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Effects of a social participation-focused virtual reality intervention for community-dwelling stroke survivors with physical disabilities: a randomised controlled trial protocol

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ABSTRACT

Introduction Studies show that stroke survivors encounter physical and psychological limitations that restrict their participation in social and community activities. Systematic reviews have yielded inconclusive evidence regarding the effectiveness of different interventions intended to support stroke survivors' social participation. Recent advances in virtual reality technology may offer promising solutions, although the optimal approach to enhance social participation among stroke survivors is yet to be determined. This trial aims to develop and evaluate the effectiveness of a social participation-focused virtual reality (SP-VR) intervention on the physical, psychological and social outcomes of community-dwelling stroke survivors with physical disabilities.

Methods and analysis A two-arm randomised, controlled, assessor-blind clinical trial will be conducted with 250 stroke survivor–caregiver dyads recruited from three acute and one rehabilitation hospitals, and three stroke nurse-led clinics. Participants will be survivors of a first or recurrent stroke within 6 months of stroke onset and able to remain in a sitting position without support, and their primary caregivers. Eligible participants will be randomly allocated to receive the SP-VR intervention or usual care which includes conventional physical therapy services. The intervention group will receive a newly developed 6-week novel custom-made SP-VR application comprising two sessions weekly. Three SP-VR modules will cover key aspects of survivors' social health needs, namely functional rehabilitation, social participation, and social interaction and recreation. The primary outcome for stroke survivors is social participation, and secondary outcomes include depressive symptoms, participation self-efficacy, physical function, functional mobility and social support. User satisfaction will be evaluated among both survivors and caregivers. Data will be collected in person at baseline, immediately after, and 3 months postintervention.

Ethics and dissemination Ethical approval has been obtained from the Joint Chinese University of Hong Kong-New Territories East Cluster Research Ethics Committee (Ref. No.: 2019.676). Study results will be disseminated through peer-reviewed journals and conference presentations.

Trial registration number ChiCTR2100050850.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The randomised controlled trial design is the gold standard for evaluating intervention effectiveness.
⇒ Caregiver outcomes will also be studied in addition to stroke survivor outcomes.
⇒ Data collection at baseline, immediately after and 3 months postintervention will allow for better understanding of immediate and long-term effects of the intervention.
⇒ Only stroke survivors residing in the community will be recruited, which would exclude potential inpatient survivors who would also benefit from the intervention.

INTRODUCTION

Stroke is the second leading cause of death and a leading cause of disability worldwide.[1] Social participation, a core aspect of participation, refers to a person's engagement in activities with family, friends, peers or community members.[2 3] Studies have demonstrated consistently that survivors of even a mild stroke encounter subsequent physical and psychological limitations that inhibit their participation in social and community activities.[4 5] For example, more than half of stroke survivors experience challenges related to social interaction and participation in leisure activities more than a year after stroke.[6] These restrictions in social participation are associated with depression, social isolation and a poor health-related quality of life (HRQoL) in stroke survivors.[7]

Optimal poststroke rehabilitation depends integrally on social participation. Recent guidelines for stroke survivors emphasise social participation in the community during the period of chronic recovery.[8] Evidence suggests that stroke survivors who can meet these social demands by re-engaging in their prestroke social and leisure activities experience greater life satisfaction.[9] Systematic reviews have yielded inconclusive evidence regarding the effectiveness of different interventions intended to support stroke survivors' participation in social and community activities. Moreover, only exercise training may have a small beneficial impact. Research has also identified issues involving stroke survivors' low level of interest in adhering to rehabilitative interventions and the effects of low adherence.[10 11]

Virtual reality (VR) has been used increasingly to improve people's health outcomes. VR refers to the simulation of real-world events or objects via computer-based information technologies, which can be experienced by users.[12] Compared with conventional therapies, VR has been shown to better enhance users' motivation and participation, and it can provide prompt feedback and unlimited training repetitions for optimal motor learning.[12] Thus, it appears to offer great potential for improving social participation among community-dwelling stroke survivors.

