (n=1), content (n=9), construct (n=37) and criterion (n=5). Responsiveness was only measured once in a paper by Gao & Boehm-Davis.[74] See Appendix 9.13 for an overview of psychometric properties per questionnaire.

Questionnaire recommendations

To help researchers select the most appropriate questionnaires when evaluating VR, we provided several recommendations per construct. These recommendations were based on available questionnaires that were identified in this review and suggested based on the content, number and clarity of items, psychometric properties, and current usage (i.e., based on number of citations) of the questionnaires. The recommendations can be found in Table 9.1 and were divided into shorter questionnaires (≤15 items) and more in-depth questionnaires (>15 items), depending on the aim of the questionnaire user. For the constructs immersion, simulator realism, embodiment, and virtual therapist alliance, recommendations were not provided, due to the small number of questionnaires. Given the association between self-presence and embodiment, the virtual embodiment questionnaire[68] was included as a recommendation for a self-presence questionnaire.

Table 9.1. Questionnaire recommendations

Construct	Short (≤15 items)	In-depth (>15 items)
Presence		
Spatial presence	Igroup Presence Questionnaire[75]	Presence Questionnaire[38]
Social presence	Co-presence and social presence in VEs scale[36]	Questionnaire on presence, co-presence, and social presence[76]
Self-presence	Virtual Embodiment Questionnaire[68]	Self-presence questionnaire[77]
Combination of spatial, social and self-presence	Multimodal presence scale[45]	Temple Presence Inventory[78]
UX	VRSUQ[41]	UX in IVE questionnaire[79]
Motion sickness	VRSQ[59]	Simulator sickness questionnaire[39]

Discussion

This scoping review identified 56 articles, describing 58 questionnaires, used to evaluate VR. Through thorough analyses of these questionnaires, it became apparent that there was a large variety of constructs measured, actual usage, and usability of questionnaires. Psychometric properties were reported in most original articles (59% reported reliability and 72% reported validity). Definitions of VR-related constructs (including presence and immersion) differed considerably between questionnaires. Therefore, in the following sections these definitions will be discussed in relation to the main review findings, in order to guide the selection of appropriate instruments.

Presence

This review showed that presence is the most frequent construct among included questionnaires and a complex construct consisting of different elements. In general, three forms of presence can be distinguished of which a clear understanding can guide the selection of appropriate measures: spatial, social and self-presence.[80,81] Spatial presence (also known as place illusion),[82] virtual or physical (tele) presence[83,84] is defined by the International Society for Presence Research (ISPR) as: "… a psychological state or subjective perception in which even though part or all of an individual's current experience is generated by and/or filtered through human-made technology, part or all of the individual's perception fails to accurately

acknowledge the role of the technology in the experience.".[85] Spatial presence was the main construct in most presence questionnaires,[43,44,86] with items like "I felt like I was actually there in the environment of the presentation".[86] In relation to social presence, a distinction should be made between social and co-presence. Social presence can be defined as the individual's perception of the VR device to connect them to each other and create sociable, warm, and intimate interaction,[87] while co-presence can be defined as a sense of being together and focusing on the psychological connection of minds.[88] Social presence was included in multiple questionnaires[36] and included items like "I felt connected to the other people". Lastly, self-presence can be explained as "a psychological state in which virtual self/selves are experienced as the actual self in either sensory or nonsensory ways",[81] which is related to feelings of agency and embodiment in VR. This construct was the main topic of for example the questionnaire by Ratan & Hasler[77] and included items like "When using the VE, how much do you feel your avatar is a part of your body?". To conclude, presence consists of three separate constructs and researchers should specifically state what type of presence they aim to measure and use items that address the type that is relevant for their study.

Motion sickness

Analysis of measures of simulator-, motion-, and cyber-sickness indicated that these constructs are treated as synonymous and share a common core of discomfort during an experience, mainly including symptoms of nausea, eye-strain, and fatigue. Motion sickness was chosen as the main term to describe it, as it covers symptoms that one experiences during any kind of motion.[89] Simulator sickness describes the side effects experienced during and the use of a simulator.[90] This involves all types of simulators, not only VEs. Meanwhile, cybersickness addresses discomfort during VEs, mainly when visual motion stimuli are experienced, while remaining stationary.[89] According to Dużmańska et al.[90] the term simulator sickness is used more and more interchangeably with cybersickness because of the adoption of HMDs. Although presented as separate concepts simulator-, motion-, and cyber-sickness questionnaires all seemed to have the same core feature of discomfort driven by real or simulated motion. The consistency of discomfort symptoms between all sickness questionnaires could be explained by the SSQ.[39] This questionnaire has set a baseline of important symptoms to address in this category (oculomotor, disorientation, nausea) and most other developed motion

sickness questionnaires were inspired by (e.g., VRSQ by Ames et al.[59]) or compared to (e.g., FMS by Keshavarz and Hecht[31]) the SSQ. Although the differences between the terminology of simulator-/motion-/cyber-sickness was addressed, two new descriptions in this category have emerged during the systematic scoping review: neuroscience and[58] and HMD VR symptoms.[59] However, these questionnaires do not provide any new symptom categories, only as an addition the VR neuroscience questionnaire incorporates questions regarding the investigation of software features. To sum up, aside from some technology-specific adjustments or additional subscales, the core of simulator-/motion-/cyber-sickness construct has not changed throughout the years and thus, there is no need for development of new motion sickness questionnaires.

Immersion

Some VR researchers regard immersion as a technical construct, including the number of sensory modalities and resolution of the VR device,[9,61,91] while others regard immersion more as a subjective experience or psychological state overlapping with presence.[38,46] A recent review on definitions of immersion also makes a distinction between system immersion and sensory or perceptual immersion.[92] System immersion could be regarded as an objective characteristic of a VR system and therefore for example, HMD is classified as immersive VR, while screen-based VR is classified as non-immersive VR.[93] Sensory or perceptual immersion could be viewed as a subjective experience, resembling spatial presence. Based on our findings, this category can be divided even further specifying questionnaires before and after VR use. Two questionnaires found in this systematic scoping review focus on immersion (or immersive tendencies) before VR use[38,46] and one after.[62] These findings show a clear lack of system immersion questionnaires, focusing on more technical aspects of a VR system. However, it remains unclear whether such questionnaires are necessary considering the quality of current displays.

Usability of older VR questionnaires

As previous discussions in this review have explored and appraised various constructs meant to evaluate VR, the usability of older VR questionnaires in capturing these constructs is also important to address. Recently, VR has seen substantial technological advancements,[94] including haptics, eye-tracking and standalone VR. This poses the question to what extent older, frequently cited,

VR questionnaires (e.g., Slater Usoh Steed Presence Questionnaire (SUS-PQ)[10]) are still suitable to evaluate current VR. The construct presence has been studied from the early 1990s in relation to Ves,[95] using a similar definition that is still being used. This is reflected in newer questionnaires (e.g., "While I was in the virtual environment, I had a sense of "being there"" (item 4) from Makransky et al.[45]) that still use similar items to those being used in older questionnaires (e.g., "Please rate your sense of being in the virtual environment" (item 1) from Slater et al.[10]). On the other hand, new questionnaires aimed at evaluating system immersion differ on specific items (e.g., "It's easy for me to align the middle of VR glasses with the split screen" (item 5)[53]) from older questionnaires that do not include this type of items, for example in question regarding standalone VR. Although, it should be noted that older questionnaires (e.g., Witmer and Singer[38]) do include items on technological domains like haptics and interaction with virtual objects. Furthermore, as many of the questionnaire topics identified in this review are on fundamental concepts (e.g., presence),[95] it could be expected that questionnaires measuring these concepts remain applicable. All in all, it could be stated that older VR questionnaires are mostly still usable today.

Reporting (psychometric) properties

One of the initial goals of this scoping review was to identify and compare psychometric properties of questionnaires. As one of the most important indicators of psychometric properties of a questionnaire, reliability was only reported in 59% of the original papers, this number increased to 75% after the follow-up search. These low numbers were surprising, since reliability is the simplest psychometric property to report and interpret for the whole scale, subscales, or both. Validity was reported in 72% of the original papers and this number increased to 80% after the follow-up search. Mainly construct validity was reported. The popularity of construct validity compared to other validity measurements could be explained by how simple it is to calculate and to compare the obtained score to other questionnaires.[95,96] According to the recommendations provided by Taherdoost,[97] questionnaire reliability, construct and criterion validity should always be reported. Future questionnaire authors should address criterion validity more often, also taking into account face and content validity which are recommended. In this scoping review, although definitions varied widely, overall, all questionnaires demonstrated good psychometric properties according to author-defined definitions. To continue

developing best practices authors of new questionnaires should be responsible to always ensure that they provide all the necessary information about their measure and ensure that it is effective.

Strengths and limitations

This study possesses two major strengths. The first one is that this scoping review explores all available scientific and grey literature in a search of questionnaires which can evaluate VR experiences. It provides a first extensive overview of questionnaires evaluating VR that are currently available in a variety of fields, explains definitions of constructs, investigates the differences between interpretations of constructs, compares different questionnaires, and gives recommendations on most optimal questionnaires to use and constructs that should be explored further. Although in the first round the interrater reliability was found to be moderate, according to Sun[98] compared to other studies it is a common agreement rate, which in the following round only increased. The second strength is that this study not only investigates the available papers, but also checks and reports a variety of important details (e.g., psychometric properties) to consider before choosing a questionnaire. It also reports on the availability, translations, and adaptations of the identified questionnaires.

