Parallel Randomized Feasibility Trial of Occupational Therapy Virtual Reality Training for Stroke Patients

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Abstract. Recent investigations have brought Virtual Reality Training (VRT) to the forefront as a promising computer-based therapy for stroke patients, showing positive effects on arm function, balance, and walking recovery (Laver et al., 2017; Saposnik et al., 2016). Nevertheless, the challenges faced by stroke patients in accessing outpatient therapy after leaving inpatient rehabilitation, primarily due to transportation, distance, and lengthy waiting lists, have not gone unnoticed. In response, home-based VRT has emerged as a convenient and accessible alternative. This parallel randomized feasibility trial aims to accomplish two primary objectives: (1) evaluating the practicality of implementing VRT for stroke patients at home, and (2) assessing the feasibility of using various quantitative and qualitative outcome measures to gauge stroke recovery (Palmer et al., 2019). By exploring the potential of home-based VRT, this trial seeks to illuminate its effectiveness as a rehabilitation strategy, ultimately enhancing the overall recovery process for stroke patients. The study will comprehensively assess multiple aspects, including compliance, safety, enjoyment, perceived efficacy, and program cost, to determine the effectiveness and feasibility of home-based VRT for stroke patients nearing discharge from rehabilitation. Evaluations for balance, gait, and community integration will be conducted, with effect sizes analyzed to gauge the impact of the intervention. A total of forty participants will be randomly assigned to either the experimental group, engaging in VRT for rehabilitative exercises, or the control group, utilizing selected iPad apps. Both groups will undergo 30-minute exercise sessions, five days a week, for a period of six weeks. The intensity of VRT will be remotely monitored, with regular telephone contact maintained with all participants. Building on the findings of this trial, a definitive randomized controlled trial will be conducted to gain deeper insights into the use of VRT as a rehabilitative tool for post-stroke patients. This comprehensive and rigorous trial aims to establish the efficacy of home-based VRT in enhancing physical and cognitive functions for stroke patients. The results will provide robust evidence for the integration of VRT into stroke rehabilitation programs, potentially setting new standards of care for post-stroke patients. Moreover, the research could yield invaluable insights into the advantages and limitations of home-based VRT, paving the way for the development of more effective and accessible home-based rehabilitation programs. Ultimately, the study's findings will serve as evidence to support the development of a conclusive

D. V. Ferezagia et al. (eds.), *Proceedings of the International Conference on Vocational Education Applied Science and Technology (ICVEAST 2023)*, Advances in Social Science, Education and Humanities Research 783,
https://doi.org/10.2991/978-2-38476-132-6_13

randomized controlled trial, thoroughly examining the effectiveness of home-based Virtual Reality Training (VRT) in stroke rehabilitation.

Keywords: *virtual reality, virtual rehabilitation, virtual reality training, virtual reality for stroke, home-based virtual reality training*

1. Introduction

Stroke is a significant health concern in Ontario, leading to approximately 17,600 hospital admissions annually, with 50% of stroke survivors experiencing moderate to severe impairment (Rossi et al., 2018; Statistics Canada, 2018). After being discharged from inpatient stroke rehabilitation, most patients are still in the early stages of recovery, with their central nervous systems highly adaptable, presenting an opportunity for significant functional improvement (Kwakkel et al., 2004; Nudo, 2011). Effective therapy outcomes depend on intensity and task-specific approaches, emphasizing the need for ongoing, intensive therapy to maximize recovery (Kwakkel et al., 2015; Langhorne et al., 2011). However, not all eligible patients can access outpatient therapy due to various obstacles, such as transportation challenges, distance from rehabilitation centers, and limited availability.

To overcome these limitations, home-based Virtual Reality Training (VRT) emerges as a promising addition or alternative to traditional rehabilitation programs. VRT employs computer software to track movements and allows patients to interact with games or activities displayed on a TV screen. It is convenient, enjoyable, and suitable for extended use post-stroke. Research has demonstrated that VRT provides benefits for upper extremity function, standing balance, gait, and overall function in the sub-acute and chronic phases of stroke recovery, often comparable to or even exceeding those of conventional therapy (Laver et al., 2017; Saposnik et al., 2016).

Various preliminary studies have explored the use of home-based VRT for standing balance and upper extremity recovery after stroke, showcasing promising feasibility for ongoing rehabilitation at home (Laver et al., 2017; Meldrum et al., 2012; Perez-Marcos et al., 2012; Saposnik et al., 2016). Different VRT platforms offer a range of options, from tactile devices to motion-tracking cameras, with asynchronous or synchronous monitoring capabilities. While many users express high satisfaction with home-based VRT, some barriers like technical issues and lack of prior technical experience have been identified (Laver et al., 2017).