VR is frequently used to support the physical and cognitive rehabilitation of stroke survivors. Two systematic reviews and meta-analyses of 41 randomised controlled trials (RCTs) found that VR training when compared with conventional therapy significantly improved stroke survivors' balance and gait.[13 14] A systematic literature review identified significant improvements in cognitive functions, including executive and visual-spatial abilities, speech, memory and attention, of stroke survivors who received training using custom-made or commercially available VR systems.[15] An integrative review of 13 RCTs and quasi-experimental controlled trials involving 353 stroke survivors found an association between the use of VR with commercial video games and significant improvements in the survivors' dynamic balance, upper limb motor function and HRQoL. However, the effects of VR interventions on the activities of daily living (ADL) and social participation were inconclusive because few studies had examined these outcomes. In a qualitative study to determine the value of a VR intervention, 13 occupational therapists and 12 stroke survivors reported that an intervention involving a virtual home environment would potentially enable survivors to assess safety risks. This study also explored the implications of installing assistive equipment at home and highlighted the limitations that would prevent survivors with cognitive or perceptual impairment from accruing maximal benefits.[16]

There remain notable gaps in the literature. First, studies examining the use of VR in stroke survivors have mainly focused on attempts to promote physical or cognitive functioning by presenting them with VR experiences, which required engagement in video game-based or task-specific exercises.[13–15] After returning home, however, community-dwelling stroke survivors with physical disabilities may need to adapt to and practise many social and community activities with varying levels of complexity. Inevitably, more specific simulated training is needed to improve their performance in daily life activities in both home and community settings. Second, studies examining VR interventions have rarely measured the level of social participation among stroke survivors. Therefore, a more complete understanding of the short-term and long-term effects of VR interventions on social participation is needed. Third, no consistent VR intervention-based regimen has been determined, and the ideal frequency and duration of the training sessions along with the types of commercially available or custom-made VR applications remain uncertain. Additional evaluations of these regimens would add value by contributing to guidelines on the optimal use of VR for social participation training. Fourth, few studies have examined VR interventions for both stroke survivors and their families or caregivers, or measured outcomes in caregivers. More studies are needed to investigate the effectiveness of VR interventions in terms of caregiver support.

To address these gaps, this study aimed to evaluate the effects of a social-participation focused VR rehabilitation intervention on stroke survivor and caregiver outcomes. Objectives for the study included obtaining an understanding of the short-term and long-term effects of VR interventions on stroke survivors' level of social participation, determining an optimal delivery dose and format, and to explore the effectiveness of VR interventions in improving caregiver support.

METHODS

A parallel two-arm randomised, controlled, assessor-blind clinical trial will be conducted. The trial is currently in the recruitment stage. The hypotheses include: (1) stroke survivors who receive a 6-week social participation-focused VR (SP-VR) intervention will exhibit greater improvement in social participation from baseline (T0) to immediately after (T1) and 3 months after the completion of the SP-VR intervention (T2) compared with those who receive the usual rehabilitation services (control group); (2) stroke survivors who receive the SP-VR intervention will exhibit greater improvements in depressive symptoms, participation self-efficacy, physical function, functional mobility and social support from T0 to T1 and T2 compared with those who receive the usual rehabilitation services (control group).

Participants will be allocated to the study arms using permuted block randomisation with varying block sizes in a 1:1 ratio. This will maintain a good balance of participants and optimise allocation concealment throughout the recruitment period. An independent statistician will prepare a sequence of grouping identifiers (I=intervention; C=control) in advance using computer-generated random codes. The arm allocations of the participants

will be concealed from the outcome assessors and will be made by sequential assignment according to the enrolment sequence and the corresponding a priori prepared group identifier.

