

BMJ Open Effectiveness and cost-effectiveness of a virtual multidisciplinary stroke care clinic for community-dwelling stroke survivors and caregivers: a randomised controlled trial protocol

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ABSTRACT

Introduction The virtual multidisciplinary stroke care clinic (VMSCC) is the first nurse-led clinic developed to offer support to community-dwelling stroke survivors and caregivers, and to promote poststroke recovery. This two-arm randomised controlled trial will evaluate its effectiveness on survivors' self-efficacy (SE), survivors' and caregivers' health-related quality of life (HRQoL) and cost-effectiveness on emergency admissions and length of readmission hospital stay.

Methods and analysis A consecutive sample of 384 stroke survivor-caregiver dyads will be recruited from four hospitals. An online platform that embraces readily accessible and reliable information will be developed. Participants randomly assigned to the intervention group will receive usual care plus the VMSCC service. The service includes access to a tablet containing 30 videos demonstrating appropriate self-care strategies, communication with a registered nurse monthly through video and telephone calls and regular blood pressure monitoring. Primary outcomes include survivors' SE in self-management and survivors' and caregivers' HRQoL. Secondary outcomes include survivors' performance of self-management behaviours, depression and social participation; and caregivers' coping strategies, satisfaction with caring and depression. Data will be collected at baseline, and at 3 and 6 months after commencing the intervention. Survivors' and caregivers' satisfaction with the service will be assessed at 6-month follow-up. Multivariable regressions and generalised estimating equations model will be conducted. Survivors' emergency admissions and length of hospital stay will be evaluated during the 6-month follow-up period. Cost-effectiveness analysis will be performed on the average total cost incurred.

Discussion The results will inform stakeholders about incorporating the VMSCC service into current stroke rehabilitation service.

Ethics and dissemination This protocol was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (CREC

Strengths and limitations of this study

- To the authors' knowledge, this is the first initiative to incorporate efforts of an expert panel on stroke care from different healthcare professionals including nurses, Western and Chinese medicine practitioners and pharmacists in developing and evaluating a virtual multidisciplinary stroke care clinic (VMSCC) for stroke survivors and their caregivers.
- Recruiting stroke participants and their caregivers from three acute hospitals and one rehabilitation hospital in this trial will increase the representativeness of the trial sample.
- Cost-effectiveness analyses of the VMSCC service over usual care will better inform stakeholders' decisions about integrating the service into the current stroke care service delivery.
- Due to the nature of the intervention, this trial is assessor-blind only, and blinding is not possible for the participants and the person who will deliver the intervention.

Ref. No.: 2017.660). All participants will provide written informed consent. Results will be disseminated through scientific publications, and presentations at local and international conferences.

Trial registration number ChiCTR1800016101; Pre-results.

INTRODUCTION

Stroke is the second leading cause of global deaths in 2016 and is a significant cause of disability. It can exert profound negative effects on survivors' physical and psychosocial functioning, leading to compromised health-related quality of life (HRQoL).^{1 2} Studies reported caregivers endure persistent psychological

distress.^{3,4} A longitudinal study found nearly one-third of the caregivers had a considerable burden of care 5 years after the stroke.⁵

Increasing evidence is highlighting the need to extend stroke care beyond the hospital and into the community. A study which interviewed stroke survivors and caregivers found adequate community support was essential in preventing hospital readmissions.³ The poststroke journey is multifaceted and can be demanding for survivors and caregivers. It can be further complicated by realisation of the challenges that await the survivors after returning home, when healthcare professionals' immediate support is not available.⁶ It is important to equip survivors and caregivers with adequate knowledge and skills to facilitate their adaptation to poststroke challenges and their reintegration into prestroke life and roles.

