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RESEARCH ARTICLE

# A Rehabilitation Protocol for Stroke Patients using Virtual Reality

**Moon Fai Chan[1*], Senthilkumar Ravindran[2], Hammad Al-Subhi[2], Saif Al-Riyami[2]**

[1] Department of Family Medicine and Public Health, College of Medicine and Health Sciences, Sultan Qaboos University, Muscat, Oman.
[2] Department of Physiotherapy & Rehabilitation, Sultan Qaboos University Hospital, Muscat, Oman.

*moonf@squ.edu.om

ABSTRACT

Rehabilitation training for stroke patients is mostly based on face-to-face contact. This affects the routine training during the coronavirus disease outbreak in many hospitals worldwide, including Oman. Perhaps, this problem can be overcome using a virtual reality system. This protocol study aims to compare the outcome measures of the two groups of stroke patients (virtual reality intervention *vs.* conventional control) on these two modes of rehabilitation training. A randomized controlled trial with pre-/post-study of 42 stroke patients (21 control *vs.* 21 intervention) with upper limb motor impairments, aged 18-65 years old, newly admitted to the rehabilitation clinic in Oman, will be recruited. Basic demographic data and three major outcome assessments will be collected pre-/post-period. Baseline assessment (pre) on admission to the stroke rehabilitation program and after completion (post). Participants will be assessed by Barthel Index, Action Research Arm scale, and time spent per session with costs involved by the workforce in training. Repeated measures general linear model will examine the within, between, and interaction effects while adjusted by demographic data. All analyses will use IBM SPSS software, and a statistical significance level of $p<0.05$ will be employed. This research protocol aims to evaluate the feasibility and effectiveness of VR in improving motor control in stroke patients with upper limb weakness by comparing a low-cost VR platform with face-to-face training. If the proposed training protocol is helpful and easy to use, it could become a reliable tool to assist healthcare professionals for stroke patients during their rehabilitation training. This protocol will contribute to the theoretical discussion of integrating high-tech equipment with healthcare theory for stroke patients with learning disabilities. Also, adopting a virtual reality system could aid if a sudden pandemic outbreak. It could continue offering its services while maintaining a high standard of care for stroke sufferers.

**Keywords**: Virtual reality; Rehabilitation program; Stroke patients; Oman

## Introduction

In Oman, stroke is the second leading cause of death and disability, with a mortality rate of 6.58% [1,2]. The burden of stroke lies not only in its high mortality but also in its high morbidity, which leads to up to 50% of survivors experiencing chronic disabilities [3]. Thus, stroke is a major public health illness with serious economic and social consequences. The burden of stroke on public health is expected to increase over the next several decades due to population transitions, particularly in developing countries [4]. Adapting to persistent neurological deficits after a stroke is an ongoing challenge for individuals affected by stroke [5]. In Oman, very little research was conducted to develop a new training platform to enhance stroke patients' rehabilitation process before discharge from the hospital.

Following stroke rehabilitation, the first few months are usually challenging for patients [6]. Those suffering from a stroke must use newly acquired skills in a natural environment that lacks all the protective features of a rehabilitation setting or cannot transfer their skills from the hospital to their communities [3,5,7]. In many cases, the real recovery work begins when they return home [3]. Recovery is determined by the training's regularity, compliance, and intensity. A systematic review reported that virtual reality (VR) rehabilitation improved stroke patients' motor recovery [6]. The use of VR environments in health is expanding, including education, training, and rehabilitation [8]. Patients learn about their surroundings through vision and touch in the real world. On the other hand, the virtual world comprises the same types of senses that we use in the real world, such as a joystick and a head-mounted display. Over the past several years, the VR field has grown tremendously [9]. This technology can be utilized in various fields, including health education and clinical training [3].

