DISSERTATION

The Application of Exergames Using Head-mounted Displaybased Immersion as a Rehabilitation Intervention in Older Adults with Chronic Conditions

Die Anwendung von Exergames mittels Head-Mounted-Displaybasierter Immersion als Rehabilitationsintervention bei älteren Erwachsenen mit chronischen Erkrankungen

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> von Oskar Stamm

Erstbetreuung: Prof. Dr. med. Ursula Müller-Werdan

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List of abbreviations

AR	Augmented reality
BHT	Berliner Hochschule für Technik
CAVE	Cave Automatic Virtual Environment
CG	Control group
CBP	Chronic back pain
CRS	Chronische Rückenschmerzen
EH	Essential hypertension
ET	Endurance training
EU	European Union
HMD	Head-mounted display
IG	Intervention group
Μ	Mean
MD	Mean difference
MR	Mixed reality
NASA-TLX	National Aeronautics and Space Administration task load index
NCDs	Non-communicable diseases
NRS	Numeric Rating Scale
PPG	Photoplethysmography
RQs	Research questions
SET	Strength endurance training
SD	Standard deviation
TUI	Technology Usage Inventory
UEQ	User Experience Questionnaire
VR	Virtual reality
ViRST	Virtual Reality for Pain Therapy

Abstract

Background

It is anticipated that evolving demographics may precipitate a future surge in chronic health conditions. In Germany, adults aged 70 years and above experience the highest prevalence of chronic back pain (CBP) and two-thirds of those aged 65 and older have hypertension. Individuals with non-communicable diseases in Germany are less likely to adhere to the recommended minimum 150 minutes of physical activity per week than other adults. The appearance of consumer-oriented head-mounted display (HMD) virtual reality (VR) devices offers new possibilities for the application of adherence-enhancing exergames. The aim of this dissertation was to investigate the feasibility of the application of HMD-based immersion as a rehabilitation intervention in older adults with chronic conditions, using the examples of CBP and essential hypertension (EH).

Methods

The investigation included three evaluations with older adults over 65 years of age. A qualitative analysis by conducting in-depth interviews with older adults with CBP (n = 10) and two focus groups involving physiotherapists and psychotherapists was applied to determine requirements. In the ViRST pilot study, we examined the preliminary efficacy and feasibility of immersive VR multimodal therapy over a period of four weeks in older adults with CBP (n = 22). This work focuses on the pain intensity, measured with the numeric rating scale (NRS), and the user experience, assessed with the user experience questionnaire (UEQ). The BewARe usability study compared the usability in older adults with EH (n = 22), evaluated with the usability subscale of the Technology Usage Inventory (TUI), of two exergame types: strength endurance and endurance training. Furthermore, frustration was measured with the National Aeronautics and Space Administration task load index.

Results

The requirements analysis resulted in the identification of 104 requirements that formed the basis for the design of the prototype in the ViRST project. In the pilot study, both groups showed a reduction in pain intensity on the NRS. However, the decrease was not significant within the groups in either case (intervention group: mean difference [MD] = 0.64, p = .535; control group: MD = 1.27, p = .07). The system received an "excellent"

rating on the attractiveness and perspicuity scales of the UEQ. In the BewARe usability study, the results of the TUI usability subscale revealed no significant differences between the groups (p = .656). However, frustration was rated significantly higher in endurance training than in strength endurance training (p = .038) by the older adults with EH.

Conclusion

To investigate the effectiveness of immersive VR exergames in older adults with chronic back pain, studies with higher sample sizes are needed. The usability and user experience results indicated that evaluations involving active exercise therapy using immersive VR among older adults with chronic conditions would be feasible.

Zusammenfassung

Hintergrund

Der demografische Wandel wird voraussichtlich in Zukunft zu einem Anstieg der chronischen Erkrankungen führen. In Deutschland ist die Prävalenz von chronischen Rückenschmerzen (CRS) bei Erwachsenen über 70 Jahren am höchsten und zwei Drittel der über 65-Jährigen sind von Bluthochdruck betroffen. Menschen mit nichtübertragbaren Krankheiten halten sich in Deutschland seltener an das empfohlene Minimum von 150 Minuten körperlicher Aktivität pro Woche als der Rest der Erwachsenen. Das Erscheinen kommerzieller Head-Mounted-Display (HMD) VR bietet neue Möglichkeiten für die Anwendung von adhärenzsteigernden Exergames. Ziel der Dissertation war es, die Machbarkeit der Anwendung von HMD-basierter Immersion als Rehabilitationsintervention bei älteren Erwachsenen mit chronischen Erkrankungen am Beispiel von CRS und essentieller Hypertonie (EH) zu untersuchen.

Methoden

Die Analyse umfasste drei Studien mit älteren Erwachsenen im Alter von über 65 Jahren. Zur Ermittlung der Anforderungen wurde eine qualitative Analyse durch Interviews mit älteren Erwachsenen mit CRS (n = 10) und zwei Fokusgruppen mit Physiotherapeuten und Psychotherapeuten erhoben. In der ViRST-Pilotstudie wurde die vorläufige Wirksamkeit und Machbarkeit einer immersiven multimodalen VR-Therapie über vier Wochen mit älteren Erwachsenen mit CRS (n = 22) untersucht. In dieser Dissertation wurde die Schmerzintensität mittels Numeric Rating Scale (NRS), und die User experience mittels des User Experience Questionnaire (UEQ) gemessen. In der BewARe-Usability-Studie wurde bei älteren Erwachsenen mit EH (n = 22) die Benutzerfreundlichkeit von zwei Exergame-Typen (Kraftausdauer- und Ausdauertraining) verglichen, die mit der Usability-Subskala des Technology Usage Inventory (TUI) bewertet wurde. Außerdem wurde die Frustration mithilfe des National Aeronautics and Space Administration Task Load Index gemessen.

Ergebnisse

Die Anforderungsanalyse führte zur Ermittlung von 104 Anforderungen, welche die Grundlage für das Design des ViRST-Prototyps bildeten. In der ViRST-Pilotstudie zeigten beide Gruppen eine Reduktion der Schmerzintensität auf der NRS, welche jedoch nicht

signifikant war (Interventionsgruppe: MD = 0.64, p = .535; Kontrollgruppe: MD = 1.27, p = .07). Das System erhielt auf der Attraktivitäts- und Übersichtlichkeitsskala des UEQ die Bewertung "ausgezeichnet". In der BewARe Usability Studie zeigten die Ergebnisse der TUI Usability Subskala keine signifikanten Unterschiede (p = .656). Die Frustration wurde jedoch von den älteren Erwachsenen mit EH beim Ausdauertraining signifikant höher eingeschätzt als beim Kraftausdauertraining (p = .038).

Schlussfolgerung

Um die Wirksamkeit von immersiven VR-Exergames bei älteren Erwachsenen mit chronischen Rückenschmerzen zu untersuchen, sind Studien mit größerer Stichprobengröße erforderlich. Die Usability und die User Experience deuten darauf hin, dass Studien mit aktiver Bewegungstherapie in immersiver VR mit älteren Erwachsenen mit chronischen Erkrankungen durchführbar wären.

1 Introduction

As life expectancy continues to rise and fertility rates remain below the replacement level, Germany is facing an increasingly aging society. Immigration could slow down the aging of the population, although this is difficult to predict from the current perspective. In 1950, 10% of the population of what is now the Federal Republic of Germany was 65 years or older. Compared to this, the proportion of this group of the population increased to 22% in 2021 (Statistisches Bundesamt, 2023a). The number of people aged 65 and older in Germany was 18.7 million in 2022 and is expected to rise with a moderate increase to at least 23.1 million by 2050 (Statistisches Bundesamt, 2023b, 2023c). This demographic change is accompanied by a variety of challenges, as well as opportunities.

These demographic transitions will also result in a rise in chronic conditions in the future (Nowossadeck, 2012). In particular, non-communicable diseases (NCDs), such as cardiovascular disease or cancer are associated with an aging population. At the present time, 90% of deaths in the European Union (EU) are caused by these chronic diseases (Vandenberghe & Albrecht, 2020). The World Health Organization (WHO) Global NCD Action Plan 2013–2020 identifies the following main behavioral and metabolic risk factors: a poor diet, physical inactivity, tobacco consumption, harmful use of alcohol, hyperlipidemia, high blood glucose, raised blood pressure, and being overweight or obese (World Health Organization, 2013). NCDs require expensive treatments and prolonged individual care (Muka et al., 2015). The European Commission indicates that chronic diseases represent a growing burden and will become a challenge for European healthcare systems (European Commission, 2020). This thesis will exemplarily focus on individuals with two such chronic conditions, hypertension and chronic back pain, who can especially benefit from physical activity.

Approximately two-thirds of men and women aged 65 and above have hypertension in Germany (Neuhauser et al., 2017). Hypertension is one of the most important risk factors for cardiovascular diseases, as well as one of the most common avoidable causes of mortality worldwide (Mills et al., 2020). Lifestyle modifications, especially an increase in physical activity, can be effective for both the prevention and the treatment of hypertension (Carpio-Rivera et al., 2016). The guidelines for the management of arterial hypertension by the European Society of Cardiology and the European Society of Hypertension

(ESC/ESH) recommend that adults with hypertension regularly engage in moderate intensity endurance exercises for at least 30 minutes (min) on five to seven days per week (Williams et al., 2018). The guidelines also mention that resistance exercises can be incorporated into one's routine two to three days per week (Williams et al., 2018).

Another condition that is rapidly increasing due to the aging of the population is chronic back pain (WHO, 2022). Low back pain is the primary contributor to the burden of musculoskeletal disorders worldwide (Institute for Health Metrics and Evaluation, 2019) and the leading global cause of disability (Ferreira et al., 2023; Wu et al., 2020). Low back pain affected 619 million people worldwide in 2020, and is expected to impact approximately 843 million by 2050 (Ferreira et al., 2023). When back pain lasts for more than 12 weeks, it is defined as chronic (Hall & McIntosh, 2008). Within German society, the highest prevalence of chronic back pain (CBP) is observed among individuals aged 70 years and above. In this age group, 28.0% of women and 17.4% of men have chronic low back pain, which was defined in the BURDEN 2020 study as pain that occurs almost daily and lasts three months or longer (Von Der Lippe et al., 2021). The etiology of back pain is difficult to determine in most cases and is therefore often referred to as non-specific back pain. The German national guideline for non-specific low back pain recommends that multimodal programs should be used when less intensive evidence-based therapies have been insufficiently effective in this patient group (Bundesärztekammer et al., 2017). Furthermore, based on a moderate evidence base, multimodal pain management can prevail over conventional treatment modalities (Kamper et al., 2014). The central treatment goal of multimodal pain management is functional restoration, which includes multidisciplinary measures by physicians, physiotherapists, psychologists, occupational therapists, and social workers (Poiraudeau et al., 2007). Exercise therapy, which is always a component of multimodal pain management, has demonstrated superior effectiveness in the treatment of chronic low back pain when compared with no treatment, standard care, or a placebo (Hayden et al., 2021).

Both chronic conditions described (hypertension and CBP) are united by the need for high long-term adherence to exercise therapy to achieve optimal treatment outcomes, even if they are different in each case. However, exercise continuity can be an obstacle for older adults. A study by Van Roie et al. (2015) reported the following common perceived barriers to continuing resistance exercise in older adults: a lack of time, greater Introduction

interest in other physical activities, the financial cost and seasonal reasons. Compared to the general adult population in Germany, individuals with NCDs have a lower prevalence of performing physical activities involving at least 150 min of moderate aerobic activity per week (Sudeck et al., 2021). Thus, there is a need to promote physical activity in adults with NCDs. In this case, demographic change can also be an opportunity for the further development of digital technologies in healthcare. In particular, healthy aging, the empowerment of the population and lifestyle changes are current topics in digital health (Koebe & Bohnet-Joschko, 2023).

So-called "exergames" combine exercising and video games and have existed for more than 40 years (Finco & Maass, 2014). In the past, some of the most popular exergames were Dance Dance Revolution, Wii Fit, Kinect Sports, Pokémon Go and Ring Fit Adventure. In research, exergames associated with older adults have been applied for rehabilitation, balance or cognitive training, increasing physical activity, muscle strengthening and mobility improvement, among other purposes (Kappen et al., 2019; Skjæret et al., 2016). After using the exergame Nintendo Wii Fit, older adults reported higher enjoyment than adolescents and young adults when preforming moderate intensity activities (Graves et al., 2010). Similarities between virtual dancing with the exergame Just Dance and real dance sessions in terms of blood pressure and perceived exertion have been shown (Soares et al., 2021). Initial studies demonstrated that using the Microsoft Xbox 360 could improve normalized diastolic blood pressure in a 12-week exergame program (Huang et al., 2017). Previous works have also noted the preliminary effects of employing exergames for chronic back pain. Industrial workers with chronic work-related low back pain exhibited significantly improved mental and physical health composites after utilizing a Nintendo Wii exercise program (Park et al., 2013). Furthermore, significant pain intensity reduction was confirmed in a Wii Fit yoga group of middle-aged female patients who had low back pain (S.-S. Kim et al., 2014). However, a meta-analysis by Collado-Mateo et al. (2018) revealed that there is not yet sufficient evidence for the reducing effect of exergames on musculoskeletal pain. There are also some initial papers on CBP with more recently developed technologies. The application of Nintendo Ring Fit Adventure led to a significant pain reduction in patients with chronic low back pain after eight weeks of exergaming (Sato et al., 2021).

7

Introduction

Research on the application of immersive VR in rehabilitation was first undertaken 30 years ago. A common definition from the 1990s defines immersion as: "the extent to which the computer displays are capable of delivering an inclusive, extensive, surrounding and vivid illusion of reality to the senses of a human participant" (Slater & Wilbur, 1997, p. 604). Similarly, "immersion is user's engagement with a VR (virtual reality) system that results with being in a flow state" (Berkman & Akan, 2019, p. 1). In this dissertation, the term immersive VR refers to VR experienced with head-mounted displays (HMDs), although this term can also refer to cave automatic virtual environment (CAVE) systems or projectors (Pan & Hamilton, 2018). With the appearance of consumer-oriented VR HMDs in the mid-2010s, new possibilities for the application of exergames emerged. Wang et al. (2023) clustered the application of VR in rehabilitation medicine into five topics: neurological and cardiopulmonary rehabilitation, as well as spatial neglect, psychological treatment, and pain distraction. The most popular technological tools used in rehabilitation studies until 2020 were the following commercial consoles: the Nintendo Wii (37%) and Xbox Kinect (21%). Immersive VR was employed in only 2% of the investigations (Brepohl & Leite, 2023). The application of immersive VR in rehabilitation with older adults is still at an experimental stage (Campo-Prieto et al., 2021; Tuena et al., 2020). A paper examining the feasibility of applying immersive VR technology utilizing an HMD with 360° videos as a therapy showed that none of the 66 older adults with cognitive and physical impairments reported negative side effects such as motion sickness or dizziness (Appel et al., 2020). The acceptance of VR HMDs regarding cybersickness in older adults can be considered minimal with current technology (Huygelier et al., 2019). Our own studies with older adults show that habituation to VR sickness is possible during a repeated exposure (Stamm & Dahms, 2023), but these results are not part of the dissertation, as technical requirements and risk management are not the focus of this work.

Although there are already first successful endurance games on the consumer market, such as Beat Saber or Fruit Ninja VR, there is still hardly any research regarding their effects on hypertension and even less in relation to older adults. Studies using VR head-sets showed that college students had similar blood pressure responses in VR cycling to conventional stationary cycling, yet VR cycling was perceived as more enjoyable and less intense (McDonough et al., 2020). Rutkowski et al. (2021) demonstrated that VR cycling

on an ergometer was associated with a lower heart rate than without a VR headset, resulting in a longer time to reach the target heart rate. The usability of immersive VR HMDs in exercise therapy for older adults with hypertension has not yet been evaluated.

In regard to pain management, Hoffman et al. (2000) assessed immersive VR with an HMD more than 20 years ago. Their preliminary study was the first to show that VR can distract from pain more than a video game during painful burn wound care. Jones et al. (2016) used an immersive VR application where the user travels through a 360° virtual landscape. The participants, who had a variety of chronic pain conditions, demonstrated a significant decrease in pain during and after VR use. A non-randomized trial involving a VR HMD application compared to a two-dimensional distraction video confirmed significantly greater pain reduction in hospitalized patients (Tashjian et al., 2017). A systematic review by Pourmand et al. (2018) demonstrated the potential of immersive VR usage as a distraction for short-term easing of acute and chronic pain. Garcia et al. (2022) evaluated the efficacy of an adjunctive cognitive behavioral therapy based on self-regulatory skills for chronic low back pain as a home-based VR program. The results revealed significant pain intensity reduction at the end of the eight-week program, as well as three months after the VR treatment. The VR application employed in the trial, EaseVRx (AppliedVR; Los Angeles, CA), was rated a usability score of 84.33 on the System Usability Scale. The utilization of VR HMDs in active exercise therapy for CBP has barely been examined, in contrast to the application of VR as a distraction and psychotherapy.

Beyond the medical benefits, immersive exergames could in the future possibly contribute to the motivation and enjoyment of older adults, as well as their access to exercise therapies from home, progress monitoring, and social interaction, among many other benefits. To achieve these objectives for immersive HMD-based exergames in the future, it is essential that the exergames are user-friendly, adaptable, and personalized for the intended audience. For this reason, an assessment of user experience and the usability of immersive exergames for future users is of great importance. Usability is an aspect of the user experience. Tuena (2020) describes it as being composed of learnability, efficiency, memorability, errors and satisfaction. User experience goes beyond pure usability by also taking into account the emotional and aesthetic aspects. Hassenzahl and Tractinsky (2006) believe the user experience is composed of the internal state of the user, the characteristics of the system and the context.

Overall, there is a lack of studies in the literature examining the efficacy and user experience of active exercise therapy in immersive VR with older adults. This dissertation aimed to investigate whether the use of immersive VR as a rehabilitation intervention in older adults with chronic conditions is feasible and what its potential impact could be, with the goal of developing a proof of concept. The underlying thesis therefore addresses the following research questions (RQs):

RQ1: What are the requirements for an immersive VR exergame to be used as an adjunct to multimodal pain management in older adults with chronic back pain?

RQ2: What is the preliminary impact of an immersive VR exergame prototype on the reduction in pain intensity in a four-week multimodal pain management program for older adults with chronic low back pain?

RQ3: How do older adults with chronic conditions rate the usability and user experience of immersive exergames in exercise therapy?

2 Materials and Methods

Both quantitative and qualitative methods were used to answer the research questions. With the application of a user-centered design approach in the projects, requirements were elicited at the beginning with the future user group in order to achieve the highest possible usability in the proof-of-concept prototype to be tested. Three analyses were conducted: the virtual reality for pain therapy (ViRST) requirements analysis (Stamm et al., 2020), ViRST pilot study (Stamm, Dahms, et al., 2022) and BewARe usability study (Stamm, Vorwerg, et al., 2022). A content analysis with semi-structured interviews and focus groups was conducted to ascertain the exergame requirements of older adults with chronic back pain. To investigate whether a VR prototype of an exergame can lead to a reduction in pain intensity, the preliminary efficacy was investigated in a pilot study. The usability of immersive exergames in exercise therapy for older adults with chronic diseases was evaluated based on usability testing.

2.1 Participants

All three studies included older adults with a chronic disease (N=54). In the two investigations in the ViRST project, the target group of the VR prototype developed was adults over 65 years of age with chronic back pain, and in the BewARe one, it was adults over 65 years of age with essential hypertension (Table 1).

Sociodemographic data	ViRST requirements analysis (CBP)*	ViRST pilot study†	BewARe usability study ‡				
Sample size [n]	10	22	22				
Age [mean] (standard deviation)	75.9 (6.9)	75.2 (4.9)	74.5 (3.6)				
Age range [years]	69 - 90	67 - 84	65 - 80				
Sex [female/male]	6/4	14/8	13/9				
Main chronic condition (n)	chronic	chronic	essential				
	back pain	back pain	hypertension				
	(n=10)	(n=22)	(n=22)				
CBP: chronic back pain; *Stamm et al., 2020; †Stamm, Dahms et al. 2022; ‡ Stamm, Vorwerg et al. 2022							

Table 1: Participants' characteristics.

In addition, within the VIRST requirements analysis, physical therapists and psychotherapists were interviewed as experts in two focus groups.

2.2 ViRST requirements analysis

The ViRST requirements analysis (Stamm et al., 2020) was an explorative, qualitative study (ethical approval: EA4/055/18), in which we conducted semi-structured in-depth interviews with 10 older adults with CBP. Additionally, two focus groups were conducted with physiotherapists (n = 3) and psychotherapists (n = 2). The aim was to determine the expectations, desires, preferences, and barriers of older adults over 65 years with CBP, as well as framework data from experts regarding pain management with immersive virtual reality. The semi-structured guideline-based interviews lasted approximately one hour. The interview guideline for the older adults included the following topics: "sports and gymnastics practiced in the past and today, sport as social participation, problems and difficulties in activities of daily life, strategies for dealing with pain, game experiences and preferences, hardware and software requirements for a VR exergame and requirements for motivational elements" (Stamm et al., 2020, p. 3). The focus group interviews were also guideline-based and included the topics: pain management experiences, games applications in therapy and requirements for a VR therapy system. The focus groups lasted one to 1.5 hours. Both interview forms took place in person and were conducted in German. The transcription (audio to written) of the recorded interviews was carried out by trained staff using the software f4 (f4transkript, version 7.0.6). Subsequently, a summarizing content analysis according to Mayring (2015) was performed. The analysis was carried out with the software ATLAS.ti (ATLAS.ti, version 8.0) as a gualitative data analysis tool. The content analysis, which was completed by two researchers, included the following steps: paraphrasing, generalization, and reduction. All relevant data units (quotations) were assigned manually to a developed coding manual. Sociodemographic data, as well as Von Korff's chronic pain scale, an assessment of the duration of back pain, the Short Form-12 Health Survey (SF-12) and a subjective evaluation of technology use, were analyzed descriptively with the Statistical Package for the Social Sciences (SPSS, version 23). The requirements gathered were prioritized by six older adults with CBP, three physiotherapists and one psychotherapist. The investigation was registered with the German Clinical Trials Register (DRKS00015294; UTN: U1111-1219-7539).

2.3 ViRST pilot study

The ViRST pilot study (Stamm, Dahms, et al., 2022) was an explorative guantitative study (ethical approval: EA4/213/19). In this randomized controlled pilot trial, the sample consisted of 22 participants. The aim of the pilot study was to examine the preliminary efficacy and feasibility of a VR multimodal therapy over a period of four weeks. The intervention group (IG, n = 11) conducted the multimodal pain management in VR, which consisted of exercise therapy and psychoeducation. The control group (CG, n = 11) received the usual multimodal pain therapy (same exercises as the IG), which consisted of group exercises and psychoeducation in a group setting. The eligibility of all the volunteers was assessed via personal telephone screening. The following inclusion criteria were applied: CBP for longer than six months, an age of 65 years or older, independent mobility, and the ability to actively perform exercises, as well as no intervertebral disc surgery in their medical history and no severe vestibular restrictions affecting the ability to balance (Stamm, Dahms, et al., 2022). This investigation included a baseline examination (pre-test), an intervention phase of four weeks with three sessions offered a week for about 30 min each, and a close-out visit (post-test). The assessments and measurements used are shown in Table 2.