Participants will be recruited from the stroke units of three acute and one rehabilitation hospital, and three stroke nurse-led clinics in a single region. We will recruit 250 stroke survivor–caregiver dyads. The following inclusion criteria will be applied to the stroke survivors: (1) age ≥18 years; (2) a diagnosis of ischaemic or haemorrhagic stroke resulting in physical disability; (3) study entry within 6 months poststroke; (4) the ability to remain in a sitting position with support; (5) a Montreal Cognitive Assessment score above the second percentile;[17] (6) the absence of limb deformities and other neurological or musculoskeletal disorders and (7) residing in the community. The study will include survivors of a first stroke and those with a history of stroke. Caregivers who provide most care to the survivor will also be included. Both members of the dyad must be literate and able to communicate in Chinese and will be excluded if they have (1) a psychiatric condition (eg, symptoms of delusion or hallucinations); (2) a history of vestibular deficits or severe visual impairments; (3) any seizure activity during the previous 6 months and (4) difficulty in following instructions.

The sample size for this trial has been estimated based on the primary outcome of social participation. The effect sizes of a VR-based rehabilitation programme developed by Shin *et al*[18] on the domains of social participation, mobility, ADL/instrumental ADL, emotion and hand function, as assessed using the Stroke Impact Scale, ranged from 0.52 to 2.26. The sample size was determined such that it yields an adequate power to detect a small to medium effect size[19] of 0.4 on our primary outcome. Using the power analysis software PASS V.14 (NCSS, Kaysville, USA), we estimated that a sample size of 100 participants per study arm in our proposed two-arm RCT will yield 80% power at a two-sided 5% level of significance to detect a minimum effect size of 0.4 on our primary outcome between the arms postintervention. Assuming a 20% attrition rate based on our previous study, 250 eligible participants (stroke survivor–caregiver dyads) will be recruited to ensure 125 dyads per arm.[20]

Intervention

We will develop novel custom-made SP-VR applications. The intervention group will receive an adjunct 6-week SP-VR intervention comprising two VR sessions per week (total: 12 sessions) in addition to usual care. Each session will last 90 min (three 30 min sections with 10 min breaks in between). Each 30 min section will be dedicated to one of the following three modules.

Functional rehabilitation module

This module will comprise training and activities targeting functional use of the upper limbs and general exercises to improve motor functions and ADL skills. All activities and training will be organised into task-oriented interventions and will progress gradually from minimal movements to full actions. For safety, these actions will be limited to the upper limbs or performed while sitting to reduce the risk of falls. A game-based application with motion sensors comprising levels ranging from easy to difficult will also be developed to train the survivors' fingers, wrists and arms. This stepwise training will encourage the survivors to use their weaker arm and improve their arm function poststroke.

Social participation module

This module will provide real-life training scenarios intended to improve independent ADL. It will aim to simulate environments and challenges that the survivors may encounter in their day-to-day routines and encourage normal engagement in outdoor activities. Proper use of a wheelchair in various scenarios, such as boarding a bus, parking a wheelchair, exiting a bus, using an elevator and general manoeuvring will be demonstrated. Similarly, demonstrations of the use of a walking aid will be provided. These activities will be intended to help survivors to become familiar and comfortable with their new walking aid or wheelchair and to promote regular social participation. Multiple-choice quizzes will be developed and presented at random intervals during the activities to assess the participants' level of understanding about hazard avoidance and exercises that improve balance, strength and coordination. Progression in the module will not be affected by the participants' choices and online supplemental file 1 will be provided.

Social interaction and recreational module

This module will aim to enhance the social interaction and recreation behaviour of survivors. It will enable participants to escape from reality and engage in leisure activities which may otherwise not be readily available. Virtual rooms will be set up to enable connections between survivors and their family and friends. It will aim to promote the psychosocial well-being of survivors by providing a social networking platform and virtual pastimes. All modules will be designed to allow survivors and caregivers to participate together or independently.

The SP-VR sessions will be delivered at a community-based clinic or a community centre serving the same region where the recruitment sites are located. Four community-based clinics/community centres will offer these SP-VR sessions, which will reduce the travel burden on participants. The SP-VR equipment will be set up by the research team in a dedicated secluded space at the clinics/centres. The intervention will be delivered by a nurse specialising in stroke care who has received training from coinvestigators on the use of the VR equipment and software. Interventions will be delivered at a time convenient for participants and at locations with appropriate internet capabilities. Participants can take part individually or in groups and no prior tech literacy is required as they will receive the required guidance from the interventionist.