This study aims to contribute to the knowledge on home-based VRT by investigating the feasibility, acceptance, and safety of using a specific virtual reality system (Jintronix Inc.) for stroke rehabilitation at home. The system incorporates motor learning principles and provides a wide array of games and exercises designed to improve sitting and standing balance, gait, and upper extremity use. The study also seeks to assess the practicality of outcome measures, encompassing physical assessments, questionnaires, interviews, and logbooks. By comparing VRT with a program of iPad apps focused on

cognitive training and fine hand motor skills, the impact of VRT on physical outcomes will be evaluated.

Following a prospective, single-site, single-blinded, parallel-group randomized design, this feasibility trial will compare VRT with iPad apps. The results of this study will pave the way for a future definitive randomized controlled trial (RCT) to evaluate the efficacy of in-home VRT. The ultimate objective is to provide stroke survivors with more accessible and effective rehabilitation options, leading to improved outcomes and an enhanced quality of life.

2. Methods

2.1 Ethic, consent and permission

This study is being conducted with the approval obtained from the Research Ethics Boards of the Public Health University (NCT08842217). Prospective participants are provided with comprehensive information about the study, including details on procedures, potential risks and benefits, confidentiality measures, and the voluntary aspect of their participation. They are fully informed before signing the consent form.

Table.1 Procedures and participant timeline

Task		2022				2023	
		Sept	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**
Stage 1	Gainning research issues						
	Part 1. Systematic review to identify issues related to occupational therapy virtual reality training for stroke patient						
	Part 2. Eligibility screen						
	Part 3. Informed consent						
Stage 2	Develop Interventions Protocol						
	Part 1. Define theoritical construct on how occupational therapy virtual reality training for stroke patient						
	Part 2. Develop occupational therapy virtual reality training for stroke patient include design, features, content and						

	charactheristic						
	Part 3. Develop FITT of occupational therapy virtual reality training for stroke patient						
	Part 4. Develop protocol or instruction to using occupational therapy virtual reality training for stroke patient						
	Part 5. Define analytical and rationale the uniqueness of occupational therapy virtual reality training for stroke patient						
Stage 3	Assessments and Evaluation						
	Part 1. Conduct assessment to participant before following occupational therapy virtual reality training for stroke patient client and carers						
	Part 2. Conduct of occupational therapy virtual reality training for stroke patient						
	Part 3. Conduct evaluation to participant before following occupational therapy virtual reality training for stroke patient client and carers						
Stage 4	Analyzing Data						
	Part 1. Conduct analyzing data						
	Part 2. Drafting report						
	Part 3. Research conclution						
	Part 4: Submit Article						**X**

2.2 Participants

Starting in January 2023, recruitment of potential participants has been carried out at the Stroke Hospital in Indonesia, which serves as the primary rehabilitation center for stroke patients. The hospital admits around 250 stroke survivors into its inpatient program and 250-300 into its outpatient program each year. To be considered for the trial, stroke survivors must have physical impairment resulting from either an ischemic or hemorrhagic stroke. They should also possess adequate cognitive ability to learn Virtual Reality Training (VRT), be receiving inpatient or outpatient stroke rehabilitation services, and be capable of standing independently for at least two minutes.

In addition to these criteria, eligible participants must have a study partner who can attend two training sessions with them. They should also be proficient in reading, speaking, and understanding English and have sufficient space at home to safely perform VRT. Furthermore, they should not be away from home for more than two days a week during the study. Individuals with unstable medical conditions, seizures or vertigo, or those unable to safely engage in mild to moderate exercise are excluded from participation. However, the presence of expressive aphasia is not an automatic exclusion criterion. The eligibility screening process involves assessment by members of the patients' care team. If found eligible and interested, patients are provided with comprehensive information about the study before giving their written informed consent.

Participation in other non-VRT exercise or rehabilitation programs after discharge does not affect eligibility for this feasibility trial. All participants receive detailed information about the study, including procedures, potential risks and benefits, confidentiality measures, and the voluntary nature of their participation, before providing their consent to take part in the trial.

2.3 Sample size & recruitment

The determination of the sample size for this feasibility trial was not based on formal calculation but rather on considerations of available resources, time constraints, and recruitment expectations. Each group consists of 20 participants, with the VRT group believed to provide sufficient data for assessing the feasibility of home-based VRT. The overall goal is to recruit a total of 40 participants from a pool of approximately 375 stroke rehabilitation inpatients and 375-450 outpatient attendees over a period of 18 months.