One new area to benefit from VR progress is health rehabilitation. The past ten years have seen a shift from studies and articles that primarily discussed the potential advantages of using this technology that detailed the creation of practical work systems, the evaluation of prototypes, and the initial clinical results with patients who had used some of these systems [7,8]. Numerous studies have created or evaluated the VR system for stroke recovery. Studies have indicated that patients with VR training have improved finger and thumb movement, which is used in hand rehabilitation for those with persistent strokes [9,10]. For study focus on balancing and skills training for participants with various neurological impairments using the VR system [3]. Most results showed that patients responded positively to the VR system. They developed mobility, experienced a sense of presence, and put more effort into VR training than traditional training. Askin and his colleagues[11] investigated using a VR system combined with a joystick device to train perceptual-motor skills in stroke patients. Approximately 41% of the subjects improved their response time [11]. Another study investigated the effects of VR exposure on stroke patients' spatial and object recognition memory [12]. The results of the tests showed that participants could apply what they learned in VR practice to the real world. According to a systematic analysis, stroke victims could be motivated to control their health by adopting VR technology for treatment and rehabilitation [6]. The VR system can offer a secure and monitored setting where patients can communicate, learn, and be reliably and consistently assessed [9]. Nevertheless, VR is a new service channel that may be used to improve training and learning rather than being a cure [5].

In conclusion, we anticipate that during the next ten years, a growing variety of VR systems will be created. It's crucial to keep in mind that the VR system is only a new tool that can be used to improve motor training when it comes to rehabilitation training. The degree to which it is effective will be greatly influenced by the patient's familiarity with motor learning and the particulars of the motor deficits that various clinical groups display. Therefore, the protocol aims to examine the beneficial effect of using VR in improving the motor control of stroke patients. Under this aim, we have two objectives: (1) to develop a VR rehabilitation training for stroke patients with upper limbs motor impairments; and (2) to compare the outcome measures of the two groups of stroke patients (VR intervention *vs.* conventional control) on these two modes of training. Two hypotheses were formulated:

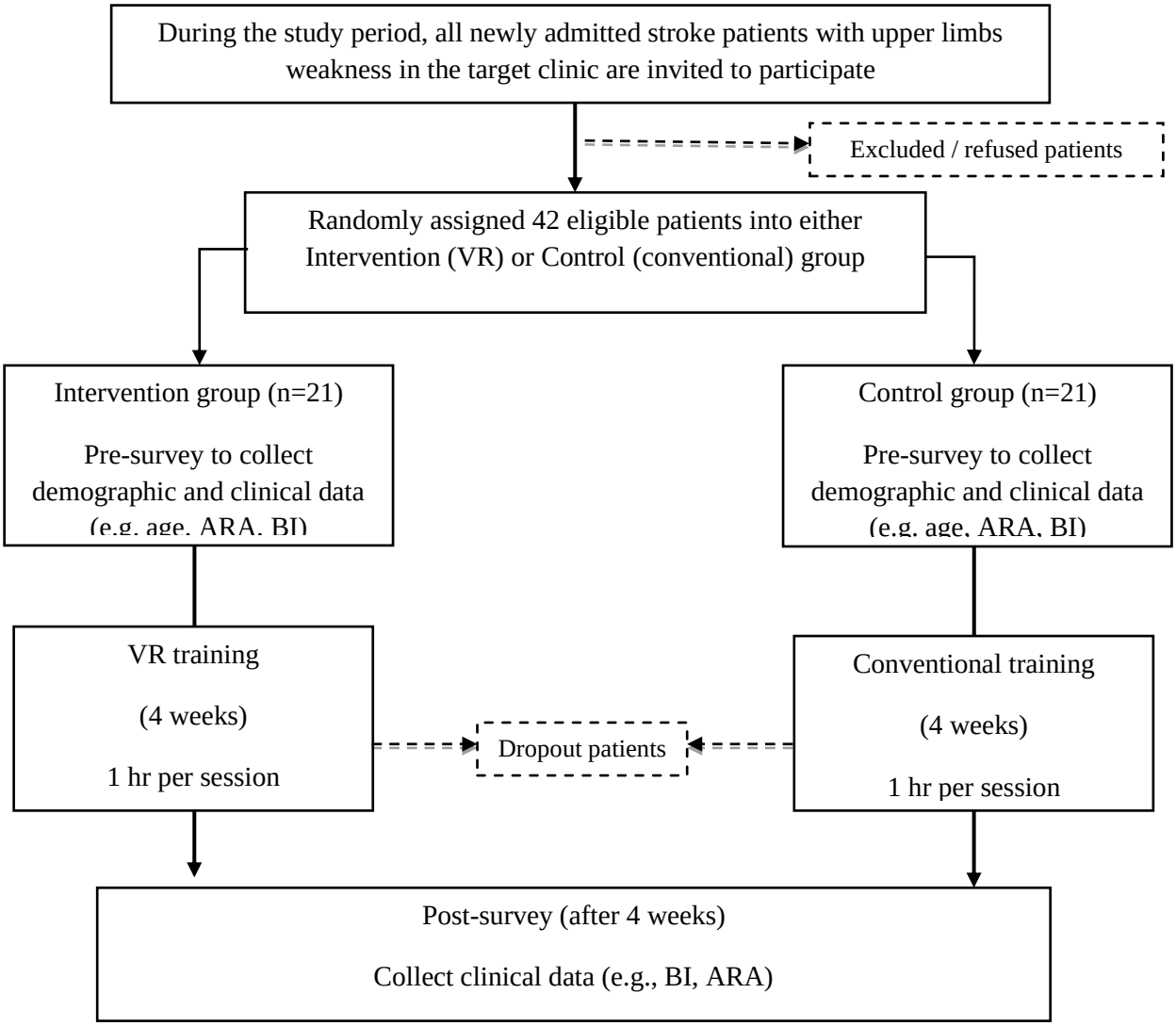
1. There are significant differences between the intervention and control groups on motion outcomes; and
2. There are significant differences between the intervention and control groups on time spent and the workforce's costs on the clinic's rehabilitation training (cost-effectiveness).