Evidence-based guidelines advocated the provision of community-based self-management support for survivors after discharge.⁷ Self-management refers to a person's active participation in managing the symptoms, medical regimens and psychosocial sequelae associated with one's condition.⁸ Recent systematic reviews consistently reported significant improvement in HRQoL and self-efficacy (SE) among survivors who participated in stroke self-management programmes (SSMPs) compared with those who received usual care.^{2,6} However, the SSMPs were disadvantaged by transportation problems and limited individual sessions.⁶ White *et al*⁸ found survivors and caregivers appreciated the provision of support and guidance in a timely and flexible manner to address their changing health needs in the community. Moreover, caregivers usually played a role as companions in the programmes. Extension of such programme benefits to caregivers is not well known.

Increasing studies suggested the potential use of telehealth and online consultations. A recent study examined the use of computer-mediated communication including video-based calls by a nurse, web forums offering communication between nurses, survivors and caregivers, and information platforms among survivors and their caregivers.⁹ The results showed this online approach was beneficial by fostering a sense of closeness and togetherness while providing privacy. It offered a convenient channel for participants to check with nurses for knowledge updates and to seek support.⁹ A systematic review showed telemedicine systems based on a virtual environment for upper extremity exercise addressed the inconvenience of travel and improved the survivors' physical health. Healthcare professionals and survivors reported high levels of satisfaction with telerehabilitation.¹⁰ However, technical problems such as Internet access need to be addressed. More evidence regarding the effects on resource utilisation and cost-effectiveness is needed.⁹

A literature review shows a multidisciplinary team of healthcare professionals plays a significant role in supporting stroke survivors' self-management. An increasing number of trials reported the effectiveness of complementary and complementary medicine such as acupuncture in promoting stroke recovery.¹¹ Integration

of Western and Chinese medicine perspectives in recovery and maintaining health would be helpful for Chinese survivors. Moreover, survivors' need for support in medication management was consistently reported.^{3,6} A study emphasised pharmacists' role in leading home blood pressure (BP) monitoring and case management to control survivors' BP compared with usual care.¹²

Support for community-dwelling stroke survivors centres on face-to-face consultations or rehabilitation at outpatient clinics or day hospitals. However, the regimens end when the survivors' conditions improve. We developed a nurse-led 4-week community-based SSMP and found significant improvement in HRQoL, SE, performance of self-management behaviours, depressive symptoms and community reintegration of survivors newly discharged from hospital. However, similar to other SSMPs, one prominent limitation was transportation. Furthermore, while different institutions and support groups provide stroke-related information on their websites, the information sometimes appears too general and haphazard.

We will develop a virtual multidisciplinary stroke care clinic (VMSCC) that builds on the advantages of SSMPs to promote survivors' recovery and improve caregivers' outcomes.

Aim and hypothesis

This study is aimed at developing and evaluating the effectiveness and cost-effectiveness of a VMSCC for community-dwelling stroke survivors and caregivers. The VMSCC is the first programme to be evaluated to inform future community stroke care service delivery.

We hypothesise that at 3 and 6 months after hospital discharge, compared with those receiving usual care.

1. Stroke survivors receiving the VMSCC service will have:
 - a. Greater improvements in SE in self-management, HRQoL, satisfaction with performance of self-management behaviours and social participation.
 - b. Fewer depressive symptoms.
 - c. Fewer emergency (ER) admissions.
 - d. Shorter length of hospital stay.
 - e. Greater satisfaction with the VMSCC service.
2. Caregivers receiving the VMSCC service will have:
 - a. Greater improvement in HRQoL.
 - b. Greater use of problem-solving strategies and perception of its usefulness.
 - c. Greater satisfaction with caring.
 - d. Fewer depressive symptoms.
 - e. Greater satisfaction with the VMSCC service.

We will conduct a cost-effectiveness analysis of the costs of the VMSCC service, direct medical costs of ER admissions and length of hospital stay during readmissions. No hypothesis is constructed as such analysis is to provide an estimation.