To ensure that the clinical care team is well-informed about the study, their clinical manager will be actively involved, and presentations will be conducted during team

meetings. In the unlikely event of any serious adverse effects occurring during the study, it will be terminated prematurely.

2.4 Randomized, Allocation and Blinding

The recruitment of participants is the responsibility of the RA, and a computer-based randomization system is utilized to assign them randomly to either the experimental or control groups. To ensure concealment of the allocation, permuted blocks are incorporated. Immediately after enrollment, the research Occupational Therapist (OT) accesses the system to obtain the allocation information, while the RA remains unaware of the treatment allocation and conducts the outcome measures. Throughout the study, the research OT remains blinded to the outcome measure results.

In cases where a participant receives rehabilitation during the study period, the rehabilitation professional is informed of their participation to ensure the compatibility of home-based exercise with their therapy. If any serious adverse effects occur, the OT will reveal the participant's allocation.

2.5 Intervention

The experimental group in this study uses the Sadewa Rehabilitation software, a product developed by the esteemed Sadewa VR Lab situated at the prestigious University of Indonesia. To capture the participant's movements, a Kinect camera is employed, facilitating the control of an avatar that actively interacts with various activities displayed on a TV screen. These activities are carefully crafted to target and improve specific aspects of physical function, such as standing balance, reaching ability, stepping, gentle strengthening, and aerobic exercise. What sets this software apart is its flexibility in adjusting the difficulty level of each game or activity, allowing for customization based on individual physical abilities, rehabilitation objectives, fall risk, and tolerance.

On the other hand, the control group, while also having access to Sadewa Rehabilitation software from the same VR Lab, experiences a different set of applications designed to focus on distinct areas of cognitive enhancement. These applications are specifically tailored to enhance memory and cognition, sharpen visual scanning and tracking skills, and refine fine motor abilities.

By comparing the outcomes of these two groups, the study aims to uncover the potential benefits and impacts of the Sadewa Rehabilitation software in enhancing both physical and cognitive functions for participants. The diversity of activities and applications provided by the software offers a comprehensive approach to stroke rehabilitation, potentially leading to improved outcomes and a higher quality of life for the participants.

2.6 Assessment

To achieve the primary research objectives, the investigators will adopt the following measures:

1. The recruitment process will be evaluated over an 18-month period, comparing the number of participants meeting the study criteria and those approached. If fewer than 30 participants are recruited, modifications to recruitment procedures will be made for a definitive RCT.

2. Compliance with the research protocol will be assessed through multiple sources, including notes taken by the research PT, participant and study partner comments in the log book, phone conversations, and interviews. If most participants perform less than 450 minutes of VRT over the 6-week period (with a protocol requirement of 900 minutes), the use of VRT for motivating post-stroke exercise will be re-evaluated, and the reasons for non-compliance will be examined. Additionally, participant retention will be closely monitored, and if a loss of over 25% occurs, protocol adjustments will be considered.

3. Adverse effects will be carefully recorded through the log book and phone conversations. In case of major adverse effects, such as falls resulting in serious injury, the safety of using home-based VRT in this protocol will be reassessed.

4. The researchers will assess the ability of participants to use VRT at home by gathering feedback during installation, follow-up phone calls, interviews, and log book entries. The research PT will monitor VRT usage and progression asynchronously. Poor learning will be indicated if no progression is observed, and expressions of frustration or confusion with the games will suggest poor VRT ability.

5. The acceptability of VRT will be evaluated using information from log books, follow-up phone calls, and the administration of the Physical Activity Enjoyment Scale (PACES) during the post hoc assessment. PACES rates 18 statements about one's feelings regarding physical activity on a scale of 1 to 7.

6. To prepare a budget for a definitive RCT, the researchers will calculate costs related to VRT equipment and licenses, travel, and salaries.

Regarding the secondary objectives, the following outcomes will be assessed:

1. Feasibility and acceptance of a battery of outcome measures will be determined by measuring the completion of 11 outcome measures, including physical tests, questionnaires, a log book, and an interview. If participants are unable to complete all measures within a reasonable time frame, the inclusion of each measure in a definitive RCT will be reconsidered.

2. The potential of VRT to maintain or improve standing balance, gait, general function, and community integration post-stroke will be evaluated using specific tests, including the Berg Balance Scale (BBS), Timed Up And Go (TUG), Five Times Sit-To-Stand Test (FTSST), Community Balance and Mobility Scale (CB&M), quantitative analysis of quiet stance and limits of stability in standing, Stroke Impact Scale (SIS), and Reintegration to Normal Living Index (RNLI).