On the other hand, some study limitations should be mentioned. Firstly, our scoping review might not have included all available questionnaires to evaluate VR, supported by the fact that out of the 26 questionnaires in the convenience list, only 15 (58%) were identified in the literature search. This was possibly because not all questionnaires in the convenience list were developed specifically for VR. However, due to the large number of hits, we had to create and stick to our strict search-strategy. This meant including only well-known constructs and might have led to omitting some others (e.g., haptics). Secondly, the biggest issue in this systematic scoping review was that many questionnaires were inspired by or overlapped with others in the same category. This made it difficult to distinguish between new, reconstructed, adapted, and modified questionnaires. To help limit the confusion, the authors of this review created some general guidelines to distinguish reconstruction (creating a new questionnaire by combining ideas and/or gaining inspiration from existing questionnaires and/or adding new items), adaptation (changes in a pre-existing questionnaire by altering specific items or

adjusting it to fit a new topic), and modification (alterations to a questionnaire without a future line, creation of a one-time use questionnaire). Finally, searches for translations and adaptations of questionnaires were done manually, via Google Scholar (see Appendix 9.5). It is possible that not all translations and adaptations have been found, but a first attempt has been made to create a structured overview of availability (see Appendix 9.4).

Practical implications

Results of this scoping review come with multiple implications for practical use of questionnaires to evaluate VR. Firstly, recommendations were provided for VR evaluation questionnaires that were based on our appraisal (using for example the questionnaires' content, availability and psychometric properties) and concordant with prior research.[99–102] Using these recommendations may contribute to greater comparability and consensus regarding VR constructs, since results from studies using different questionnaires to measure overlapping constructs might hamper interpretation and synthesis.[103] As mentioned previously, not all developed questionnaires report information on reliability and validity in their main development article nor in follow-up studies. This problem was raised in previous studies as well and could be solved by developing questionnaires following a structured approach using a framework for questionnaire design and development[104] or construct-specific frameworks (e.g., framework for creating UX questionnaires by).[105] Results of this review showed that ample questionnaires for several VR-related constructs like presence were developed, as was noted previously.[106] Therefore, we recommend the development of several questionnaires to evaluate underexamined constructs in VR, including questionnaires that examine people's technology literacy, novelty effects, expectations or openness towards the use of (therapeutic) VR, avatar-alliance, and interactivity within VR.

Theoretical implications

Since all the included questionnaires rely on the subjective appraisal of the user, it might be interesting for future studies to examine more implicit evaluation measures for VR-related constructs like motion sickness and presence.[107,108] although it should be stated that these measures are currently scarcely being used. In addition, the current study did not include information on the actual application of questionnaires across different study fields and topics. Future studies could

examine this, as was for example done for presence in immersive VR studies by Hein et al.[19] Furthermore, clear guidelines to distinguish between new, reconstructed, adapted, and modified questionnaires are necessary to establish. In addition to our proposed changes, a more systematic approach both for reporting and interpreting between each category would be desirable. Finally, the scope of this study was limited to VR, but it would be interesting to broaden this research for other types of extended reality (XR).

Conclusion

This is the first systematic scoping review aimed at identifying questionnaires to evaluate VR. Among the identified constructs, the most common focus areas were presence, UX, and motion sickness. Major discrepancies between construct interpretations and measurement were found and highlighted, for example in the definition and measurement of presence and immersion. To help researchers choose the most fitting questionnaire to evaluate VR, recommendations were provided, including the use of questionnaires that have fully reported high quality psychometric properties, and items that match the research objectives of the specific study. Also, we encourage researchers to better substantiate their choice for certain questionnaires and promote the use of similar questionnaires, to enable comparison of different VR experiences. Contrary to prior beliefs, it was found that older questionnaires remain viable options, partly because of the fundamental basis of these questionnaires. Moving forward, to optimize the use and development of new questionnaires in VR research, more focus should be laid on defining and arguing chosen constructs and using suggested questionnaire development frameworks. Finally, this systematic scoping review offers insights and directions for the future development of questionnaires to evaluate VR, including underexamined constructs such as interactivity and avatar-alliance.

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Appendices

Appendix 9.1: Selected key references of commonly used VR questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.2: Scoping review search string
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.3: Adapted search strings for each database
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.4: Available translations and adaptations of questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.5: Search strings for translations and adaptations of questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.6: Presence questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.7: UX questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.8: Motion sickness questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.9: Immersion questionnaires
URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.10: Simulator realism questionnaires

URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.11: Embodiment questionnaires

URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.12: Virtual therapist alliance questionnaire

URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2

Appendix 9.13: Reliability and validity provided in the questionnaires

URL: https://www.sciencedirect.com/science/article/pii/S2451958824001386#appsec2



Chapter 10

General discussion

General discussion

The overarching aim of this thesis was to contribute to the scientific evidence for VR treatment in physiotherapy care for patients with chronic (low back) pain.

This overarching aim was divided into the following three objectives:

1. To unravel the current state and perception of VR use in physiotherapy treatment for patients with chronic (low back) pain in a systematic approach and the effect of briefing VR on patients' treatment expectations.
2. To evaluate the effectiveness of a co-created physiotherapy with integrated VR (VARIETY) intervention for patients with CLBP.
3. To improve and standardize the reporting and evaluation of (therapeutic) VR interventions.

The general discussion starts with the main findings of the conducted studies per objective, followed by an integrated discussion including methodological considerations. Next, practical implications for primary healthcare providers like physiotherapists and directions for future research are suggested, completed by an overall conclusion.

Comparison to literature

Objective 1: Current state and perception of VR use in physiotherapy for chronic (low back) pain

Drawing on the insights from our studies, actual use and knowledge about VR in physiotherapy for chronic (low back) pain seems to be limited. This is for example reported in the survey and interview studies regarding VR use in Dutch primary care physiotherapy for CLBP, respectively **Chapter 2** and **3**. The limited uptake of VR corresponds with results from similar survey studies among physiotherapists on their VR use in Western countries. Equivalence of results from the United States,[1] United Kingdom,[2] Netherlands,[3] Norway,[4] Germany,[5] and different French- or Dutch-speaking countries[6] (i.e., France, Switzerland, Canada, Belgium, the Netherlands) is illustrated in Table 10.1. The results show the percentage of physiotherapists who used VR in their treatment, which ranged from 2% to 12%.

Table 10.1. VR usage in physiotherapy in Western countries

Study	Sampling method	Country	VR usage
Slatman et al. (2024)[3]	Random	Netherlands	7%
Alrashidi et al. (2025)[2]	Random	United Kingdom	7%
Martinsen et al. (2024)[4]	Convenience	Norway	2%
Luc et al. (2024)[6]	Convenience	French- or Dutch-speaking	12%
Felsberg et al. (2025)[1]	Convenience	United States	7%
Elser et al. (2025)[5]	Convenience	Germany	3%

However, all studies except for Alrashidi et al. (2025)[2] and ours[3] used convenience sampling (e.g., through social media) to recruit participants for their survey. Convenience sampling inherited the risk of sampling bias and an overestimation of the actual usage of VR in physiotherapy. This is reflected in the results regarding physiotherapists in the Netherlands: the study by Luc et al. (2024)[6] found that 23% used VR, compared to only 7% in our study. Further, our study specifically focused on the use of VR in physiotherapy for patients with chronic pain, while the other studies included VR use in physiotherapy in general. Selecting a specific patient group could be a reason for an underestimation of current VR use in physiotherapy practice for all patients. When interpreted in light of our study design and patient selection criteria, the findings suggest that the Netherlands has a relatively high adoption rate of VR in physiotherapy compared to other Western countries, even though overall use of VR is still limited.

Also corresponding with prior research it seemed that many physiotherapists are not familiar with VR for chronic pain (**Chapter 2** and **3**). This finding is for example reflected in multiple survey studies among physiotherapists[5,7] and qualitative studies among physiotherapists who tried VR for chronic pain patients.[8,9] Unfamiliarity may pose challenges, as knowledge about VR is needed to effectively provide it.[10] It should be noted that in line with physiotherapists, most healthy people and chronic pain patients are also not familiar with therapeutic VR, as we showed in **Chapter 4**. One possible reason for the limited uptake of and knowledge about VR in physiotherapy is the lack of attention to digital health interventions in physiotherapy curricula.[11] In addition, there is a shortage of educational courses for physiotherapists who are working in clinical practice. In our survey physiotherapists also reported unfamiliarity with VR as the main reason for not using it.

The physiotherapists who currently use VR are the innovators and early adopters, as described in the diffusion of innovation model (Figure 10.1). To support further implementation of VR in physiotherapy and subsequently reach the (early and late) majority, the key implementation barriers outlined below must be addressed.

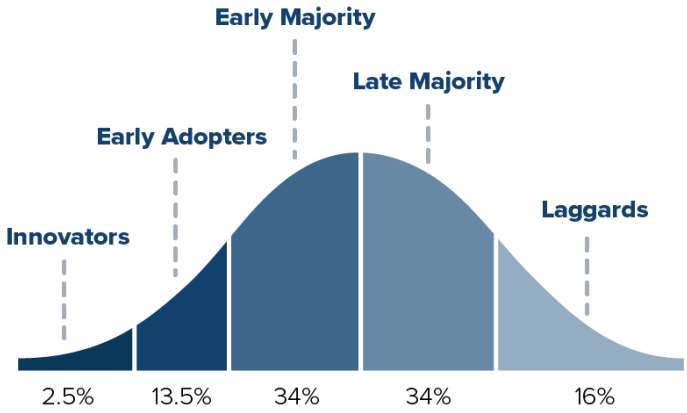


Figure 10.1. Diffusion of innovation model.[12]

Low adoption of VR can be attributed to several factors, which are captured by the five domains of the Consolidated Framework for Implementation Research (CFIR):[13] intervention, individuals, inner and outer setting, and process. First, the VR intervention is generally considered as costly and the technology is not always functioning properly.[10,14] Second, the individuals (i.e., physiotherapists) working with VR might feel they lack experience working with VR and education about VR treatment for CLBP.[15,16] Likewise, patients with CLBP sometimes feel they lack support from their physiotherapist when they are provided a VR intervention.[14,16] Third, the inner setting (e.g., physiotherapy practice) is not always ready for innovations like VR for CLBP treatment, which could hinder implementation.[17] Fourth, the outer setting could limit VR adoption, because currently there is no reimbursement for VR in physiotherapy for patients with CLBP by insurance companies.[18] Regarding the process, physiotherapists sometimes feel it is difficult to combine VR with existing CLBP therapies.[16] When placing the findings in a broader perspective, it is apparent that the aforementioned barriers are not unique to implementing VR in physiotherapy. Similar issues have been identified for other digital health technologies, such as telerehabilitation and wearable sensors.[19] Within the five CFIR domains, the individuals and outer setting seem to be the most critical barriers for

VR implementation in physiotherapy. In regard to the individuals, physiotherapists may need to move beyond a culture in which hands-on treatment is seen as the default and patients expect such approaches. Research on digital health interventions in physiotherapy shows that leaving this comfort zone can be challenging and requires support, but can ultimately enhance professional growth and improve patient engagement.[20] Regarding the outer setting, lack of reimbursement poses a barrier, as physiotherapists using VR to deliver more effective or efficient care invest money and time but receive no (financial) compensation. In contrast, other Dutch healthcare professionals, such as general practitioners, can for example use the S3 innovation reimbursement to support digital health adoption.[21] However, it is important not to focus solely on healthcare insurers and to consider alternative financing models. For example, recent research showed that people with chronic knee pain are willing to pay for telerehabilitation if they perceive it as beneficial.[22] Together, the findings suggest that addressing both individual-level (e.g., education) and outer-setting barriers (e.g., reimbursement) are essential to promote broader VR adoption in physiotherapy.

