Implementation of a Virtual Reality Intervention in Outpatient Physiotherapy for Chronic Pain: Pilot Implementation Study Protocol

Alexander Elser, Christian Kopkow, Axel Schäfer

Submitted to: JMIR Research Protocols
on: March 05, 2024

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Alexander Elser[1]; Christian Kopkow[2]; Axel Schäfer[1]

[1]University of Applied Sciences and Arts Hildesheim/Holzminden/Göttingen, Faculty of Social Work and Health Hildesheim DE
[2]Brandenburg University of Technology Cottbus - Senftenberg, Faculty 4 for Human Sciences, Department Therapy Science I Cottbus - Senftenberg DE

Corresponding Author:
Axel Schäfer
University of Applied Sciences and Arts Hildesheim/Holzminden/Göttingen, Faculty of Social Work and Health
Goschentor 1
Hildesheim
DE

Abstract

Background: Chronic pain is a global health issue that causes physical, psychological, and social disabilities for patients, as well as high costs for societies. Virtual Reality (VR) is a new treatment that provides an opportunity to narrow the gap between clinical practice and recommended care, especially in the outpatient physiotherapy setting. However, there is currently no implementation strategy to integrate VR treatments into this setting.

Objective: This protocol outlines a pilot implementation study that aims to (1) identify barriers and facilitators for implementing a Virtual Reality (VR) intervention in outpatient physiotherapy care for people with chronic pain. And (2) to develop and pilot test an implementation strategy in five practices in Germany.

Methods: The study consists of four phases. The first phase involves adapting the treatment protocol of the VR intervention to the local context of outpatient physiotherapy practices in Germany. The second phase includes the collection of barriers and facilitators via semisctructured interviews from physiotherapists and the development of a theory-driven implementation strategy based on the Theoretical Domains Framework (TDF) and the Behavior Change Wheel (BCW). This strategy will be applied in the third phase, which will also include a six-month span of using VR interventions in practices, along with a process evaluation. The fourth phase will be a final evaluation of the entire process and implementation strategy at the end of the of the study.

Results: The recruitment process and phase 1, including the adaptation of the treatment protocol, have already been completed. We recruited five physiotherapy practices in Lower Saxony, Germany, where the VR intervention will be implemented. The collection of barriers and facilitators through semi-structured interviews is scheduled to begin in February 2024.

Conclusions: This pilot implementation study aims to develop a theory-driven implementation strategy for integrating a VR intervention into outpatient physiotherapy care for people with chronic pain. The identified barriers and facilitators, along with the implementation strategy, will serve as a starting point for future randomized controlled implementation studies in different settings to refine the implementation process and integrate VR interventions into the outpatient care of people with chronic pain. Clinical Trial: German Clinical Trials Register (ID: DRKS00030862)

(JMIR Preprints 05/03/2024:58089)
DOI: https://doi.org/10.2196/preprints.58089

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Alexander Elser[1]

Christian Kopkow[2]

Axel Schäfer[1]

1 University of Applied Sciences and Arts Hildesheim/Holzminden/Göttingen, Faculty of Social Work and Health

2 Brandenburg University of Technology Cottbus - Senftenberg, Faculty 4 for Human Sciences, Department Therapy Science I

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Keywords (3 bis 10): chronic pain; implementation; virtual reality; VR; physiotherapy;

Introduction

Chronic pain defined as persistent or recurrent pain lasting longer than three months [1] is a major global health problem. Chronic pain conditions (back pain, musculoskeletal disorders, and neck pain) are three of the leading causes for years lost to disability in the last decades [2,3]. Prevalence rates in industrial nations like the USA (20.5 %) [4], Germany (28.3 %) [5], the UK (34 %) [6] and Chile (48.1 %) [7] are high, but also among low- and middle-income countries which prevalence rates ranging from 13% to 49.4% [8]. Chronic pain often results in physical disability, psychological distress, and reduced quality of life [3,9], and is associated with higher rates of divorce and suicide, and affects relationships and self-esteem [10,11]. For societies, chronic pain is an enormous financial burden on the healthcare system. The financial cost of chronic pain in the US is estimated to be between $560 billion and $635 billion in 2010, including medical costs and lost productivity [12]. In Germany chronic pain costs at least €53.9 billion annually [13]. Although evidence-based treatments and guidelines for the management of chronic pain are available [14–16], they are only partially used [17,18]. In Germany, for example, only 38% of physiotherapists in a survey reported that they work according to guidelines in chronic pain management [19].