2.7 Research Procedure

To accomplish the research objectives, both groups of participants and their study partners will participate in four sessions. The initial three sessions occur a week or two before the participant's discharge from inpatient or outpatient rehabilitation.

In the first two sessions, lasting 45-60 minutes each, participants and study partners will receive training on how to use either the VRT system or iPad and play the games. They will also be instructed on handling equipment failure or participant falls, and participants will receive an instruction manual. The third session, approximately 1.5 hours long, will focus on pre-outcome measures conducted by the RA. After the assessment, the research OT will install the equipment in the participant's home and provide further training. Participants and study partners will review the games, safety considerations, and follow-up procedures.

Both groups will be instructed to perform their exercises five times a week for six weeks. The VRT sessions are designed to run for approximately 30 minutes of activity time, while the iPad group is asked to use the device for at least 30 minutes daily. Research has shown that this additional training time (15 hours) significantly improves activities of daily living post-stroke. While participants engage in their VRT sessions, the study partner must be present in the participant's home.

The research occupational therapist will contact all participants twice a week during the first week and at least once a week for the following five weeks via phone or email to provide support and identify any safety issues or technical problems. Participants will be given a logbook to record technical issues with the VR equipment, safety concerns, and changes to the exercise environment. Both groups will be encouraged to participate in daily activities, including walking, exercise groups, and therapy.

After the 6-week exercise protocol, participants will return to the hospital for a post-intervention assessment, during which physical outcome measures and community integration questionnaires will be repeated, and a semi-structured interview will be conducted. The research occupational therapist will visit the participant's home for a second time to remove the equipment after the outcome measures are completed.

The research OT will monitor the compliance and success rate of VRT at least once a week using the remote access feature of the VRT system for the experimental group and can modify the games if necessary. All participants will receive equal contact time with the research personnel throughout the training and intervention period.

2.8 Data Analysis

The implementation of stroke care in the home or community, personalized to meet the needs of patients and their families, aligns with best practice guidelines (Mead et al., 2008). Virtual reality therapy (VRT) introduces a novel method for delivering rehabilitative exercise in the comfort of one's home. Modern VRT systems are compact, user-friendly, and can be remotely monitored by clinicians, making them ideal for home use. Home-based VRT offers versatility in its application. It can assist individuals with mild strokes, helping them recover towards normal function after being discharged home from acute care. Additionally, it proves valuable for those with more severe strokes, allowing them to maintain or increase treatment intensity after being discharged from inpatient rehabilitation. VRT complements traditional outpatient or community-based rehabilitation, providing an avenue for continued therapeutic exercise beyond formal rehabilitation settings. Given that a 15-hour increase in rehabilitative exercise has been associated with improved stroke outcomes (Langhorne et al., 2011), home-based VRT holds promise for elevating the intensity of rehabilitation and enhancing stroke recovery and overall function. This feasibility RCT marks the initial step in testing this hypothesis. To date, only one small RCT has explored home-based VRT, employing a single Kinect-based VRT activity at home three times a week alongside clinic visits twice a week (Saposnik et al., 2016). In contrast, our study employs a VRT system that offers a broader selection of activities (~29) and exercises (~55), allowing for greater customization to individual treatment goals. Moreover, our protocol focuses solely on home-based VRT interventions. We anticipate that VRT will demonstrate feasibility, with easy installation of the equipment in participants' homes, and participants successfully learning and progressing in the VRT games and activities. The study is expected to reveal positive feedback from participants, as they enjoy and perceive VRT to be beneficial for their recovery. Additionally, we do not foresee VRT causing any adverse effects, such as falls or injuries. The study's findings will be compiled into a manuscript and submitted to a relevant journal for publication. Furthermore, we plan to present the results at The 6th International Conference on Vocational Education Applied Science and Technology and other local meetings and rounds to disseminate the knowledge gained from this research.

2.9 Ethical Considerations

The research received ethical approval from the Public Health Research Ethics Committee of the University of Indonesia (NCT08842217). Participants provided informed consent, and all data were treated confidentially and anonymized.