Objective 2: Evaluation of VR in physiotherapy for CLBP

The previous objective showed that VR is a novel technology with limited adoption among physiotherapists. As a result, research on the effectiveness of VR integrated into physiotherapy for patients with CLBP is scarce, motivating the current objective. Results of our studies (**Chapters 2** and **3**) showed that VR could be of added value when integrated in physiotherapy for patients with CLBP, although the results of our trial (**Chapter 7**) showed no statistically significant or clinically important difference between the intervention and control conditions. This ambiguity is also reflected in systematic reviews on the added value of VR for patients with CLBP, as some reviews state that VR is effective,[23] while others state the effects are not clear yet.[24] Table 10.2 provides a detailed overview of RCTs studying the effectiveness of stand-alone HMD VR interventions for patients with CLBP, including the results of the VARIETY trial as described in **Chapter 7**. The final column (i.e., within-group effect) shows the percentual pre/post intervention within-group change on physical functioning (measured with the ODI) and pain intensity (measured using the VAS or NPRS). Notably, the included studies have a large variety in study design, patient recruitment methods, and intervention content.

Table 10.2. Effectiveness of comparable stand-alone HMD VR interventions for CLBP

	Intervention			Within-group improvement	
RCT	Content	Duration	n	Physical Functioning	Pain intensity
VARIETY trial[Chapter 7]	Exercise therapy, relaxation and distraction and pain education and management VR	12 weeks	25	42%†	40%†
Darnall et al. (2020)[25]	Skills-based VR with elements of CBT, relaxation and mindfulness	3 weeks	35	n/a	30%*
Garcia et al. (2021)[26]	Skills-based VR with elements of CBT, ACT, mindfulness and pain education	8 weeks	89	n/a	43%*
Yalfani et al. (2022)[27]	Exercise therapy VR	8 weeks	13	n/a	67%*
Stamm et al. (2022)[28]	Exercise therapy and psychoeducation VR	4 weeks	11	n/a	18%†
Maddox et al. (2023)[29]	Skills-based VR with elements of CBT, ACT, mindfulness and pain education	8 weeks	536	20%*	30%*
Groenveld et al. (2023)[30]	VR with elements of pain education, CBT, ACT, mindfulness and hypnotherapy	4 weeks	20	19%†	n/a

* Significant improvement.
† No significant improvement.

Table 10.3 reports RCTs on physiotherapy with integrated VR for chronic pain compared to usual care physiotherapy. Provided the lack of physiotherapy with integrated VR for CLBP RCTs, also trials with chronic neck pain31 and chronic pain in general[32] were included. The results shown in both Tables (10.2 and 10.3) exemplify the limited research conducted on VR for CLBP (in physiotherapy), the large heterogeneity in intervention content and duration and the ambiguous effectiveness results of VR.

The mixed results of the effectiveness of VR are also reflected in a qualitative study among patients with CLBP who received one of the three VR modules that was used in our trial (i.e., Reducept).[14] Some participants reported benefits from using the VR intervention (e.g., feeling relaxed), but effects generally remained small and for example translation to behavior in the patient's daily life was troublesome. The inconsistent findings regarding the effectiveness of VR are also found in qualitative studies among physiotherapists who use VR for chronic pain treatment. Given that studies specifically on VR in physiotherapy for patients with CLBP are limited, we

included studies that examine physiotherapists' perception of VR in general chronic pain treatment.[8,15] Findings indicate that physiotherapists generally believe that VR has the potential to be of added value in physiotherapy treatment. However, they mention that further development of the intervention is needed before implementation and that only specific patients will benefit. The same can be concluded from the results of the survey study in **Chapter 3**. Physiotherapists in this study expressed their beliefs that VR is most effective in specific subgroups, for example patients with adequate levels of digital skills. Prior research showed that analgesic VR seems most effective in more complex and younger participants.[34,35] All in all, the comparison of both quantitative and qualitative literature shows that the added value of VR in physiotherapy for patients with CLBP is inconclusive and seems to be dependent on specific participant characteristics. Moreover, stratifying patients by specific characteristics (e.g., digital skills) might improve VR treatment effectiveness, but requires a clear understanding of the VR intervention's underlying working mechanisms in CLBP.

Table 10.3. Effectiveness of comparable HMD VR intervention in physiotherapy

	Intervention				Within-group improvement	
RCT	Content	Duration	Condition	n	Physical Functioning	Pain intensity
VARIETY trial[Chapter 7]	Exercise therapy, relaxation and distraction and pain education and management VR	12 weeks	CLBP	25	42%†	40%†
McConnell et al. (2024)[33]	Usual care physiotherapy + pain education and relaxation VR	6 weeks	CLBP	19	20%†	26%†
Guo et al. (2024)[31]	Usual care physiotherapy + range of motion, proprioception and velocity VR training	4 weeks	Chronic neck pain	31	n/a	57%*
Sakuma et al. (2025)[32]	Usual care physiotherapy + relaxation VR	12 weeks	Chronic pain	32	n/a	27%†

* Significant improvement.
† No significant improvement.

VR working mechanisms

So far it remains largely unknown how VR exerts its influence on patients with CLBP.[36] Several proposed classifications of VR working mechanisms have been suggested. One review on VR specifically for patients with CLBP makes a distinction between distraction, neuromodulation and graded exposure as VR working mechanisms.[37] Another review on VR for patients with chronic pain in general, classifies VR interventions on a spectrum ranging from distraction to skill building (e.g., breathing exercises), with focus shifting between those two.[38] A third review on VR interventions for chronic pain makes a distinction between interventions addressing kinesiophobia and psychobehavioral modulation.[39] However, the proposed working mechanisms of VR for CLBP are not yet all-encompassing and omit important factors like increased motivation and engagement through for example gamification that were areas of interest in our trial.[40] Also, limited research has investigated mechanisms in detail, leaving most of the proposed largely hypothetical. When looking at effective therapies for people with CLBP, several of the aforementioned working mechanisms are referred to. One example is graded exposure therapy, which is effective in reducing kinesiophobia in patients with CLBP.[41] Although, it is important to make a distinction between the proposed working mechanism (graded exposure) and clinical aim (reducing kinesiophobia). Provided that CLBP is a complex condition with many different biopsychosocial factors causing and maintaining complaints, it is crucial to study which specific aspects of VR interventions are the active ingredients.

Objective 3: Improve and standardize VR research

As discussed in the previous two objectives, VR is a novel technology that is in its infancy in physiotherapy for CLBP. The limited research that has been conducted on this subject so far shows large heterogeneity in study outcomes, quality and designs. To help researchers standardize their VR research, we conducted the Delphi study that resulted in the VR intervention reporting guideline (**Chapter 8**) and a systematic scoping review that identified and appraised questionnaires to evaluate VR (**Chapter 9**). Using the guideline and recommendations increases the possibility for study replication and pooling of VR studies in systematic reviews and meta-analyses. Besides the Delphi study and systematic scoping review, multiple studies have been conducted to provide guidance in analgesic VR research. One study was conducted to compile a set of core outcomes for chronic pain VR research.

Results showed that chronic pain VR studies should at least include the following five outcome measures: pain interference, pain intensity, adverse events, user experience, and psychological constructs.[42] In another study, recommendations were provided for designing appropriate controls, sham conditions and comparators in VR for chronic pain research.[43] Further, recent guidelines were published on the safe and effective application of extended reality (XR) in children, which include for example recommended session times and supervision practices.[44] The RATE-XR manuscript reporting guidelines were developed to support scientific manuscript writing of VR research for chronic pain.[45] Combined, the previously mentioned studies provide guidelines and recommendations for scientists to improve and standardize VR research.

Another consideration regarding the need for standardization in VR research is the struggle to accurately define VR itself. Multiple reviews have been conducted on VR definitions in healthcare[46,47] and over a hundred definitions of the term VR were identified with little homogeneity, which warrants a call to unify the definition of VR in healthcare.[48] A recent review on VR in chronic pain research recommends to distinguish non-immersive VR in analgesic VR and renaming it "*non-immersive fully artificial environments*",[49] which aligns with our view. Although, another recent paper on VR use in pain management suggests to define immersive VR as HMD VR with additional sensory input (e.g., through haptics or touch) and HMD VR as non-immersive VR.[50] It is crucial to classify different VR systems to prevent pooling of studies that are not comparable and ensure correct clinical application.[51,52] To further expand the discussion, it is important to note that the term immersion is inappropriate since someone reading a book could be completely immersed as well, and therefore using the term sensory immersion seems to be more suitable.[53] A final overarching aspect to consider in VR for chronic pain studies, is the fact that some scientific articles present 'spin', defined as reporting practices that distort the interpretation of results and mislead readers so that results are viewed in a more favorable light.[54] Using spin could lead to (unconscious) interpretation and reporting of results somewhat more positively than data supports,[55] setting unrealistic expectations of analgesic VR interventions of patients, healthcare providers, VR companies, and researchers. The use of spin might partly be due to some VR researchers having a conflict of interest, for example because they are employed by the VR company that developed the VR intervention they study.