METHODS AND ANALYSIS

Design

A two-arm randomised controlled trial (RCT) will be conducted. [Figure 1](#) shows the flow of the study. We

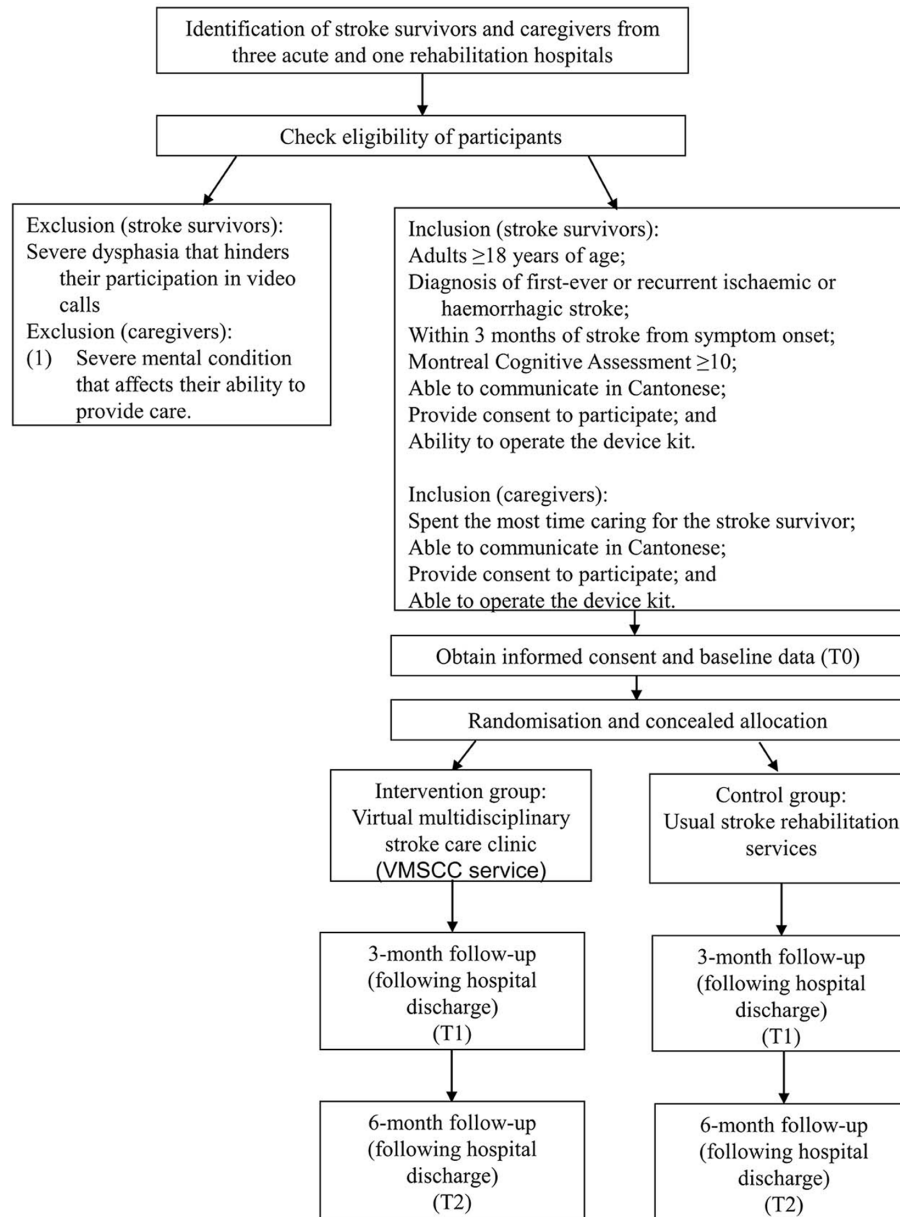


Figure 1 Diagram of the flow of the study.

adhere to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines when preparing this protocol.¹³

Settings

Participants will be recruited from the nurse-led stroke clinics and acute stroke units of three acute public hospitals, and rehabilitation wards of one rehabilitation hospital. The multidisciplinary stroke care teams in these four hospitals follow the same integrated stroke care pathway endorsed by the Hong Kong Hospital Authority. The available multidisciplinary care expertise and resources are comparable. The nurse-led stroke clinics follow-up stroke patients after their discharge from the hospitals.