## Methodology

### *Design*

This is a randomized controlled trial (RCT) pre-/post-design. Adults with stroke patients who had not previously participated in rehabilitation training will recruit. Patients will randomly assign either the intervention (VR) or control (conventional) group for their rehabilitation training (Figure 1).

**Figure 1. The study flowchart of the proposed protocol**




***Setting***

In a rehabilitation clinic of the Sultan Qaboos University Hospital in Oman.

***Subjects and sample sizes***

The inclusion criteria are adults (age 18-65 years old), those who are new inpatients of the study clinic of stroke onset, and with upper limb weakness and/or motor impairment as a primary deficit, muscle strength greater than 2/5 on the Medical Research Council (MRC) scale[13], a stable medical condition; ability to communicate; good cognitive ability as indicated by a 15+ score on the Mini-Mental State Examination (MMSE)[14]; Motricity Index[15] score 26+. The exclusion criteria were patients with 1) ataxia or any other cerebellar symptoms; 2) Orthopaedic changes or pain syndrome in the upper limbs; 3) upper extremity-specific peripheral nerve injury; 4) visual or hearing impairment; 5) severe hemispatial neglect; 6) severe shoulder or hand pain (unable to volitionally position the hand in the workspace without pain); 7) insensate forearm and /or hand, edema of the affected forearm and /or hand; 8) uncontrolled seizures disorder; 9) severe depression (>13 on Beck Depression inventory); 10) severely impaired cognition or comprehension. The power of the study was estimated based on the Barthel index (BI) outcome measure. From previous studies[6,8,12], an overall effect size (=0.89) between intervention and control groups was chosen. Therefore, the required sample size for each group was 21 (total = 42) to achieve 80% power at a 5% significance level [16].

***Outcome measures***

Demographic (e.g., gender, age, occupation, marital status), clinical and biomedical data (e.g., type of chronic diseases, time since stroke, type of stroke, right/left hand dominant, right/left

hemiparesis, type of medicine/dose), time (hours/mins) spend on the training per session. Its costs (e.g., cost of therapist per hour) will collect at the post-survey, and the 2 outcomes were measured by:

*The Barthel Index (BI)* consists of 10 self-care activities, including grooming, mobility, stairs, feeding, toilet use, transfer, etc., with a total score ranging from 0 to 100. The higher the score, the more independent their daily activities; It has good validity (0.82) and reliability (0.83) [17,18].