Methodological considerations

A major strength of the studies is that most were embedded in the context of daily clinical physiotherapy care for patients with CLBP, enhancing the external validity of study results. Another strength of the studies is the combination of both qualitative (i.e., **Chapters 3**, **5**, and **8**) and quantitative (i.e., **Chapters 2**, **4**, **6**, **7**, and **9**) study designs to answer the posed research questions. Further, the VARIETY trial (**Chapter 7**) evaluated an intervention that was developed and tested during a thorough, iterative co-creation process with relevant stakeholders (i.e., patients, physiotherapists and researchers) (**Chapter 5**), and conducted based on an a priori published study protocol that included a statistical analysis plan (**Chapter 6**).

On the other hand, the results of the studies should be interpreted with caution due to several limitations. Given the rapid development of VR technology, some of the results have a short 'shelf-life' and may become outdated quickly. Future VR interventions for patients with CLBP might incorporate new additions, like smart glasses that also use augmented reality (AR), haptics and biofeedback (e.g., through eye tracking).[56] The additions might enhance treatment fidelity, engagement and therapeutic effect. As a result the effectiveness reported in older studies might underestimate the potential of future VR interventions. Since some of the technological advancements are evolving fast, classic RCTs to evaluate intervention effectiveness might be less appropriate due to high costs and long duration. Consequently, new evaluation methods (e.g., N-of-1 trials) are warranted.[57,58] Another limitation is the fact that most studies were conducted in primary care physiotherapy practices in the Netherlands. Other countries might have a different healthcare system and for example do not use the mandatory private insurance plans like the Netherlands, but for example use a government-run healthcare system. Healthcare system differences can influence factors such as reimbursement policies, access to VR technologies, and physiotherapists' willingness to adopt innovations. Consequently, the feasibility and effectiveness of VR interventions demonstrated in the Dutch context may not be directly transferable to other healthcare systems, underscoring the need for international replication studies. A final limitation is the small sample size in our prime RCT, the VARIETY trial (**Chapter 7**). The small number of participants may be partially explained by Lasagna's Law, which describes the phenomenon that the number of participants available

for study recruitment usually turns out to be lower than estimated in advance.[59] After study completion, we conducted a focus group with physiotherapists who participated in the trial to examine perceived reasons for the challenges in patient recruitment and possible solutions for future studies. Results revealed various reasons physiotherapists thought patient recruitment was slow. First, the used stringent in- and exclusion criteria were perceived as hindering for patients to enroll in the trial (e.g., the ODI score ≥30 and newly admitted patients who already had CLBP). Also, physiotherapists sometimes expected patients would score poorly on physical functioning, but patients often scored better due to adapting their physical functioning and perceiving fewer limitations. Second, some physiotherapists perceived study participation as burdensome and an additional load to an already busy work schedule, partly because the questionnaires used during the trial differed from the questionnaires the physiotherapists routinely use. Third, physiotherapists reported that it was difficult to introduce the trial to CLBP patients during their first consultation, as building a patient-therapist alliance was prioritized. Future studies might prevent most pitfalls for patient recruitment by extensively consulting practicing physiotherapists and CLBP patients before study commencement and by conducting a pilot-RCT, before conducting a large-scale RCT.[60]

Clinical implications

The results suggest multiple implications for clinical physiotherapy practice for VR treatment of patients with CLBP. The use of VR interventions in physiotherapy practice is feasible and could be of added value when integrated in the physiotherapy treatment of patients with CLBP. However, the effectiveness of VR appears to be dependent on several (context) factors, including the right CLBP patient (e.g., open to try innovative interventions), right physiotherapists (e.g., experienced with using VR), right intervention (e.g., fitting with the patient's aims) and right patient expectations (e.g., not expecting too much (or too little) from VR).[14] Another implication is that education for physiotherapy students and courses for physiotherapists working in practice on VR treatment for patients with CLBP in physiotherapy are lacking and many physiotherapists report to be unfamiliar with VR for CLBP. It is important to expose students and physiotherapists to digital solutions like VR, both in physiotherapy curricula and once they start working as physiotherapist. This may enhance their confidence and ability to

integrate VR into rehabilitation practice. However, as VR is still in its infancy and evidence regarding effectiveness is inconclusive, VR should not yet be treated as a fully established technology in education. Further, as it is hard to stay up-to-date on new digital health innovations like VR for practicing physiotherapists, tools are needed that can inform physiotherapists about new technologies. Websites like www.beweegtech.nl and www.uptimise.org are crucial for practicing physiotherapists and should be brought to their attention, along with the time needed to explore them. To further adopt and effectively provide VR in physiotherapy for CLBP, clinical treatment guidelines for VR are warranted to help physiotherapists who currently provide, or intend to provide, the optimal VR treatment for patients with CLBP. The need for a clinical treatment guideline was also mentioned as a prerequisite to adopt VR in physiotherapy practice in a qualitative study among physiotherapists regarding VR for shoulder pain.[8] Further, VR for CLBP offers the opportunity to mimic current effective physiotherapy treatment modalities for patients with CLBP (e.g., exercise therapy) and for example provide it at home. In addition, VR also holds promise to expand the treatment options physiotherapists have. One physiotherapy study among patients with CLBP for example showed that embodying a superhero in VR could improve body image.[61] Another study showed that using VR illusions or "*manipulating visual-proprioceptive feedback*" of patients with CLBP could influence pain thresholds.[62] The examples show that VR could be used to provide current physiotherapy treatment modalities, but also opens new avenues outside current physiotherapy approaches for the assessment and treatment of patients with CLBP. Finally, it is important to note that the findings are most likely not limited to physiotherapy, but are also relevant for other (allied) healthcare providers like occupational therapists. All in all, the implications advocate for a context-sensitive integration of VR in physiotherapy for patients with CLBP that should be supported by adequate training. Also, VR interventions should be developed based on and utilize the unique qualities of the technology instead of only mimicking current CLBP treatments.

Future research

Given that the application of VR in the treatment of CLBP represents a novel and rapidly evolving field, existing studies are often exploratory and methodologically diverse. Therefore, it is crucial to conduct more high-quality experimental research

on VR for CLBP.[36] Instead of doing experimental research, many researchers seem to prioritize conducting reviews on the few experimental VR studies that have been performed in patients with CLBP.[23,24,37,63–68] It is noteworthy that the aforementioned examples exclude reviews that focused somewhat broader on for example chronic spinal pain[69–71] or chronic pain in general.[72–74] A recent editorial noticed that the number of reviews on VR for chronic pain even outnumbered the number of clinical trials.[75] Besides the limited added value of all the reviews and possible research waste, many of the reviews erroneously pool studies that are not comparable.[52] Further, a recent umbrella review on VR for patients with chronic musculoskeletal pain showed that the systematic reviews have a high overlap of included studies.[76] Future high-quality (experimental) studies should not solely focus on VR effectiveness for patients with CLBP, but also include other research questions. The topics include the actual (instead of the proposed) working mechanisms of VR for CLBP through pre-specified mediation analyses, prognostic factors that predict intervention success (e.g., through individual participant data (IPD) meta-analyses and subgroup analyses) and optimal intervention characteristics (e.g., duration and dosage). Such studies are essential not only to determine whether VR is effective, but also to understand how and for whom it works and under what conditions it is most effective.[77,78] Acquiring more knowledge will allow interventions to be optimized, tailored to specific patient subgroups, and implemented more efficiently in clinical practice. Further, future studies should be conducted in real-world settings, for example using pragmatic N-of-1 trials, hybrid effectiveness-implementation designs or patient preference clinical trials.[79–81] Employing pragmatic study designs better capture the complexity of routine physiotherapy practice, generate findings that are directly applicable to everyday care and usually require fewer resources. Preferably, the research topics should be prioritized in a research agenda with consensus from other VR researchers. Also, as highlighted previously in the general introduction and discussion, this high-quality research should be based on and reported using the available recommendations and guidelines to conduct research on VR for CLBP. Using the recommendations and guidelines will enable appropriate study replication, interpretation and comparison. Finally, results from future studies should inform VR intervention developers to optimize VR interventions for patients with CLBP, including innovative aspects of VR like embodiment, integration of biofeedback and multi-user environments. Concluding, the focus on VR for CLBP

research should shift from quantity to quality and from synthesizing past studies to conducting new experimental studies.

Conclusion

VR in physiotherapy for patients with CLBP is still in its infancy, with limited adoption and ambiguous evidence regarding effectiveness. Our studies highlight both the promise of VR interventions and the challenges in implementing them effectively, from clinician familiarity to patient matching. Achieving the full potential of VR depends on rigorous research, insight into underlying mechanisms, and effective professional education. By addressing the barriers, VR could become a tool that expands physiotherapy practice and enhances patient care.

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Addendum

Summary

Dutch summary (samenvatting)

Research data management statement

List of publications

PhD portfolio

Curriculum vitae

Dankwoord

Summary

Chapter 1 provides a comprehensive introduction into the relevance, knowledge gaps and potential added value of VR interventions in chronic (low back) pain.

Chronic pain is a major global health problem, affecting around one in five adults and contributing substantially to disability, reduced quality of life, and socioeconomic costs. Chronic low back pain (CLBP) is the most common form of chronic pain and a leading cause of disability worldwide. Physiotherapy is a common treatment option for CLBP and should be an individualized, multimodal treatment based on the biopsychosocial model, with exercise therapy and pain education at its core. However, physiotherapy treatment effects remain modest, partly due to difficulties in implementing biopsychosocial care, low adherence to home exercises, and the complexity of patient needs and expectations. In recent years, eHealth innovations such as virtual reality (VR), emerged as promising tools to enhance physiotherapy for patients with CLBP. Yet, VR interventions for CLBP in physiotherapy lack high-quality evidence and standardized evaluation methods to guide further implementation. The aim of this thesis was threefold:

1. To unravel the current state and perception of VR use in physiotherapy treatment for patients with chronic (low back) pain in a systematic approach and the effect of briefing VR on patients' treatment expectations.
2. To evaluate the effectiveness of a co-created physiotherapy with integrated VR (VARIETY) intervention for patients with CLBP.
3. To improve and standardize the reporting and evaluation of (therapeutic) VR interventions.