	STUDY PERIOD					
	Enrolment	Baseline pre-test		ek interve tion-to-tre proach)		Close-out post-test
TIMEPOINT	-t1	0	t1	t 2-11	max. t 12	t post
ENROLMENT:						
Eligibility screen	Х					
Informed consent	Х					
Allocation		Х				
INTERVENTIONS:						
VR exergame			+			
chair-based group exercises			Ļ			
ASSESSMENTS:						
Sociodemographic data		Х				
NRS (Childs et al., 2005)		Х	+			Х
CPGQ (Von Korff et al., 1992)		Х				Х

Table 2: SPIRIT schedule of enrolment, interventions and assessments (own illustration)
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Ffb-H-R (Kohlmann & Raspe, 1996)	Х			Х
TSK-11 (Rusu et al., 2014)	Х			Х
SF-12 (Ware et al., 1996)	Х			Х
TUI [IMM] (Kothgassner et al., 2012)	X*			Х
UEQ (Laugwitz et al., 2008)	Х			Х
SSQ (Kennedy et al., 1993)		Х*		Х
MVIC	Х			X†

^{*}Only for the intervention group. [†]This assessment was planned but not undertaken in the post-test. The facility conducting the measurement was unable to perform the measurements due to the COVID-19 pandemic. NRS, numeric rating scale (11-item); CPGQ, Chronic Pain Grade questionnaire; Ffb-H-R, Hannover Functional Ability Questionnaire for measuring back pain-related disability; TSK-11, Tampa Scale of Kinesiophobia; SF-12, Short Form-12 Health Survey; TUI [IMM], the immersion scale of the Technology Usage Inventory; UEQ, user experience questionnaire; SSQ, Simulator Sickness Questionnaire; MVIC, maximum voluntary isometric contraction.

In this dissertation, pain intensity is outlined with a pre-post comparison of the NRS in both groups. An intention-to-treat analysis was utilized in this investigation. We applied the Kolmogorov-Smirnov and Shapiro-Wilk tests to examine the normal distribution. Since the data was not normally distributed, a Wilcoxon signed-rank test was applied for the NRS data. Furthermore, a Spearman's rank correlation was computed to assess the relationship between the number of training units completed and the pain intensity reduction. SPSS (SPSS, version 26) and RStudio (RStudio, version 2022.02.2) were used as the statistical software for the analysis. The study was registered with the German Clinical Trials Register (DRKS00020576; UTN: U1111-1247-3130).

2.4 BewARe usability study

The analysis of usability in the BewARe project was performed in a preliminary study (ethical approval: EA1/019/20). One of the objectives was to compare the usability of two exergames through "simulated mixed reality (MR)" prototypes demonstrated using a VR HMD. The two exergames represented two different training types: strength endurance training (SET) and endurance training (ET). The sample consisted of 22 participants with essential hypertension. The eligibility of all volunteers was assessed via personal telephone screening and the fall risk was screened in presence prior to visit 1. The following

inclusion criteria were applied: individuals with an age \geq 65 years, diagnosed with essential hypertension (stage I), with independent mobility, and at least one fully completed training session (Stamm, Vorwerg, et al., 2022).

The investigation consisted of two visits. The experimental procedure performed on both days remained identical, with the sole exception being the variation in the applied exergame. The evaluation was conducted in the mobile truck laboratory called the VI-TALab.Mobile. The interior of the VITALab.Mobile with all the interactive sports equipment was reconstructed in VR, referred to as "simulated MR" in this work. On both days prior to the intervention, the participants first completed the Technology Usage Inventory (TUI) pre-test. Subsequently, the participants received a briefing on the HMD headset. Uniformly, all participants tested the exergames in the same sequential arrangement (visit 1: SET, visit 2: ET). In the first week, each participant performed the SET exergame, followed by the execution of the ET exergame in the following one. The time interval between visit 1 and visit 2 was no more than one week for all the participants. The training sessions of each exergame was intended to be approx. 25 minutes each. Following the intervention, the TUI post-test and the National Aeronautics and Space Administration task load index (NASA-TLX), among others, were completed by the participants during both visits.

This dissertation focuses on the differences between the two types of training in the TUI usability scale in more detail, as well as the subscale of the NASA-TLX measuring frustration. Data analysis was performed with SPSS (SPSS, version 27). Each data set was examined for its conformity to a normal distribution. If the data showed a normal distribution, a paired t-test was conducted. In the event of a non-normally distributed data, the Wilcoxon signed-rank test was used. An alpha level of .05 was utilized for all statistical tests. The study was registered with the German Clinical Trials Register (DRKS00022881; UTN: U1111-1257-1836).

2.5 Materials

In each of the studies presented, different VR headsets were used as functional prototypes developed by the consortium (Table 3).

Paper	Headset	Resolution	Field of view	Application	Accessories
ViRST requirements analysis (Stamm et al., 2020)	Dell Visor VR118	1440 x 1440px per eye	Max. 110°	VR prototype by Metric- Minds GmbH: platform on a lake, collecting coins [interactive VR]	Dell Visor controllers VRC100
				HoloTour by Microsoft Cor- poration: real- istic looking travel [360° video]	
ViRST pilot study (Stamm, Dahms et al., 2022)	HTC Vive	1080 x 1200px per eye	Max. 110°	VR prototype by Metric- Minds GmbH: 12 exercise tasks on a farm and 4 psychoeduca- tional videos [interactive VR]	HTC Vive controllers; HTC Vive Trackers (2.0) on feet and back; stress as- sessment by PPG sensor
BewARe usability study (Stamm, Vorwerg et al., 2022)	HTC Vive Pro	1440 x 1600 per eye	Max. 110°	Simulated MR prototype by ART+COM & BHT in a living lab (truck): ET and SET exer- game [simulated MR in VR]	Valve Index controllers; HTC Vive Trackers (2.0) on dumbbells, chair and hands; Polar M600 smart- watch

Table 3: Headsets, apps and accessories used in the studies presented (own illustratio	n)
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VR: virtual reality; MR: mixed reality; BHT: Berliner Hochschule für Technik; ET: endurance training; SET: strength endurance training; PPG: photoplethysmography.

3 Results

This chapter presents the results from the following investigations: the ViRST requirements analysis, ViRST pilot study, and BewARe usability study.

3.1 ViRST requirements analysis

The requirements analysis (Stamm et al., 2020) enabled the identification of requirements for an exergame to be used in multimodal pain management for the target group of older adults with CBP. Table 4 illustrates the results of the analysis with the requirements ranked highest by the stakeholders during the prioritization process. The analysis revealed mandatory requirements for these four dimensions: the overall system, the hardware, the software and the gamification elements. Each dimension consisted of semantic levels, representing the code groups that emerged in the summarizing content analysis.

Dimension	Semantic Level	Highest-ranked requirement
Overall System	Briefing/instruction	The system should offer an individual briefing
	Handling	The system should be easy to handle
	Duration of use	The system should offer breaks between exer- cises
	Safety	The system should be used in a safe place with sufficient space
	Price/financing	The system should be offered for rent
Hardware	N/A	The patients should be able to put on the goggles [VR headset] by themselves
Software	In-game environment	The system should perform an individual calibra- tion (e.g., to detect movement limitations)
	Application of game	The system should enable the therapist to intervene on patients (e.g., pain, anxiety, incorrect execution)
	Exercises	The patients should perform everyday exercises
Gamification/game inte- gration	Display of feedback	The feedback in the system should always rein- force positively, never negatively
	Biofeedback	The exergame is intended to provide the user with behavioral recommendations (e.g., advice on how to relax)
	Progress	The system should display praise and rewards (e.g., text "Hooray", "Congratulations")
	Storytelling	The system should not tell a continuous story

Table 4: Results of the requirements analysis, modified from source: (Stamm et al., 2020)

N/A: Not applicable, as no semantic level was defined due to the small number of quotes for hardware

This overall system consisted of the following semantic levels: briefing/instruction, handling, duration of use, safety and price/financing. The participants considered the physical therapists to be the most important stakeholders in this dimension. Apart from the requirements listed in Table 3, the following requirements regarding the usage time should be emphasized: "*The exercises should last a maximum of 30 min*"; "*The system should offer 15 min of relaxation*" (Stamm et al., 2020). Furthermore, the following was stated about the utilization scenario: "Yeah, that would really have to be under guidance, yeah. [...] *So they* [peers] wouldn't be able to do it alone", CBP patient, female, 80 years (Stamm et al., 2020). The requirement to use the system under personal supervision should be considered for application in the target group of older adults with CBP.

Due to the limited count of requirements regarding hardware, no hierarchical levels were introduced in the prioritization process for this dimension. Thus, this dimension solely encompasses a single level. The participants considered the physical therapists to be primary stakeholders in this context.

The software dimension included the levels: the in-game environment, application of the game and exercises. In the prioritization process for this dimension, physical therapists were also perceived by the participants as the most important stakeholders. The therapists have emphasized that contingencies can occur in the target group, such as severe pain in the back, strongly deviant exercise execution and unexpected reactions to the immersion (anxiety or cybersickness). All of these require interference by the supervising therapist, which must be considered in the software development. "Well, definitely intervene when there's fear, when there's irritation [...] [there] can be a technical problem. [...]", physiotherapist, female, 4 years in the profession (Stamm et al., 2020).

This gamification/game integration dimension was composed of the levels: display of feedback, biofeedback, progress, and storytelling. The participants identified the psychotherapists as the most important stakeholders for this dimension. The psychotherapists emphasized that psychoeducational aspects must be built into the feedback. Psychoeducation is an integral part of cognitive behavioral therapy, which is the basis for many pain management programs. "*Well, education, I think, is of course very, very important in terms of stability of the spine, for example, if there are fears, like: 'that breaks everywhere and [...]"* psychotherapist, female, 24 years in the profession (Stamm et al., 2020). The content analysis of the interviews with the CBP patients (n = 10) and the focus groups with the physiotherapists (n = 3) and psychotherapists (n = 2) identified 104 requirements. The requirements formed the basis for the design of use cases for an exergame prototype in the ViRST project which aimed at developing a user-friendly and adherence-enhancing VR exergame for older adults with chronic low back pain.

3.2 ViRST pilot study

The aim of the ViRST randomized controlled pilot study (Stamm, Dahms, et al., 2022) was to examine the preliminary effects of a VR exergame for older adults with CBP under laboratory conditions. In the following section, the results of the pain intensity progression are presented using a pre-post comparison of the NRS outcomes within the two groups (IG: VR multimodal pain therapy; CG: conventional multimodal pain therapy).

An intention-to-treat analysis was performed with a total of 22 participants. The course of pain intensity was compared for both groups in terms of the mean difference. To calculate this, mean values of the NRS measured before the first session and after the last session of individual treatment were used. Due to the COVID-19 pandemic regulations implemented in March 2020, some participants preempted last session and chose not to risk infection through further intervention appointments. Thus, the IG completed M = 9.18 (SD = 1.47) sessions and the CG finished M = 10.81 (SD = 1.60) sessions over the four-week period.

Stamm, Dahms et al. (2022) found that participants in the CG evaluated their pain intensity before first session with a mean score of M = 2.91 (SD = 2.38, 95% CI [1.31, 4.51]), and after the last session with a mean score of M = 1.64 (SD = 1.50, 95% CI [0.63, 2.65]). This resulted in a decrease in pain with a mean difference of MD = 1.27 (SD = 2.24, Z = -1.79, p = .07, r = .54). Prior to their initial treatment, participants in the IG reported a mean pain intensity rating of M = 3.55 (SD = 2.38, 95% CI [1.95, 5.15]). Following the final treatment, the mean pain intensity for the IG was M = 2.91 (SD = 2.02, 95% CI [1.55, 4.27]). Consequently, the mean reduction in pain intensity within the IG amounted to an MD = 0.64 (SD = 3.29, Z = -0.62, p = .535, r = .19) and was thus not as high as in the CG. The pain reduction in both groups was not significant at the pre-specified significance level of 5% (α = 0.05), even though the CG was noticeably closer to a significant reduction than the IG. However, in both groups, a decline in pain intensity was observed over the

course of four weeks. In order to assess the relationship between the number of sessions completed and the reduction in pain intensity, a Spearman's rank correlation coefficient was calculated. The results showed no significance in both groups (IG: $r_s(9) = -0.154$, p = .550; CG: $r_s(9) = 0.205$, p = .650).

3.3 The usability and User Experience of immersive VR

3.3.1 The usability of exergames in older hypertensive adults

The preliminary study in the BewARe project (Stamm, Vorwerg, et al., 2022) compared the usability of two exergames, which represented two different training types: SET and ET. The participants (older adults with essential hypertension) evaluated the usability of the two exergames with the usability subscale of the Technology Usage Inventory. The results of the usability subscale after the application of SET were M = 16.55 (SD: 3.49), Mdn = 17.00, 95% CI [15.00-18.09] and after ET M = 16.29 (SD: 3.81), Mdn = 18.00, 95% CI [14.55–18.02]. In the absence of a normal distribution, a Wilcoxon signed-rank test was applied and indicated no statistically significant differences between the training types in terms of usability (Z = -0.445, p = .656).

Furthermore, frustration was measured among the other outcomes using the NASA-TLX for both training types in the BewARe usability study (Stamm, Vorwerg, et al., 2022). Participants rated frustration after each training type on average as follows: ET (M= 62.50, SD = 115.99) and SET (M= 3.86, SD = 12.72). Perceived frustration was significantly higher for the ET than the SET (p = 0.038).

3.3.2 User experience in older adults with chronic back pain

Older adults with CBP, who were participants in the IG of the ViRST investigation (n = 11) and thus tested the VR system, rated the user experience after four weeks of intervention with the UEQ (Stamm, Dahms, et al., 2022). To gain a clearer impression of the quality of the tested prototype, the measured data were compared to benchmark data from 20,190 participants across 452 studies on various products (Schrepp, 2023). The system received an "excellent" rating on the attractiveness and perspicuity scales (Figure 1 & Table 5). The efficiency, dependability and stimulation scales were evaluated as

"good", and the novelty of the VR prototype was "above average" compared to the benchmark data.

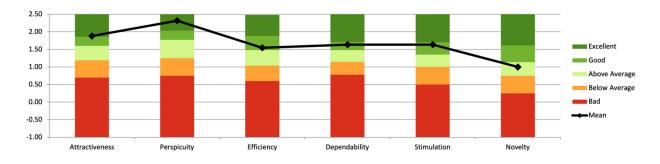


Figure 1: UEQ results of the evaluated ViRST prototype compared to benchmarks (Stamm, Dahms, et al., 2022)

Table 5: User experience questionnaire results for the ViRST study, modified from source: (Stamm, Dahms, et al., 2022)

Scale	Mean (SD)	Comparison to Benchmark	95% CI	Interpretation
Attractiveness	1.88 (0.79)	Excellent	1.42-2.34	In the range of the 10% best results
Perspicuity	2.32 (0.78)	Excellent	1.86-2.78	In the range of the 10% best results
Efficiency	1.55 (0.67)	Good	1.15-2.78	10% of results better, 75% of results worse
Dependability	1.64 (0.85)	Good	1.14-2.14	10% of results better, 75% of results worse
Stimulation	1.64 (1.07)	Good	1.00-2.27	10% of results better, 75% of results worse
Novelty	1.00 (1.24)	Above average	0.27-1.73	25% of results better, 50% of results worse

Evaluated prototype compared to benchmark (Schrepp, 2023) confidence intervals (p = 0.05) per scale

4 Discussion

The underlying dissertation summarized the results from three different investigations: the ViRST requirements analysis (Stamm et al., 2020), ViRST pilot study (Stamm, Dahms, et al., 2022) and BewARe usability study (Stamm, Vorwerg, et al., 2022). With the aim of developing a proof of concept, we investigated whether the use of immersive VR as a rehabilitation intervention in older adults with chronic conditions is feasible and what its potential impact could be.

4.1 Short summary of the results

The requirements analysis determined the specifications through in-depth interviews with older adults with CBP, as well as frameworks for the application of VR in rehabilitation through focus groups with physiotherapists and psychotherapists. The requirements analysis resulted in the identification of 104 requirements that formed the basis for the design of the prototype in the ViRST project. A summarizing content analysis enabled these to be divided into four dimensions: the overall system, the hardware, the software, and the gamification elements.

Based on the requirements analysis, the proof-of-concept prototype was developed in the project and evaluated in the pilot study. To determine the feasibility of the application of HMD-based VR in the rehabilitation, the changes in pain intensity during the application of a four-week multimodal VR pain program were observed in a pilot study. Both the IG and the CG showed a decline in pain intensity on the NRS. However, the decrease was not significant within the groups in either case (IG: MD = 0.64, p = .535 and CG: MD = 1.27, p = .070).

The usability results for older hypertensive adults using two different types of training (strength endurance and endurance training) in immersive VR measured with the TUI usability subscale revealed no significant differences (Z = -0.445, p = .656). However, the hypertensive older adults gave frustration a significantly higher rating in ET than in SET (p = .038) by. In older adults with chronic back pain, user experience was measured

after four weeks of intervention. Compared to the benchmark, two scales were classified as "excellent", three as "good" and one as "above average" in the analysis.

4.2 Interpretation of the results

The results of the ViRST requirements serve to answer the following research question: "what are the requirements for an immersive VR exergame to be used as an adjunct to multimodal pain management in older adults with chronic back pain?". Since the skills and capabilities of older adults differ widely, experts rated the following requirement very highly: "The system should perform an individual calibration" (Stamm et al., 2020). Physical and cognitive impairments must be considered in the development of an immersive exergame for older adults (Eisapour et al., 2018; Szanton et al., 2016). Stanica et al. (2020) evaluated an immersive neurorehabilitation VR system, which captures real-time movements and detects the range of motion degree of the upper and lower extremities. This shows that the use of low-cost consumer devices in combination with VR headsets could be useful for the detection of functional limitations. Accordingly to Seifert et al. (2021), it is important to invest time in educating older adults on the usage of a VR or AR system, as the individual needs and skill levels can be very diverse. In the ViRST requirements analysis, it was also mentioned that an individual briefing is mandatory. Furthermore, the requirements included the following: "The system should be used in a safe place with sufficient space" (Stamm et al., 2020). This alludes to the fact that when utilizing an HMD, the potential fall hazards are not seen by the older adults, who may already be at risk of falling. In addition, cybersickness can also increase the risk of falls when users are wearing the HMD. In this regard, Seifert et al. (2021) also write that the specific conditions of the living environments of older adults should be taken into account and that care staff should be involved in the process of development.

The results of the ViRST pilot study will be used to answer the following research question: "what is the preliminary impact of an immersive VR exergame prototype on the reduction in pain intensity in a four-week multimodal pain management program for older adults with chronic low back pain?". To classify the clinical significance of the results, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) provisional benchmarks can be employed to interpret changes in clinical trial results for chronic pain (Dworkin et al., 2008; Maughan & Lewis, 2010). Pain intensity utilizing the NRS in regard to this benchmark is interpreted as minimally important at a 10%-20% decrease, moderately important at a \geq 30% decrease, and significantly important at a \geq 50% decrease (Dworkin et al., 2008). Within the IG in the ViRST pilot study, a decrease of 18.02% on the NRS was observed, which can be interpreted as minimally clinical important. In contrast, the CG demonstrated a reduction of 43.64%, which corresponds to moderate importance.

Explanations for the smaller decline in pain intensity in the IG than in the CG could include, first, better exercise performance in the CG without a VR headset, and second, the group dynamics that might have contributed to a higher pain decrease in the CG. Further investigations with a higher sample size would be needed to explore this. As reference, a common three-week multidisciplinary pain management program showed an NRS reduction with an MD: 1.44, which is approximately in line with that observed in our CG (Nees et al., 2020). Cognitive behavioral therapy and various relaxation techniques from this approach, such as progressive muscle relaxation (PMR) techniques, which were also used in the prototype by Stamm et al. (2022), were able to lead to a significant reduction in pain intensity (Garcia et al., 2022; Rothbaum et al., 2023). However, there is a lack of evaluations involving the group of older adults with CBP that employ exercise therapy in immersive VR. The results of the work by Stamm, Dahms et al. (2022) provide valuable preliminary insights into the pain intensity reduction utilizing immersive VR exergames, based on which further studies are necessary.

The third research question was: "how do older adults with chronic conditions rate the usability and user experience of immersive exergames in exercise therapy?" To answer this research question, the results of the usability subscale of the TUI, the frustration subscale of the NASA-TLX from the BewARe usability study and the results of the UEQ from the ViRST pilot study will be considered. Developing user-friendly VR exergames was the goal of both projects, as this is fundamental to enable older adults with chronic conditions to achieve a higher level of motivation and, consequently, exercise adherence. Since the usability subscale of the TUI consists of three items, the scale sum value lies between 3 and 21 according to the manual (Kothgassner et al., 2013). High values on the scales in the TUI indicate a high expression of the construct, in this case, a high level of usability. Compared with the reference group of individuals over 65 years of age from the TUI evaluation (Kothgassner et al., 2013), who received a VR scenario from a coffee house as stimulation, the usability was rated better in both exergames (M = 14.06, n = 51). The

significantly higher frustration in NASA-TLX can be explained by the qualitative data of Buchem et al. (2021), which were obtained in the same investigation. Technical difficulties, such as when the headset lost tracking, which resulted in a black screen caused by the truck moving too strongly, occurred more in the ET. Due to the movements in the room in the ET, such as dancing, the loss of the tracking appeared more often, which was mentioned negatively and could lead to higher frustration. Furthermore, some participants perceived the sequence of dance steps as too complicated. This may also have increased their frustration.

The UEQ measures the attractiveness, which is a valence dimension and is divided into two quality aspects: 1. pragmatic quality with the perspicuity, efficiency, and dependability scales, and 2. hedonic quality with the stimulation and novelty scales (Schrepp, 2023). After four weeks of use, the older adults with chronic back pain rated the pragmatic quality in two subscales as good and in one as excellent, while the hedonic quality was rated in the subscales as good and above average. A possible explanation as to why the novelty was only rated above average can be found in the exercises, which are in general very familiar to anyone with chronic back pain. Thus, it can be assumed that it was not the technology that was assessed, but the exercises. Lorenz et al. (2023) compared a younger group (M = 23.9 years) with an older one (M = 53.4 years) with the UEQ following the use of a cave automatic virtual environment (CAVE). The UEQ showed higher results for the older group. However, the usability was lower in that age group compared with the younger one. The authors suggest that there is a relationship with novelty, which is inconsistent with the ratings from the ViRST pilot study, which demonstrated low novelty. Tuena et al. (2020) recommend in their systematic review on the usability of VR in older adults that more works should focus on immersive VR, as mainly non-immersive or semiimmersive systems have been tested in research and new forms of VR and price reductions can be expected.