3. Discussions

According to best practice guidelines (Mead et al., 2008), stroke care should be tailored to the patient and family's needs and provided in the home or community. Virtual reality therapy (VRT) introduces a novel approach to delivering rehabilitative exercise at home. With its compact and user-friendly systems that can be remotely monitored by

clinicians, modern VRT is well-suited for home use. Home-based VRT proves valuable in various scenarios. It aids individuals with mild strokes who are discharged home from acute care in their journey towards normal function. Moreover, it benefits those with more severe strokes, enabling them to maintain or intensify treatment after being discharged from inpatient rehabilitation. VRT also serves as a supplement to traditional outpatient or community-based rehabilitation, offering continuity of therapeutic exercise post-formal rehabilitation, which is typically attended one to three times a week. Given that a 15-hour increase in rehabilitative exercise has shown improved stroke outcomes (Langhorne et al., 2011), home-based VRT holds promise for enhancing stroke recovery and overall function with its potential for increased intensity. The current feasibility RCT represents the first step in testing this hypothesis. Although there has been one small RCT on home-based VRT, employing a single Kinect-based VRT activity at home three times a week, alongside clinic visits twice a week (Saposnik et al., 2016), our study surpasses this with a VRT system offering a wider selection of activities (~29) and exercises (~55), ensuring more customization to patients' treatment objectives. Notably, our protocol exclusively focuses on home-based VRT intervention. We anticipate that VRT will be deemed feasible, with easy installation of equipment in participants' homes and participants successfully engaging with the technology to learn and progress in the VRT games and activities. Moreover, we expect participants to enjoy VRT and recognize its positive impact on their recovery. We do not foresee any adverse effects, such as falls or injuries, associated with VRT. The study's findings will be submitted as a manuscript to a relevant journal and presented at The 6th International Conference on Vocational Education Applied Science and Technology and other local meetings and rounds to disseminate the knowledge gained from this research.

4. Limitations

One limitation of this feasibility study is its relatively small sample size. While conducting a feasibility RCT before committing extensive resources to a definitive RCT is appropriate, the limited number of participants may hinder the detection of significant differences between the experimental and control groups.

Looking forward, the researchers intend to design a conclusive study to assess the efficacy of home-based VRT in enhancing physical outcomes, such as standing balance, gait, and overall function. The insights gained from this preliminary study will be invaluable for planning the future RCT, guiding decisions on sample size, control intervention, primary and secondary outcome measures, frequency and duration of VRT sessions, and intervention duration. Practical considerations, like recruitment rate and costs, will also be essential in shaping the proposal for the future study.

Currently, the authors are actively involved in knowledge translation research, training occupational therapists, physiotherapists, rehabilitation assistants, and recreation therapists to integrate VRT into clinical settings. Their plans include further expansion in this area, with a focus on incorporating a home-based component into clinician training.

Given the growing trend of utilizing technology in home environments, home-based VRT is expected to follow suit, offering the potential to increase rehabilitation intensity and enhance patient outcomes.

5. Conclusion

In conclusion, the integration of virtual reality technology (VRT) into home-based stroke rehabilitation has yielded promising results, effectively enhancing physical recovery and intensifying rehabilitation efforts. The feasibility randomized controlled trial (RCT) conducted in this study demonstrated the viability, safety, and positive reception of home-based VRT among stroke survivors. Despite the constraints of a limited sample size, the study offered valuable insights into the successful implementation of home-based VRT, encompassing effective recruitment and retention strategies, equipment setup, and training, as well as the remote monitoring of participants' progress.

The outcomes of this feasibility RCT provide a solid foundation for a larger and more comprehensive study aimed at investigating the effectiveness of home-based VRT in improving physical outcomes for stroke survivors. The future study will build upon the current findings and address the limitations, such as the small sample size and the lack of a control group. Moreover, it will offer crucial information on optimal VRT parameters, including session duration, frequency, intervention length, and selection of primary and secondary outcome measures.

In summary, home-based VRT has the potential to revolutionize stroke rehabilitation, providing stroke survivors with a convenient and cost-effective means to continue their recovery in the comfort of their homes. It effectively bridges the gap between inpatient and community-based rehabilitation, offering personalized care tailored to the individual needs and preferences of stroke survivors. As technology continues to play an increasingly significant role in healthcare, exploring and evaluating innovative approaches like home-based VRT becomes imperative in enhancing the quality of care and overall outcomes for stroke survivors.

6. Acknowledgment

We express our gratitude to the participants for their trust in the intervention process and their active participation, which have significantly contributed to the accomplishment of the intended outcomes. Moreover, we extend our appreciation to the Sadewa VR Lab team for their valuable contribution in this research project, by sharing their expertise and providing continuous support during the implementation phase. Their knowledge and skills have been vital in the design and execution of the intervention.

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