Present use of VR in physiotherapy for chronic (low back) pain and evaluating the effect of a briefing about VR on patients' treatment expectations

The survey among 265 Dutch primary care physiotherapists (**Chapter 2**), showed that VR use for patients with chronic pain is currently limited. The low number of physiotherapists, who used VR in chronic pain treatment (approximately 7%), were moderately positive about VR. They started using VR recently and only in a small proportion of their patients. Treatment goals were diverse, with pain reduction (68%), improved coordination (50%), and enhanced mobility (45%)

being the most common. Larger practices were significantly (twice as much) more likely to employ VR, suggesting that organizational resources facilitate VR adoption. According to the physiotherapists who did not use VR for chronic pain treatment, unfamiliarity with VR was the main reason. These findings indicate that VR implementation is still at an early stage, characterized by heterogeneous applications and the absence of standardized protocols.

The results of the previous chapter are partly reflected in the results of the interview study among eleven Dutch physiotherapists who used or had used VR for CLBP treatment (**Chapter 3**). These physiotherapists also stated that VR is in its infancy and is still unknown to many colleagues and patients. Physiotherapists generally did not see VR as a threat that could replace their own role but described it as an addition to the physiotherapist's toolbox. Moreover, they recognized possibilities of VR beyond conventional physiotherapy treatment, because of its immersive, interactive, and gamified elements. Another recurrent theme in the interviews was the fact that participants reported that physiotherapists should have additional skills, attitudes and knowledge to effectively provide VR for patients with CLBP.

Two double-blinded RCTs studying the effect of a physiotherapist's briefing of therapeutic VR on treatment expectations were conducted (**Chapter 4**). Study 1 included healthy participants (n=127) and study 2 included patients with chronic musculoskeletal pain (n=115). Participants were randomized to watch a video in which VR therapy was explained by either positive or neutral language. Results showed that treatment expectations between the neutral and positive language use groups did not differ in terms of the outcome measures, as both groups reported better outcomes after the video, in both study 1 and 2. Around 90% of participants across both studies (healthy participants and patients with chronic musculoskeletal pain) were open to trying VR. Overall, these findings show that a short verbal briefing about therapeutic VR improves treatment expectations in both healthy participants and patients with chronic pain.

Evaluation of the effectiveness of VR in physiotherapy for CLBP

To study the added effect of VR in physiotherapy for patients with CLBP, an intervention was developed (**Chapter 5**). The intervention in this mixed-methods study was developed based on the Medical Research Council framework in five phases, in co-creation with patients, physiotherapists and researchers (n=22).

First, a literature review was conducted, followed by focus group interviews with the three aforementioned stakeholders to develop a concept intervention. The concept intervention was tested in a feasibility study and evaluated in focus group interviews with patients and physiotherapists, which provided input to shape the final intervention. The resulting 'VARIETY' intervention comprised 12 weeks of physiotherapy with three integrated, home-based VR modules: pain education, exercise therapy and relaxation exercises.

The VARIETY intervention was subsequently evaluated for its effectiveness in a multicenter, pragmatic cluster-RCT with CLBP patients in the Netherlands, compared to guideline-based, usual care physiotherapy. Cluster-randomization was conducted on the practice level, implying that patients were allocated to the group their physiotherapists were randomized to. Patients had severe complaints with among other a combination of severe disability and severe pain intensity. The primary outcome was physical functioning and secondary outcomes included pain intensity, pain-related fears, pain self-efficacy, and quality of life. Effectiveness of the intervention, compared to the control condition, was evaluated using intention-to-treat, linear mixed-model analyses. All methodological aspects of this cluster-RCT were described in detail in the study protocol (**Chapter 6**).

Recruitment challenges severely limited this cluster-RCT (**Chapter 7**) to 25 participants in the VARIETY intervention group and 7 in the VARIETY control group. This control group was supplemented with 18 control participants from comparable trials, forming the total control group (n=25). Despite the recruitment challenges, the VARIETY intervention group showed a 42% reduction in physical functioning, compared to 26% in the VARIETY control group and 22% in the total control group. Secondary outcome measures, including pain-related fears, catastrophizing, self-efficacy, and physical activity, also tended toward greater improvement in the intervention group, although differences were not statistically significant. These results suggest that integrating VR into physiotherapy for severe CLBP is feasible, safe, and potentially beneficial. Although, results should be interpreted with caution because of the restricted sample size.

Improve and standardize virtual reality research

To further support rigorous VR research, a three-round modified eDelphi study with a validation meeting was conducted to develop an intervention reporting

guideline for therapeutic, immersive VR interventions (**Chapter 8**). An international expert panel of 61 VR researchers from 13 countries completed the study. The developed reporting guideline consists of 16 key reporting items, divided into the following six categories: theory, content, deployment, development, safety, and context. Its implementation could strengthen the quality, comparability, and reproducibility of VR research and facilitate appropriate adoption of VR interventions in clinical practice.

A systematic scoping review was conducted to map and evaluate questionnaires used to assess VR interventions (**Chapter 9**). From 4,461 screened records, 56 papers describing 58 distinct questionnaires were included. Seven overarching constructs were identified, of which the 'sense of presence' (45%), user experience (26%), and motion sickness (10%) were most commonly used. However, the review highlighted substantial heterogeneity with similar constructs being inconsistently defined and operationalized across questionnaires. The findings emphasize the need for standardized evaluation of VR interventions. We provided questionnaire recommendations for different constructs to evaluate VR.

The final **Chapter 10** provides a general discussion of the main findings of this thesis, reflecting on the current use and perceptions of VR in physiotherapy for patients with CLBP. It synthesizes insights from each of the (survey, interview, experimental, Delphi and review) studies from this thesis, and compares them with the literature. This chapter also outlines methodological considerations, clinical implications for physiotherapy practice, and future directions for high-quality VR research.

Dutch summary (samenvatting)

In **hoofdstuk 1** worden de relevantie en potentiële meerwaarde van VR-interventies bij chronische (lage rug)pijn uitgebreid geïntroduceerd en bestaande kennislacunes besproken.

Chronische pijn is een gezondheidsprobleem dat ongeveer één op de vijf volwassenen treft en aanzienlijk bijdraagt aan een verminderde kwaliteit van leven en sociaaleconomische kosten. Chronische lage rugpijn (CLRP) is de meest voorkomende vorm van chronische pijn en wereldwijd een belangrijke oorzaak van verminderd functioneren. Fysiotherapie is een veelgebruikte behandelingsoptie voor CLRP en zou een geïndividualiseerde, biopsychosociale, multimodale behandeling moeten zijn, met oefentherapie en pijneducatie als belangrijkste behandelpijlers.

De effecten van fysiotherapie bij CLRP zijn klein, onder andere door belemmeringen bij de implementatie van biopsychosociale zorg en lage therapietrouw aan thuisoefeningen. In de afgelopen jaren zijn eHealth-innovaties zoals virtual reality (VR) opgekomen als veelbelovende instrumenten om fysiotherapie voor patiënten met CLRP te verbeteren. Wetenschappelijk bewijs van hoge kwaliteit naar VR-interventies voor CLRP binnen de fysiotherapie ontbreekt echter grotendeels, evenals gestandaardiseerde evaluatiemethoden om implementatie te ondersteunen.

Het doel van dit proefschrift was drievoudig:

1. Het onderzoeken van het huidige gebruik en de percepties over VR in de fysiotherapie voor patiënten met chronische (lage rug)pijn en het evalueren van het effect van het uitleggen van VR op de behandelverwachtingen van patiënten.
2. Het evalueren van de effectiviteit van een fysiotherapeutische interventie met geïntegreerde VR voor patiënten met CLRP (VARIETY).
3. Het verbeteren van de consistentie in het rapporteren en evalueren van therapeutische VR-interventies.

Huidig gebruik van VR in de fysiotherapie bij chronische (lage rug)pijn en het effect van uitleg over VR op de behandelverwachtingen van patiënten

De enquête onder 265 Nederlandse eerstelijns fysiotherapeuten (**hoofdstuk 2**) liet zien dat het gebruik van VR voor patiënten met chronische pijn beperkt is.

Het lage aantal fysiotherapeuten dat VR in de behandeling van chronische pijn gebruikte (ongeveer 7%), was gematigd positief over VR. Ze waren recent begonnen met het gebruik en zetten het slechts voor een klein deel van hun patiënten in. De behandeldoelen waren divers. Pijnvermindering (68%), verbeteren van coördinatie (50%) en mobiliteit (45%) kwamen het meest voor. Grotere praktijken maakten significant vaker gebruik van VR, wat suggereert dat organisatorische randvoorwaarden de adoptie van VR vergemakkelijken. Onbekendheid met VR was volgens fysiotherapeuten zonder ervaring de belangrijkste reden om het niet in de praktijk te gebruiken. De bevindingen geven aan dat de implementatie van VR nog in een vroeg stadium verkeert, dat VR heterogeen wordt toegepast en dat gestandaardiseerde protocollen ontbreken.

De resultaten van het vorige hoofdstuk komen gedeeltelijk overeen met de uitkomsten van de interviewstudie onder elf Nederlandse fysiotherapeuten die VR gebruikten of hadden gebruikt voor de behandeling van CLRP (**hoofdstuk 3**). Fysiotherapeuten gaven ook aan dat VR nog in de kinderschoenen staat en bij veel collega's en patiënten onbekend is. Over het algemeen zagen fysiotherapeuten VR niet als een bedreiging voor hun eigen rol, maar beschreven het als een nieuw hulpmiddel in de 'gereedschapskist' van de fysiotherapeut. Bovendien erkenden fysiotherapeuten mogelijkheden van VR die meerwaarde hebben ten opzichte van de huidige fysiotherapeutische behandeling, onder andere vanwege het onderdompelende karakter en de spelelementen van VR. Een terugkerend thema in de interviews was dat deelnemers aangaven dat fysiotherapeuten aanvullende vaardigheden, attitudes en kennis moeten hebben om VR effectief in te kunnen zetten bij patiënten met CLRP.