Implementation studies offer an opportunity to improve this situation by developing and testing targeted implementation strategies for evidence-based interventions [20].Frameworks, models and theories are recommended to use in the development of implementation interventions and strategies [21]. One model to guide the process of implementation is the Knowledge to Action (KTA) cycle [22]. The KTA cycle is a process model, which is increasingly used since its introduction in 2006 [23–26]. The KTA was developed from a concept analysis of 31 planned action theories to make sense of the complex implementation process. It provides a comprehensive view by integrating concepts of knowledge creation and application. At each stage of the action cycle, other frameworks or theories can be applied [22].

One such framework to determine barriers and facilitators is the Theoretical Domains Framework (TDF) [27,28]. The TDF was created to enhance healthcare researchers' access to psychological theory by providing a systematic and simplified approach to behavior change theories. Consisting of 14 theoretical domains derived from 33 theories and 128 constructs, this framework serves as a valuable tool for examining the barriers and facilitators that influence professional behavior change. Based on these factors, a strategy can be developed with the use of the Behavior Change Wheel (BCW) [29]. The BCW is a comprehensive framework that incorporates behavioral theory to effectively capture and address the mechanisms of action within interventions. Developed through expert consensus and a rigorous validation process, the wheel is organized into three levels. Its central element is the COM-B model, which includes aspects of **C**apability (both physical and psychological), **O**pportunity (both social and physical), and **M**otivation (both automatic and reflective). It is proposed that people need these three factors to increase the likelihood of performing the **B**ehavior in question [29].
A new evidence-based intervention for people with chronic pain is virtual reality (VR) [30]. It is used in physiotherapy in many specialties such as neurology and orthopedics to manage pain [31]. VR treatments include VR games, mindfulness-based interventions, practical exercises and visual illusions for people with chronic pain [32]. A meta-analysis showed large effects of VR interventions on pain (SMD 1.6; 95 % CI 0.83 – 2.36) and body functioning (SMD 1.4; 95 % CI 0.13 – 2.67) in people with chronic pain [32]. However, it is unknown how often VR treatments are used in the care of people with chronic pain. A recent review about the barriers and facilitators in the implementation of VR intervention for people with chronic pain shows barriers such as the context of implementation and the skills of the VR user, but also facilitators such as positive beliefs about

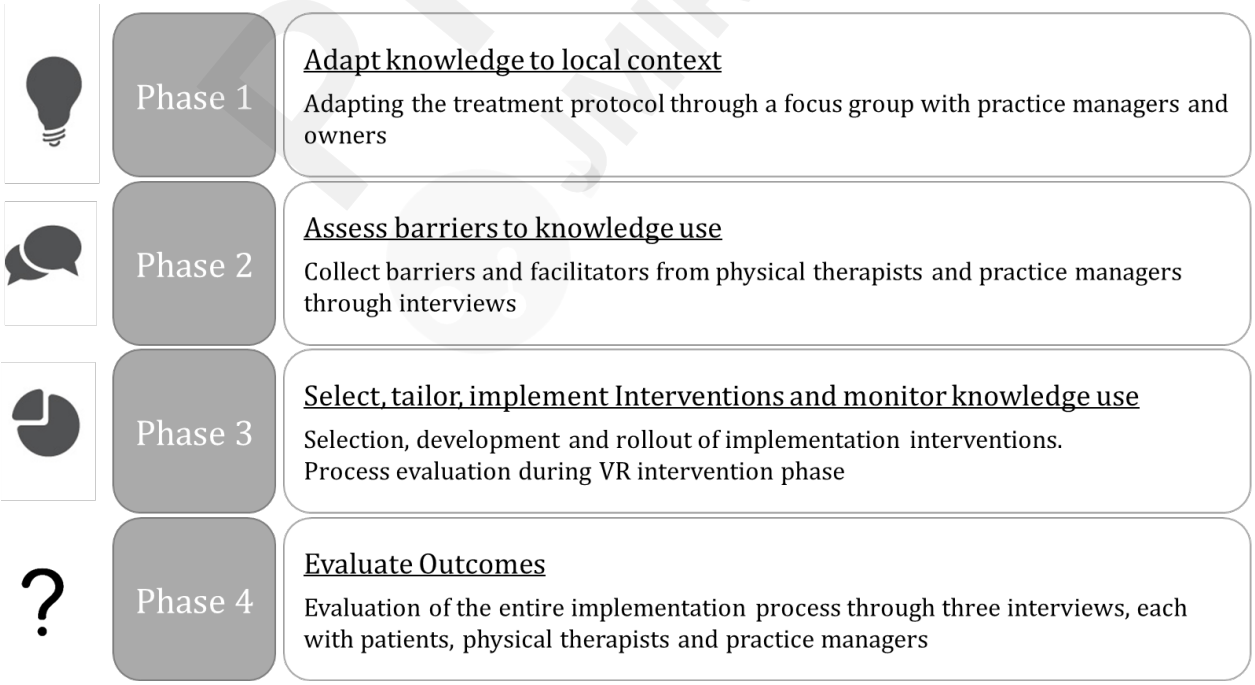
consequences from a patient perspective [33]. However, little is known regarding barriers and facilitators from a health professional perspective. The next step in the implementation of VR interventions into health care is the development of an initial implementation strategy, supported by implementation frameworks focusing on behavior change of all stakeholders [34]. Therefore, the aim of this study is (1) to identify barriers and facilitators from the perspective of health care professionals and (2) to develop and test a strategy for the implementation of VR interventions in outpatient physiotherapy practices.