Participants

All stroke survivors admitted to the study hospitals will be recruited if they are (1) ≥ 18 years, (2) diagnosed with

an ischaemic or a haemorrhagic first-ever or recurrent stroke, (3) immediately after discharge from the hospital till within 3 months of stroke onset, (4) assessed of having a Montreal Cognitive Assessment score ≥ 10 , (5) communicable in Cantonese, (6) consent to participate and (7) able to operate the study device kit. Survivors will be excluded if they have severe dysphasia or hearing impairment that hinders their participation in video calls. Otherwise, there will be no exclusion criteria on the stroke survivors' neurological deficit and functional status.

Caregivers' inclusion criteria include (1) spends the greatest amount of time in caring the survivor, (2) communicable in Cantonese, (3) consent to participate and (4) able to operate the study device kit. Exclusion criterion includes having a severe mental condition that affects their ability to provide care. The survivor-caregiver dyads will be excluded if the survivor is lost to follow-up.

Randomisation

Eligible participants (survivor–caregiver dyads), after consenting and baseline assessment, will be allocated in a 1:1 ratio to either an intervention group or a control group according to a computer-generated random sequence of grouping identifiers by using blocked randomisation with a block size of 12. Concealed allocation will be performed sequentially according to the participants' enrolment.

Blinding

Due to the nature of the intervention, only the outcome assessors will be blinded from group allocation. The person who will deliver the intervention and research assistants who will conduct interviews with the participants about their satisfaction with the service will know the group assignment. The research assistants will be responsible for entering their data collected and will not be involved in data analysis and results reporting.

Intervention

Participants in the intervention group will receive the following interventions.

Multidisciplinary stroke care online platform

An online platform that embraces readily accessible and reliable information to promote stroke recovery and offer support to survivors and caregivers will be developed as a core part of the VSMCC service. It is the first initiative to incorporate efforts of an expert panel on stroke care from different healthcare professionals (nursing, Western and Chinese medicine and pharmacy). The platform will include 30 videos that demonstrate appropriate self-care strategies. Survivors will be invited to share their post-stroke recovery experiences (table 1).

Table 1 List of videos to be developed for the multidisciplinary stroke care online platform

Videos	No of videos to be developed
Overview of stroke	2
Pharmacist advice on commonly used medications for stroke	2
Integration of traditional Chinese and Western medicine in stroke care	2
Skills to enhance independent living after stroke	6
Nutrition and health	2
Exercise and health	3
Healthy lifestyle and tips to maintain health	3
Rehabilitation and community resources	2
Social participation	1
Stroke support groups	4
Recurrent stroke prevention	1
Support to caregivers	2

VSMCC service

Each survivor–caregiver dyad will be offered a device kit (a tablet and a clinically validated wireless home BP monitoring device).¹⁴ The dyads will use the tablet to review all resources stored on the platform and to communicate with the nurse via video calls. Furthermore, the survivor participants will be asked to store and share the BP readings weekly with the nurse via an apps preinstalled in the tablet.

A VSMCC will be set up to facilitate interactions between the participants and healthcare professionals. A call centre will be established in one study hospital where a nurse will conduct Skype-based video calls with each survivor–caregiver dyad and discuss issues about stroke recovery and self-management. Each video call will last for 30–45 min and be conducted monthly for 6 months. The nurse will review the BP readings before the video calls and use the resources including videos available on the online platform to reinforce self-management knowledge and skills, and measures to master caregivers' strain.

Monthly telephone calls for 6 months will be arranged (one for survivor and one for caregiver each month). The telephone call will be scheduled within a week before the video call session to allow the survivors and caregivers to express their feelings, needs, concerns and challenges in private. It enables the nurse to tailor the video calls to meet the survivor–caregiver dyads' needs. The participants' privacy and confidentiality will be respected. The call serves as a reminder of the video call and transmission of the BP readings.