In **hoofdstuk 4** werden twee dubbelblinde gerandomiseerde en gecontroleerde studies (RCT's) uitgevoerd om het effect te onderzoeken van het uitleggen van de VR-behandeling door een fysiotherapeut op de behandelverwachtingen. Studie 1 werd uitgevoerd met gezonde deelnemers (n=127) en studie 2 met patiënten met chronische pijn (n=115). De deelnemers werden gerandomiseerd om een video te bekijken waarin VR werd uitgelegd met positief taalgebruik of met neutraal taalgebruik. De behandelverwachtingen tussen de groepen die de video's met neutraal of positief taalgebruik hadden gezien, verschilden niet wat betreft de uitkomstmaten. Beide groepen rapporteerden na het bekijken van de video betere uitkomsten, zowel in studie 1 als studie 2. Ongeveer 90% van de deelnemers in

beide studies (gezonde deelnemers en patiënten met chronische pijn) stond open voor het uitproberen van VR. Over het geheel genomen tonen de bevindingen aan dat een korte mondelinge uitleg van therapeutische VR samenhangt met verbeterde behandelverwachtingen bij zowel gezonde deelnemers als patiënten met chronische pijn.

Evaluatie van de effectiviteit van VR in de fysiotherapie bij CLRP

In **hoofdstuk 5** ontwikkelden wij een interventie om het aanvullende effect van VR op gebruikelijke fysiotherapie voor patiënten met CLRP te onderzoeken. De interventie werd in vijf fasen ontwikkeld met een 'mixed-methods' ontwerp volgens het Medical Research Council raamwerk, in co-creatie met patiënten, fysiotherapeuten en onderzoekers (n=22). Eerst werd een literatuurstudie uitgevoerd, gevolgd door focusbijeenkomsten met de drie groepen stakeholders om een conceptinterventie te ontwikkelen. De conceptinterventie werd vervolgens getest in een haalbaarheidsstudie en geëvalueerd in focusbijeenkomsten met patiënten en fysiotherapeuten. De verkregen feedback werd gebruikt om de definitieve interventie te verfijnen. De uiteindelijke interventie, genaamd VARIETY, bestaat uit een fysiotherapeutisch programma van 12 weken met drie geïntegreerde VR-modules: pijneducatie, oefentherapie en ontspanningsoefeningen.

De effectiviteit van de VARIETY-interventie werd vervolgens onderzocht in een multicenter, pragmatische cluster-gerandomiseerde trial met CLRP-patiënten en vergeleken met richtlijnconforme, gebruikelijke fysiotherapeutische zorg in Nederland. De cluster-randomisatie vond plaats op praktijkniveau, wat betekent dat een patiënt werd toegewezen aan de fysiotherapeut die van tevoren was gerandomiseerd aan de interventie of de standaardbehandeling. Deelnemers waren patiënten met een combinatie van ernstige beperkingen en ernstige pijn. De primaire uitkomstmaat was fysiek functioneren; secundaire uitkomstmaten waren pijnintensiteit, pijngerelateerde angst, kwaliteit van leven en de haalbaarheid van de interventie. De effectiviteit van de interventie werd geëvalueerd met 'intention-to-treat' lineaire mixed-modelanalyses. Alle methodologische aspecten van de cluster-RCT zijn uitgebreid beschreven in het studieprotocol (**hoofdstuk 6**).

Door wervingsproblemen moest de VARIETY-studie vroegtijdig worden gestopt (**hoofdstuk 7**). In totaal konden 25 deelnemers in de interventiegroep en zeven in de controlegroep worden geïncludeerd. Om de controlegroep te vergroten,

werden 18 controles uit vergelijkbare studies toegevoegd tot een totaal van 25. De interventiegroep liet sterkere verbeteringen zien, met een gemiddelde afname van beperkingen in fysiek functioneren van 42% vergeleken met 26% in de VARIETY-controlegroep en 22% in de totale controlegroep. Ook bij de secundaire uitkomstmaten, zoals pijngerelateerde angst, catastroferen en fysieke activiteit, werd een (niet significante) trend gezien in het voordeel van de interventiegroep. De resultaten suggereren dat het integreren van VR in de fysiotherapeutische behandeling van patiënten met ernstige CLRP haalbaar en veilig is, en mogelijk effectief. Vanwege het beperkte aantal studiedeelnemers moeten de resultaten met grote voorzichtigheid worden geïnterpreteerd.

Verbeteren en standaardiseren van VR-onderzoek

Om de kwaliteit en consistentie van VR-onderzoek verder te versterken, is een gemodificeerde eDelphi-studie met drie rondes en een validatiebijeenkomst gedaan, gericht op de ontwikkeling van een rapportagerichtlijn voor therapeutische, immersieve VR-interventies (**hoofdstuk 8**). Een internationaal panel van 61 VR-onderzoekers uit 13 landen nam deel aan de studie. De uiteindelijke rapportagerichtlijn omvat 16 kernonderdelen, verdeeld in zes categorieën: theorie, inhoud, inzet, ontwikkeling, veiligheid en context. Implementatie van de rapportagerichtlijn kan de kwaliteit, vergelijkbaarheid en reproduceerbaarheid van VR-onderzoek verbeteren en een zorgvuldige toepassing van VR-interventies in de klinische praktijk bevorderen.

Tevens werd een systematische scopingreview uitgevoerd om vragenlijsten te inventariseren en te beoordelen die worden gebruikt voor de evaluatie van VR-interventies (**hoofdstuk 9**). Van de 4.461 gescreende publicaties werden 56 artikelen met in totaal 58 unieke vragenlijsten 'gescoped'. Er werden zeven overkoepelende constructen geïdentificeerd, waarvan 'sense of presence' (het gevoel aanwezig te zijn in de VR-wereld) (45%), gebruikerservaring (26%) en simulatorziekte (10%) het meest voorkwamen. Uit de review bleek een aanzienlijke heterogeniteit aan studies, waarbij vergelijkbare constructen verschillend werden gedefinieerd en geoperationaliseerd tussen verschillende vragenlijsten. De resultaten onderstrepen de noodzaak van verdere standaardisatie voor het evalueren van VR-interventies. Op basis van de bevindingen worden aanbevelingen gedaan voor het gebruik van geschikte vragenlijsten per construct.

Tot slot biedt **hoofdstuk 10** een algemene discussie van de belangrijkste bevindingen van dit proefschrift, met een reflectie op het huidige gebruik en de percepties van VR binnen de fysiotherapie voor patiënten met CLRP. Het hoofdstuk integreert inzichten uit de verschillende deelstudies (enquête-, interview-, experimentele, Delphi- en reviewonderzoeken) en plaatst ze in de context van de bestaande literatuur. Daarnaast worden methodologische overwegingen besproken, klinische implicaties voor de fysiotherapeutische praktijk belicht en aanbevelingen gedaan voor toekomstig VR-onderzoek.

Research data management statement

Ethics and privacy

Most chapters of this thesis are based on the results of medical-scientific research with physiotherapists, patients with chronic pain and healthy participants (**Chapters 2, 3, 4, 5, 7, and 8**). These studies were conducted in accordance with the principles of the Declaration of Helsinki, the guidelines of Good Clinical Practice, and RadboudUMC policy. The privacy of study participants was warranted by the use of pseudonymization and the pseudonymization key was stored separately on a secured network that was only accessible by the coordinating researcher. Written informed consent was obtained from participants to collect and process their data for this research project. Consent was not obtained for sharing and reuse of the (pseudonymized) data for future research. Therefore, data of the VARIETY intervention development study and trial (**Chapters 5 and 7**) were anonymized before publishing. Anonymizations was done by destroying the pseudonymization key file before publishing the data.

Before the start of each study, a study protocol was reviewed and approved by the recognized Medical and Ethical Review Board of the HAN University of Applied Sciences (HAN ECO), University of Twente (UT), or the Medical Ethical Review Committee 'METC Oost-Nederland'. More information on review board and pre-registration of the individual chapters is provided in Table 1 below.

Table 1. Review board and study registration information per chapter

Chapter	Review board and ID	Registration and ID
2	HAN ECO: 347.04/22	N/a
3	UT: 240074	N/a
4 – healthy participants	HAN ECO: 503.11/23	ClinicalTrials.gov: NCT06307912
4 – patients with CMP	HAN ECO: 525.02/24	ClinicalTrials.gov: NCT06282757
5	HAN ECO: 319.01/22	N/a
7	METC: 2022–15794	ClinicalTrials.gov: NCT05701891
8	HAN ECO: 564.06/24	OSF doi: 10.17605/osf.io/hfp4m

Data collection and storage

Data from the (quantitative) studies reported in **Chapters 2, 4, 5, 7 and 8** was collected in Qualtrics using secured online questionnaires. This data was converged to and processed in Microsoft Excel, SPSS and Stata. Data from qualitative studies (**Chapters 3 and 5**) was collected and stored in a secured Microsoft Teams environment only accessible by project members working at the HAN, and processed in Atlas.ti. Anonymized data from **Chapters 2, 3, 4, 5, 7 and 8** was stored and analyzed on the HAN research drive and only accessible by project members working at the HAN. Recordings of interviews and focus groups were deleted after transcription.

Data sharing according to the FAIR principles

All articles reporting these studies are or will be published open access under a CC-BY 4.0 license. The anonymized data of the survey study (**Chapter 2**), VR explanation studies (**Chapter 4**), and VARIETY clinical trial (**Chapter 7**) is published with open access at DANS Data Station Life, Health and Medical Sciences. The anonymized data of the VARIETY intervention development study (**Chapter 5**) is published with restricted access at the Radboud Data Sharing Collection. Data was published using interoperable file formats and made reusable by adding sufficient documentation. See Table 2 for data sharing information per chapter. The data used for **Chapter 3 and 8** are not owned by RadboudUMC. The data are archived by the HAN University of Applied Sciences. Questions about the data can be addressed to lectoraten.aps@han.nl. Anonymized data will be stored for 15 years. **Chapter 6** describes the VARIETY study design and rationale and did not use data. **Chapter 9** is based on existing data which was obtained from published literature.