4.3 Embedding the results into the current state of research

The ViRST requirements analysis led to the identification of 104 requirements, which were included in the supplementary files of the publication and are available to the wider public. To our knowledge, this is the first elicitation of requirements for an immersive VR exergame with a group of older adults with chronic back pain. By employing a VR user

experience demo, we were able to build a common understanding of the technology's use among older adults and conduct in-depth interviews. Birckhead et al. (2019) identified methodological recommendations for VR clinical trials in healthcare with a group of experts. They recommend conducting individual interviews with patients to learn more about their needs, concerns, and expectations, as well as focus groups with relevant experts, which we did in the ViRST project in the same manner. Similarly, based on their lessons learned from the user-centered design of serious games for older adults, Brox et al. (2017) suggest that semi-structured interviews represent one of the most important user-centered design methods. This requirement was the basis for the design of the prototype in the ViRST project and can also be the basis for others who are planning to develop a design for this specific target group.

The ViRST pilot trial evaluated an immersive VR prototype based on a multimodal approach for older adults with CBP. The multimodality involved, on the one hand, a physiotherapeutic approach with active exercise therapy, and on the other a psychotherapeutic one with progressive muscle relaxation and psychoeducation. The investigation expands upon several key findings from previous research. The decrease of pain intensity in chronic low back pain using cognitive behavioral therapy techniques in immersive VR has already been demonstrated (Garcia et al., 2021; Rothbaum et al., 2023). However, limited exceptions could be found utilizing active exercise therapy for pain reduction through immersive VR (Hennessy et al., 2020; Tuck et al., 2022). Most prior works employed relaxation procedures (Darnall et al., 2020) or distraction techniques (Hoffman et al., 2019). In their feasibility study, Tuck et al. (2022) showed that adults with chronic pain who played commercially available active VR games exhibited more enhancements in activity levels and pain intensity. They also expressed higher levels of satisfaction with their treatment compared to both the waitlist and the conventional treatment groups.

A systematic review with a meta-analysis by Mo et al. (2023) examined the impact of exergaming on musculoskeletal pain in older adults. However, this publication mainly used exergames that did not utilize immersive VR. The two exceptions are the papers cited in this dissertation by Stamm et al. (Stamm et al., 2020; Stamm, Dahms, et al., 2022) and Beltran-Alacreu et al. (2022), which implemented immersive VR with older adults with chronic neck pain and also demonstrated results in favor of the control group. This sys-

tematic review indicates that the quality of the available evidence on the effects of exergaming on pain in older adults is considered low, and the analyses featured had small sample sizes. The conducted ViRST evaluation was a pilot study with the main objective of investigating whether it is feasible to conduct a larger randomized controlled trial applying multimodal pain management in VR. As it is not designed to assess the effectiveness of a particular intervention, the preliminary results must be interpreted with caution. The descriptive results are relevant for further examinations, e.g., to calculate the sample size. In their systematic review of immersive VR as physical therapy in older adults, Campo-Prieto et al. (2021) noted that research in this area is still at an early stage. Similarly, our outcomes are in line with those of feasibility evaluations.

Our investigations in the BewARe and ViRST projects contribute to the understanding of the usability and user experience of immersive exergames that use active exercise therapy in older adults with chronic conditions. Consistent with previous works, the usability of immersive VR was rated high by participants with chronic conditions (Garcia et al., 2021). Kim et al. (2020) confirmed in their systematic review on user experience evaluations of VR systems that most focused on non-elderly participants. Most notable in our findings is the investigation of the usability of exergames in the context of different types of training, as this has not yet been considered in the literature. The results demonstrating similar usability in the endurance and strength endurance training enable utilizing the training types in a future combined exercise program. Tuena et al. (2020) stated in their systematic review that non-HMD systems are generally regarded as more suitable for older adults. Moreover, a study by Plechatá et al. (2019) indicated that the user experiences did not differ between immersive and non-immersive VR in memory assessments of older adults. Our usability and user experience results indicate high scores and would need to be evaluated in direct comparison with a CAVE system to make a statement regarding the favored immersive VR system in older adults. The future will show whether larger studies, such as the one planned by Slatman et al. (2023), will demonstrate the effectiveness and applicability of physical therapy VR treatments.

4.4 Strengths and weaknesses of the studies

The strength of the ViRST requirements analysis is the incorporation of older adults in the development of an innovative rehabilitation intervention. It is often younger potential user groups that are assessed regarding the requirements for technical solutions. Furthermore, chronic back pain is often associated with 50-year-old sedentary office workers, whereas our study was able to capture the needs and desires for a technical solution for older adults over 65 years. One limitation was that the included older adults had no prior experience with VR, which in some cases resulted in a low level of understanding of the technology being used. To address this, an exergame user experience prototype was tested with all the interviewees. Due to the short duration of the project and the limited resources, no inter-rater reliability between the investigators performing the analysis was calculated. This also explains the small and imbalanced number of experts, as two focus groups were conducted with three physiotherapists and two psychotherapists, who were already very difficult to recruit. The results should be interpreted with caution, as they may not be generalizable to the very heterogeneous age group of 65 and older due to the small sample size. Nevertheless, an initial theoretical saturation could be achieved from the sample.

There were also notable strengths and certain limitations in the ViRST pilot evaluation of the functional prototype developed from the requirements. In contrast to many other works in which an exergame was played over a short period of time, the pilot study involved numerous treatment sessions over a period of four weeks and was thus comparable in length to a real multimodal pain management program. However, a primary limitation regarding the generalizability of the investigation is the relatively small sample size. With a sample size this narrow, the statistical power of the analysis is limited. The risk of producing a type II error is increased. However, each individual could be carefully tested, and the analysis benefited from comprehensive data on all of the participants. The inclusion and exclusion criteria made it possible to precisely study a group of older adults with chronic back pain.

A further limitation was the imbalance in the sex distribution in the samples, even though it was not significantly divergent. Due to the outbreak of the COVID-19 pandemic at the end of the evaluation in March 2020, several participants in the IG no longer took up the workout offer because of a fear of contagion. This may also have influenced the perception of pain in the IG in some participants. In addition, in the evaluation, group therapy was used in the CG and individual therapy in the IG. This is also a limitation in the comparability of the examinations and should be considered more closely in the future. Thus, conservative individual and group therapy could be examined against those types in VR. Furthermore, the user experience was only measured in the IG. A comparison with the assessment of the conservative intervention in the CG would be better than to a benchmark, as otherwise this absence poses a potential threat to the internal validity of the user experience outcome. It should be emphasized that the aim of the pilot study was to produce a proof of concept and not clinical trial efficacy. This work serves as a valuable preliminary exploration of the topic. It provides a foundation for additional, more extensive research that can build upon the findings.

The preliminary "BewARe usability study" also had certain strengths and weaknesses. A major strength was the uniqueness of the setup. The investigation took place in a living lab, which was a VR/AR laboratory in a truck. Similarly original was the use of a VR headset for the replication of the real world in VR to test the preliminary usability of an MR application. Another strength was the target group of older adults with hypertension, who have hardly been investigated in VR research. However, one weakness was the lack of a control group. Even though two groups are compared in this work, the comparison to a group that does not use simulated MR is missing. In light of the COVID-19 pandemic, the evaluation encountered challenges in achieving the predetermined sample size of 34. In addition, a major limitation was the non-randomization of the groups. Nevertheless, the same order was followed for each participant: VR SET in the first week and VR ET in the second week. Technical defects are unavoidable in such a functional prototype. These rarely occurred, although they may have affected usability when they did happen. In this work, the potential influence of cybersickness on usability was not discussed, the results on cybersickness with the same cohort were also collected and have already been published: (Stamm & Vorwerg, 2021). The generalizability of the outcomes to all stages of hypertension is not possible because this work included older people with stage I hypertension. However, the results are valuable, as to our knowledge the usability of this potential VR user group has not yet been investigated.

4.5 Implications for future research

There is still a long way to go before exergames with head-mounted display-based immersion can be used in a clinical rehabilitation setting for older adults with chronic conditions. The findings of the presented investigations have several practical implications and Discussion

suggest directions for future research. Older adults are rarely included in the technology development process. The iterative user-centered design process in the described projects, which began with a requirements analysis and ended with a preliminary efficacy study, shows that involving older adults in the development can lead to a high user experience for them. For the design of future exergames, it is advisable to have a larger and balanced number of experts for the framework during the requirements elicitation, since they also represent the users as possible future supervisors. The analyses have demonstrated where the weak points of our prototypes were.

For further evaluations with the prototypes, the individualization of the range of motion must be considered. Developing a one-size-fits-all exergame is challenging due to the different sizes of the participants, but it is urgently necessary when it comes to movement restrictions that often occur in older adults. Ensuring inclusivity in game design and providing adaptive technology is crucial. In the future, testing in a mobile living lab can facilitate the recruitment of large numbers of subjects and make it easier for older adults to participate by not having to travel to the research site. However, the exergames must be tested extensively in advance and adapted so that such a mobile lab does not limit the user experience due to technical difficulties. The ViRST pilot study provides a basis for designing an investigation with a larger sample size. To examine the effectiveness of immersive VR exergames in older adults with chronic back pain, larger-scale versions are needed. Even though the blinding of assessors in rehabilitation examinations is difficult, this should be attempted in the future by, e.g., the addition of a non-immersive VR placebo application. This could simultaneously serve as a control when evaluating usability or user experience, thus increasing the internal validity. In additional analyses, the crucial parameters of motivation and adherence should also be evaluated. For safety reasons, we would recommend only supervised active exercises with a specialist, e.g., a physiotherapist, when using immersive exergames with older adults with chronic conditions.

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5. Conclusions

In conclusion, this dissertation aimed to investigate the feasibility of the use of immersive VR as a rehabilitation intervention in older adults with chronic conditions and its potential impact. Considering the high prevalence of chronic conditions among older adults in the increasingly aging German society and the struggle of this age group regarding long-term adherence to physical activity guidelines, immersive exergaming could be a potentially useful tool.

These analyses have contributed to the preliminary investigation of two specific groups that have not been previously evaluated with this technology in this form. Older adults with chronic back pain and with essential hypertension were assessed while undertaking active exercise therapy in immersive VR. The findings provide valuable insights and have implications for future studies.

Our requirements analysis determined 104 requirements for the design of the ViRST prototype used in the later pilot study. The pilot project evaluated a multimodal VR therapy in a laboratory setting over four weeks. However, the pain intensity decrease was not significant within the groups in the pre-post comparison. The results of the intervention group suggest that pain reduction in older adults can be interpreted as minimally clinical important. The user experience was predominantly rated as good or excellent by the older adults with chronic back pain after the four weeks of intervention. The usability outcomes reported by hypertensive older adults showed no significant differences in the use of strength endurance and endurance training in immersive simulated MR. However, frustration during immersive intervention was rated significantly higher by the hypertensive older adults in endurance training in the living lab and to the sequence of dance steps, which was perceived as too complicated by some participants.

To investigate the effectiveness of immersive VR exergames in older adults with chronic back pain, investigations with higher sample sizes are needed. The ViRST pilot study provides a basis for designing a larger-scale version. The usability and user experience indicated that evaluations using active exercise therapy in immersive VR with older adults with chronic conditions would be feasible. The application of head-mounted display-

based exergames as a rehabilitation intervention is a promising way to promote physical activity in older adults with chronic conditions. The effectiveness of the application is uncertain at this point and needs to be further examined in the future.

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Statutory Declaration

"I, Oskar, Stamm, by personally signing this document in lieu of an oath, hereby affirm that I prepared the submitted dissertation on the topic: The Application of Exergames Using Head-mounted Display-based Immersion as a Rehabilitation Intervention in Older Adults with Chronic Conditions (German: Die Anwendung von Exergames mittels Head-Mounted-Display-basierter Immersion als Rehabilitationsintervention bei älteren Erwachsenen mit chronischen Erkrankungen), independently and without the support of third parties, and that I used no other sources and aids than those stated.

All parts which are based on the publications or presentations of other authors, either in letter or in spirit, are specified as such in accordance with the citing guidelines. The sections on methodology (in particular regarding practical work, laboratory regulations, statistical processing) and results (in particular regarding figures, charts and tables) are exclusively my responsibility.

Furthermore, I declare that I have correctly marked all of the data, the analyses, and the conclusions generated from data obtained in collaboration with other persons, and that I have correctly marked my own contribution and the contributions of other persons (cf. declaration of contribution). I have correctly marked all texts or parts of texts that were generated in collaboration with other persons.

My contributions to any publications to this dissertation correspond to those stated in the below joint declaration made together with the supervisor. All publications created within the scope of the dissertation comply with the guidelines of the ICMJE (International Committee of Medical Journal Editors; http://www.icmje.org) on authorship. In addition, I declare that I shall comply with the regulations of Charité – Universitätsmedizin Berlin on ensuring good scientific practice.

I declare that I have not yet submitted this dissertation in identical or similar form to another Faculty.

The significance of this statutory declaration and the consequences of a false statutory declaration under criminal law (Sections 156, 161 of the German Criminal Code) are known to me."

Date

Signature

Declaration of your own contribution to the publications

Publication 1: Oskar Stamm, Rebecca Dahms, Norbert Reithinger, Aaron Ruß, Ursula Müller-Werdan, Virtual reality exergame for supplementing multimodal pain therapy in older adults with chronic back pain: A randomized controlled pilot study, Virtual Reality, 2022

Contribution by Oskar Stamm:			
Study planning	Conception and planning of the study design, development of the research questions and the study documents. As prin- cipal investigator, obtaining the ethics approval, consulting the CTO, creating the data protection concept and register- ing the study with the DRKS.		
Study execution	Recruitment, screening, informing participants and obtaining informed consent, conducting the study, data collection		
Analysis	Data entry, preparation, control and analysis in SPSS and R		
Publication	Stamm conceived, designed and wrote the entire manu- script as first author, conducted the literature search, cre- ated all figures and tables, submitted the manuscript to the journal, revised it as part of the review process		

Publication 2: Oskar Stamm, Rebecca Dahms, Ursula Müller-Werdan, Virtual reality in pain therapy: A requirements analysis for older adults with chronic back pain, Journal of NeuroEngineering and Rehabilitation, 2020

Contribution by Oskar Stamm:				
Study planning	Conception and planning of the study design, development of the research questions. The study documents were cre- ated together in the study team. Significant contribution to the preparation of the application documents for the ethics committee, consulting the CTO, creating the data privacy concept and registering the study with the DRKS.			
Study execution	Recruitment, screening, informing participants and obtaining informed consent, conducting the study, data collection			
Analysis	Entry, preparation, control and analysis of data. Stamm eval- uated the qualitative data in the study team using ATLAS.ti and evaluated the quantitative data independently in SPSS			
Publication	Stamm conceived, designed and wrote the entire manu- script as first author except for part of the discussion, con- ducted the literature search, created all figures and tables, submitted the manuscript to the journal, revised it as part of the review process			

Publication 3: Oskar Stamm, Susan Vorwerg, Michele Haink, Kristian Hildebrand, Ilona Buchem, Usability and Acceptance of Exergames Using Different Types of Training among Older Hypertensive Patients in a Simulated Mixed Reality, Applied Sciences, 2022

Contribution by Oskar Stamm:				
Study planning	Stamm designed the study together with the co-author Su- san Vorwerg, he independently developed the questions and the study documents for the usability assessments. He con- tributed to the following: Significant contribution to the prep- aration of the application documents for the ethics commit- tee, consulting the CTO, creating the data privacy concept and registering the study with the DRKS			
Study execution	Recruitment, screening, informing participants and obtaining informed consent, conducting the study, data collection was carried out by Stamm and the study team			
Analysis	Entry, preparation, control and analysis of data. Stamm eval- uated the data in SPSS.			
Publication	Stamm conceived, designed and wrote the entire manu- script as first author, conducted the literature search, cre- ated all figures and tables, submitted the manuscript to the journal, revised it as part of the review process			

Signature, date and stamp of first supervising university professor

Signature of doctoral candidate

Excerpt from Journal Summary List

Publication 1: Oskar Stamm, Rebecca Dahms, Norbert Reithinger, Aaron Ruß, Ursula Müller-Werdan, Virtual reality exergame for supplementing multimodal pain therapy in older adults with chronic back pain: A randomized controlled pilot study, Virtual Reality, 2022 (Impact Factor: 4.20)

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Publication 2: Oskar Stamm, Rebecca Dahms, Ursula Müller-Werdan, Virtual reality in pain therapy: A requirements analysis for older adults with chronic back pain, Journal of NeuroEngineering and Rehabilitation, 2020 (Impact Factor: 4.26)

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Publication 3: Oskar Stamm, Susan Vorwerg., Michele Haink., Kristian Hildebrand, Ilona Buchem, Usability and Acceptance of Exergames Using Different Types of Training among Older Hypertensive Patients in a Simulated Mixed Reality, Applied Sciences, 2022 (Impact Factor: 2.70)

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RESEARCH



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Virtual reality in pain therapy: a requirements analysis for older adults with chronic back pain

Oskar Stamm^{*}[®], Rebecca Dahms and Ursula Müller-Werdan

Abstract

Background: Today immersive environments such as Virtual Reality (VR) offer new opportunities for serious gaming in exercise therapy and psychoeducation. Chronic back pain (CBP) patients could benefit from exergames in VR. The requirements in older CBP patients for a VR pain therapy have not yet been determined in studies. The aim of the study was to perform a requirements analysis for the user group of geriatric patients with CBP for a VR exergame. The objective was to find out the expectations, desires, preferences and barriers in order to collect them as requirements for this vulnerable group and to determine frameworks of therapy by physiotherapists and psychotherapists.

Methods: We conducted a requirements analysis through semi-structured interviews with 10 elderly participants with CBP. Furthermore, two focus groups were conducted with three physiotherapists and two psychotherapists to determine frameworks of therapy programs for the target group. The qualitative data were transcribed and examined through a structuring content analysis. Subsequently, the results of the analysis were prioritized by all participants of the study.

Results: The results of the requirements analysis indicate mandatory requirements for the overall system, hardware, software and gamification elements. The key requirements were target-group-specific applications of the VR exergame through e.g. individual briefing, user-friendly handling, inclusion of movement limitations, presentation of everyday scenarios in combination with biofeedback, age-appropriate feedback through praise and awards and a maximum exercise duration of 30 min and 15 min of relaxation.

Conclusion: It should be possible to use the determined requirements productively to create user-friendly VR exergames that motivate elderly chronic back pain patients to perform exercises regularly.

Trial registration: The study is registered in the German Clinical Trials Register (DRKS-ID: DRKS00015294 12.10.2018).

Keywords: Chronic Back pain, Virtual reality treatment program, Exergame, Geriatrics, Physiotherapy, Psychotherapy

* Correspondence: oskar.stamm@charite.de Geriatrics Research Group - Age and Technology Charité -Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Reinickendorfer Strasse 61, 13347 Berlin, Germany



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Introduction

Background

Back pain is the most common musculoskeletal condition and a major health problem. Back pain can be acute, when it lasts for less than 4 weeks, or subacute, when the pain lasts between 4 weeks and 3 months. If the pain persists for more than 12 to 24 weeks, a chronic course is assumed [1]. Although back pain is often considered a job-related condition, it is also a major disabling health condition among older adults. More than 50% of Europeans over the age of 75 suffer from moderate to severe pain [2]. In Germany the highest prevalence of chronic back pain (CBP) in women and men is in the age group over 70 years old [3].

CBP has a multifactorial etiology and patients have often kinesiophobia, fear avoidance beliefs and passive coping strategies, which can lead to illness behavior and physical disability [4]. Since psychosocial factors in particular are crucial for a chronic development of back pain, it is important to include the patients' beliefs and coping strategies in addition to the physical treatment. Readjusting the developed beliefs by learning new strategies leads to a change of behavior and to psychological changes. Therefore, CBP is often treated by multimodal pain therapy, usually consisting of medical, physiotherapeutic, physical and psychotherapeutic pain therapy. Several studies have shown that multimodal pain therapy has greater effectiveness than conventional treatment e.g. for improving pain intensity and increasing physical function [5].

One of the most important factors for the treatment of CBP is the adherence to regularly performed home exercises. An effective therapy requires a high degree of initiative by the patients, which can be an obstacle for many. Studies in physiotherapy indicate that patients who did not adhere to exercises had less treatment effect [6-8]. In the course of multimodal pain therapy, the patient learns exercises helping him or her to reduce pain even after completion of the therapy. However, home exercises are too rarely performed by the patients. Slujis et al. [9], showed that only 35% of the instructed subjects (N = 1178) performed exercises at home. Similar results were shown by Göhner et al. [10]. So-called exergames, which are games that combine exercises and gameplay could decrease the non-adherence for prescribed home exercises and motivate patient to a long-term use with a higher training frequency. Thus, gamification elements can be used specifically as encouragement in a targeted manner for patients. First studies in this field indicated that a specially developed Nintendo Wii exergame could be a biopsychosocial intervention for chronic low back pain [11, 12]. Furthermore, the Microsoft Kinect was utilized in a study [13], which compared a group receiving an exergame treatment with a conventional treatment

group. The study showed a significant improvement in muscle strength in the subjects of the exergame group in contrast to the conventional training group.

Immersive environments such as Virtual Reality (VR) nowadays offer new opportunities for serious gaming in exercise therapy. The most popular VR game of the year 2019 according to Steam's Top Sellers List as measured by gross revenue was the rhythm game Beat Saber, which was the only VR title on the list. Kivelä et al. showed that VR games can be played as physical work out. In their study it was shown that the heart rate increases by playing Beat Saber [14]. Laver et al. [15] displayed in their systematic review about VR for stroke rehabilitation, that VR may be beneficial in improving upper limb function and activities of daily living function when used as an adjunct to usual care. Jones et al. [16] showed the impact of a low-motion VR game application on chronic pain. The pain of the participants in this study was reduced after the VR treatment by 33%. Tashjian et al. [17] indicated similar results in their study comparing 3D VR and a 2D video for the purposes of pain reduction, finding that the pain reduction was greater in the VR cohort than in the control group. These results show that VR can be utilized for pain management. Appel et al. demonstrated that it is feasible and safe to expose older adults with various levels of cognitive and physical impairments to immersive VR [18]. However, there are hardly any studies or applications on the market offering a VR active exercise therapy and psychotherapeutic pain therapy beyond the pure VR pain distraction applications. Furthermore, there are no studies investigating an active VR exergame with an HMD for older chronic back pain patients. The review of Skjæret [19], which included 60 exergame studies, revealed that the Nintendo Wii console was the most frequently used console in exergame studies and measures of balance were the most frequently used outcome measures (e.g. [20-22]). In order to secure an effective long-term therapy for chronic back pain patients, a multimodal approach in the VR is necessary in the future.

Within the scope of the ViRST project, we plan not only to determine measurements for various physiological outcomes, but also offer psychological exercises and behavioral recommendations to manage fear avoidance beliefs or poor stress management during the back pain treatment training. In this context, the aim of our study was to explore the question: what are the requirements for an exergame, which could be used to supplement the multimodal pain therapy to increase the adherence of CBP patients. Therefore, we wanted to find out the expectations, desires, preferences and barriers of the patients on one hand and determine frameworks of therapy by physiotherapists and psychotherapists on the other hand.

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Methods

General

The target group of geriatric patients often has difficulties accessing existing technology, which can lead to the exclusion of this vulnerable group from some technologies. For this reason, a user-centered design is indispensable for older chronic back pain patients. In order to create user-friendly, adaptive, personalized system that is tailored to the target group, we conducted a requirements analysis as a first step.