Positive reinforcement will be given towards participants' valued activities such as self-monitoring BP or using the device kit to learn. To enhance the participants' adherence, the video and telephone call appointments will be scheduled at a time convenient to the survivors and caregivers. An appointment sheet will be given to the participants before discharge.

The nurse will respond to non-urgent health concerns and psychological issues through a hotline (Monday–Friday, 09:00–17:00; Saturday, 09:00–13:00). The nurse will work closely with the research team to enable the participants to obtain advice from a broad range of clinical experts including Western and Chinese medicine practitioners, pharmacists and nurses. The nurse will respond to the participants' non-urgent health concerns and psychological issues, and will answer the participants' queries regarding their health conditions after discussing with the clinical experts of the research team. The participants will be suggested to obtain medical help from an emergency department if emergencies occur.

The nurse will meet the participants of the intervention group after enrolment and guide them to use the device kit and view at least five videos available on the online platform. The participants will be encouraged to view the videos and instructional materials according to their health needs. Technical problems encountered after discharge will be supported via the hotline by the nurse.

Additional technical support via home visit or telephone contacts may be scheduled as needed.

Eight 3-hour training sessions will be provided to build on the nurse's skills in managing the VMSCC and delivering the intervention. The knowledge and skills will include therapeutic communication and counselling skills, stroke self-management and core self-management skills, and methods to empower participants to make healthy decisions.

Patient and public involvement

User engagement in development of the intervention

The user-centred design methodologies¹⁵ will be adopted. Potential users (four survivors and four caregivers) fulfilling the eligibility criteria will be recruited. Discovery interviews¹⁶ will be conducted to have an in-depth understanding of the survivors' and caregivers' needs, and to include the users' input in developing a tailored online platform and the VMSCC service. Topics discussed will include survivors' and caregivers' poststroke experiences, perceived needs, self-management habits, expectations about the online platform and the VMSCC service, aspects of delivery and receipt process that may bring about satisfaction with the service and how they incorporate self-management behaviours into their lifestyle.

The same group of potential users will be asked to review the deliverables. The cycle of feedback loops

between the potential users and the research team will be initiated 3 months afterwards. The online platform and the VMSCC service will be finalised taking into consideration the potential users' feedback. The survivors and caregivers involved in the user engagement process will be acknowledged.

Furthermore, eligible stroke survivors and their caregivers who have not been involved in the user engagement of the intervention will be involved in the recruitment and conduct of the study. The key study results will be disseminated to the participants in written format on request. The burden of the intervention will be assessed by the stroke survivors and their caregivers.

Control group

Participants in the control group will receive usual stroke rehabilitation services: hospital-based health education, information about local community-based rehabilitation services and outpatient rehabilitation services at day hospitals.

Outcome measures

The following outcomes will be measured at baseline (T0), and at 3 (T1) and 6 (T2) months after commencing the intervention for both survivors and caregivers (table 2).

Table 2 Outcome measures and data collection time points

Outcome measures	Instruments	Participants		Data collection time points		
		Survivors	Caregivers	T0	T1	T2
Primary outcomes						
Self-efficacy in stroke self-management	SSEQ	í		í	í	í
Health-related quality of life	EQ5D-5L	í		í	í	í
	SF-36v2		í	í	í	í
Secondary outcomes						
Depressive symptoms	GDS	í	í	í	í	í
Satisfaction with performance of stroke self-management behaviours	SSBPS	í		í	í	í
Social participation	RNLI	í		í	í	í
Coping strategies	CAMI		í	í	í	í
Satisfaction with caring	CASI		í	í	í	í
Health service utilisation (emergency admission and length of readmission hospital stay)	–	í			í	í
Participants' satisfaction—survey	USQ	í	í			í
Participants' satisfaction—interview	–	í	í			í
Adherence to the video call sessions	–	í	í		í	í
Costs	–	–	–		í	í

T0: Baseline.

T1: At 3 months after commencing the intervention.

T2: At 6 months after commencing the intervention.