*The Action Research Arm (ARA) test*, a 4-point scale (from 0 = no movement to 3 = movements are performed normally) per item (19 items in total) that measures upper limb (arm and hand) function [19,20]. ARA assesses a stroke patient's daily life by 4 basic movements: grasp, grip, pinch, and gross. The ARA test included 19 items scores may range from 0-57. A higher score indicates better performance.[21] It can be completed in 8-10 minutes and with good reliability (0.98-0.99) and validity (0.94-0.98) [21,22].

***Randomization***

All eligible subjects will be invited to join the study. Once they accept, the pre-survey will be collected, including self-reported demographic and health history data and ascertaining their ARA and BI levels as the baseline information. Then, they will be randomly assigned to either the intervention or control group. Patients who are eligible and agree to participate will be allocated a number from 1 to 42. The random procedure will be according to the patient number. The research randomizer, an online software, will generate 21 unique random numbers from 1 to 42 [23]. Those patient numbers matching the generated number will be assigned to the intervention group, and those not matched will be assigned to the control group.

***Control (conventional program) group***

Patients in the control group will be received a one-to-one rehabilitation program while it is currently provided in the study hospital. An instructor (trainer) will assign each participant for training. Demographic and clinical data and their treatment cost will collect before participating and after completing the rehabilitation program. The training aimed to enhance functional recovery for patients with upper limb weakness. The training consist of two main exercises:

(1) Wolf Motor Function Test (WMFT): a time-based method to evaluate upper extremity performance motor function test well established [24]. It consists of 15 tasks (e.g., Pick up a pencil using a 3-jaw chuck grasp; Pick up a basket by grasping the handles and placing it on the bedside table; stack checkers onto the center checker, etc.). It will take 20 mins in training, and the time (hours/mins) taken to complete it will be collected.

(2) Box and Block Test (BBT) measure gross unilateral manual dexterity in stroke patients [25]. This test assesses a stroke patient moving as many wooden blocks as possible from one end of a partitioned box to the other. Patients are scored based on the number of blocks they transfer within 1 minute. The instrument has demonstrated strong validity and reliability [22]. It will take 20 mins in training, and the time (hours/mins) taken to complete it will be recorded.

***Intervention (Viral Reality program) group***

Patients in the VR group will receive the VR training program in the hospital. With its built-in hand tracking function, the Meta Quest 2 ®, 256M (former name is Oculus Quest 2 ®) will provide all the training for the participants in the 3D environment [26]. Training materials for the VR training are from the Hand Physics Lab ®. From the Lab, a hand track game named "*Touch. Pinch. Grab. Punch*" is used for the training available in the official Quest Store for download in the Meta Quest 2 system. Tasks for the VR group to perform are similar to the control group, and the only difference is that participants in the VR group will use VR as a training platform. Demographic, clinical, and biomedical data and their treatment cost will collect before participating and after completing the rehabilitation program.

***Data collection for the intervention and control group***

Recruitment will occur in the target clinic, as shown in Table 1. All eligible patients will invite to join the study. The ARA and BI data were not self-reported, so a physiotherapist (one researcher from the research team) will assess them in the study clinic. *Pre-survey*: baseline data (demographic, health history, clinical data, ARA, BI levels, and no. of hours/mins spent) will be collected and take around 20 minutes. *Post-survey*: After finishing the program (4 weeks), post data (ARA, BI, and no. of the hour/min spent per training session) will be collected on the post-survey, facilitating a direct pre-and post-comparison. In the pre-/post assessment, the physiotherapist does not know who is assigned to the intervention or control groups.

All participants will receive standard rehabilitation consisting of 1 hour of daily occupational and physical therapy. All training is therapy bases that consist of a basal task and diary activity-oriented training by physiotherapists. This training includes grasp, grip, pinch, gross, and finger-hand coordination movements. Patients in the

intervention group will receive VR training, while patients in the conventional (control) group will receive conventional training. Each training program will take around 1 hour for one session per day, 5 times per week, over a maximum of 4 weeks. The training presented a one-on-one that allowed interaction between the instructor (or VR system) and the participant.