The study had an explorative, qualitative approach. In addition, quantitative assessments were only used for gathering baseline data from the CBP. The study consisted of two focus group interviews with three physiotherapists and with two psychotherapists and semi-structured interviews with 10 geriatric CBP patients. The purpose was to find out the expectations, desires, preferences and barriers of this vulnerable group and the experts. The study protocol was approved by the ethics committee and data protection committee of the Charité. All participants gave their written informed consent to take part in the interviews.

Procedure

Interviews with older CBP patients

The purpose of first part of the qualitative study was to assess the requirements of a VR exergame for geriatric patients with CBP. The sample (n = 10) consisted of older adults over 65 years with diagnosed chronic back pain. Interested persons were first informed about the study in a telephone call and then, if accepted, asked about inclusion and exclusion criteria in a screening. After initial screening and formal inclusion, the participants completed an informed consent form, the SF-12 Health Survey (Short Form 12 German translation) and the chronic pain grade questionnaire (CPGQ). Subsequently semi-structured interviews were conducted in order to investigate the requirements of the seniors. The semi-structured interview guideline created by the Geriatrics Research Group included the following main content categories:

- sports and gymnastics practiced in the past and today,
- sport as social participation,
- · problems and difficulties in activities of daily life,
- strategies for dealing with pain,
- game experiences and preferences (traditional and digital games),
- hardware and software requirements for a VR exergame
- · requirements for motivational elements.

The interviews with the CBP patients lasted 40–60 min and were divided into three parts; a first part for personal requirements, a second in which the subjects tested a user experience demo in a VR environment, and a third concerning the requirements for a VR pain therapy system. Afterwards the interviews were transcribed and analyzed. The Ethics Committee of the Charité approved the study protocol (no. of approval: EA4/055/18).

Focus group

The second part of the qualitative study included two focus groups. The intention was to gather framework data and requirements from physiotherapists (n = 3) and psychotherapists (n = 2) who have expertise in older CBP patients. The partly standardized focus group interviews were carried out with guidelines, which included questions on pain management experiences and games applications in therapy. The first part of the guidelines included the following sub-topics:

- Experience in the treatment of chronic pain patients,
- adherence of patients (physiotherapists) /
- overcoming the fear-avoidance behavior (psychotherapists),
- acceptance and experience with game applications in pain therapy.

Subsequently, a short film sequence about Virtual Reality Therapy was presented to show already existing concepts. The second part of the guidelines included questions about requirements for a VR therapy system with the following sub-topics:

- Software (patient's UI), software (therapist's UI),
- hardware,
- and communication with therapists / forwarding of data.

The survey in the focus groups lasted 1-1.5 h.

Materials

Assessments

The SF-12 Health Survey tested on older adults was found to be reliable and valid [23]. Likewise, the chronic pain grade questionnaire is a valid and reliable tool. The internal consistency shown with Cronbach's alpha = 0.74 for chronic back pain was determined by Korff et al. [24]. The study of Penny et al. [25] had shown a relationship between the CPGQ score and the Short Form 36 Health Survey (SF-36). The results of the study confirm that a higher chronic pain grade is associated with poorer health in all aspects such as poorer physical, psychological, and social health, which supports a multimodal pain management approach.

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VR headset

During the task-based part of the semi-structured interviews the seniors and experts tested two applications on the Dell Visor VR118 Headset. This headset has a 105-degree horizontal field of view and a display rate up to 90 Hz. This VR headset was chosen because of the two high-resolution displays at 1440 × 1440, so that the testing group was not exposed to cyber sickness.

VR apps

In order to create a common understanding for VR in the sample of seniors an exergame user experience prototype was used (Fig. 1). In the prototype, the player stands on a platform on a lake and has to collect pink coins. These appear for a short time around the player. The player's straight posture is determined by the headset height at the beginning of the application, and subsequent malposition of the back turns the player's surroundings from a colorful landscape to black and white one. The software prototype did not contain any other gamification aspects, e.g. a story, in order not to influence the user's requirements on this topic.

The second application was the HoloTour by Microsoft Corporation. The aim was that the player experiences the feeling of immersion in a realistic-looking virtual space.



Data analysis

The interviews with the seniors were recorded and subsequently transcribed using the transcription software f4. A summarizing content analysis by Mayring (Mayring 2015) was applied for the data analysis. As an analyzing tool, we used the qualitative data analysis software Atlas.ti 8. The structuring content analysis contains paraphrasing, generalization to abstraction level and reduction. The transcripts were coded manually according to specially drafted coding rules. The coding was carried out by two scientists, using the four-eyes principle to ensure reliable coding. The coding and analysis were controlled reciprocally. A total of 130 codes were assigned and 1329 quotations were classified as relevant.

Participants

Chronic back pain patients

Ten participants with CBP were included in the semistructured interviews. One subject had to be excluded from the study. The inclusion criteria were:

- Geriatric patients with chronic back pain longer than 6 months
- ≥ 65 years
- No cognitive impairments
- Independent mobility
- Able to perform exercises actively
- No spinal malignancies, spondylitis and spondylodiscitis, fibromyalgia
- No disc surgery in his or her medical history
- No strong vestibular disturbances that affect balance ability

The exclusion criteria were defined as:

- Patients with chronic back pain shorter than 6 months
- < 65 years
- Cognitive impairments
- · Immobility or mobility only possible with help
- Sensory and / or motor impairments
- Unable to do exercises actively
- Spinal malignancies, spondylitis and spondylodiscitis, fibromyalgia
- Disc surgery in his or her medical history
- Strong vestibular disturbances that affect balance ability

On average the CBP patients were 75.9 years (SD 6.9) old. Seven participants of the sample had a low disability and a low intensity of pain, corresponding to Grade I in Von Korff's chronic pain scale [24]. The pain severity of one participant was classified as Grade II, which means: low disability and high intensity. Two participants had a

high disability, which is moderately limiting and corresponds to Grade III. None of the probands' pain was classified as Grade IV with a high disability, which is severely limiting. All participants had back pain for more than 6 months and were able to perform exercises actively. None of the subjects had cognitive limitations or severe balance limitations. The subjects had in the Short Form (12) Health Survey, which is a shorter version of the SF-36, a mean mental health score of 53 (SD 8.0) and a physical health score of 37 (SD 10.7) on a scale from 0 to 100. Both mean values of the SF-12 are slightly higher than the comparative values of patients with lumbar back pain (mental health: 47.3 and physical health: 35.1) [26]. In a questionnaire for the subjective evaluation of technology use, the majority of subjects (n = 6)stated that they frequently use their technology devices. All subjects stated that they use a telephone and a radio. As VR still requires a PC or at least a smartphone, the question of PC and smartphone usage has been an important clue to starting conditions in the sample. Eight subjects stated that they use a PC and six that they use a smartphone.

Experts

As physiotherapists and psychotherapists are an important part of multimodal treatment teams, they have been included as experts concerning the requirements of a potential VR exergame. The inclusion criteria were:

- Experience in the treatment of chronic back pain patients
- at least 3 years professional experience with back pain patients
- Currently working as physiotherapist or psychotherapist

Two focus group interviews were conducted, one with three physiotherapists and one with two psychotherapists. Among the physiotherapists, two of the participants are employed in a geriatric rehabilitation clinic and one in a physiotherapy center. The professional experience among the physiotherapists was between 4 and 10 years. The second focus group was attended by two psychotherapists, one of whom works in a clinic with focus on acute geriatric medicine and one who owns a psychotherapy practice. The professional experience of the participants was 6.5 and 14 years.

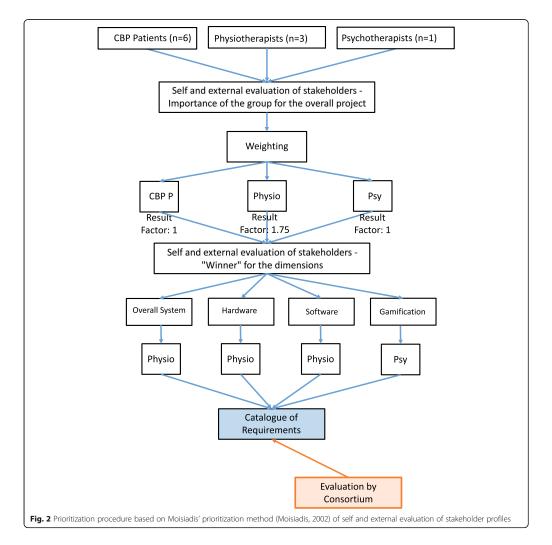
Prioritization of the requirements

The requirements analysis summarizes the requirements determined in a catalogue, which is the basis for the conception of the joint project and the further structuring of the VR training program. In order to create a common understanding among the stakeholders about the importance of the requirements, a prioritization was carried out. Following the content analysis, the reduced requirements of the semi-structured interviews and the focus groups were prioritized by six CBP patients, three physiotherapists and one psychotherapist. The prioritization procedure (Fig. 2) was based on Moisiadis' prioritization method (Moisiadis, 2002). The prioritization aimed at a self-prioritization and external prioritization of the requirements by various stakeholders. Rankings of 1 to 3 were used to determine the rankings of the three stakeholders (1 = CBP patients, 2 = physiotherapists, 3 = psychotherapists) for the overall project and for each of the four dimensions (overall system, hardware, software, gamification). A weighting for the requirements was calculated from the rankings for the overall project. The requirements in the four dimensions were also ranked according to their subjective importance and calculated with the weighted stakeholder factor. Within the stakeholder groups, mean values were used to determine the average stakeholder ranking for the requirements, resulting in a ranking of the requirements per stakeholder that could be compared between the stakeholders. The stakeholder rankings in the dimensions made it possible to determine a "winner stakeholder" for each dimension. The requirements of these stakeholders were subsequently included in the catalog of requirements for each dimension and evaluated again by the consortium using the MoSCoW prioritizations [27] according to the project relevance.

Weighting of the requirements

In order to evaluate the importance of the opinion of the expert groups involved (CBP patients, physiotherapists, psychotherapists) for the overall project, the stakeholders were rated. Profile models similar to Moisiadis' prioritization method were created for the stakeholders. As part of the prioritization process, the stakeholders were assessed by the participants using subjective and objective ratings. All participants were involved in advance in the interviews to determine the requirements. The rankings were subsequently decoded, with 3rd place receiving 0 points, 2nd place 50 points and 1st place 100 points. Afterwards a weighting was calculated from the mean values of the scores. The evaluation showed that the physiotherapists achieved 1st place and the psychotherapists and CBP patients achieved 2nd place together. The physiotherapists received a 1.75 times higher rating than both other stakeholders, which resulted in a factor of 1.75 for further rating of the four dimensions. The further dimensions, which were ranked on a weighted basis in addition to the overall project, were: overall system, hardware, software and gamification. The categories will be presented in the following.

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Results

In the following, the results for the identified dimensions from the summarizing content analysis of the interviews with the CBP patients and the focus groups with the physiotherapists and psychotherapists will be presented. The dimensions consist of semantic levels, which resulted from the clustering of the content analysis and represent the code groups that emerged. Each level consists of the requirements that were gathered from interviews with all stakeholders. After decoding of the requirements rankings (transformation of rankings into percentiles) we were able to calculate average values within the stakeholder groups for the requirements. The rating of each stakeholder's opinion for each dimension made it possible to identify a "winning stakeholder". Each semantic level of the dimensions is presented in the following by the requirements that were prioritized as the most important.

Overall system

This dimension consists of the following levels: *briefing/ instruction, handling, duration of use, safety and price//financing.* In the dimension *overall system,* the participants identified the physiotherapists as the most important stakeholder. The psychotherapists were ranked 2nd and the CBP patients 3rd. The ranking of the requirements of physiotherapists were taken over for this dimension.

The physiotherapists considered the requirement: **The** system should offer an individual briefing as the most important requirement in the semantic level *briefing/in-struction*. There are several ways that the system could be made usable for geriatric chronic back pain patients. The system should offer a demo (tutorial) for correct operation was prioritized as the second most important requirement. The briefing should be carried out by personal assistance was prioritized with rank three. Both of these requirements are possible solutions for an individual briefing.

On the level of *handling* the most important requirement was: **The system should be easy to handle.** For some subjects the demo in the task-based part was already too difficult to use. "Yeah, that would really have to be under guidance, yeah. [...] So they [peers] wouldn't be able to do it alone" (CBP patient). This underlines the importance of the user-centered design, which is applied in the project through usability evaluations with the purpose of creating the most appealing and functional operation possible for the age group; if this is not possible, then use of the system under personal supervision must be considered.

The physiotherapists considered the requirement: The system should offer breaks between exercises to be the most important requirement in the level duration of use. Especially during home exercises, patients showed inconsistency in taking breaks. "No, it then automatically follows that one stops or does not stop" (CBP patient). Mostly the seniors in the groups performed the exercises all at once and without a break as a matter of course. Newcomers may be prone to overestimating themselves; especially in cases of chronic pain, overambitiousness can lead to severe pain. The patients should learn for their everyday life what individual dose of exercise is right for them and therefore they should have the opportunity to take a break. Another requirement the participants stated, was: The exercises should last a maximum of 30 min. Further a very important requirement was: The system should offer 15 min of relaxation. Psychoeducation plays an important role in multimodal pain therapy. The requirements analysis showed that relaxation therapy in VR can be offered in addition to movement training, but it should take less time in the game.

The physiotherapists considered the following requirement to be important in the level of *safety*: **The system should be used in a safe place with sufficient space**. Due to the lack of perception of the real space, many older adults can be exposed to the risk of falling. "*Of* course, you must do such things [...] in a safe environment where there's just enough room that you can't knock anything over or put yourself in danger" (CBP patient). This implies that a concept for safe use of the exergame is needed. **The system should allow you to sit down**. This approach also involves the risk of falling, which can result from overexertion, for example. A possibility of sitting or even executing the exercises in seated position would minimize the danger of falling. The following requirement was also given: **The system must contain a help button**.

In the level of financing the requirement: **The system should be offered for rent** was preferred. *"Renting would be a good solution."* (CBP patient). This proposal would allow multiple users to share the system and make it available to a larger number of potential users.

Hardware

This dimension did not consist of various levels. Due to the small number of requirements and semantically similar requirements, code groups were not created in the content analysis and were not presented in the prioritization as levels for this dimension. For this reason, this dimension consists of only one level. In the dimension hardware, the participants also identified the physiotherapists as the most important stakeholder. The psychotherapists were ranked 2nd and the CBP patients 3rd.

The physiotherapists determined the most important requirement to be the following: **The patients should be able to put on the googles by themselves**. This requirement is associated with another important requirement: **The goggles should be easy to put on and take off**. The ability to put the goggles on and take them off independently was perceived as important in order to enable the system to be used independently at home by older CBP patients. Here the hardware design must be adapted to the requirements of the seniors.

Software

The software dimension consists of the following levels: *in-game environment, application of game* and *exercises*. In the dimension *software*, the participants identified the physiotherapists as the most important stakeholder. The psychotherapists were ranked 2nd and the CBP patients 3rd.

The decisive requirement in the level *in-game environment* was: **The system should perform an individual calibration (e.g. to detect movement limitations)**. The desire for calibration was mainly expressed by the physiotherapists. With an individually adapted environment, limitations of the patients could be integrated into the game. Patients are thus not forced by the game environment to make movements that they cannot functionally

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perform, e.g. due to a limited range of motion in a joint. "Yes, but I could imagine, for example, that [...] the environment knows how big the patient is. Or how high he can stretch to get it calibrated" (Physiotherapist). The physiotherapists stated that they could imagine, for example, a movement assessment in the VR to be carried out by the patient before the start of the game.

In the semantic level application of game the requirement: The system should enable the therapist to intervene on patients (pain, anxiety, incorrect execution) was prioritized in first place. This requirement of course depends on the setting in which the exergame is performed. If the exergame is performed in a setting in which the therapist stands next to the patient, immediate intervention is possible. In a setting where the patient performs exercises independently at home, a concept must be considered for the therapist's intervention (e.g. though a help button/emergency-supporting system). "Well, definitely intervene when there's fear, when there's irritation [...] can be a technical problem. [...] And of course even if I feel like someone can't handle it, or do something completely different than (laughing) actually the model" (Physiotherapist). The physiotherapists could consider an intervention, e.g. by assisting or stopping the game, if the patient experiences severe pain during the game, is afraid while playing, or performs the exercises incorrectly, which can lead to danger or increased back pain. During the task-based part, the phenomenon of cybersickness in a subject was detected once, but disappeared after a short break (approx. 5 min).

In the level of *exercise* the requirement: **The patients should perform everyday exercises** was preferred. The physiotherapists see the VR as a chance to try out tasks that are close to everyday life in a realistic way. "*In the training program one could use environments / tasks that are attractive for many older people or are close to everyday life – such as the garden … planting something, harvesting or maybe shopping"* (physiotherapist).

Gamification / game integration

This dimension consists of the following levels: display of feedback, biofeedback, progress, and storytelling. In the dimension: gamification / game integration, the participants identified the psychotherapists as the most important stakeholder. The physiotherapists were ranked 2nd and the CBP patients 3rd.

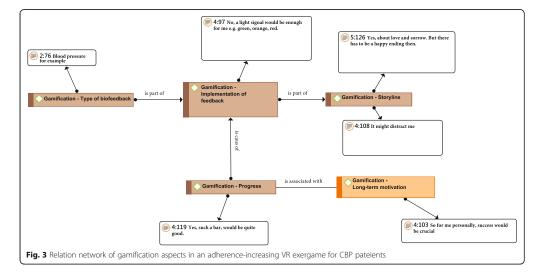
At semantic level *display of feedback* the following requirement was perceived as the most important: **The feedback in the system should always reinforce positively, never negatively.** In the interviews, the physiotherapists also named this as an important method for giving feedback. This is particularly important in order to stabilize a long-term intrinsic motivation of CBP patients during the exercises in the exergame in order to support long-term training adherence.

In the level of *biofeedback* the participants considered the requirement: The exergame is intended to provide the user with behavioral recommendations (e.g. advice on how to relax) to be the most important requirement in the level of *biofeedback*. During the interviews the psychotherapists always expressed their views on psychoeducation in the exergame: "Well education, I think, is of course very, very important in terms of stability of the spine for example, if there are fears, like: 'that breaks everywhere and [...]" (Psychotherapists). In classical multimodal pain therapy, behavioral therapeutic aspects play an important role. These aspects should also find their place in an exergame for CBP patients. Particularly in forming habits, patients must be aware of why they perform the exercises and what can cause them harm. It is precisely through misconceptions that many patients develop fear avoidance beliefs or poor stress management. In order to avoid and counteract these negative strategies, the system can be supported by e.g. stress sensors that measure the pulse during training and to give positive feedback of vital parameters. By using quantitative measurable methods, behavioral recommendations can be made usable, comprehensible for the user, which contribute to therapy adherence (Fig. 3).

On the level of progress the most important requirement was: The system should display praise and rewards (for example, text "Hooray", "Congratulations"). The seniors often stated during the interviews that rewards after completing a task in the game would please them. "Well, all right. A reward if you do the task or something. Like I said, I'm not the person who wants to win while playing. The thing itself has to be fun and it has to have something to do with creativity" (CBP patient). Figure 3 shows how progress is structured in the game and how it can lead to long-term motivation for the exercises, which is necessary in the case of chronic back pain. Since training progress is required with chronic patients, because of the poor exercise adherence and the risk doing exercise wrongly, the current training status (progress display) is needed in the game. In order to be able to control the progress of the patients in the exergame, feedback needs to be implemented in the game. This feedback has to be biofeedback, which records e.g. the movements or stress of the patients with sensors. The feedback used in the game should be also part of the storyline, if there is one, which would have a further motivating effect.

On the level of *storytelling* the most prioritized requirement was: **The system should not tell a continuous story**. The psychotherapists said that longer-term success would be possible through an appropriate individual division of work and recovery phases. This speaks

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against a strict story, as it is difficult to divide it up individually. Also some subjects said that a continuous story is not imaginable for them. *"I think that would kind of distract me. Then I would listen to the story and become inactive when I listen to it"* (CBP patients). On the other hand, five of the 10 test persons said that they could imagine a continuous story and would like to experience it in the VR.

Discussion

Within the ViRST requirements analysis, we gathered mandatory requirements for the conception of a VR HMD-based active exergame for older users with chronic back pain.

The key requirements of the overall system showed a desire for an individual briefing for the system. In addition, a sufficient instruction is considered necessary not only by the CBP patients, but also by the therapists. These requirements call for a differentiated consideration of the target group of older people. Especially due to a strong divergence in the acceptance of technology, it is necessary to take a closer look at the existing skills and abilities of the target group. Wright's study [28] showed that especially in geragogy, older adults are often nervous when it comes to independently mastering new technology. For this reason, it is important to take away the fear of new technologies in this vulnerable group if they are to use a VR exergame. Oesch et al. [29] showed in their study that self-regulated exercise using instruction leaflets were superior to exergames regarding adherence in a geriatric inpatient rehabilitation setting. However, this study was not tested with a VR system but with a Microsoft Kinect exergame, through the effect of immersion this result should be tested with a VR system, because different effects could occur.

The therapists recommended that the exercises should last a maximum of 30 min. This also matches the health and safety warning of the oculus [30]. They suggest taking at least a 10 to 15-min break every 30 min. It also corresponds to the conventional treatment time at the physiotherapist.

We determined in the requirements analysis also that a user-friendly handling of the system and hardware is important and can also contribute to an easier access for the peer group. In addition, older persons need expert training and instruction in the use of the system, especially with regard to immersion in VR and the risk of falls, which can be plausible with a wired VR HMD. For the user group, a wireless HMD would be the preferred option. The focus group with the physiotherapists confirmed, that the system should be used in a safe place with sufficient space and with appropriate safety regulations such as to allow the patient to sit down in VR or to use a help button. If the older users do not get along with the operation of the system, an instructor may be considered to be present during the exergame. Palazzo et al. [31] came to the result that the feeling of being supported by care providers is important in a homebased exercise program for patients with chronic low back pain. First and foremost, with the HMD, senior subjects cannot perceive dangers in the room, which exposes them to the risk of falling. In addition, cybersickness could occur that patients cannot deal with. If a VR game is to be implemented at the patient's home, there

must be a proven safety concept and the patient must know what to do in case of emergency. For this reason, further laboratory research is necessary in which patients can first test the system under supervision and the researchers can detect potential safety hazards during the use of VR HMDs by seniors.

Considering the use of augmented reality and its applications in comparison to VR systems, it is obvious that the handling AR involves a lower risk of falls [32, 33] but leads to other effects. Serious games with an AR approach for example can include physical-related interventions for motivating to do physical activities. In the AR virtual objects that coexist in the same space as the real world are displayed in addition to the real world for improved perception. Older adults, whose technical abilities in dealing with new technologies due to cognitive, physical, financial and social resources [34, 35] are lower than those of younger people, and whose generation did not grow up with digital technologies [36], could be overloaded by these effects [37]. Nevertheless, there is a lack of research not only in this respect. In general, less research has been done in the field of augmented reality in connection with pain therapy compared to VR [16, 38]. Besides, AR systems and their applications are more cost-intensive compared to VR. The application of AR for CBP patients who would like to train with a back pain program like ViRST in their own home would represent a major financial hurdle for them.