Table 2. Data sharing information per chapter

Chapter	Collection	DOI	License
2	DANS	10.17026/LS/YUBFQK	CC-BY-NC-4.0
4	DANS	10.17026/LS/MPZUYJ	CC-BY-NC-4.0
5	RDR DSC	10.34973/rd6q-pj66	CC-BY-NC-4.0
7	DANS	10.17026/LS/4R2HJP	CC-BY-NC-4.0

List of publications

Published in peer-reviewed journals

Luc, A., Slatman, S., Everard, G., Huygelier, H., Pitance, L., & Detrembleur, C. (2026). Knowledge, Practices and Acceptance of Physiotherapists Regarding the Use of Immersive Virtual Reality in Clinical Practice: a Cross-Sectional Online Survey. *Disability and Rehabilitation*. https://doi.org/10.1080/09638288.2026.2622898

Slatman, S., Ostelo, R., van Goor, H., Satink, T., Staal, J. B., & Knoop, J. (2026). "A New Tool for My Toolbox": Physiotherapists' Perceptions on Therapeutic Virtual Reality for Chronic Low Back Pain – a Qualitative Descriptive Study. *Musculoskeletal Science & Practice*, *81*, 103475. https://doi.org/10.1016/j.msksp.2025.103475

Slatman, S., Harvie, D., van der Heijden, M., Bulle, L., Dejaco, B., van Goor, H., Groenveld, T., van de Hoef, P. A., Kragting, M., Ostelo, R., Spiegel, B., Staal, J. B., Trost, Z., Ummels, D., & Knoop, J. (2026). Reporting Guideline for Therapeutic Immersive Virtual Reality Interventions: International eDelphi Study (INVIRTUE). *Journal of Medical Extended Reality*, *2*(1), 345-361, https://doi.org/10.1177/29941520251404744

Slatman, S., van Lankveld, W., Staal, J. B., van Goor, H., Ostelo, R., Westendorp, J., & Knoop, J. (2025). The Effect of Physiotherapists' Explanation of Therapeutic Virtual Reality on Treatment Expectations in Healthy People and People With Chronic Musculoskeletal Pain: Two Online RCTs. *PEC Innovation*, *8*, 100443. https://doi.org/10.1016/j.pecinn.2025.100443

Slatman, S., Heesink, L., Achterkamp, R., Broeks, J., Lemans, B., de Oliveira, N. M., ... Tabak, M. (2025). Cluster-Randomised Controlled Trial of At-Home Virtual Reality for People With Chronic Musculoskeletal Pain on the Waiting List. *European Journal of Pain*, *29*(6), e70073. https://doi.org/10.1002/ejp.70073

Slatman, S., Heesink, L., Achterkamp, R., Broeks, J., de Oliveira, N. M., ter Riet, R., ... Tabak, M. (2025). At-Home Virtual Reality Intervention for Patients With Chronic Musculoskeletal Pain: Single-Case Experimental Design Study. *JMIR XR and Spatial Computing (JMXR)*, *2*(1), e58784. https://doi.org/10.2196/58784

Elser, A., Ohse, M., Frankenstein, C., Leeuw, M., Schiebler, S., Schmieder, S., Slatman, S., & Schäfer, A. G. M. (2025). Usage of Virtual Reality Technology in Physiotherapy in Germany: Results from a Survey. *Bioengineering*, *12*(2), 106. https://doi.org/10.3390/bioengineering12020106

Bareišytė, L., Slatman, S., Austin, J., Rosema, M., van Sintemaartensdijk, I., Watson, S., & Bode, C. (2024). Questionnaires for Evaluating Virtual Reality: a Systematic Scoping Review. *Computers in Human Behavior Reports*, *16*, 100505. https://doi.org/10.1016/j.chbr.2024.100505

Slatman, S., Groenveld, T., Ostelo, R., van Goor, H., Staal, J. B., & Knoop, J. (2024). Development of a Multimodal, Personalized Intervention of Virtual Reality Integrated Within Physiotherapy for Patients With Complex Chronic Low-Back Pain. *Journal of Medical Extended Reality*, *1*(1), 30-43. https://doi.org/10.1089/jmxr.2023.0002

Slatman, S., Staal, J. B., van Goor, H., Ostelo, R., Soer, R., & Knoop, J. (2024). Limited Use of Virtual Reality in Primary Care Physiotherapy for Patients With Chronic Pain. *BMC Musculoskeletal Disorders*, *25*(1), 168. https://doi.org/10.1186/s12891-024-07285-5

Slatman, S., Ostelo, R., van Goor, H., Staal, J. B., & Knoop, J. (2023). Physiotherapy With Integrated Virtual Reality for Patients With Complex Chronic Low Back Pain: Protocol for a Pragmatic Cluster Randomized Controlled Trial (VARIETY study). *BMC Musculoskeletal Disorders*, *24*(1), 132. https://doi.org/10.1186/s12891-023-06232-0

Slatman, S., Mossink, A., Jansen, D., Broeks, J., van der Lugt, P., Prosman, G. J., & d'Hollosy, W. O. N. (2022). Factors Used by General Practitioners for Referring Patients With Chronic Musculoskeletal Pain: a Qualitative Study. *BMC Primary Care*, *23*(1), 1-12. https://doi.org/10.1186/s12875-022-01743-6

Westerhof, G. J., & Slatman, S. (2019). In Search of the Best Evidence for Life Review Therapy to Reduce Depressive Symptoms in Older Adults: a Meta-Analysis of Randomized Controlled Trials. *Clinical Psychology: Science & Practice*, *26*(4), 11. https://doi.org/10.1111/cpsp.12301

Other publications

Slatman, S., Staal, J. B., & Knoop, J. (2024). Letter to the Editor concerning" Virtual reality is effective in the management of chronic low back ache in adults: a systematic review and meta-analysis of randomized controlled trials" by V. Kumar et al.(Eur Spine J [2023]: doi: 10.1007/s00586-023-08040-5). *European Spine Journal*, *33*(4), 1700-1701. https://doi.org/10.1007/s00586-024-08166-0

Knoop, J., Slatman, S., & Staal, B. (2024). Response to In-Home Virtual Reality Program for Chronic Lower Back Pain: A Randomized Sham-Controlled Effectiveness Trial in a Clinically Severe and Diverse Sample. *Mayo Clinic Proceedings: Digital Health*, *2*(1), 38-40. https://doi.org/10.1016/j.mcpdig.2023.11.010

Submitted manuscripts

Slatman, S., de Kam, D., Barten, D.J., & van de Hoef, P. A. (2025). Clinically Relevant Kinematic and Spatiotemporal Outcome Measures of People With Knee Osteoarthritis Modifiable by Physiotherapy: Systematic Review and Qualitative Synthesis. *BMC Musculoskeletal Disorders*

Slatman, S., van Goor, H., Köke, A., van Lankveld, W., Maas, E., Ostelo, R., Poolman, E., Tabak, M., de Vries, M., Staal, J. B., & Knoop, J. (2025). Physiotherapy With Integrated Virtual Reality for Patients With Complex Chronic Low Back Pain: Cluster-Randomized Controlled Trial (VARIETY). *BMC Musculoskeletal Disorders*

Bakker, M., ten Klooster, P., Bode, C., Gerritsen, D., Slatman, S., Hegeman, M., & Vonkeman, H. (2025). Effectiveness of Virtual Reality for Chronic Pain in Patients With Inflammatory Arthritis (VIRTUAL Trial): Study Protocol for a Randomized Controlled Clinical Trial. *BMC Rheumatology*

de Kam, D., Slatman, S., & van de Hoef, P. A. (2026) "Remote Physiotherapy" Supported by Sensor Technology and Video Conferencing for Musculoskeletal Conditions: a Focus Group Study on Perspectives of Primary Care Physiotherapists. *BMC Musculoskeletal Disorders*

Todd, J., Slatman, S., Finn, D., Suter, G., de Villiers, E., & Aspell, J. (2026). Examining the Impact of Virtual Reality Embodiment Illusions on Pain Perception: a Systematic Review. *European Journal of Pain*

PhD portfolio of Syl Slatman

Department: **Surgery**
PhD period: **October 2021 – September 2025**
PhD Supervisor(s): **Prof. dr. H. van Goor, Prof. dr. R.W.J.G. Ostelo**
PhD Co-supervisor(s): **Dr. J. Knoop, Dr. J.B. Staal**

Training activities	Hours
Courses	
- Radboudumc - eBROK course (2022)	42.00
- University of Twente - Career prospects for young professionals (2023)	24.00
- RU - Qualitative Research Methods and Analysis (2023)	84.00
- Radboudumc - Introduction in R (2024)	12.00
- PANACEA - International summer school on placebo and nocebo (2024)	40.00
- Radboudumc - Scientific integrity (2025)	20.00
Conferences	
- VR4Rehab, Wijchen, the Netherlands - Visiting (2022)	16.00
- KNGF Wetenschapsdag, Den Bosch, the Netherlands - Visiting (2022)	8.00
- Virtual Medicine, Los Angeles, USA - Visiting (2023)	16.00
- Supporting Health by Technology, Enschede, the Netherlands - Oral presentation (2023)	24.00
- VR4Rehab, Amsterdam, the Netherlands - Oral presentation (2023)	24.00
- International Back and Neck Pain Forum, Groningen, the Netherlands - Poster presentation (2023)	32.00
- KNGF Wetenschapsdag, Kamerik, the Netherlands - Visiting (2023)	8.00
- Sint Maartenskliniek “Verder in beweging”, Nijmegen, the Netherlands - Visiting (2023)	8.00
- PA!N Congress, Veenendaal, the Netherlands - Poster presentation (2023)	16.00
- TeamNL Papendal, Arnhem, the Netherlands - Masterclass (2024)	16.00
- MMM+M in de Pijngeneeskunde, Veenendaal, the Netherlands - Oral presentation (2024)	16.00
- MSG Science Network Conference, Amsterdam, the Netherlands - Poster presentation (2024)	10.00
- KNGF Wetenschapsdag, Kamerik, the Netherlands - Visiting (2024)	8.00
- World Congress on Virtual Rehabilitation, Amsterdam, the Netherlands - Poster presentation (2024)	24.00
- Performance Based Healthcare, online - Webinar (2024)	10.00
- Denkfysio, online - Webinar (2025)	10.00
- Virtual Medicine, Los Angeles, USA - Oral presentation (2025)	24.00
- Rugsymposium, Apeldoorn, the Netherlands - Oral presentation (2025)	16.00
- International Back and Neck Pain Forum, Davos, Switzerland - 2 Poster presentations (2025)	10.00
- XR4Rehab, Lecco, Italy - Oral presentation (2025)	24.00
- KNGF Wetenschapsdag, Utrecht, the Netherlands - Visiting (2025)	8.00
- Fysio Forward, Eindhoven, the Netherlands - Workshop (2025)	16.00
- PA!N Congress, Veenendaal, the Netherlands - Workshop (2025)	16.00
- Capita Selecta, Amsterdam, the Netherlands - Oral presentation (2026)	10.00