Methods

Overview

The four phases [Figure 1] of the pilot implementation study are derived from the KTA cycle [22] and the entire implementation process is accompanied by a formative evaluation [35]. The implementation takes place in five outpatient physiotherapy practices in Germany. In the first phase (Adapt knowledge to local context), the treatment protocol of the VR intervention is adapted to the context of outpatient physiotherapy practices. The second phase (Assess barriers to knowledge use) consists of collection of specific barriers and facilitators to the implementation of the VR intervention from a health care professional perspective. Participating therapists first receive training in the use of the VR glasses and the VR intervention, and then semi-structured interviews are conducted with them. This will be the basis for the development of an implementation strategy with tailored implementation interventions in phase 3 (Select, tailor, implement interventions and Monitor knowledge use). After the implementation strategy has been carried out, the physiotherapists will use the VR intervention in the practice with an accompanying process evaluation. Finally, the entire process and implementation strategy will be evaluated and adapted in phase 4 (Evaluate outcomes).
The reporting of this protocol follows the CONSORT 2010 statement: extension to randomised pilot and feasibility trials [36]. The study was registered with the German Clinical Trials Register (ID: DRKS00030862).

Figure 1 Phases of the implementation study



Phase 1

The first phase of the implementation process consists of adapting the treatment protocol of the VR intervention to the context of outpatient physiotherapy practices in Germany.

Five physiotherapy practices in Lower Saxony (Germany) will participate in the study and implement the VR intervention. At least five physiotherapists must work in the practices to be eligible to participate in the study. Practice managers or owners and two researchers will participate in guided focus groups to adapt the treatment protocol of the VR intervention. Focus groups are a good method to investigate what participants think and why they think it [37]. In addition, the group setting can stimulate new ideas that may be hidden in individual discussions [38]. Another goal is to establish collaboration and networking among participants. The focus group guideline will be developed using the implementation outcomes of acceptability, appropriateness, adoption and feasibility [39]. The guideline will be pre-tested and adapted, if necessary.
The focus group will take place at the University of Applied Science and Art in Hildesheim/Holzminden/Göttingen (Germany) and will last approximately 2 hours. One researcher will moderate the focus group, while a second researcher will take care of technical aspects, keep time and take notes on important aspects or special incidents.
At the beginning of the focus group, the moderator gives an introduction in which the process and goals of the overall study and the focus group are stated, followed by a presentation of the VR treatment protocol. A table listing the content and length of the six sessions of VR treatment is displayed during the focus group. The main section of the focus group addresses the four outcomes mentioned above in relation to the treatment protocol. The final section is an open-ended question and answer session before participants complete an online demographic survey. The audio of the focus group is recorded with an audio recorder for the entire duration.
Qualitative content analysis according to Kuckartz will be used to analyze the data[40]. The VR treatment protocol will be adapted based on the results of this focus group. In addition, the data will be used to extract barriers and facilitators for the subsequent phases. MAXQDA (MAXQDA Plus 2022, Release 22.0.1) will be used for the qualitative analysis.