With regard to the financing of the system, a concept should also be considered for how the system could be affordable for the target group. In our requirement analysis the stakeholder preferred, that the system should be offered for rent. In view of the increasing poverty among the elderly in Germany [39] it is necessary for the price to exclude as few as possible. Obviously, this has to be considered differently for each country.

On the other hand, the physiotherapists stated, that virtual reality offers the opportunity to safely test everyday scenarios. The multimodal pain therapy experts suggest that exercises should be transferable to the everyday life of seniors. The requirement "the exergame is intended to provide the user with behavioral recommendations" was also raised in the requirement analysis for exergames by Paulino et al. [40]. Behavioral therapeutic aspects should also be integrated into an exergame for CBP patients. Valenzuela et al. [41] conducted a study for a home-based cognitive-motor step training displayed on a monitor for older adults. Our results show similarities to their qualitative main findings, which indicate that positive feedback on performance is important to increase self-efficacy for the peer group. The interviewees in our study confirmed that the feedback in the system should always reinforce positively, never negatively. In addition, the study also suggests that the system should be easy to handle to reduce barriers to the use of technologies. The study of Valenzuela et al. is in fact in the same age group, however it examines a different clinical condition and the exergame applied does not use a VR HMD, for this reason the openness of the subjects to use the technology at home must be questioned. In our study with CBP patients and a VR system we propose a proven safety concept as mentioned above if a VR game is implemented at the patient's home.

The physiotherapist emphasized that the system should perform an individual calibration in order to detect movement limitations. From a technical point of view, it would be possible to use tracker, inertial measurement units (IMUs) or cameras for human pose estimation to detect the range of motion of the relevant joints of the patients and to adapt the objects in the VR. Stănică et al. also suggested to use movement tracking equipment and biosensors for training session configuration in VR systems in neurorehabilitation [42].

In psychoeducation a combination with biofeedback would be possible e.g. by a measurement of heart rate variability (HRV). This would be an easy way to measure stress and react appropriately in game situations to show seniors their stress level and to teach them how to change their behavior. As further biofeedback the controllers can be used and additionally trackers could be attached to the back of the patients to enable posture correction. Barmpoutis showed a way give haptic-based guidance in tele-therapy by using wearables with vibrator motors [43]. The biofeedback serves as a basis for gamification elements and the necessary feedback to achieve training progress. Through age-appropriate motivation, e.g. praise and rewards etc., the usage frequency of the exergame can increase, leading to guided training progress and long-term motivation and adherence, thereby relieving pain.

Limitations

Nevertheless, the study had some limitations. An external limiting factor was the small number of participants. Due to a small and imbalanced number of experts, the results cannot be generalized easily. Furthermore, within the older participants, who all had no previous experience with VR, there was a lack of technical skills and a low understanding of the applied technology. However, an initial saturation of the results could be achieved. Furthermore, this study was a first step, as the current application was an exergame user experience prototype whereas a more specified application with a proven therapeutic benefit is expected to be developed in the course of the project. In this respect, the requirements must be tested and specified with older users in a VR back pain exergame with implemented gamification aspects.

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Conclusion

Within the scope of the requirements analysis 104 requirements could be identified, which represent the basis for the conception of an exergame and the use cases in the ongoing ViRST project to create a user-friendly VR exergame that motivates older chronic back pain patients to perform exercises regularly. If the exergame is a user-centred VR back pain training program, it is quite conceivable in the future to adapt it for other target groups and to transfer the system from the inpatient area to the domestic environment of the patients. Therefore, it should be ensured that the safety and motivational elements correspond to the expectations of the target group. A more effective multimodal pain therapy could be achieved by a higher adherence of the homebased exercises, which could reduce the long-term cost of the health system.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10. 1186/s12984-020-00753-8

Additional file 1

Abbreviations

CPGQ: Chronic Pain Grade Questionnaire; CBP: Chronic back pain; VR: Virtual Reality

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Authors' contributions

OS conceived, designed, wrote the article, performed the study and evaluated the data, RD performed the study, evaluated the data, wrote a part of the discussion, revised and edited the manuscript. UMW supervised the work, was the clinical head of the project, reviewed the study contents and raised funds for the project. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study protocol was approved by the ethics committee and data protection committee of the Charité - Universitätsmedizin Berlin (No: EA4/ . 055/18). All participants gave their written informed consent to take part in the interviews

Consent for publication All authors have approved the manuscript for submission.

Competing interests

The authors declare that they have no competing interests

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ORIGINAL ARTICLE



Virtual reality exergame for supplementing multimodal pain therapy in older adults with chronic back pain: a randomized controlled pilot study

Oskar Stamm¹ • Rebecca Dahms¹ · Norbert Reithinger² · Aaron Ruß² · Ursula Müller-Werdan¹

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Abstract

Immersive Virtual Reality (VR) with head-mounted displays (HMD) can be a promising tool for increasing adherence to exercise in older adults. However, there is little known about the effectiveness of an interactive multimodal therapy in VR for older chronic back pain (CBP) patients. The aim of the exploratory randomized controlled trial was to examine the preliminary effectiveness of a VR multimodal therapy for older adults with CBP in a laboratory setting over a period of four weeks. The intervention group (IG; n = 11) received a multimodal pain therapy in VR (movement therapy and psychoeducation) and the control group (CG; n = 11) received a conventional multimodal pain therapy (chair-based group exercises and psychoeducation in a group setting). Although the VR therapy (IG) did not reach the pain intensity reduction of the CG (IG: MD=0.64, p = .535; CG: MD=1.64, p = .07), both groups showed a reduction in pain intensity on the Numeric Rating Scale. The functional capacity in the IG improved from Visit 1, $\bar{x} = 73.11\%$ to Visit 2, $\bar{x} = 81.82\%$ (MD=8.71%; p = .026). In the changes of fear avoidance beliefs and general physical and mental health, no significance was achieved in either group. Although the IG did not reach a significant pain intensity reduction compared to the CG, the results of the present study showed that a pain intensity reduction can be achieved with the current VR application.

Keywords Physical therapy \cdot Psychotherapy \cdot Virtual reality \cdot Multimodal pain therapy \cdot Serious gaming \cdot Chronic back pain

1 Introduction

Back pain is one of the most common musculoskeletal conditions. Globally, low back pain has been the leading cause of disability measured by years lived with disability (Vos et al. 2017). When the pain persists for more than 12 to 24 weeks, a chronic course can be assumed (Dionne et al. 2008). In Germany, the highest prevalence of chronic back pain (CBP) is found among adults aged 70 years and older

(28%) (Von Der Lippe et al. 2021). CBP is a complex multidimensional disorder, in which kinesiophobia, fear-avoidance beliefs and passive coping strategies may often occur (Waddell 2004; O'Sullivan 2012). Therefore, multidisciplinary treatment programs including psychological interventions in addition to physical treatment have become standard in the treatment of CBP patients. Most guidelines recommend behavioral interventions, several recommend considering fear-avoidance beliefs (Reese and Mittag 2013). Systematic reviews found evidence of moderate quality in terms of the effectiveness of behavioral therapy for chronic low back pain (Brox et al. 2008; Baez et al. 2018). Research indicates that patients with CBP receiving multimodal pain therapy and rehabilitation experienced less pain intensity (0.5 to 1.4 units on the Numeric Rating Scale) and disability (1.4 to 2.5 points on the Roland Morris Disability Questionnaire), and a greater increase in their physical function, compared with patients receiving a standard treatment that focuses only on physical function (Pfingsten et al. 1997; Kamper et al. 2014).

Oskar Stamm oskar.stamm@charite.de

Department of Geriatrics and Medical Gerontology, Working Group Age and Technology, Charité - Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Reinickendorfer Straße 61, 13347 Berlin, Germany

² DFKI, Deutsches Forschungszentrum Für Künstliche Intelligenz GmbH (DFKI), Alt-Moabit 91c, 10559 Berlin, Germany

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CBP programs performed by patients alone could be facilitated by new technologies (Palazzo et al. 2016). Socalled exergames (exercise games) might be a potential approach to adherence enhancement and could provide adjuvant therapy to multimodal pain management. Studies indicate that exergames can lead to an increase in motivation and can be a promising tool for increasing adherence to exercise in older adults (Brox et al. 2011; Meekes and Stanmore 2017). Recent studies showed that a specially developed Nintendo Wii exergame could be a biopsychosocial intervention for chronic low back pain (Graves et al. 2010; Park et al. 2013; Kim et al. 2014). Hoffman et al. (2000) have shown in early scientific work with immersive virtual reality that VR can distract from high levels of pain during wound care. Immersive Virtual Reality (VR) with head-mounted displays (HMD) offers new opportunities in exercise therapy. In the systematic review of Mallari et al. (2019), there was some research that suggested VR can reduce chronic pain during the intervention. Jones et al. (2016) showed a significant decrease in pain during a low-motion VR game application on chronic pain. However, there is a dearth of studies using VR active exercise therapy (Villafaina et al. 2019; Cao et al. 2021; Kruse et al. 2021) and psychotherapy (Fodor et al. 2018) together. Most of the VR studies in chronic pain patients are using distraction as a pain reduction technique. Also vision has been used to augment the embodied experience. Visual feedback by watching the site of the chronic back pain may be helpful in alleviating the pain (Diers et al. 2016). An initial therapy study with exercises in VR by Alemanno et al. (2019), using a six-week VR treatment to teach patients to execute correct movements with the painful body parts, showed significant reductions in pain rating scale scores and significant improvements of quality of life in the domains of physical functioning.

However, there are no studies investigating an active VR exergame with an HMD for older CBP patients. In order to secure an effective long-term therapy for CBP patients, a multimodal approach in VR is necessary. Within the scope of the ViRST project, we determined measurements for various physiological outcomes, but also offer psychological exercises and behavioral recommendations. Based on a requirements analysis (Stamm et al. 2020), the ViRST application was developed in a two-year project. The aim of the evaluation was to examine changes in pain intensity, functional capacities and fear-avoidance beliefs. Within this evaluation, the researchers aimed to answer the following research questions:

1.1 Primary research question

Does the VR system contribute to an effective, multimodal pain therapy for the treatment of CBP in older adults? The following aspects will be considered:

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- · Changes in pain intensity and severity of chronic pain
- Changes in functional capacities
- Changes in fear-avoidance beliefs (kinesiophobia)

1.2 Secondary research questions

What impact does the use of the VR system have on the health-related quality of life of the older adults with CBP patients after usage?

- Changes in general physical and mental health How do older people with CBP rate the user experience of a four-week multimodal pain therapy in virtual reality?
- Rating of the degree of the immersion
- Evaluation of the user experience

2 Material and methods

2.1 Study design

In the monocentric study, we conducted randomized controlled pilot trial with a parallel arm design (1:1 allocation ratio) in older adults with CBP. The study took place between January and March 2020 under laboratory conditions to compare the impact of a VR exergame on pain intensity progression, functional capacities, fear-avoidance beliefs and general physical and mental health with a standard practice (multimodal pain therapy). In addition, the user experience was evaluated regarding the use of VR in therapy. Important changes to methods after the trial took place due to the COVID-19 pandemic and the associated lockdown and contact restrictions: the maximum force measurement could not be performed with the intervention group in Visit 2 and it does not appear as part of the data analysis. Ethical approval was gained from Ethics Committee of the Charité - Universitätsmedizin Berlin (No. EA4/213/19). The trial is registered at the German Clinical Trials Register (DRKS-ID: DRKS00020576).

2.2 Study population

We applied the following inclusion criteria: (1) CBP for longer than six months, (2) being 65 years of age or older, (3) independent mobility, (4) able to actively perform exercises, (5) no intervertebral disc surgery in medical history and (6) no severe vestibular restrictions affecting the ability to balance. We excluded candidates with (1) immobility or those whose mobility was possible only with assistance, (2) with sensory and motor failure, (3) with spinal malignancies, spondylitis or spondylodiscitis, (4) severe vestibular impairment which effects the ability to balance, such as dizziness or severe visual impairment (oscillopsia).

2.3 2.3 Procedure

We assessed the eligibility of all volunteers prior to the start of the study via personal telephone screening. Subsequently, the subject information was sent to the candidates by mail or e-mail and all screened subjects had at least 24 h to decide whether or not to participate. If the criteria for inclusion in the study were met, the participants were then sent the subject information. Informed consent was obtained from all participants before enrollment. The study was conducted in the facilities of the research group at the Charité and the Sport-Gesundheitspark Berlin.

Data collection was limited to conducting the survey with older adult patients with CBP at different times: Visit 1: approximately 45 min; intervention phase: four weeks; Visit 2: approximately 45 min. Before the intervention phase started, an anamnesis interview and an orthopedic examination with a sports scientist and physiotherapist took place to identify possible contraindications for testing and further study continuation. This was a one-off examination lasting about 30 min. Subsequently, questionnaires were given to the participants in Visit 1.

During the intervention phase, each group was provided with multimodal pain therapy for CBP patients three times a week for about 30 min. A total of 12 exercise units were offered to each participant on a voluntary basis. This training consisted of both physiotherapeutic and psychotherapeutic exercise units. In order to determine the course of pain, a pain diary was used before and after each exercise session, i.e., ideally a total of 24 times. At the end of the intervention phase, i.e., in the last unit (Visit 2), the same questionnaires were given to the participants again.

2.4 Study interventions

The participants were divided into an intervention group (IG; VR exergame) and a control group (CG; chair-based group exercises). The IG received a multimodal pain therapy in VR (movement therapy and psychoeducation) for four weeks, with three appointments per week lasting approximately 30 min in a laboratory setting. The CG completed a four-week conventional multimodal pain therapy (movement therapy as seated exercises and psychoeducation in a group setting) for four weeks, with three appointments per week lasting approximately 30 min.

2.5 IG (VR exergame)

In the course of the intervention phase, attention was paid to the implementation of a multimodal concept for the treatment of back pain patients, which had a physiotherapeutic and psychotherapeutic focus. A training session of the IG was conducted by participants under physiotherapeutic supervision with a VR HMD headset using the ViRST VR application, which was developed in the course of the ViRST research project. The training session, consisting of 12 exercises, was structured as follows: (1) warm up (training of the upper and lower extremities); (2) main part (strengthening of the abdominal and back muscles, core stability); (3) cool down (stretching, progressive muscle relaxation exercise); (4) psycho-educative units (topics: physiology of pain, pain management, stress management, everyday training). The IG psychoeducative units were always shown using the VR headset at the end of each training week.

2.6 CG (chair-based group exercises)

The intervention phase in the CG differed from IG mainly in the use of VR technology. The participants in the CG took part in conventional sitting gymnastics consisting of 12 exercises identical to those in the VR group, but under the guidance of a physiotherapist in a circle of chairs in small groups rather than individually using VR. Depending on the participants' preference for a timed session, a maximum group size of six participants was targeted. The psychoeducative units (physiology of pain, pain management, stress management, everyday training) were offered at the end of a training week, analog to the IG. The psychoeducation was provided in the CG in a conservative manner using interactive patient training, in which a therapist presented information on a flip chart.

2.7 Outcomes

The primary outcome was a composite outcome, which included change in pain intensity and the severity of chronic pain, changes in functional capacities, changes in fear-avoidance beliefs (kinesiophobia) and changes in the maximum strength of the trunk muscles and muscular imbalances (not further described, unable to complete because of COVID-19). For this purpose, the following validated assessments were applied: the Numeric Rating Scale (NRS) (Hilfiker 2008) to assess current pain intensity; the Chronic Pain Grade Questionnaire (CPGQ) (Von Korff et al. 1992) to assess the severity of chronic pain; Hannover Functional Ability (Pfb-H-R) (Kohlmann and Raspe 1996) to assess functional capacities; the Tampa Scale of Kinesiophobia (TSK-11) (Rusu et al. 2014) to assess fear-avoidance beliefs.

As secondary outcomes, we investigated general physical and mental health with the Health Survey SF-12 (Ware et al. 1996), the immersion of the applied VR system with the Technology Usage Inventory (TUI) (Kothgassner

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et al. 2012) and the user experience with the User Experience Questionnaire (UEQ) (Laugwitz et al. 2008).

2.8 Measures

2.8.1 NRS

The participants' pain intensity progression was recorded in a pain diary using the NRS, in which the current pain intensity before and after each training session was recorded. The NRS is a scale to assess self-reported pain intensity that ranges from 0 to 10, where 0 means 'no pain' and 10 means 'the worst pain imaginable.'

2.8.2 CPGQ

CBP was assessed by the CPGQ. The questionnaire by von Korff et al. assesses the severity of chronic pain. All items are rated on an 11-point Likert scale. The scores enable the classification of chronic pain into functional chronic pain (grades I and II) and dysfunctional CBP (grades III and IV). Grade 0 means no pain, grade I means low disability-low intensity, grade II means low disability-high intensity, grade III means high disability-moderately limiting and grade IV means high disability-severely limiting. The translated German version of the CPGQ was used.

2.8.3 Ffb-H-R

Both groups received the Ffb-H-R for measuring back painrelated disability. This questionnaire by Kohlmann and Raspe serves to assess the functional limitations in activities of daily living due to back pain. It is a self-report instrument consisting of 12 items, each with three response options. The result of the evaluation represents the functional capacity in percent of the patient, where 100% means the maximum and 0% means the minimum of functional capacity. The German version of the Ffb-H-R was used.

2.8.4 TSK-11

The TSK is one of the most commonly used measures of pain-related anxiety in back pain patients. We used the shortened version of the TSK, the TSK-11 (Woby et al. 2005). The items of the TSK-11 are scored from 1 (strongly disagree) to 4 (strongly agree), giving a total score of 11–44 points, with higher scores indicating greater pain-related fear.

2.8.5 SF-12

The SF-12 is a shortened version of the SF-36. The SF-12 provides two scores: the physical scale score and the mental

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health score. Possible scores range from 0 to 100 points, with 0 representing the greatest possible health limitations and 100 representing the absence of health limitations. The SF-12v2 in German was used.

2.8.6 TUI

The TUI is used to assess technology-specific and psychological factors that contribute to the actual use of a technology. The instrument contains the following eight scales: Curiosity, Anxiety, Interest, Ease of Use, Immersion, Usefulness, Skepticism and Accessibility. In addition, the procedure contains the Intention to Use (ITU) scale. This paper will discuss Immersion in more detail, which was applied in the IG.

2.8.7 UEQ

The UEQ measures the user experience of interactive products and the full version in German was used. It examines the valence dimension 'attractiveness,' which is subdivided into two quality aspects: pragmatic quality (Perspicuity, Efficiency, Dependability) and hedonic quality (Stimulation, Novelty). The UEQ contains six scales of the quality aspects with 26 items scaled from -3 (most negative) to +3(most positive).

2.9 ViRST VR game

The developed VR game was composed of two software interfaces: a therapist interface (Fig. 1), which allows for setting the exercises and monitoring the live image of the participant, and the VR game (Fig. 2), in which the participant performs interactive tasks on a farm (e.g., rowing, turning on light bulbs, or sorting vegetables). The desired effect on the user during gameplay was to achieve an 'immersiveness' of the environment, i.e., the player is immersed in a computergenerated environment and temporarily perceives it as real. For this purpose, an HTC-Vive VR system (consisting of VR headset and two controllers) and a laptop were used. The interaction between the user and the VR system was facilitated by a speech-based dialog system that guided the user through the exercise. To avoid excessive strain, we integrated a real-time stress assessment by photoplethysmography (PPG). Detected changes in the cardiac rhythm are classified with regard to strain. The heart rate was displayed on the therapist interface in real-time and also served as a control for the therapist. In case of exceeding the target training heart, the dialog system interacts with the user, e.g., to pause the game. The training heart rate was 0.75 max HRR + resting HR: where max HRR is the maximum Heart Rate Reserve, and resting HR is resting Heart Rate (Kent 2007). However, this was not exceeded in any case during

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<	Back to exercise selection			×
	Therapist screen			
	Exercise: Rowing		Instruction	
	Goal: Aerobic training to incr	ease self-efficacy. Improvement of core stability.	Instructions: Grab the ears of the boat. Then row forward and stay within the marks. Try to row the entire distance.	
	Camera height		Read instruction Play tutorial v	video
	Object height			1400
	Duration	150 Seconds		
	Heartrate	182		
	Score Back			Sec.
	Stop exercise Pause	e, 196225 Remaining: 124 sec. Reset Next exercise		
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Fig. 1 Therapist user interface



Fig. 2 Left: user view of the VR game, right: patient set-up

the test. The dialog system uses off-the-shelf speech recognition and synthesis modules. The hybrid dialog control module merges automaton based and Neural Network based approaches. The PPG stress sensor was trained on the heart rate signals collected from participants.

The warm-up included the exercises: "marching" and "rowing." The aim of the marching on the spot was the activation of the circulation of the lower extremities. Here, the users had to step on buttons coming toward them on the floor in a certain rhythm. Trackers attached to the feet allowed users to interact with the virtual world. In the second warmup exercise, participants rowed on a lake and had to maintain a course between buoys (Fig. 2). To do this, the participants had to grip the oars with the HTC Vive controllers by pressing the trigger button. Once the oars had been gripped, they remained fixed to the virtual hands. This exercise serves to activate the circulation of the upper extremity.

The first exercise in the main part was the "balloon pump." This exercise was designed to strengthen the back extensors. In this exercise, the participant bent down and came back up halfway. There they performed small forward and backward movements with a straight back. In VR, the participant saw an air pump with which they blew up balloons. The next exercise was called "hurdles." Here, the

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participants lifted both feet while sitting and kept abdominal tension and their balance. Through the trackers on the feet, they could see their virtual feet. While lifting the feet, they jumped over hurdles in virtual reality. The goal of the exercise was to strengthen the abdominal muscles. The subsequent exercise: "the bridge" focused on improving core stability and strengthening chest and shoulder muscles. With their bodies bent forward, participants rocked forward on a bridge over the lake by pulling forward on the bridge's ropes through trigger buttons of the controllers. In the "light bulbs" exercise, participants climbed a ladder at the farmhouse by grasping the rungs through the trigger button. Once at the top, they screwed in light bulbs with the controllers, by releasing the triggers the light bulb could be released. The focus was on mobilizing the shoulder joint as well as the cervical and thoracic spine. In the "shaking bottles" exercise, the user's shoulder blades were fixed while the arms were pushed through at the elbow. Then small quick movements were made with the controllers out of the shoulder. The participants shook bottles in the VR until the corks popped. The exercise was designed to strengthen the deep back muscles and improve core stability. In the "ball bucket," the participant stretched both arms out to the side with the controllers in their hands and tries to make small quick movements up and down with the arms. Abdominal muscle tone was built and one leg was lifted. After a while the other leg was lifted while continuing small arm movements. The participants had the task in VR to empty the self-filling buckets as quickly as possible. The exercise was designed to strengthen the deep back muscles and improve core stability.