Training activities	Hours
Other	
- PEDro rater (79) (2022)	20.00
- Peer reviewing international journals (9) (2023)	18.00
- Scientific committee World Congress on Virtual Rehabilitation 2024, 2026 (2024)	40.00
- Co-application grant “VIRTUAL Trial” (not granted) (2024)	10.00
- Co-application grant “Homework Exercises” (granted) (2024)	10.00
- Co-organiser Chronic Pain Network Twente (PijnWijs) & Organizing Start Conference (2024)	20.00
- Scientific committee XR4Rehab 2025 (2025)	20.00
- Abstract screening ISVR – Rehabweek Conference 2025 (2025)	5.00
Teaching activities	
Supervision	
- Bachelor students’ thesis (17) (2022)	85.00
- Master students’ thesis (4) (2023)	20.00
Total	**840.00**

Curriculum vitae



Syl Slatman was born on September 25th of 1993 in Denekamp, the Netherlands. After completing his primary and secondary education in Oldenzaal (2011) he began studying Human Geography and Spatial Planning at the University of Utrecht. Realizing this study was not the right fit, in 2012 he started the bachelor of Physiotherapy at Saxion University of Applied Sciences in Enschede. In 2017 he obtained his bachelor's degree and started the pre-master and master's program of Health Psychology and Technology at the University of Twente in Enschede, which he finished in 2019.

During his master's degree, he worked as a physiotherapist at Pro Corpus in Enschede. After his graduation in 2019, he started working as a teacher and researcher at the department of Psychology, Health & Technology of the University of Twente. In 2020, he also started working as data analyst at OCA rehabilitation in Amsterdam. Motivated by his interest in research and the intersection of physiotherapy and psychology, he started as a PhD candidate (2021) at HAN University of Applied Sciences in Nijmegen. His research focused on the added value of virtual reality integrated within physiotherapy for people with chronic low back pain. Alongside his PhD research (three days per week), he also worked as a researcher at the University of Twente in Enschede and HU University of Applied Sciences in Utrecht (two days per week).

In 2025 he completed his PhD thesis and continued his career as a researcher at the HAN and HU Universities of Applied Sciences, focusing on the role of technology in enhancing physiotherapy.

Dankwoord

En dan is het ineens zo ver, na vier jaar onderzoek doen ben ik aangekomen bij het schrijven van mijn dankwoord. Een uitgelezen kans om verschillende mensen in het zonnetje te zetten die bewust of onbewust een bijdrage hebben geleverd aan dit proefschrift. Mijn dank gaat allereerst uit naar de leden van mijn promotieteam, die dit traject niet alleen leerzaam maar ook ontzettend plezierig hebben gemaakt.

Jesper, als dagelijks begeleider stond jij het dichtst bij mij tijdens dit promotietraject. Zowel op persoonlijk als professioneel vlak heb ik het contact en onze samenwerking altijd als enorm prettig ervaren. Je hebt me de ruimte geboden voor eigen inbreng en ideeën, maar hield ook altijd de focus op het VARIETY project, met name als ik weer eens te veel tegelijk wilde doen en overal ja op zei. Bedankt hiervoor en ik zou iedereen een Jesper in zijn of haar promotieteam gunnen!

Bart, ik heb veel geleerd van je ruime onderzoekservaring bij mensen met chronische pijn en in de fysiotherapiesetting. Door jouw epidemiologische kennis kregen mijn onderzoek en ideeën vaak meer diepgang en daarnaast behield je oog voor het menselijke, door mij onder andere als advies te geven om soms ook gewoon eens uit het raam te staren. Hier wil ik je graag voor bedanken en ik kijk uit naar onze toekomstige samenwerking.

Raymond, bedankt voor de fijne samenwerking en ondersteuning. Ik heb het erg op prijs gesteld dat je mijn plannen om een tijd naar Australië te gaan voor mijn onderzoek hebt aangemoedigd. Daarnaast heb ik inhoudelijk veel gehad aan je kennis over fysiotherapie en chronische pijn, je scherpe blik, kritische vragen en methodologische deskundigheid.

Harry, ook jou wil ik graag bedanken voor je onuitputtelijke bron van out-of-the-box ideeën en de visionaire blik waarmee je naar de gezondheidszorg kijkt. Ook kijk ik met veel plezier terug op de congressen die we hebben bezocht, waaronder vMed in Los Angeles, en de gezellige etentjes. Je weet me constant uit te dagen, te enthousiasmeren en te inspireren.

Wim, tot slot wil ik jou graag bedanken voor je rol in mijn promotieteam tot aan je pensioen. Je perspectief als psycholoog in het fysiotherapie vakgebied is een betekenisvolle inbreng geweest. Verder bewonder ik je vermogen om werk te combineren met een rijk privéleven.

Daarnaast wil ik graag de **fysiotherapeuten** en **deelnemers** bedanken die aan onze onderzoeken hebben meegedaan. Zonder jullie waardevolle bijdragen en betrokkenheid hadden we deze onderzoeken nooit kunnen doen. Ook dank ik graag **Reducept** en **Luuk** van **SyncVR Medical** voor hun hulp en het gebruik van hun VR-programma's. Verder een woord van dank aan alle **bachelor**- en **master-studenten** van de HAN, Saxion en Universiteit Twente, die bij hebben gedragen aan verschillende (deel)onderzoeken. Ook wil ik **ZonMw** graag bedanken voor het verstrekken van de subsidie die dit onderzoek mogelijk heeft gemaakt.

Ik zou ook graag de stuurgroep van het VARIETY project willen bedanken, die vanaf de aanvraag betrokken is geweest bij dit onderzoek: **Albère**, **Marjan** en **Leen**, hartstikke bedankt. Daarbij ook een speciaal woord van dank aan de fysiotherapie beroepsgroep, het KNGF, en specifiek: **Elon** en **Arno**.

Daarnaast zou ik graag mijn prettige HAN **collega's** van ons lectoraat Werkzame Factoren in de Beweegzorg, de bachelor en master fysiotherapieopleidingen en het iXperium willen bedanken.

Naast dit vierjarige promotietraject ben ik als onderzoeker werkzaam geweest voor verschillende projecten. Toen ik als promovendus begon was ik al werkzaam bij de Universiteit Twente op het PReferral project. **Wendy** en **Gert-Jan**, bedankt voor jullie vertrouwen in mij en jullie begeleiding bij mijn eerste stappen in de bijzondere wereld van academisch onderzoek. Ook dank aan de andere betrokken **onderzoekers** en **behandelaren** vanuit Saxion, Roessingh, Nocepta en het ZGT. Daarbij zou ik specifiek **José** nog willen bedanken voor onze fijne samenwerking en interessante gesprekken.

Na het PReferral project kon in bij de Universiteit Twente doorgaan met het Wait & Work project, waarbij we onderzoek deden naar de inzet van VR bij patiënten met chronische pijn. Vanuit dit project zou ik graag **Monique** en **Lieke** willen bedanken voor de ontzettend prettige samenwerking. Daarnaast wederom een woord van dank aan de **partners** van dit project vanuit het Roessingh, Nocepta, Deventer Ziekenhuis en Revalidatie Friesland.

Toen dit project voorbij was ben ik op de Hogeschool Utrecht gestart met het Fysiotherapie op Afstand project. **Sander**, **Digna** en **Di-Janne**, hartstikke bedankt voor de fijne samenwerking en super dat we in de toekomst samen onderzoek blijven

doen. Daarnaast natuurlijk ook een woord van dank aan al mijn geweldige **collega's** van de Hogeschool Utrecht en onze voormalig lector **Cindy** voor de "productieve" schrijfdagen, kopjes koffie en gezellige lunchwandelingen.

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Ook wil ik graag **Silvia** van het XR4Rehab consortium bedanken voor het betrekken van mij bij deze organisatie en het congres. Jullie hebben mij als beginnend onderzoeker een podium geboden om mijn onderzoek onder de aandacht te brengen en mijn (internationale) netwerk van VR-onderzoekers verbreed. A special thank you to the international researchers I was able to collaborate with on different interesting studies: **Alexander**, **Alexandre**, **Brennan**, **Zina** and **Jenny**.

A huge cheers to **Dan** from the University of South Australia. Thank you so much, and also your family and your research group, for hosting me in Adelaide and

making me feel welcome. I truly appreciated your hospitality, the engaging discussions about research and many fun (Fringe) activities during the period I visited. It was a fantastic and memorable experience, both personally and professionally.

De leden van de leescommissie en oppositie wil ik graag bedanken voor de tijd en moeite die zij in het beoordelen van dit proefschrift hebben gestoken: prof. dr. **Philip van der Wees**, prof. dr. **Jeanine Verbunt**, prof. dr. **Maud Graff**, prof. dr. **Wendy Scholten-Peeters**, prof. dr. **Monique Tabak** en prof. dr. **Thomas Hoogeboom**.

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