CAMI, Carer's Assessment of Managing Index; CASI, Carer's Assessment of Satisfaction Index; EQ5D-5L, 5-level EuroQol-5D version; GDS, Geriatric Depression Scale; RNLI, Reintegration to Normal Living Index; SF-36v2, Medical Outcomes Study Short-Form General Health Survey; SSBPS, Stroke Self-Management Behaviours Performance Scale; SSEQ, Stroke Self-Efficacy Questionnaire; USQ, User Satisfaction Questionnaire.

Survivor-specific outcomes

Primary outcomes

- I. SE: survivors' SE in performing daily functional activities and self-management will be measured by a 13-item Chinese version of the Stroke Self-Efficacy Questionnaire.¹⁷ Each item is rated on an 11-point scale (0='not at all confident'; 10='very confident'). The construct validity is supported by its significant correlations with the General Self-Efficacy Scale. High internal consistency was reflected ($\alpha=0.92$).¹⁷
- II. HRQoL: survivors' HRQoL will be measured by the Chinese (HK) version of the EQ5D-5L.¹⁸ It is a standardised instrument of health outcomes that can be used to calculate quality-adjusted life years in economic evaluation. It comprises the dimensions of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Its psychometric properties have been well established and found to be a valid and reliable measure of HRQoL in patients with acute stroke.¹⁹

Secondary outcomes

- III. Stroke self-management behaviours: an 11-item Chinese version of the Stroke Self-Management Behaviours Performance Scale²⁰ will be used to measure survivors' satisfaction with their performance of self-management behaviours. The scale was developed by the investigators based on an extensive literature review and validation in Chinese community-residing survivors. A high internal consistency ($\alpha=0.93$) was shown. Each item is rated on an 11-point Likert scale (0='very dissatisfied'; 10='very satisfied').
- IV. Social participation: the 11-item Reintegration to Normal Living Index will be used to measure the survivors' level of social participation after stroke.²¹ It measures a person's extent of involvement in six domains: mobility, self-care, activities, role within the family, comfort with relationships and ability to handle life events. Each item is rated on a 4-point scale (1='does not describe my situation'; 4='fully describes my situation'). It has high internal consistency ($\alpha=0.90$ ²¹; for the Chinese version, $\alpha=0.92$).²²

Caregiver-specific outcomes

Primary outcome

- I. HRQoL: the Chinese (HK) version of the Medical Outcomes Study Short-Form General Health Survey will be used to measure the caregivers' HRQoL.²³ It measures eight dimensions: physical functioning, role limitations caused by physical problems, bodily pain, social functioning, mental health, role limitations caused by emotional problems, vitality-energy/fatigue and general health perception. The scale shows high internal consistency (α for subscales ranging from 0.65 to 0.87).¹⁸

Secondary outcomes

- II. Coping strategies: the 36-item Carer's Assessment of Managing Index (CAMI) will be used to assess caregivers' coping with difficult caring situations and whether they perceive these strategies helpful. It contains three domains: problem solving, emotional cognitive and dealing with the consequences of stress. Each item is rated on a 4-point Likert scale (1='I don't use this'; 4='Very helpful'). It has high internal consistency ($\alpha=0.85$).²⁴
- III. Satisfaction with caring: the 30-item Carer's Assessment of Satisfaction Index (CASI) will be used to assess caregivers' satisfaction with caring. It contains three domains: person cared for as main beneficiary, caregivers and interpersonal dynamics. Each item is rated on a 4-point Likert scale (1='This does not apply to me'; 4='A great deal of satisfaction'). It has well-established content validity and high internal consistency ($\alpha=0.91$).²⁴

We will translate the original language version of CAMI and CASI into Chinese, ensure its cultural and semantic equivalence and validate among Chinese stroke caregivers.