Control

Participants in the control group will receive the usual rehabilitation services which include conventional physical therapy, occupational therapy or exercise training offered at community centres and outpatient rehabilitation services at a day hospital.

Outcomes

The outcomes will be measured at baseline (T0), immediately at the end of the 6-week intervention (T1) and 3 months postintervention (T2).

Survivor-specific outcomes

Social participation

The Reintegration to Normal Living Index (RNLI)[21] will be used to measure survivors' social participation, covering their satisfaction with aspects of daily functioning and self-perceptions. This index comprises 11 items in 6 domains, namely 'mobility', 'self-care', 'activities', 'role within the family', 'comfort with relationships' and 'ability to handle life events'. A 4-point scale ranging from 1=does not describe my situation to 4=fully describes my situation will be used to respond to each item. The RNLI has a high level of internal consistency (Cronbach's alpha (α)=0.90; Cronbach's α for the Chinese version is 0.92).[22]

Depressive symptoms

The 30-item Geriatric Depression Scale (GDS)[23] will be used to assess depressive symptoms, with scores of 11 and 17 indicating mild and severe depression, respectively. GDS has been used extensively as a clinical screening tool in stroke populations, and its psychometric properties, including construct and convergent validities, have been well established. The Chinese GDS has a high Cronbach's α of 0.89.[24]

Participation self-efficacy

The 35-item Participation Strategies Self-Efficacy Scale (PS-SES)[25] will be used to measure the survivors' SE in managing home participation (five items), staying organised (three items), planning and managing community participation (nine items), managing work/productivity (six items), managing communication (seven items) and advocating for resources (five items). Each item will be measured on a 10-point Likert scale (1=not at all confident, 10=totally confident). The PS-SES has a high internal consistency (α=0.88–0.93) and exhibits good construct validity.[24] The Chinese PS-SES has a high Cronbach's α of 0.98.[26]

Physical function

The Modified Barthel Index[27] will be used to measure the degree of independence in performing various self-care and mobility ADL. The index has a high test–retest reliability, intrarater reliability and internal consistency (alpha=0.90).[24]

Functional mobility

Functional mobility, including gait, balance and transfer, will be assessed using the Rivermead Mobility Index (RMI).[28] The construct and predictive validities of the Chinese RMI have been established and are sensitive to change over time.[29]

Social support

The Social Support Questionnaire (SSQ6)[30] will be used to determine the perceived quantity of availability and satisfaction with SS. In this questionnaire, the respondents will indicate the number of support persons (range: 0–9) available for the six situations (number score) and rate their overall satisfaction with the provided support using a 6-point Likert scale (satisfaction score). The SSQ is highly reliable, and the Chinese version of the SSQ6-satisfaction also has a high Cronbach's α of 0.95.[24]

Adverse events

All adverse events observed, for example, dizziness, motion sickness, headache, pain, falls or other discomforts, will be documented.

Outcomes for survivors and caregivers

User satisfaction

Participant (all survivors and caregivers in the intervention group) satisfaction will be measured at T1 using a self-developed User Satisfaction Questionnaire (USQ). This tool will measure the participants' satisfaction with the SP-VR in terms of its usefulness, acceptability and their recreational satisfaction. Each item on this questionnaire will be rated on a 5-point Likert scale, with a higher score indicating a higher level of satisfaction. The USQ will include three open-ended questions to identify the participants' perception of the usefulness of the intervention for enhancing social participation and reducing depressive symptoms.

Qualitative semistructured interviews will be conducted. A subset of 30 purposive samples (~10% of the intervention group) comprising 15 survivors and 15 caregivers will be identified from the USQ (with high, middle and low satisfaction ratings), and their experiences will be examined. Domains of interest include perceived effects of the SP-VR intervention on their level of social participation, favourite and least favourite intervention components, and suggested modifications.

Adherence will be defined as attendance in at least 80% of the SP-VR sessions (for both survivors and caregivers). The reasons for absence will be documented.

Disease-specific information about stroke survivors

The comorbidity, type and number of strokes, length of stay in acute and rehabilitation hospitals, readmission and other changes in the survivors' condition will be recorded.