The next exercises were part of the cool-down. First, the focus was on stretching the rotational muscles. In "vegetable sorting," participants stood in front of a conveyor belt and had to take turns sorting vegetables into a box on the right and left. By pressing the trigger, they were able to grab the vegetables. The goal was to stretch the serratus anterior muscle and the pectoralis major muscle. In the boiler exercise, the participants stood next to the farmhouse in the VR and had to regulate the temperature in the boiler. To do this, they had to use the controllers to push one handle up and one handle down. This exercise was designed to stretch the latissimus dorsi muscle and the quadratus lumborum muscle. In the "apple tree" exercise, the arms were brought together above the head in a seated position and stretched upwards. Then, the upper body is tilted to one side at a time. In VR, the participant imitates the movements of a tree. The last exercise was progressive muscle relaxation. The participant learned how the muscles feel when tense by tensing the hands and arms and relaxing the muscles after a while. In VR, the participant stands on a dock by the water, accompanied by relaxation music, and imagines warmth by making a fist, symbolized by coloring his fists red. Tightening the muscles is done by firmly grasping the controllers, while the

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grip button was pressed. The psychoeducational sessions were shown through the VR headset at the end of each week in the form of interactive videos.

2.10 Randomization

The assignment of the participants to a group was done with a randomized block design. To obtain as comparable a study group as possible, randomization was stratified with respect to gender. A unique number was generated for each participant after eligibility screening by the study investigators. Randomized participants received therapy during the study period according to the intervention they were allocated.

2.10.1 Sample size

Moore et al. (2011) recommend at least 12 participants for pilot studies to conduct within single centers to provide valuable preliminary information. With a sample size of 22 participants, we were considerably above the rule of 12.

2.10.2 Statistical analysis

For the reduction in pain intensity (NRS) in the pre-post comparison when using the exergame/conventional training, as well as for the CPGQ, Ffb-H-R, TSK-11 and SF-12, a normal distribution was not present in the data collected and an ordinal scaling was present, thus a Wilcoxon signed-rank test was applied. A Mann–Whitney *U* Test was applied to evaluate the difference between IG and CG of the mean NRS differences in the pre-post comparison per training session. In order to check whether the number of training units was related to pain intensity reduction, a Spearman's rank correlation coefficient was calculated for both groups because of the non-normal distribution. The statistical software SPSS 26 and RStudio were used for the analysis.

3 Results

3.1 Study population

The total sample included 22 participants with CBP (Table 1), who met the eligibility criteria and were randomized between January and March 2020. The IG consisted of 11 pain patients aged 67 to 84 years (M=75.0, SD=5.8), who suffered from back pain for an average of 15.8 years (SD=12.7). The average pain intensity measured by the NRS was 3.36 (SD=1.91). The CG included 11 pain patients aged 68 to 84 years (M=75.5, SD=4.4). The participants had been suffering from back pain for 26.4 years on average (SD=16.6). The average pain intensity measured by the NRS was 2.91 (SD=1.64) in the CG. The gender Table 1 Study characteristics

Sociodemographic data	Intervention Group	Control Group	p value
Sample size total [n]	11	11	
Gender (Female/Male)	8/3	6/5	.659*
Age [M (SD)]	75 (5.80)	75.5 (4.39)	.838†
Highest educational attainment [n]			.300‡
University	6	4	
Advanced technical college certificate	0	2	
High school	3	0	
Secondary school	2	2	
Main school	0	3	
Pain intensity during anamnesis [NRS (SD)]	3.36 (1.91)	2.91 (1.64)	.562‡
Duration of back pain [M in years (SD)]	15.8 (18.67)	26.4 (16.57)	.196†
Diagnoses (most common) [n]			-
Lumbar spine –Syndrome	4	4	
Lumbar disc herniation	1	1	
Thoracic disc herniation	1	0	
cervical disc herniation	1	0	
Facet joint arthrosis	1	1	
Scoliosis	2	2	

*Fisher's exact test

†t-test

[‡]Mann–Whitney-U

distribution in both groups was balanced (54.5% female). In both groups, the most common diagnosis was lumbar spinal syndrome. There were no serious adverse events reported in either group during the study. The study was terminated as the treatments in the study were completed and the study reached the planned sample size (Fig. 3).

3.2 Primary outcomes

The summarized results of the applied assessments in the study can be found in Table 2.

3.2.1 Pain intensity progression

The primary analysis was intention-to-treat and involved all participants who were randomly assigned. The pain intensity decreased over time in both groups. Due to the regulations imposed by the COVID-19 pandemic, some participants in the IG completed the intervention phase early, bringing forward Visit 2 (Fig. 4). Therefore, the progression of pain intensity was compared for both groups between NRS scores measured before the first treatment (Visit 1) and after the last individual treatment performed (Visit 2). The IG completed an average of 9.18 (SD=1.47) training units and the CG completed an average of 10.81 (SD=1.6) training units. Participants in the IG rated their pain intensity before the first treatment as $\bar{x} = 3.55$ (SD=2.38, 95% CI [1.95, 5.15]) on the NRS. In Visit 2 after the last treatment

(Fig. 4), the mean pain intensity in the IG reduced to $\bar{x} = 2.91$ (SD = 2.02, 95% CI [1.55, 4.27]). Thus, the resulting mean pain intensity reduction in the IG was 0.64 (SD = 3.29, Z = -0.62, p = 0.535). Participants in the CG assessed their pain intensity before the first treatment (Visit 1) as $\bar{x} = 2.91$ (SD = 2.38, 95% CI [1.31, 4.51]). In Visit 2 after the last treatment, the mean pain intensity in the CG reduced to $\bar{x} = 1.64$ (SD = 1.50, 95% CI [0.63, 2.65]). In the CG, a higher pain intensity reduction could be observed than in the IG, with a mean difference of 1.27 (SD = 2.24, Z = -1.79, p = 0.07).

In order to check whether the number of training units was related to pain intensity reduction, a Spearman's rank correlation coefficient was calculated for both groups. The results showed a weak correlation (IG: $r_s = -0.154$, p = 0.550, n = 11; CG: $r_s = 0.205$, p = 0.650, n = 11), however, both values of the correlations are not significant (Fig. 5).

The NRS mean difference of participants in the pre-post comparison per training session, measured before the session and immediately after, was calculated from 101 sessions in the IG and 119 sessions in the CG. To evaluate the difference between IG and CG of the mean NRS differences in the pre-post comparison per training session a Mann–Whitney U Test was applied. The test revealed insignificant differences in the mean NRS differences of the IG (Median = -0.57, n = 11) and CG (Median = -0.06, n = 11), U = 36.00, z = 1,610, p = 0.116, r = 0.34. The null

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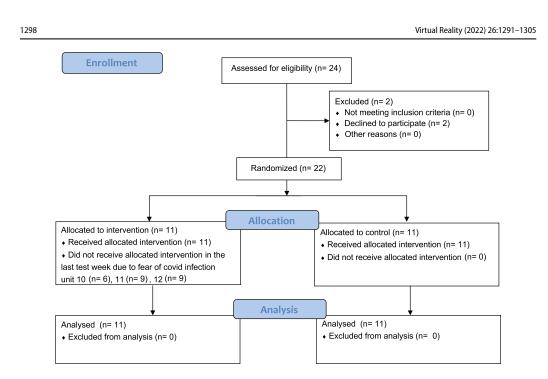


Fig. 3 Flow Diagram (Schulz et al. 2010)

Tab	le 2	Summary	table	of results	
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Variables	Group	Pre intervention Mean (SD)	Pre intervention Median [95% CI]	Post interven- tion Mean (SD)	Post intervention Median [95% CI]	p value	Effect size r
NRS	Intervention	3.55 (2.38)	3.00 [1.95–5.15]	2.91 (2.02)	3.00 [1.55-4.27]	.535	.19
	Control	2.91 (2.38)	3.00 [1.31-4.51]	1.64 (1.50)	1.00 [.63-2.65]	.070	.54
Ffb-H-R	Intervention	73.11 (10.60)	70.83 [65.98-80.23]	81.82 (11.22)	79.16 [74.28-89.36]	.026	.67
	Control	69.80 (16.84)	70.83 [58.49-81.11]	72.73 (15.74)	70.83 [62.15-83.30]	.330	.29
TSK-11	Intervention	19.27 (5.92)	18.00 [15.30-23.25]	17.82 (4.69)	17.00 [14.67-20.97]	.440	.23
	Control	21.55 (6.71)	21.00 [17.04-26.06]	20.73 (8.14)	17.00 [15.26-26.19]	.690	.12
SF-12 physical	Intervention	40.97 (7.83)	42.05 [35.37-46.58]	39.30 (8.01)	40.34 [33.91-44.68]	.575	.18
	Control	35.85 (7.91)	34.07 [30.19-41.51]	37.76 (7.27)	37.63 [32.87-42.65]	.441	.24
SF-12 mental	Intervention	46.44 (10.64)	48.70 [38.83-54.06]	48.39 (7.13)	49.87 [43.60-53.19]	.445	.24
	Control	50.31 (7.66)	53.60 [44.83-55.80]	56.23 (4.77)	56.18 [53.03-59.43]	.011	.81
TUI immersion	Intervention	-	-	19.09	24.00 [13.35-24.83]	-	-

hypothesis: the distribution of the mean NRS difference in the pre-post comparison across the two groups is identical, is therefore retained (Fig. 6).

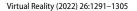
3.2.2 Severity of chronic pain

In the IG, six participants could be classified as grade I before the first treatment (Visit 1). After the intervention

(Visit 2), no changes could be detected in grade I. Four participants were classified as grade II and thus remained at the same classification after the intervention. Only one participant showed any change, from grade III before the intervention to grade IV after the intervention. In the CG, seven participants could be classified as grade I before the first treatment (Visit 1), and after the four-week conservative therapy (Visit 2), nine participants were subsequently

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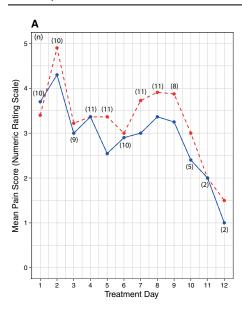


Fig. 4 Pain intensity progression during treatment A IG, B CG

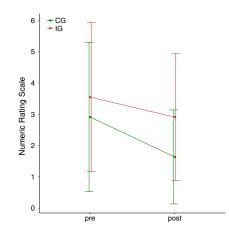
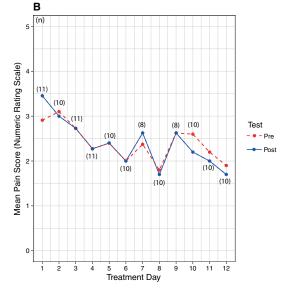


Fig. 5 Pre/post comparison of the pain intensity in the intervention and control group with error bars

classified as grade I. The number of grade II participants was reduced from three to two. Prior to the intervention (Visit 1), the CG included one participant at grade III and none at grade IV. After the therapy there were no grade III participants (Fig. 7).



3.2.3 Functional capacities

The results of the Ffb-H-R showed that a significant improvement in subjective functional capacity in the IG was perceived in the context of basal everyday activities from the mean functional capacity in Visit 1, $\bar{x} = 73.11\%$ (SD = 10.60, 95% CI [65.98, 80.22]), to Visit 2, $\bar{x} = 81.82\%$ (SD = 11.22, 95% CI [74.28, 89.36]). The mean difference (MD) was 8.71% (Z=-2.23, p=0.026), which was significant. In the CG the functional capacity improved from Visit 1, $\bar{x} = 69.80\%$ (SD = 16.84, 95% CI [58.49, 81.11]), to Visit 2, $\bar{x} = 72.73\%$ (SD = 15.74, 95% CI [62.15, 83.30]), resulting in a MD of 2.93%. However, there was no significant difference in functional capacity in the pre/post comparison of the CG (Z=-0.97, p=0.33).

3.2.4 Fear-avoidance beliefs

The IG results showed a reduction from 19.27 (SD = 5.92, 95% CI [15.30, 23.25]) to 17.82 (SD = 4.69, 95% CI [14.67, 20.97]) points (MD: 1.45, Z = -0.77, p = 0.44) on the TSK-11 in the pre/post comparison. The CG showed a reduction in pain-related fear from 21.55 (SD = 6.71, 95% CI [17.04, 26.06]) to 20.73 points (SD = 8.14, 95% CI [15.26, 26.19]) (MD: 0.82, Z = -0.40, p = 0.69). Neither group showed significant results (Fig. 8).

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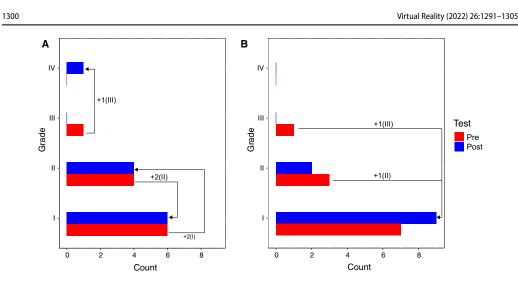


Fig. 6 Pre/Post comparison of the global severity of chronic pain in subjects assessed with the CPGQ. A IG, B CG

3.3 Secondary outcomes

3.3.1 General physical and mental health

In the IG, before the treatment (Visit 1), the physical cumulative score on the SF-12 was 40.97 (SD = 7.83, 95% CI [35.37, 46.58]) and the mental cumulative score was 46.44 points (SD = 10.64, 95% CI [38.83, 54.06]). After the

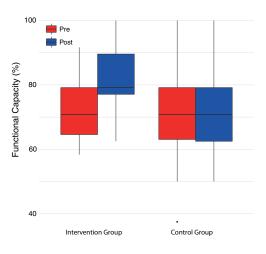


Fig.7 Results of the Ffb-H-R in both groups in pre/post comparison. Values around 70% functional capacity are considered moderate functional impairment, values from 80 to 100% correspond to normal functional capacity, which was achieved in the IG after the treatment

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application of the four-week multimodal VR therapy (Visit 2), a value of 39.30 points (SD = 8.01, 95% CI [33.91, 44.68]) was measured on the physical cumulative scale and a value of 48.39 points (SD = 7.13, 95% CI [43.60, 53.191) on the mental cumulative scale. Neither change was significant (physical p = 0.575; mental p = 0.445). In the CG, at Visit 1, a value of 35.85 points (SD = 7.91, 95% CI [30.19, 41.51])) was measured on the physical cumulative scale and a value of 50.31 points (SD = 7.66, 95% CI [44.83, 55.80]) on the mental cumulative scale. After the application of the four-week multimodal therapy (Visit 2), a score of 37.76 points (SD=7.27, 95% CI [32.87, 42.65]) was recorded on the physical cumulative scale and 56.23 points (SD = 4.77, 95% CI [53.03, 59.43])) on the mental cumulative scale. The physical cumulative scale showed no significance (p = 0.441), whereas a significant increase was recorded on the mental cumulative scale (p = 0.011). The mental cumulative scale of the CG showed a significant increase on the pre/post comparison of the SF-12 in both groups.

3.3.2 Degree of immersion

Since this scale was only collected after the use of VR, an average score of all participants of the IG was calculated, which was 19.09 points (percentile rank 60–77) (min = 3, max = 28), corresponding to a higher degree of immersion. Only 23% of the reference population achieved a higher value in comparison to the VR group investigated here.

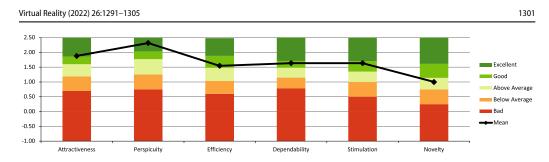


Fig. 8 UEQ scales of the evaluated VR system compared to benchmarks

3.3.3 User experience

The participants rated the VR system as at minimum above average on each individual subscale of the UEQ. The VR system achieved an 'excellent' rating for attractiveness and perspicuity. Efficiency, dependability and stimulation were rated as 'good,' while the originality of the VR solution was rated as 'above average.'

The measured data were subsequently set in relation to benchmark data (Table 3). The benchmark data set contains data from 20,190 participants from 452 studies concerning different products (business software, web pages, web shops, social networks).

4 Discussion

4.1 Main findings

The aim of this unblinded randomized controlled pilot study was to evaluate a four-week multimodal pain management in the form of a VR therapy. We conducted the study with older adults with CBP, in which the IG received movement therapy and psychoeducation in a VR exergame, and the CG received movement therapy as chair-based group exercises and psychoeducation in a real-world group setting.

Although the VR therapy (IG) did not reach the pain intensity reduction of the CG (IG: MD = 0.64; CG:

Table 3 User experience questionnaire results

MD = 1.64), the results of the present study showed that a pain intensity reduction can be reached with the current VR exergame prototype, albeit not significantly. In the study of Nees et al. (2020), chronic non-specific back pain patients completed a conventional three-week multidisciplinary pain management program. The mean pain intensity decreased from 5.24 ± 2.08 to 3.80 ± 2.02 (MD: 1.44). The mean pain intensity reduction roughly corresponds to that of our CG. On average, a reduction of approximately two points or approximately 30% on the NRS represents a clinically important difference for chronic low back pain (Farrar et al. 2001; Maughan and Lewis 2010). In the IG, a pain intensity reduction of 18.02% was achieved, whereas the CG reached a reduction of 43.64%. In the pilot study of Darnall et al. (2020), a VR cognitive behavioral therapy treatment for chronic pain led to an average pain intensity reduction of 30% (NRS MD = 1.48 SD = 2.08) in a 21-day treatment period. Considering the pain intensity values after 12 days, similar results were achieved as in our study with the IG. The proof-of-concept study of Alemanno et al. (2019) showed greater pain reduction in the use of a VR headset in conjunction with an exercise therapy for CBP. Patients who underwent a six-week neurorehabilitative treatment (12 sessions) using VR showed a significant average pain reduction of 4.5 on the NRS. Possible explanations for a lower reduction in pain intensity in the CG are, on the one hand, the higher accuracy of the exercise execution without VR headset and, on the other hand, group therapy was offered in

Scale	Evaluated Prototype compared to benchmark Confidence intervals ($p = 0.05$) per scale					
	Mean	Std. Dev	Conf. interval	Comparison to Benchmark	Interpretation	
Attractiveness	1.88	0.79	1.42-2.34	Excellent	In the range of the 10% best results	
Perspicuity	2.32	0.78	1.86-2.78	Excellent	In the range of the 10% best results	
Efficiency	1.55	0.67	1.15-1.94	Good	10% of results better, 75% of results worse	
Dependability	1.64	0.85	1.14-2.14	Good	10% of results better, 75% of results worse	
Stimulation	1.64	1.07	1.00-2.27	Good	10% of results better, 75% of results worse	
Novelty	1.00	1.24	0.27-1.73	Above average	25% of results better, 50% of results worse	

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the control group. The social aspect should not be neglected in the target group, as the exchange can act like a support group. Participants often came a little earlier or stayed a little longer after the training session to communicate with other group members. This illustrates that a certain group dynamic was present. The social component in particular is an important factor in therapy adherence and should not be

Mehra et al. 2016). The results of the present study showed a significant improvement in the IG (p=0.026) in the subjective functional capacity (Ffb-H-R) in the context of activities of daily living (mobility, personal hygiene, getting dressed and undressed). In the IG after the therapy in VR, the values improved from a functional capacity classified as moderate functional impairment (73.11%) to a normal functional capacity (81.82%).

underestimated for the target group (Picorelli et al. 2014;

In terms of fear-avoidance behavior (TSK-11), both groups showed a reduction compared to the data before the four-week intervention, however, without significance. The IG showed a reduction from 19.72 to 17.82 points and the CG reduction from 21.55 to 20.73 points. Part of the Fear-Avoidance model (Leeuw et al. 2007) is catastrophizing pain; studies using VR in CBP also observed a significant decrease in pain catastrophizing over time, which may be consistent with the decreasing results of the TSK-11 score in our study. However, the reference data of people with chronic pain (Hapidou et al. 2012) show a TSK-11 score of 30.4 (SD = 6.6), which is considerably above the achieved pre and post values in the present study. The comparable study data suggest that fear avoidance was underrepresented in our two cohorts.

In both groups, an increase in the mental summative scales was observed in the results of health-related quality of life (SF-12). Only the CG increased its value in the physical cumulative scale of the SF-12. Further, users of the VR system perceived an immersion that can be interpreted as 'higher degree of immersion' according to the TUI. The participants of the IG rated the VR system as at least above average in the UEQ. The VR system achieved a 'excellent' rating for attractiveness and perspicuity.

An important factor for the treatment outcome of CBP is the adherence to home exercises or exercise behavior outside of the physiotherapy sessions (Mannion et al. 2009). Studies in physiotherapy indicate that higher exercise adherence is associated with improved physical function (Thomas et al. 2002; van Gool et al. 2005). However, maintaining the exercise regimen at home can be difficult for many patients. Slujis et al. (1993), showed that only 35% of participants (N=1,178) performed exercises at home. To increase motivation and adherence, a VR exergame under physiotherapeutic supervision for the treatment of older patients with CBP would be a conceivable adjunctive therapy to multimodal pain management. However, VR therapy should not replace conventional multimodal pain therapy, as its effectiveness is too low according to our study.

4.2 Feasibility

The pilot study demonstrated it would be feasible to conduct a larger RCT study using a multimodal pain management in VR. Nevertheless, some adjustments are required in order to conduct a larger study. One challenge that some participants had when using the VR game was their own body size. For some participants, for example, the arm span was not sufficient to place the vegetables from the conveyor belt into the boxes to the right and left of them during the "vegetable sorting." A possible solution would be to adapt the exercise by improving the camera and object height integrated into the system. Furthermore, participants shared that the achieved score of some exercises were not immediately or not at all apparent or judged the interpretation of the score as intransparent. In a subsequent VR games, attention should be paid to the visualization of the player's achieved score as well as that of the maximum score to be achieved. Furthermore, some of the test persons noticed that a wrong execution of some exercises did not result in any (negative) consequence (e.g., torn hurdle during the exercise "hurdles"). As a solution, more attention should be paid in future to the game mechanics. Furthermore, it became apparent during the execution of the exercise that the positioning to the respective object shown in VR varied in part and that equal distances to the center of the object were not given (e.g., during the exercise "ball bucket"). This led to the fact that the object could not be grasped precisely. Likewise, in future, the exercise needs to be adapted by adjusting the position of the respective object.

With regard to the voice dialog system, the assignment of voice commands did not function correctly. Voice commands, such as "One more time." or "Repeat exercise." did not result in correct execution of the VR software. In addition, some participants criticized the latency between voice recording and execution by the VR software. Last, participants shared that they would like to see more variation in the communication of praise.

Regarding a future RCT, blinding of the assessors, e.g., by blinding the outcome assessment to limit observer bias, also called "detection bias" would be advisable. This was not applied in the pilot study. Further, future studies should examine CBP's motivation and adherence during the VR training period. Although user experienced was measured in the IG in this study, a comparison to a control group is necessary to compare the results. The user experienced was only considered in the intervention group to explore initial results. For this reason, this would be an interesting outcome for a future RCT.