Secondary outcomes for both survivors and caregivers

- I. Depression: a Chinese version of the Geriatric Depression Scale (GDS) will be used to measure the presence of depressive symptoms among survivors and caregivers. On a 30-item scale with yes/no answers, a score of 11 indicates mild depression and that of 17 severe depression. It has good psychometric properties. Correlational analysis revealed the Chinese version of GDS has excellent convergent validity when assessed against the London Handicap Scale.²⁵

The following secondary outcomes will be measured during the 6-month follow-up period.

Health service utilisation

The number of ER admissions and the total length of readmission hospital stay will be retrieved from the hospital clinical management system.

Participants' satisfaction (at 6 months)

- I. Survey: participants' satisfaction (all survivors and caregivers of the intervention group) will be measured by a self-developed 21-item User Satisfaction Questionnaire (USQ). The USQ measures the participants' satisfaction with the VMSCC service in terms of usefulness, acceptability and satisfaction with the support received from the VMSCC nurse. Each item is rated on a 5-point Likert scale. A higher score indicates a higher level of satisfaction. The USQ includes three open-ended questions to retrieve participants' perception of the VMSCC service.
- II. Interview: individual semistructured interviews will be conducted to obtain user feedback on the VMSCC service in terms of acceptability, usefulness,

difficulties, utility and satisfaction within home setting. A subset of 20 purposive samples (10 survivors and 10 caregivers) will be identified from the USQ (those with high, middle and low satisfaction ratings) to probe into their experiences.

Adherence

Defined as attendance in at least 80% of the video call sessions by a survivor–caregiver dyad. The estimated duration (minutes/hours per week) and frequency of viewing the videos on the platform, and the number of videos viewed will be collected from the survivors and caregivers.

Costs

The components of the total cost included in the cost-effectiveness analysis are listed in [box 1](#).

Sociodemographic and clinical data including the survivors and caregivers' age, sex, marital status, educational level, occupation, living arrangement, financial status, relationship between survivors and caregivers and caregivers' health history will be recorded. The National Institutes of Health Stroke Scale and the Barthel Index will be used to measure survivors' neurological and functional status. The survivors' medication therapy and health education received during the study period will be recorded.

Sample size calculation

The study is powered to detect effect sizes of interventions similar to ours on the primary outcomes of SE and HRQoL among survivors. From published systematic reviews and RCTs, we identified various survivor and caregiver interventions that emphasise self-management that are relevant to our proposed intervention.^{2 4 6} The estimated effect sizes from these studies on survivors' SE and HRQoL measures ranged from 0.34 to 0.78 and 0.32 to 0.59, respectively. By using the power analysis software PASS V.13.0 (NCSS, Kaysville, Utah, USA), it is estimated that a sample size of 154 eligible participants per study arm will give the two-arm RCT 80% power at two-sided 5% level of significance to detect an effect size of at least 0.32 for an outcome after the intervention.

Further allowing for an attrition rate of 20%, 384 survivor–caregiver dyads (192 dyads per arm) will be recruited.

Data collection

A research assistant (RA) will regularly visit the hospitals and assess stroke patients' eligibility against the inclusion and exclusion criteria. Eligible participants who agree to participate will be asked to sign a written consent. All questionnaire data for the survivors and caregivers will be collected shortly before discharge by an interview using a demographic form and self-reported scales. At 3 and 6 months after commencing the intervention, survivors' and caregivers' data in both groups will be collected by another RA in outpatient clinics. The assessment will be arranged within 1 week of the data collection schedule and will align with the survivors' medical follow-up appointment if possible. We will make appointments with the stroke participants if they do not have appointments scheduled in alignment with the data collection intervals. Six months were chosen as the second follow-up period rather than an earlier time point because the survivors' social condition would be more stabilised at 6 months.²⁶ Survivors and caregivers in the intervention group will be interviewed at 6 months over the telephone to elicit feedback on the service.

The RAs will undergo training and will be required to follow standard procedures for recruitment, blinding, data collection, maintaining confidentiality and safeguarding data. The RAs' skills will be assessed by a coinvestigator in a pilot testing of four survivor–caregiver dyads. Appropriate referrals will be provided if any participant experience severe emotional distress during the interview.