Demographic information of survivors and caregivers

Participants' age, gender, marital state, educational level and occupation will be recorded.

Data collection procedures

Baseline data will be collected from consenting participants before discharge from the hospital or nurse clinics by a research assistant. Subsequently, the appropriately numbered envelopes prepared by the statistician will be opened, and participants will be randomly assigned to the intervention or control group. The second phase of data collection (T1) will be conducted at the community-based clinic/community centre offering the SP-VR sessions. A subset of 30 purposive samples of survivors and caregivers will be invited to participate in individual semi-structured interviews at T1 to investigate their experiences regarding the SP-VR sessions. During the third phase of data collection (T2), the survivor–caregiver dyads will be interviewed and assessed in the survivors' homes or during clinical follow-ups. A research assistant, who will be blinded to the participants' group allocation, will conduct outcome assessments and collect T1 and T2 data except user satisfaction data, which will be collected by a different research assistant.

Data management

All data collected will be used for research purposes only. Quantitative data will be entered into a statistics software and qualitative data will be recorded on word processing software. The data will be cross-checked independently by two research assistants. Data in hard copies will be stored in a locked cabinet while soft copies will be stored in an encrypted hard disk. Only the investigators will have access to the data. All data will be destroyed 6 years after the completion of the study.

Data analysis

The data will be summarised using descriptive statistics. The normality of continuous variables will be assessed using skewness and kurtosis statistics, and normal probability plots. The homogeneity of the participants' baseline characteristics between the two arms will be assessed using the independent t, χ^2 or Fisher's exact test, as appropriate. A generalised estimating equation (GEE) model will be used to compare differential changes in each primary and secondary outcome over time between the two arms, and an appropriate link function will be used to fit different types of outcome variables. The GEE model will also address the issue of randomly missing data. The intention-to-treat principle will be applied in evaluating the effects of the VR intervention on the primary and secondary outcomes. All statistical tests will be two-sided (level of significance=0.05). All statistical analyses will be performed using IBM SPSS V.25.0 (IBM). All feedback provided by survivors and caregivers regarding user satisfaction will be coded and thematically analysed by two researchers independently and organised into themes and categories that correspond to study objectives and purposes.

Data monitoring

An internal monitoring committee consisting of the investigators of the research project, advanced practice nurses at the recruitment venues and coordinators of the intervention clinics will be set up to oversee the conduct of the study and to manage any data or safety issues that may arise. Any adverse events will be documented and reported to the relevant ethics committee. In the event that modifications to the protocol are required, investigators will reach a concensus and submit the modified protocol to the relevant ethics committee for approval.

Patient and public involvement

Participants will be invited to give feedback on the SP-VR intervention at T1 and T2 through a user statisfaction survey and in-depth semi-structured interviews. Data collected will be used to identify strengths and limitations of the novel intervention and to advocate for improvements in its design and application. Findings will also likely inform the development of future VR interventions for stroke survivors and caregivers.

ETHICS AND DISSEMINATION

Ethical approval has been obtained from the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (Ref. no: 2019.676). We will protect the participants' rights and safety by adhering to local laws, the Hong Kong Personal Data (Privacy) Ordinance, the Declaration of Helsinki, institutional policies and the ICH-GCP. Research assistants will recruit participants at study hospitals and stroke nurse clinics. All eligible survivor–caregiver dyads will be asked to participate after receiving an explanation of the study purpose, the potential risks and benefits, and their rights to confidentiality and withdrawal at any time. Those who agree to participate will be asked to sign a consent form (online supplemental file 1). Potential participants will be informed that their refusal to participate will not influence the treatment received by the survivor. Study results will be disseminated through peer-reviewed journals and conference presentations.

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Contributors JPCC and SHSL conceived the study, acquired funding and ethical approval. AYLL, VWYL and DRT assisted in the preparation of the study protocol. KCC advised on the statistical plan and data analysis. ECFK advised and supported the development of the SP-VR intervention. All author made substantial contributions to the editing of the manuscript and approved of the final version.

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Competing interests None declared.

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