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4.3 Limitations

The interpretation of the study findings is limited because of the small sample size. The study of a demonstrator created in the grant guideline is more of a proof-of-concept than a large-scale clinical trial. The VR system represents a pre-economic demonstrator. For this reason, further investigation with older people with chronic low back pain using multimodal VR therapy is needed. The tested demonstrator needs further adaptation for future successful use and further research with larger samples. Another limitation was the unequal gender distribution in the two samples, although it did not differ significantly. However, considering the prevalence of chronic back pain, 28.0% of women and 17.4% of men aged 70 or older have this condition in Germany (Von Der Lippe et al. 2021). Therefore, a targeted representation of these numbers could be considered in a larger study for both groups. The study duration of four weeks is a minimum for such a pain management program; the system could be tested in further studies over a longer period of time. A bias could have occurred from the fact that the CG received group therapy, which could have led to increased motivation through group dynamic processes. The VR exergame of IG, represented individual therapy, therefore, in future, a more adequate control group would be with individual therapies instead of group therapy or the application of group therapy in the exergame. Due to the onset of the COVID-19 pandemic toward the end of the study, several participants in the IG did not attend the final appointments of the intervention phase through fear of infection. Furthermore, the usability of the system was limited by the handling of the dialog system, which required a learning phase by the participants in the IG. Other technical problems in the IG included connection problems with the base stations and Internet problems, which led to a brief interruption of the image transmission in the VR headset.

5 Conclusion

This exploratory pilot study examined the preliminary effectiveness of a VR HMD multimodal therapy in a laboratory setting for older CBP patients. Our findings showed only a significant improvement in the subjective functional capacity (Ffb-H-R) after the completion of a four-week multimodal pain therapy in VR (movement therapy and psychoeducation). In the changes of fearavoidance beliefs and general physical and mental health, no significance was found in either group. Although the VR therapy did not reach the pain intensity reduction of the conventional multimodal pain therapy, the results of the present study showed that a pain intensity reduction can be achieved with the current VR therapy. The users perceived a higher degree of immersion and rated the user experience as mostly good and excellent in attractiveness and perspicuity.

The pilot study has provided important insights for further studies. Further research is needed to assess the motivation and adherence. In its current state, the prototype would only be a viable option for the treatment of elderly patients with CBP under physiotherapeutic supervision. In general, such a solution would be considered as an adjunctive therapy to the multimodal pain management, but cannot be used as a replacement.

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Authors' contributions OS conceived, designed, wrote the article, acquired and evaluated the data. RD performed the study, acquired the data, revised and edited the manuscript. NR and AR revised and edited the manuscript for important intellectual content and provided the technical or material support. UMW was responsible for the funding acquisition and supervised the study. All authors read and approved the final manuscript.

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Data availability The datasets generated are available from the corresponding author on reasonable request.

Declarations

Conflict of interest We have no knowledge of any declared conflicts of interest in connection with this publication. The authors declare they have no financial interests.

Ethical approval The study protocol was prepared in accordance with the standards of the Declaration of Helsinki and approved by the Ethics Review Committee and the Data Protection Committee of the Charité. All participants gave their written informed consent to take part in the study. In addition, the study is listed in the German Clinical Trials Register under the number DRKS00020576.

Consent to participate All participants were informed of study procedures and gave their written consent to participate.

Consent for publication Use of data and materials for purposes of reporting and publishing findings was included in the informed consent procedures and all participants gave their written consent allowing use of their data for publication. All authors have approved the manuscript for submission.

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Usability and Acceptance of Exergames Using Different Types of Training among Older Hypertensive Patients in a Simulated Mixed Reality

Oskar Stamm^{1,*}, Susan Vorwerg¹, Michele Haink¹, Kristian Hildebrand² and Ilona Buchem³

¹ Department of Geriatrics and Medical Gerontology, Charité—Universitätsmedizin Berlin,

- Corporate Member of Freie Universität Berlin and Humboldt-Universität zu Berlin, 13347 Berlin, Germany
- ² Department of Informatics, Berlin University of Applied Sciences, 13353 Berlin, Germany
 ³ Department of Economics and Social Sciences, Berlin University of Applied Sciences, 13353 Berlin, Germany
- Correspondence: oskar.stamm@charite.de; Tel.: +49-30-450-553-784

Abstract: Virtual and augmented reality (VR/AR) exergames are promising tools for increasing training motivation. However, the use of exergames with mixed reality (MR) headsets remains under-researched. Older adults with hypertension could also benefit from the increased training adherence associated with MR. Endurance and strength endurance exercises are recommended for this group to lower blood pressure. The aim of the preliminary study (n = 22) was to compare the usability and acceptance of two exergames, which represent two different training types—strength endurance training (SET) and endurance training (ET). The developed exergame prototypes were applied in "simulated MR" using a VR head-mounted display. We examined the following outcomes: usability (TUI), intention to use (TUI), subjective task load (NASA-TLX), frustration (NASA-TLX), and presence (PQ). The results showed that frustration was significantly greater in the ET than in the SET (p = 0.038). Presence was significantly higher in the SET (p = 0.002). No significant differences in usability and acceptance were found in the exergames. The results indicate that usability and acceptance are not related to the type of training when utilizing MR exergames. Whether the results are transferable with a real MR headset must be determined in further research.

Keywords: virtual reality; hypertension; rehabilitation; UX; presence; immersion

1. Introduction

According to the results of the German Health Update (GEDA) 2014/2015 European Health Interview Survey (EHIS) study, nearly one in three German adults has medically diagnosed hypertension. Almost two-thirds of adults aged 65 and older (63.8% of women and 65.1% of men) in Germany are known to have high blood pressure [1]. Physical activity may be beneficial for both the prevention and treatment of hypertension [2]. Moderate-intensity endurance and strength endurance exercises are recommended for older adults with hypertension to lower blood pressure. Following the guidelines of the European Society of Cardiology and the European Society of Hypertension (ESC/ESH), hypertensive adults should perform at least 30 min (min) of dynamic aerobic exercise of moderate intensity five to seven days per week and additional resistance exercise on two to three days per week [2].

The BewARe project, which is a three-year research and development project founded by the German Federal Ministry of Education and Research (BMBF), aimed to develop a sensor-supported augmented reality (AR)/mixed reality (MR) system as a form of movement training for seniors with hypertension. The main goal was to enhance motivation and achieve adherence to exercise training since continuity of practice can be an obstacle for many older adults (aged 65 and older). To accomplish these goals, it was necessary to create a user-friendly, adaptive, personalized AR/MR exergame tailored to the target group. For

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Copyright: © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). this reason, a user-centered design (UCD) was developed in the project. As recommended in a systematic review by Duque et al. [3], it is advisable to involve elderly people from the initial steps onward, including collecting the essential specifications for the framework. The papers of Stamm et al. [4] and Vorwerg et al. [5] described the requirements for the system and movement training. In the current paper, the usability and acceptance of two types of training will be compared using a functional VR prototype developed based on the requirements gathered previously. In the requirements analysis, Stamm and Vorwerg showed that AR exergames should focus on the endurance component, as well as other concepts, and adapt training to the user's health profile and fitness level through precise training control via heart rate monitoring. The older adults wanted an interactive exergame with motivating, playful elements. The results suggest that many seniors would prefer an AR system to a VR system because of the lower risk of falls. Furthermore, a requirement of the experts was that four to five 30-min training sessions be carried out per week. A virtual agent was the first solution to the requirement of a multiplayer exergame. Due to the existing limitations of AR/MR headsets, such as the field of view in the HoloLens, the consortium decided to implement a high-fidelity prototype VR that simulates an ideal MR.

Since the definition of MR is ambiguous in the scientific community, it is first necessary to define what is meant by it in this paper. Milgram and Kishino's reality-virtuality continuum [6] introduced the term "mixed reality". They defined MR as a subset of VR-related technologies that involve the merging of real and virtual worlds regardless of the environment. Skarbez et al. [7] revised Milgram and Kishino's reality-virtuality continuum, considering the new technological possibilities, and provided a new taxonomy for describing MR experiences with dimensions including the extent of world knowledge, immersion, and coherence. Speicher et al. [8] conducted expert interviews and a literature review from which six notions of MR were derived. As a consortium, we considered MR to be a "stronger" version of AR involving possible interactions between the user and the virtual objects as well as the latter and the real environment, as described by Speicher et al. [8,9]. The developed high-fidelity prototype was applied in a room that was exactly replicated in VR, simulating the feeling of reality for the study participants and creating a "simulated MR" with a VR head-mounted display (HMD).

The motivation behind this preliminary study was to ascertain whether different types of training have an influence on the usability and acceptance of older adults in relation to an MR exergame. In this way, a better estimation of usability and acceptance can be made for an MR training program that includes both types of training. Based on previously mentioned exercise guidelines for nonvirtual training in adults with hypertension, an MR training program would probably offer a maximum of one type of training preday to avoid the risk of an exercise-related acute cardiac event. If the usability is significantly lower for a certain training type, there is a risk of low adherence on that day, and the entire MR training program could be cancelled due to the decreasing level of motivation. In order to analyze in this preliminary study the usability and acceptance of two exergame versions, which represent two different training types (strength endurance training (SET) and endurance training (ET)), the following hypotheses were developed:

Hypothesis 1 (H1). There is no significant difference in <u>usability</u> between the guided SET exergame and the gamified ET exergame.

We tested Hypothesis 1 against the following alternative hypothesis.

Hypothesis 2 (H2). There is a significant difference in <u>usability</u> between the guided SET exergame and the gamified ET exergame.

Hypothesis 3 (H3). There is no significant difference in acceptance (intention to use, ITU) between the guided SET exergame and the gamified ET exergame.

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We tested Hypothesis 3 against the following alternative hypothesis.

Hypothesis 4 (H4). There is a significant difference in <u>acceptance</u> (ITU) between the guided SET exergame and the gamified ET exergame.

Hypothesis 5 (H5). There is no significant difference in <u>subjective task load</u> between the guided SET exergame and the gamified ET exergame.

We tested Hypothesis 5 against the following alternative hypothesis.

Hypothesis 6 (H6). There is a significant difference in <u>subjective task load</u> between the guided SET exergame and the gamified ET exergame.

Hypothesis 7 (H7). There is no significant difference in the <u>frustration</u> experienced between the guided SET exergame and the gamified ET exergame.

We tested Hypothesis 7 against the following alternative hypothesis.

Hypothesis 8 (H8). *There is a significant difference in the <u>frustration</u> experienced between the guided SET exergame and the gamified ET exergame.*

Hypothesis 9 (H9). There is no significant difference in the <u>presence</u> perceived between the guided SET exergame and the gamified ET exergame.

We tested Hypothesis 9 against the following alternative hypothesis.

Hypothesis 10 (H10). There is a significant difference in the <u>presence</u> perceived between the guided SET exergame and the gamified ET exergame.

2. Related Work

2.1. Technology Acceptance Models

Technology acceptance models are used to explain how people utilize or accept a particular technology. Intention to use can be considered a predictor of behavior, according to Davis' technology acceptance model (TAM) [10]. The TAM is based on Fishbein and Ajzen's theory of reasoned action [11], in which behavioral intention is defined as an individual's subjective probability of performing a particular behavior [11,12]. According to Davis, there are three factors that affect technology acceptance: perceived usefulness and ease of use, as well as attitude toward using. Over the years, there have been several extensions of the TAM to improve the predictive accuracy of technology use [13]. The most inclusive model is the unified theory of acceptance and use of technology (UTAUT), which integrates elements from eight different technology acceptance models [14]. It is common to adopt the TAM and the UTAUT to assess the intention of older people to adopt new technologies. Cechetti et al. [15], for example, formulated a questionnaire based on the TAM to evaluate a mobile health application for hypertension monitoring in order to improve user engagement. However, relevant psychological factors, as well as theories regarding aging, which are crucial in the actual employment of technologies, were not considered in these technology acceptance models. Kothgassner et al. [16] developed an instrument, the Technology Usage Inventory (TUI), which includes key psychological factors to better reflect accessibility, usability and acceptability and is thus intended for older adults. Longo [17] investigated the relationship between usability and mental workload and found that these are two non-overlapping constructs that can be used together to improve the prediction of human performance.

2.2. The Usability and Acceptance of HMD-Based VR Exergames in Older Adults

In a systematic review by Miller et al. evaluating the effectiveness and feasibility of the use of VR/gaming systems by older adults at home to enable physical activity, the authors assessed the evidence as weak with a high risk of bias. In studies analyzing feasibility, strong retention (\geq 70%) and adherence (\geq 64%) were reported [18]. Nevertheless, this systematic review must be put into perspective since rapid technical development means that completely different systems are available in the current commercial market. For example, Miller et al. did not consider HMD technology in 2014.

Tuena et al. [19] analyzed the usability, user experience (UX), and feasibility of VR clinical systems with older adults in a more recent systematic review. Regardless of a number of technical and interactional issues, the included studies showed that the usability of clinical VR systems is good, well-accepted, appropriate, effective, and useful [19]. However, the findings indicated that non-HMD systems are considered better for older people. Huygelier et al. [20] assessed the acceptance of VR HMDs with 76 older adults. The participants positively accepted and tolerated the VR HMD. The self-reported cybersickness was minimal and was not associated with VR exposure.

Nevertheless, the digital divide between younger and older adults may inhibit older adults from achieving the benefits of immersive technologies [21]. Older people are confronted with individualized challenges when using VR or AR. They vary widely in terms of their use of and attitudes toward technology. Therefore, developers of VR/AR software and hardware should consider individual needs and skills [22,23]. Physical and cognitive abilities can vary among older adults. Thus, mobility impairments, dementia and visual or hearing losses may occur. Especially in VR, these can lead to an increased risk of falls or limited use of the application. Therefore, it is important that these are considered in the development of VR/AR systems [23].

Initial analyses also showed a high acceptance and usability in relation to sports activities with a VR HMD system [24–26]. The Virtual Park, a VR-based system on a cycle-ergometer, aims at improving the performance of elderly patients during endurance exercise training. The training was found to be feasible and positively accepted by elderly people with chronic respiratory diseases. After a single session, the preliminary results for a group of eight patients demonstrated excellent usability and high acceptability [27]. A canoeing game was also tested on older people as a VR HMD. The results indicated that Canoe VR was received very well and can be utilized as an additional fitness tool [28]. Other types of training outside of the endurance category have been considered in only a few investigations involving older adults and HMD-based VR. Hoeg et al. employed virtual reality-based high-intensity interval training for pulmonary rehabilitation in their feasibility and acceptability study [29]. The use of VR in their study did not lead to cardiovascular demands, higher dyspnea, tension or any serious adverse events or severe cybersickness.

A few works have examined physical activity over a longer period of time in multiple training sessions. In a pilot study by Shabbir et al. [30], 30 older adults tested nine VR applications that promote physical activities, among other tasks, for 15 min twice a week for six weeks. The older adults perceived VR as useful, easy to use, and an enjoyable experience. In an investigation by Chau et al. [31], training for 30 min three times a week for six weeks in the VR was recommended for older individuals with disabilities. Most of the 135 participants accepted the VR training, and 65.2% provided positive comments.

In some works, immersive HMD VR systems have been compared with traditional video exercises. Kruse et al. [32] conducted a study with 25 older adults in order to compare a recorded 2D gymnastics video with an immersive VR exergame. The acceptance observed in the investigation suggests that a VR exergame can be a suitable alternative but not a replacement for 2D video-based exercise activities.

2.3. Exergames Using Holographic MR Headsets

Although there are already VR exergames that are used by older adults, it is difficult to identify any publications on exergames for MR headsets. Kunze et al. [33] described a new research field called "Superhuman Sports" as human augmentation, which combines the competitive and physical elements of a sport with technology to overcome the limitations of the real world. Kegeleers et al. [34] developed such a "Superhuman Training" application for AR, which is an adventure shooter for the Microsoft HoloLens and represents a multiplayer game. Through social interaction, players work together to destroy an energy core. An initial survey showed that 7 out of 10 participants were satisfied with the level of physical exertion of the game. The game League of Lasers by Miedema et al. [35] is a combination of football and Pong in which two teams compete against each other while both wearing a HoloLens. In a user study with 32 participants, the game was rated as fun to play, intuitive and immersive. Another multiplayer augmented reality game is VRabl [36], which is a dodgeball game based on two Microsoft HoloLenses. The first evaluation indicates that VRabl is also enjoyable and immersive for older adults.

An initial prototype exergame in an MR environment for rehabilitation was evaluated with ataxic patients [37]. The exergame is a HoloLens 2 application involving a pointing and reaching exercise to improve control over upper limbs. Currently, there is a dearth of exergames for holographic MR headsets, which is certainly related to the novelty of the technology and the limitations that still exist with MR headsets. Consequently, there is a lack of studies evaluating MR exergames in the context of rehabilitative interventions.

2.4. Data Already Published from the Study

Vorwerg et al. [38] presented a part of the data collected in this study and showed in the results that both VR exergames can lead to a positive short-term effect on lowering blood pressure. Heart rate was measured in the training sessions via smartwatches. Furthermore, the rate of perceived exertion (RPE) and the NASA-TLX subscales of mental, physical, temporal demand, and effort were presented in the work. Stamm et al. [39] compared VR sickness (Simulator Sickness Questionnaire [40]) between a strength endurance-based and an endurance-based VR exergame. Significant differences were found only for the scale "oculomotor", which was higher for the endurance exergame. Buchem et al. [41] described the gamification design of the exergame and investigated the user experience of the endurance-based exergame with the User Experience Questionnaire [42]. The results showed for all scales a score of at least above average compared to the benchmark. The "stimulation" and "novelty" scales were classified as "good". In a further paper, Buchem [43] presented the design for rapport with virtual agents in a simulated mixedreality environment.

3. Materials and Methods

The aim of the preliminary study was to evaluate the usability and acceptance of two VR exergame versions, which represent two different training concepts. The first exergame is a strength endurance training (SET) game, and the second is an endurance training (ET) game. Both exergames were developed as part of the BewARe project [44] for the physical training of older patients with hypertension. The VR exergame prototypes used "simulated" MR environments in order to complete an initial pilot study with older hypertensive adults in an ideal environment. Ethical approval was gained from the Ethics Committee of the Charité—Universitätsmedizin Berlin (No. EA1/019/20) and was registered in the German Clinical Trials Register (DRKS-ID: DRKS00022881).

3.1. General

The pilot study applied a mixed-method approach and included quantitative and qualitative instruments for data collection. This paper focuses on the quantitative results. The investigation was conducted in a VR setting in a mobile laboratory truck called the VITALab.Mobile in 2020.

3.2. Procedure

The participants were recruited via the internal sample database of the Geriatrics Research Group of the Charité Berlin or by flyers via a university for seniors and a facility for health sports. A personal telephone screening was conducted to clarify which volunteers matched the inclusion criteria. On the first visit, before the volunteers were included, the Tinetti test [45] took place, which measured the risk of falling. Participation was only possible if there was no increased risk of falling involved. The following inclusion criteria were applied: $(1) \ge 65$ years, (2) diagnosed with essential hypertension (stage I), (3) independent mobility, and (4) at least one fully completed training session. Participants who did not complete the first training session had to be excluded. The exclusion criteria were: (1) the existence of a legal guardianship, (2) mild cognitive impairment (MCI) and severe cognitive impairment (Telephone Interview for Cognitive Status, (6) medical conditions associated with a high risk of falling (stroke, Parkinson's disease), and (7) an increased risk of falling (Tinetti test < 24 points). All participants were informed about the study procedure and provided their written consent to participate.

The included participants undertook the same procedure on both visits. The only difference was the use of various "simulated" MR applications (ET and SET). First, the participants filled in the Technology Usage Inventory pre-test [16], which was the first part of the questionnaire (pre-testing) and had to be submitted before the intervention. During Visit 1, the immersive tendencies questionnaire [47] was conducted before the task-based application. The participants were then briefed about the HMD headset. After that, the trackers were attached to their hands, and the VR headset was put on. The taskbased application of the movement training in VR subsequently followed. All participants performed the training in the same order. On visit 1, they performed the strength endurance training application, and on visit 2, they performed the endurance training application. There was no more than one week between visit 1 and visit 2 for all the participants. Both applications consisted of five different training sequences (introduction, warm-up, training, cool-down, and evaluation). The training sessions lasted about 25 min each. After the applications, the following assessments were completed by the participants during both visits: the TUI post-test [16], the National Aeronautics and Space Administration (NASA) task load index [48] and the presence questionnaire [47]. Other assessments which are not described in this publication were also applied. The remaining assessments are mentioned in Section 2.4 and can be found in the publications named.

3.3. Measures

3.3.1. Technology Usage Inventory

The Technology Usage Inventory [16] is employed to assess technology-specific and psychological factors that contribute to the actual use of new technology. The instrument is based on the TAM and contains the following eight scales: curiosity, anxiety, interest, ease of use, immersion, usefulness, skepticism and accessibility. In addition, the procedure contains a scale measuring intention to use (ITU). The internal consistencies (Cronbach's alpha) of the eight scales range from $\alpha = 0.70$ to $\alpha = 0.89$ [16].

3.3.2. NASA Task Load Index

The NASA task load index (TLX) [48] is a subjective instrument for assessing workload. In our case, we applied the NASA-TLX to evaluate the task load during the use of taskbased exergames. The NASA-TLX calculates an overall score based on a weighted average of ratings on six subscales: mental, physical and temporal demand, as well as performance, effort and frustration. The German version of the NASA-TLX showed a high internal consistency (Cronbach's $\alpha = 0.84$) [49]. 3.3.3. Immersive Tendencies Questionnaire and Presence Questionnaire

The immersive tendencies questionnaire (ITQ) [47] was developed to measure the tendency of individuals to be involved or immersed in virtual environments. The presence questionnaire (PQ), which was also developed by Witmer and Singer, measures the degree to which individuals perceive presence in a virtual environment. The ITQ consists of the following subscales: focus, involvement, emotions and game. The PQ includes subscales measuring realism, possibility to act, quality of interface, possibility to examine, self-evaluation of performance, sounds and haptic perception. The internal consistencies (Cronbach's alpha) for the ITQ and PQ were 0.75 and 0.81 [47].

3.4. Materials

3.4.1. VITALab.Mobile

The study took place in the Living Lab VITALab.Mobile [50], which is a project associated with the BewARe project. The VITALab.Mobile (Figure 1) is a mobile VR/AR laboratory set up in a truck for case, field studies and clinical trials in extended reality (XR) research. During the evaluation, the VITALab.Mobile was placed on the campus of the Evangelisches Geriatriezentrum Berlin.



Figure 1. The study took place in the VITALab.Mobile, a mobile VR/AR laboratory for case and field studies.

Since, at the time of the study, the limitations of MR headsets for the safe and effective use of MR training could not be guaranteed, the consortium decided to use a high-fidelity prototype in VR. To achieve this as effectively as possible, the interior of the VITALab.Mobile truck was recreated in VR, here referred to as "simulated MR". Based on a training room (Figure 2), it contains various real training objects, which were also recreated in VR to enhance the feeling of immersion. The participants were supposed to experience the feeling that they had put on an MR headset through which they could see the exact same room.

3.4.2. Equipment

In the study, an HTC Vive Pro was used as a VR HMD headset in order to simulate an MR system, which will be a future use scenario. In addition to the headset, two different hand controllers were utilized. While in the SET exergame, the trackers were attached to the hands of the users, Valve Index controllers were employed in the ET exergame. The trackers in the SET exergame allowed the participants to interact with objects (dumbbells and a chair), which also had attached trackers. The Valve Index controllers, on the other hand, enabled finger tracking and thus grasping, releasing, and throwing in the ET exergame. The Valve Index Base Station 2.0 devices were positioned diagonally to each other under

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the ceiling of the truck. A Polar M600 smartwatch was utilized to monitor and record the heart rate during the exergame application.