Phase 2

The second phase is derived from the "Assess barriers to knowledge use" step of the KTA cycle [22]. Two physiotherapists from each practice will participate in the study and receive a training on the use of the VR intervention including handling of VR devices (PICO 4). In addition, participants will receive information on how the VR intervention should be applied to people with chronic pain. This information will also be made available on demand on an online platform. The VR intervention (Reducept, NL) is a therapeutic VR application that provides pain education based on the "Explain Pain" guidelines [41] and pain management skills. The VR intervention uses techniques from cognitive behavioral therapy (CBT), acceptance and commitment therapy (ACT), mindfulness and hypnotherapy [42]. After training, the acceptance, appropriateness, and feasibility of the VR intervention from the therapists' perspective will be assessed via an online survey using the German versions of the Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM) questionnaires [43,44]. Then they receive the VR devices to test the intervention at home. Approximately two weeks later, an optional online meeting will be offered to therapists to answer any remaining questions.
The barriers identified in the focus group and online survey after the training will be used to define the behaviors that need to be changed or implemented when the VR intervention is used in practices. From a list of all potential candidate behaviors, the study team will select one or two core behaviors that appear promising to support implementation of the VR intervention. The target behaviors will be

selected based on each behavior's potential impact, potential multiplier effect, and feasibility of measurement. These target behaviors are specified by the question: Who needs to do what differently, when, where, how, and with whom [45]?

Approximately one week after the online meeting, semistructured interviews will be conducted with the participating physiotherapists to identify and specify barriers and facilitators to the implementation of the VR intervention. An interview guideline will be developed to understand the factors that may influence the implementation of VR interventions in practices. It will be based on the previously defined target behaviors and the domains of the Theoretical Domains Framework (TDF)[27,28]. Before being used, the interview guide is pilot-tested with two physiotherapists to test its comprehensibility.
The interviews are expected to last approximately 45 to 60 minutes and will be conducted online via Zoom (Zoom Video Communications, Inc.). Participants will receive written informed consent prior to participation in the study. Interviews will be audio-recorded and transcribed verbatim. Data collection and storage will be pseudonymized. The data will be analyzed using qualitative content analysis according to Kuckartz [40]. The TDF domains will be used as deductive codes to which the data will be assigned. Data will be analyzed using MAXQDA (version 22; VERBI GmbH) software.

Phase 3

Based on the qualitative and quantitative assessed barriers and facilitators in phase 1 and 2 and the barriers and facilitators found in a scoping review [33], an implementation strategy, consisting of various implementation interventions, will be developed. The identified domains of the TDF will be mapped to implementation interventions (e.g. training, modelling, environmental restructuring) using the Behavior Change Wheel (BCW) [29]. In our study, we will not include policy categories such as regulation, fiscal and legislation, as recommended by the BCW framework. This exclusion is due to the limited timeframe and scope of our project, which does not extend to policy-level changes.

The developed implementation strategy will be discussed with the stakeholders from the participating practices, to specify the execution of the implementation interventions. The strategy will then be executed in all five practices and evaluated via an online questionnaire. The strategy will be reported according to the standards of Proctor et al [46].

Patients are eligible if they are older than 18 years, have chronic pain and are able to understand and speak the German language. Patients will be excluded if they have a current or previous diagnosis of epilepsy, dementia, migraine or other neurological conditions that may prevent the use of VR or lead to adverse effects, hypersensitivity to flashing lights or severe hearing impairment. Pain intensity, disability due to pain, fear of movement, pain catastrophizing, quality of life and pain-related self-efficacy will be assessed using the German versions of the Numeric Pain Rating Scale [47,48], Pain Disability Index [49], Tampa Scale for Kinesiophobia [50], Pain Catastrophizing Scale [51], EQ-5D-5L (quality of life) [52] and a questionnaire assessing pain-related self-efficacy[53] before and after the VR intervention. Physiotherapists will fill out an online questionnaire to document each session and assess fidelity and adverse events, and will use the VR intervention in their practices for six months. Prior to participation in the study, written informed consent will be obtained from participants.