**Table 1.** The study schedule, including patient enrolment, training progress, and outcome assessments

| Works | Enrolment | $T_0$ | Training | $T_1$ |
|---|---|---|---|---|
| Eligibility screens | X | | | |
| Informed consent | X | | | |
| Randomization | X | | | |
| *Data collection* | | | | |
| Demographic and clinical data | | X | | |
| Training (Intervention) | | | ← 4 weeks → | |
| Training (Control) | | | ← 4 weeks → | |
| *Assessment (outcome)* | | | | |
| Barthel Index | | X | | X |
| Action Research Arm Score | | X | | X |
| Time spent per training session | | | | X |
| Costs to complete the training | | | | X |

$T_0$, Pre-survey before starting the training; $T_1$, Post-survey after completing the training; Intervention, Virtual reality (VR) training using Meta Quest 2 ®; Control, convention face-to-face training provided in the clinic.

***Statistical analysis***

Descriptive statistics (e.g., mean, standard deviation, frequency, percentages) will describe the groups' characteristics. Chi-square or t-test will be used to examine any difference between the VR and control groups on basic demographic outcomes to ensure homogeneity. Normality tests will be used to examine the distribution of the outcomes. If outcomes are normal, repeated measures general linear model will examine the within, between, and interaction effects adjusted by subjects' demographic data if needed. Otherwise, non-parametric tests will be used (e.g., Wilcoxon signed-rank test). All missing values will be replaced by group mean. Intention-to-treat and pre-protocol analyses will be performed to ensure sustainable findings. All analyses will use IBM SPSS software, and a statistical significance level of $p<0.05$ will be employed.

***Recruitment status***

The subject's recruitment is started in August 2022 to July 2023. At the time of this writing, in September 2022, 15 subjects were approached to join the study. The finding of this study will be published in peer-reviewed scientific journals.

**Discussion and Implications**

This research protocol aims to evaluate the feasibility and effectiveness of VR in improving motor control in stroke patients with upper limb weakness by comparing a low-cost VR platform with face-to-face training. If the proposed training protocol results are helpful and easy to use, it could become a reliable tool to assist healthcare professionals (e.g., physiotherapists) for stroke patients during their rehabilitation training. There are two major values in this research protocol, one theoretical and one practical. The protocol will contribute to the theoretical discussion of integrating high-tech equipment with healthcare theory for stroke patients with learning disabilities. As outlined in the Chronic Care Model for disabled individuals [4], a VR system is capable of providing convenient care to stroke patients who have limited access to healthcare. It takes a long time to get an appointment with many public healthcare services. A VR system might also increase routine healthcare delivery and improve healthcare services [6]. The second practical application of this study is that the findings can direct medical personnel using VR to assist stroke patients in motivating their self-care from passive to active learning. Additionally, the traditional training of stroke patients takes time and is costly. The practical application of this study is that its findings can help healthcare professionals by assisting stroke patients in transferring their learning strategies from inpatient rehabilitation training to regular community living scenarios through the use of VR environments. Furthermore, the intervention might be easily adapted for other categories of patients needing support. Another benefit that adopting a VR system could aid if a sudden pandemic outbreak

(e.g., coronavirus disease pandemic) occurs. It could continue offering its services while maintaining a high standard of care for stroke sufferers.

**Ethical Approval**

This protocol was approved by the Ethics approval from the Institutional Review Board of Sultan Qaboos University (MREC #2593) and was registered on ClinicalTrials.gov (NCT05178758).

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**Contributions**: Protocol design: Moon Fai Chan, Senthilkumar Ravindran; Manuscript preparation: Moon Fai Chan, Senthilkumar Ravindran, Saif Al-Riyami, Hammad Al-Subhi

**Data availability**: The data supporting this study's findings are available from the corresponding author upon reasonable request.

**Conflicts of Interest**: The authors have no conflicts of interest to disclose.

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