Figure 2. (**A**) Participant in the VITALab.Mobile with the real training objects: chair and dumbbells; (**B**) recreated interior of the VITALab.Mobile in VR with the virtual equivalents of the training objects and the virtual trainer agent Anna. Both images (**A**,**B**) were taken independently of each other at different times; thus, e.g., the chair is not in exactly the same position in the images, which, however, was, the case during the test.

3.4.3. SET Exergame

The strength endurance training (SET) exergame included strength endurance-based exercises in the main part. Only the main part (excluding the introduction, warm-up, cool down and training analysis) differed between the two exergames. The SET exergame represented guided instruction-based training. The participants performed five exercises ((A) squat, (B) overhead press, (C) lateral raise, (D) leg raise, and (E) heel raise), during which they remained in a static position (Figure 3). The trainer agent "Anna" instructed and supported the participants during the use of the exergames. First, the participants began the SET with a learning phase. In this stage, the participants were supposed to observe the virtual trainer during each exercise. The trainer showed the execution as well as explained important hints about the posture for the current exercise. After Anna's demonstration, the participants were asked to repeat the exercises three times each. This was completed with all five exercises. Subsequently, in the exercise phase, a set with 20 repetitions was performed for each of the five exercises (with the exception of the leg raise involving 12 repetitions). Between the exercises, a short break of 20 s was executed. During the active break, the participants walked around the room and touched colored bubbles, causing them to burst. To go beyond pure VR and simulate an MR, training objects were equipped with trackers (chairs and dumbbells) in the SET exergame. These could be moved freely in the space after the participants were prompted by Anna.

For the time orientation, a time bar was placed behind Anna, which functioned during the exercises at the speed of Anna's pace. A repetition counter was operated manually and was displayed to the left of Anna. The participants assumed that the repetitions were recognized automatically. This was not resolved for the participants during the interventions based on the Wizard of Oz methodology. Later in the project, automatic repetition counting will be enabled through motion detection. When the participants looked at their wrists, they saw a smartwatch, which they wore around their wrists in the same place as the one they had in the real world. This allowed the live-streamed heart rate (HR) to be read. A green display meant they were in the individual target HR as calculated for them; a blue one meant that they were below it, and a red one meant that they were above it. Behind Anna, the participants could see which exercise was being performed, and the exercise name was shown. Furthermore, the participants were told that voice control was possible, so the participants could say "pause" and Anna would recognize this. The Wizard of Oz methodology was again followed, in which the study staff paused the game when the command was given.

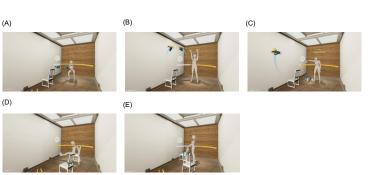


Figure 3. Five exercises of the SET exergame: (A) squat; (B) overhead press; (C) lateral raise; (D) leg raise; (E) heel raise.

3.4.4. ET Exergame

The endurance training (ET) exergame represented a gamified training session (Figure 4) and included three endurance-based exercises ((A) a ball game, (B) high five and (C) hustle dance). In the ET exergame, the participants actively interacted with the trainer, in contrast to the SET one. During the ball game, the participants threw a virtual ball into a virtual ring held by the agent, Anna. Within the given time, Anna moved the ring into different positions. The participants caught the ball with the Valve Index controllers through a gripping movement of the fingers. By spreading the fingers in combination with a throwing motion, the ball was thrown out of their hands. In the high-five game, Anna held her hands in different positions. The participant had to mirror her movements and touch the circles on Anna's hands with the controllers. In the hustle dance exercise, the participants were taught various dance steps by the trainer, which they tried to imitate first without music and then with music. The participants learned a certain sequence of steps consisting of four dance elements: a basic step, a cross step, the Travolta and a mixer. The ball and high-five games lasted 2–3 min, and the hustle dance lasted 12 min.

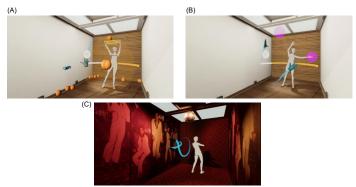


Figure 4. Three exercises of the ET exergame: (A) ball game; (B) high five; (C) hustle dance.

In the ball game and high-five exercises, a counter provided information about the number of ball hits and touches of the circles. As before, the Wizard of Oz method was used, and an automatic count was simulated. In addition, there was a time bar displayed during the two exercises behind Anna. As with the SET exergame, the participants could also look at the smartwatch during the exercises.

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3.5. Participants

The sample included 22 participants with essential hypertension. There were two dropouts due to motion sickness experienced in the first moments of using the VR headset. The sample was composed of 13 female and nine male participants. The average age of the participants was 75.4 \pm 3.6 years. No participants had any cognitive impairment measured with the Telephone Interview for Cognitive Status—TICS (37.3 \pm 2.6 points) or an increased risk of falls measured with the Tinetti test (27.6 \pm 0.8 points). Ten participants already had prior VR experience. The participants performed sports on average 2.5 times per week up to the time of the study.

3.6. Statistical Analysis

The data were analyzed with descriptive and inductive statistical methods using IBM Statistical Package for the Social Sciences (SPSS) Statistics 27. Based on the results, we presented descriptive data with means (M), standard deviations (SD), medians (Mdn) and 95% confidence intervals (CI). In the inductive analyses, each dataset was examined for a normal distribution. When the data were normally distributed, a paired *t*-test was applied. If there was no normal distribution, the Wilcoxon signed-rank test was employed. For all tests, statistical significance was set at an alpha level of 0.05.

4. Results

4.1. Technology Usage Inventory

To assess the level of technology acceptance (intention to use) and its specific aspects for the two exergame versions, the Technology Usage Inventory was used. No significant differences in mean scores were found in any of the subscales (Table 1). A Wilcoxon signed-rank test indicated that the median TUI post-test ranks of the VR-SET in the subscale usability, Mdn = 17.00, were not significantly different from the median TUI post-test ranks of the VR-ET in the same subscale, Mdn = 18.00, Z = -0.445, p = 0.656. On average, the intention to use was higher for the VR-SET exergame version, Mdn = 147.00, than in the VR-ET, Mdn = 132.00. However, no significant results could be achieved, Z = -0.261, p = 0.794. Thus, the acceptance did not differ between the guided instruction VR-SET and the gamified VR-ET exergame.

Table 1. Results of the Technology Usage Inventory (TUI) for the strength endurance training (SET) and endurance training (ET).

TUI	Training	Mean (SD)	Median (95% CI)	Z-Score	<i>p</i> -Value
Interest	SET ET	16.50 (5.48) 16.59 (5.78)	17.00 (14.07–18.93) 19.00 (14.03–19.15)	-0.035	0.972
Usability	SET ET	16.55 (3.49) 16.29 (3.81)	17.00 (15.00–18.09) 18.00 (14.55–18.02)	-0.445	0.656
Immersion	SET ET	16.68 (5.41) 16.86 (5.06)	17.00 (14.28–19.08) 16.00 (14.62–19.10)	-0.141	0.888
Usefulness	SET ET	13.55 (6.11) 13.82 (4.49)	13.00 (10.83–16.26) 14.00 (11.83–15.81)	-0.358	0.720
Skepticism	SET ET	10.18 (5.23) 11.67 (4.95)	10.00 (7.87–12.50) 13.00 (9.41–13.92)	-1.196	0.232
Accessibility	SET ET	10.18 (4.03) 11.77(3.61)	10.00 (8.39–11.97) 12.00 (10.17–13.37)	-1.734	0.083
Intention to Use	SET ET	134.00 (78.30) 140.68 (86.99)	147.00 (99.29–168.71) 132.00 (102.11–179.25)	-0.261	0.794

Results shown as arithmetic mean (standard deviation) and median (95% confidence interval). Scale minimum and maximum: Interest (min.: 4, max.: 28), Usability (min.: 3, max.: 21), Immersion (min.: 4, max.: 28), Usefulness (min.: 4, max.: 28), Skepticism (min.: 4, max.: 28), Accessibility (min.: 3, max.: 21), Intention to Use (min.: 3, max.: 20). Inter-group differences were calculated by Wilcoxon signed-rank test.

4.2. NASA-TLX

To determine the perceived task load, the NASA-TLX was performed (Figure 5). This paper will cover the weighted rating and both adjusted ratings of the NASA-TLX subscales relating to performance and frustration. The other subscales were reported by Vorwerg et al. [38]. The performance subscale measures how successfully the participants rate their performance of the task. The perceived performance level was significantly higher (p = 0.010) in the VR-ET (M = 139.55, SD = 76.31) than in the VR-SET (M = 102.50, SD = 73.11). The frustration level measures how insecure and discouraged (higher score) or secure and content (lower score) the participant felt during the task. The frustration experienced was also significantly higher (p = 0.038) in the VR-ET (M = 62.50, SD = 115.99) than in the VR-SET (M = 3.86, SD = 12.72). The weighted rating did not show any significant differences. A Pearson correlation coefficient was used to assess the linear relationship between the subjective task load (NASA-TLX weighted rating for the SET and ET) and the usability (TUI scale "Usability" for the SET and ET). There was no significant correlation between the variables of the NASA-TLX weighted rating and usability for the SET (r(20) = -0.33, p = 0.146) and between the variables of the NASA-TLX weighted rating and usability for the ET (r(20) = 0.00, p = 0.987). Moreover, no significant correlation was found for either type of training when combined with the TUI scale "Intention to Use" and the NASA-TLX weighted rating or "Intention to Use" and the Frustration subscale of the NASA-TLX.

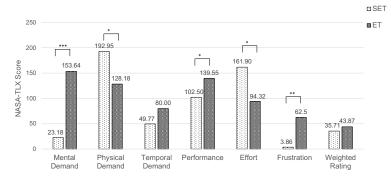


Figure 5. Results of the adjusted ratings of the subscales and the weighted rating of the NASA-TLX. The white columns represent the strength endurance training, and the gray ones represent the endurance training. Significance: * p < 0.05, ** p < 0.01, *** p < 0.001.

4.3. Immersive Tendencies Questionnaire

The immersive tendencies questionnaire was conducted prior to the task-based application during Visit 1. There were no significant differences between the sample (n = 22) and the reference sample (n = 94) based on either the subscales of the ITQ or the total score (Table 2). The mean total score was M = 65.59 (SD: 10.75) with a maximum score of 126.

4.4. Presence Questionnaire

In order to measure the degree to which the participants experienced presence in a virtual environment, the presence questionnaire was used (Table 3). A Wilcoxon signed-rank test indicated that the median PQ ranks of the VR-SET in the total score, Mdn = 117.00, were significantly different from the median PQ ranks of the VR-ET, Mdn = 107.00, Z = -3.114, p = 0.002. Furthermore, significant differences were found in the following subscales of the PQ: realism (p = 0.008), possibility to act (p = 0.001), self-evaluation of performance (p = 0.046) and haptic perception (p < 0.001).

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Table 2. Results of the immersive tendencies questionnaire (ITQ) and a reference sample from the Université du Québec en Outaouais (UQO) Cyberpsychology Lab.

ITQ	Sample	Mean (SD)	<i>p</i> -Value	Cohen's d
Focus	Pre VR Reference ¹	25.55 (3.97) 24.81 (7.54)	0.395	0.185
Involvement	Pre VR Reference ¹	15.41 (4.96) 15.33 (8.67)	0.941	0.016
Emotions	Pre VR Reference ¹	12.77 (3.73) 14.25 (6.70)	0.077	0.396
Game	Pre VR Reference ¹	6.64 (2.87) 6.56 (4.95)	0.902	0.027
Total Score	Pre VR Reference ¹	65.59 (10.75) 64.11 (13.11)	0.525	0.138

¹ 94 French-Canadian participants tested by the UQO Cyberpsychology Lab, Gatineau (Québec). Results shown as arithmetic mean (standard deviation). Inter-group differences were calculated by Wilcoxon signed-rank test. Effect size was determined by Cohen's d.

Table 3. Results of the presence questionnaire (PQ) for the strength endurance training (SET) and endurance training (ET).

PQ	Training	Mean (SD)	Median (95% CI)	Z-Score	<i>p</i> -Value
Realism	SET ET	40.09 (6.29) 37.00 (7.25)	41.00 (37.30–42.88) 39.00 (33.79–40.21)	-2.667	0.008
Possibility to Act	SET ET	22.18 (3.88) 18.77 (4.81)	22.00 (20.46–23.90) 20.00 (16.64–20.91)	-3.213	0.001
Quality of Interface	SET ET	14.59 (3.42) 13.86 (3.36)	15.00 (13.08–16.11) 13.00 (12.38–15.35)	-1.049	0.294
Possibility to Examine	SET ET	16.55 (3.08) 15.41 (3.40)	17.00 (15.18–17.91) 16.00 (13.90–16.92)	-1.858	0.063
Self-Evaluation of Performance	SET ET	11.77 (1.57) 10.82 (2.46)	12.00 (11.08–12.47) 11.00 (9.73–11.91)	-1.998	0.046
Sounds	SET ET	17.05 (3.51) 16.91 (3.80)	18.00 (15.49–18.60) 18.00 (15.22–18.60)	-0.400	0.689
Haptic	SET ET	11.73 (2.27) 10.05 (2.59)	12.00 (10.72–12.73) 11.00 (8.90–11.19)	-3.336	< 0.001
Total ¹	SET ET	112.59 (12.82) 104.00 (15.83)	117 (106.91–118.27) 107 (96.98–111.02)	-3.114	0.002

¹ Without the "sounds" and "haptic" sub-scores. Results shown as arithmetic mean (standard deviation) and median (95% confidence interval). Total score maximum without "sound" and "haptic": 126. Inter-group differences were calculated by Wilcoxon signed-rank test.

A Pearson correlation coefficient was computed to assess the linear relationship between the immersive tendencies (total score of ITQ) and presence (total score of PQ for the SET and ET). There was a significant negative correlation between the variables ITQ and PQ for the SET (r(20) = -0.45, p = 0.037) and a weak negative correlation between the variables ITQ and PQ for the ET (r(20) = -0.16, p = 0.479). The findings of Witmer and Singer regarding high ITQ scores resulting in a greater presence (positive correlation) could not be replicated with our exergames. Furthermore, a Pearson correlation coefficient was calculated to assess the linear relationship between the usability (TUI scale "Usability" for the SET and ET) and presence (total score of PQ for the SET and ET). There was a significant positive correlation between the variables Usability for the SET and PQ for the SET (r(20) = 0.48, p = 0.023) and also between the Usability for the ET and PQ for the ET (r(20) = -0.56, p = 0.008). However, no significant correlation was found for either type of training when combined with the TUI scale "Intention to Use" and presence.

5. Discussion

The aim of this pilot study was to compare the usability and acceptance of two simulated MR exergames, which represented two training types (strength endurance training and endurance training).

5.1. Principal Findings

The usability was measured with a scale derived from the Technology Usage Inventory. There was no significant difference, according to this scale, between the SET and ET exergames. Therefore, Hypothesis 1 cannot be rejected, and the alternative hypothesis H2 must be rejected, which implies that the two exergames are equally perceived as simple and easy to understand. Compared to the reference group in Kothgassener's TUI study, both VR exergames (SET and ET) were rated more highly in terms of usability (>65 years old (y.o.): M = 14.06) [16]. Preliminary investigations with small samples also demonstrated high usability in endurance training with immersive exergames [27]. One of the few papers that examined strength endurance in VR showed that overall, 59.4% of middle-aged adults and 37.5% of older adults were very and moderately willing to perform the VR dumbbell exercise. The group provided positive feedback about the usability [51].

Acceptance was also measured with the TUI, so the intention to use was examined. Hypothesis 3 cannot be rejected, and Hypothesis 4 must be rejected. There was no significant difference according to the scale measuring intention to use between both exergames. In Kothgassener's TUI study [16], similar scores were reached in the same age group (>65 y.o.: M = 112.43) [16]. Xu et al. [52] evaluated the technology acceptance model with older Chinese adults and VR exergames. The results showed that a more favorable attitude toward VR exergames was evident among older adults who are younger and retired, in addition to having higher education, better financial resources, and good health. This could be included as participant frame data in future research. In an investigation by Khundam [53], who did not examine older adults, the participants preferred aerobic (arm swings) more than strength exercise (squats) for a long period of exercise in VR. However, for a short period of exercise, they favored strength exercise more.

The subjective task load was examined with the NASA-TLX. There were no significant differences between the two exergames in the weighted rating. For this reason, Hypothesis 5 cannot be rejected. The similar results of the weighted task loads confirm the comparability of the two exergames. This would be useful if the two types of training were applied in a joint exercise program, as then a similar task load could be assumed, and an overload could be avoided. Exercise programs in a physiotherapeutic or sports medicine field include a variety of different training components, e.g., endurance, strength, mobility and coordination. Thus, both SET and ET could be present as single courses in one therapy program for hypertensive people. Kruse et al. [32] also used the NASA-TLX but not the weighted and adjusted ratings. They reported the NASA-TLX as the mean value, and by calculating the mean value for our dataset, we obtained values of M: 28.22, SD: 12.41 for ET as well as M: 39.36, SD: 8.41 for SET, which in comparison to those of Kruse et al. (M: 19.77, SD: 11.91) indicates a higher task load for our SET and ET. These results were to be expected considering the exercises in the two studies.

The results for the scale of the NASA-TLX measuring frustration were significantly higher for the ET than for the SET exergame. This leads to a rejection of Hypothesis 7, which implies we fail to reject alternative Hypothesis 8. One possible explanation is that the gamification of the ET allows for a greater motivational impact as well as more action options and therefore more opportunities for potential errors that may not occur as frequently in a guided instruction setting (SET). This could lead to increased frustration for the gamified ET exergame. According to the results of the qualitative interviews described in the paper by Buchem et al. [41], the dance sequence was too fast for some participants, and the steps were too difficult. This could explain why frustration was rated more highly in the ET. In the future, a practice phase for the dance steps, as well as an application over a longer period of time, are planned. In this target group especially, it is

necessary to introduce the users slowly to new technology. Another aspect that may have contributed to the higher frustration in the ET was the difficulty in handling the Valve Index controllers. These recognize finger movements, but the handling is a matter of habituation. The participants complained that they could not see their own hands in the ball game, which was an unfamiliar sensation. To achieve lower frustration, a longer learning period for the technology will be included in future studies, and thus, higher usability can possibly be achieved. They also complained about latency when throwing the ball, which did not correspond to the speed in reality. This also needs to be improved for the future prototype.

The results of the presence questionnaire total score indicated a significantly higher perception of presence in the SET than in the ET exergame. Thus, Hypothesis 9 must be rejected, and it is impossible for us to reject the alternative Hypothesis 10. Witmer assumed that a significant positive correlation existed between immersive tendencies (ITQ) and presence (PQ) [47]. This could not be demonstrated with our sample. In the same sample analyzed by Stamm and Vorwerg [39], the participants reported more symptoms of VR sickness or cybersickness in the ET exergame than in the SET one. In their systematic review, Weech et al. [54] showed that the number of studies that found a negative correlation between cybersickness and presence outweighs those that identified a positive one. In our investigation, this would be consistent as presence was higher in the SET than in the ET and VR sickness was higher in the ET than in the SET. Stamm and Vorwerg [39] assumed that the increased movement in space could be a cause of a higher VR sickness in the ET. This could also explain why a lower level of presence was perceived during the ET. Since presence correlates with usability, the main finding for VR exergames would be that it may be beneficial, although no causality should be assumed, to aim for high presence in exergames with older people.

Apart from the data collected using the named assessments, a motion analysis via the Microsoft Azure Kinect ran during the training. Motion data were collected for the next development stage, which should enable individual exercise feedback in a future prototype version. One of the purposes of the dashboard used was to determine the individual moderate exercise intensity zone. This dashboard provides the interface to the VR application and the Polar M600 smartwatch used. By recording the real-time heart rate through the smartwatch, the individual intensity zone could be displayed on the virtual smartwatch of the participants. In the dashboard, the medical professionals can monitor the heart rate of the participants in retrospect or via a monitor; the VR application could be displayed in real-time to, e.g., therapists or physicians. With the integration of the exercise feedback, a further step towards the individualization of the training is aimed to be achieved and can lead to better health-promoting effects in hypertension. The future prototype should be compared with the current study results, as the planned changes may have an impact on usability and acceptance.

5.2. Limitations

Technical problems involving the exergame prototypes in the test sessions have not yet been completely avoidable with the current state of the functional prototypes. For example, the base stations lost the tracking of the HTC Vive headset due to participants moving too forcefully in the truck. These technical issues could have had an impact on usability and could also be associated with increased frustration. For future testing, the truck should be supported by construction props. Due to the limited ceiling height in the truck, the base stations, which are responsible for tracking the headset and the tracker/controller, had to be mounted in quite a low position. With taller participants, a brief loss of headset position was observed, which resulted in a black screen for a few seconds or a short period of loss in the tracking of the trackers/controllers when they were raised very high. This could potentially have affected usability and frustration assessments, even though the aforementioned phenomena did not occur frequently. Furthermore, the fixed order of the interventions could have had an influence on the results. 85

The experience with the VR system from the first day of the study could have had an influence on the handling and execution. By testing both training programs several times over a longer period of time or randomizing the order of the training program type with several participants, this could be avoided. Since the training types differed in terms of the exercises, comparability was not easy. The training programs were different in content, included various controllers and training tools, and had slightly dissimilar intensity and duration. In addition, because only subjects with stage I hypertension were included, the results are not generalizable to subjects with other hypertension stages.

The Tinetti Test, which includes a gait and balance examination, was used to rule out impaired mobility during walking. However, the range of motion of the shoulder joint was a problem in a few participants, which resulted in some tasks not being performed under a clean execution. For an extension of the prototype, an individual adaptation of the possible range of motion is important; otherwise, use is only possible without movement restrictions.

6. Conclusions

In the preliminary study, we compared the usability and acceptance of two exergames representing two training types, strength endurance training (SET) and endurance training (ET), in older adults with hypertension. The exergame prototypes developed were applied in "simulated MR" using a VR HMD. The results indicate that usability and acceptance are not related to the type of training when using MR exergames with older adults. The subjective task load also did not differ significantly between the two types of training in the simulated MR. Nevertheless, major dissimilarities were found in terms of frustration. Thus, frustration was significantly higher in the gamified ET. There were also large variations in relation to presence. Presence was perceived to be significantly higher in the SET. Moreover, ideas for future improvements became evident through the investigation. For example, a longer practice phase, especially for ET, would be useful and should lead to less frustration. The external environment is also important, so preventing the wobbling of the truck due to movements should eliminate tracking losses in the future and thus also lower the level of frustration and possibly increase the perception of presence. Whether the results are transferable with a real MR headset must be determined in further research with a larger sample.

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Data Availability Statement: The data presented in this study are available on request from the corresponding author.

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Curriculum Vitae

My curriculum vitae does not appear in the electronic version of my paper for reasons of data protection.

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