Phase 4

The final phase will be an evaluation of the overall implementation process and an analysis of the

health-related outcomes of the patients.

The evaluation of the implementation process will be done through semistructured interviews with three patients, three therapists and three practice owners. Prior to the interviews, all therapists will again complete the AIM, IAM and FIM questionnaires. The data from the questionnaires and the process evaluation in phase 3 will be used to develop an interview guide. The outcomes adoption, acceptability, appropriateness, feasibility, fidelity and implementation costs will be assessed to determine how successful the implementation strategy was, how the VR intervention was used in the practices, and how patients perceived the use of the VR intervention. Prior to use, the interview guide is pilot-tested with people from the same background who are not part of the study to ensure comprehensibility.

The interviews will be conducted online via Zoom (Zoom Video Communications, Inc.) and are expected to last approximately 60 minutes. Written informed consent will be obtained from participants prior to participation in the study. Interviews will be audio-recorded and transcribed verbatim. Data collection and storage will be pseudonymized. Data will be analyzed using Kuckartz's qualitative content analysis [40]. Data will be analyzed using MAXQDA (MAXQDA Plus 2022, Release 22.0.1) software. Health outcome data are checked for normal distribution and sphericity and then analyzed using repeated measures ANOVA using SPSS (28.0.1.0, IBM Corp.).

This data will be used to adapt the implementation strategy and to create recommendations for the implementation of VR interventions for people with chronic pain in outpatient physiotherapy practices.

Ethical Considerations

Ethical approval for the study has been obtained from the ethics committee of the University of Applied Science and Art in Hildesheim/Holzminden/Göttingen (Germany) (April 3, 2023). The principles of the Declaration of Helsinki [54] will be strictly followed in this research project. Eligible participants will be informed of the objectives and procedures of the study. Prior to inclusion, written informed consent will be obtained from all patients. Participation will be voluntary, and participants will be free to withdraw from the study at any time.

Results

The recruitment process and phase 1 with the adaption of the treatment protocol are already conducted. Five physiotherapy practices were identified in which the VR intervention is to be implemented. A focus group with four practice owners was held in November 2023. Due to personal appointments, one owner had to cancel the focus group at short notice and was subsequently interviewed via a semistructured interview about the treatment protocol. The data was then analyzed via qualitative content analysis and used to adapt the treatment protocol.

Discussion

The described pilot implementation study will provide insight into the implementation of VR interventions for people with chronic pain managed in outpatient physiotherapy practices.

The insights into the perspective of healthcare professionals will play an important role in the further implementation of VR interventions for people with chronic pain, as they play an important role in

the implementation of digital interventions [55]. In addition, the insights from more stakeholders can lead to targeted recommendations for the future development of VR interventions, with focus on implementation.

Past research indicates that organizational structures and VR technology itself have been barriers to the implementation of VR interventions in various health care settings [34,56,57]. Regarding the use of VR in physiotherapy, VR itself seems to be the main barrier due to technical issues, lack of guidelines for VR interventions, and patient-related factors [31]. In contrast, staff and health care professionals can act as facilitators by reducing anxiety about new technologies and changing attitudes toward VR [31,34,57]. There is also a general interest in the use of VR in rehabilitation among health care professionals [34]. The implementation study described here can merge these results to develop an initial implementation strategy. This strategy can be a first step towards increasing the uptake and use of VR interventions in the area of chronic pain, leading to better treatment for patients. The next step in implementing VR interventions in physiotherapy practices should be to assess real world effectiveness within a controlled trial.

Acknowledgements

This study is part of the project „Zukunft FH-PROF“ at the HAWK University of applied sciences and arts and was supported through the funding program called “FH Personal” by the German Federal Ministry of Education and Research and the state Lower Saxony (funding code: 03FHP179).

Authors' Contributions

AE, CK, and AS were responsible for the conception of the research project and the drafting of the manuscript. All authors contributed to the preparation of this manuscript and read and approved the final version for publication.

Conflicts of Interest

None declared.

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Supplementary Files

Figures

Phases of the implementation study.