Pilot study

A pilot study of four telephone call (two survivors and two caregivers) and four video call sessions with four survivor–caregiver dyads will be conducted to test the feasibility and acceptability of the protocol. Three investigators will comment on the process. The results and experiences of the pilot study will inform refining the logistics of the study.

Statistical analyses

Baseline characteristics and outcome variables will be presented using descriptive statistics. Skewed variables will be transformed to correct their skewness before inferential analysis. The baseline characteristics between the two arms will be compared with independent t, χ^2 or Fisher's exact tests, as appropriate. All outcomes will be analysed on the basis of intention-to-treat principles.

For the primary and secondary outcomes, the generalised estimating equations model will be used to compare the differential changes in each outcome across the time points T0 and T1 and T2 between the two arms. This type of model can account for intracorrelated repeated measures data and produce unbiased estimates even in the presence of missing data, provided the data are

Box 1 The component items of total cost and direct medical costs

Cost input parameters

Virtual multidisciplinary stroke care clinic (VMSCC) service

- ▶ Cost of the VMSCC service I: staff and administrative costs (including costs of video calls, hotline, teaching, assessment and others [administrative cost]).
- ▶ Cost of the VMSCC service II: hardware (tablet, blood pressure monitoring device, Internet fee).
- ▶ Cost of the VMSCC service III: operation cost (hosting fee).

Stroke-related direct medical cost

- ▶ Emergency department visit.
- ▶ Hospitalisation (general ward).
- ▶ Hospitalisation (intensive care ward).

missing at completely random. Multivariable regressions will be used to compare the number of ER admissions and total length of readmission hospital stay over the 6-month study period between the two arms.

A cost-effectiveness analysis will be performed on the average total cost incurred in both arms, and incremental cost-effectiveness ratios expressed as incremental cost per (1) one ER admission reduced and (2) 1 day of hospital stay reduced over the 6-month study period among the survivors. All cost data will be expressed in Hong Kong dollars and valued on the basis of non-subsidised cost on the study start date.

All the statistical analyses will be performed using SAS V.9.4. All statistical tests will be two-sided with the level of significance set at 0.05.

Ethics and dissemination

The research team will protect the participants' rights and safety by adhering to local laws, the Declaration of Helsinki, institutional policies and the International Conference on Harmonization - Good Clinical Practice (ICH-GCP). Agreements were made with the four hospitals on arrangements for participant recruitment. Eligible participants who agree to participate will be asked to sign a written informed consent. All information collected will be kept strictly confidential. Results of this RCT will be disseminated via peer-reviewed journals, and presentations at local, national and international conferences.

DISCUSSION

The use of computer-mediated communication such as video-based calls by a nurse, telemedicine systems based on a virtual environment^{9 10} or integrated efforts by a multidisciplinary team of healthcare professionals were shown associated with positive results on stroke survivors' health outcomes.¹¹ However, this is the first RCT to develop and evaluate the effectiveness and cost-effectiveness of the VMSCC service that blends the technological innovation and the multidisciplinary healthcare team in a virtual clinic to support stroke survivors and their caregivers in the community. The study results will provide evidence on its sustainability and monetary value, and hence informs stakeholders' decisions in integrating this new model into the current community stroke care services. The VMSCC is the first initiative to incorporate efforts of an expert panel of stroke care from different healthcare disciplines including nursing, medicine (Western and Chinese) and pharmacy. It is anticipated that the service would become a central one-stop point in the community to retrieve information and obtain support among stroke survivors and caregivers. The VMSCC using online Skype-based video calls and hotline will eliminate transport difficulties, and provide timely and pragmatic health advices on survivors' daily self-management. The regularly scheduled online video calls also help detect early care problems, or signs and symptoms of recurrent stroke and address healthcare issues without

presenting unnecessarily to emergency health services. It is expected to instil a sense of being cared of, monitored and follow-up to the survivors and caregivers after they have returned home.

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Competing interests None declared.

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