BMJ Open

Coaching Ongoing Momentum Building On stroKe rEcovery journeY ('COMBO-KEY'): a randomised controlled trial protocol

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To cite: Lo SHS, Chau JPC, Chang AM, *et al*. Coaching Ongoing Momentum Building On stroKe rEcovery journeY ('COMBO-KEY'): a randomised controlled trial protocol. *BMJ Open* 2019;**9**:e027936. doi:10.1136/bmjopen-2018-027936

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2018-027936).

Received 17 November 2018
Revised 18 February 2019
Accepted 26 February 2019

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ABSTRACT

Introduction Systematic reviews reporting self-management interventions are associated with significant improvements in stroke survivors' self-efficacy, health-related quality of life (HRQoL) and independence. However, common barriers such as transportation and availability of carers were identified. Health coaching is suggested as an innovative and cost-effective care model with potential benefits in managing chronic diseases. A randomised controlled trial is proposed to evaluate the effectiveness of an enhanced self-management programme by health coaches on stroke survivors' recovery outcomes.

Methods and analysis All adult community-dwelling stroke survivors with a modified Rankin Scale Score ≥3 will be recruited from a community rehabilitation network. Eligible participants will be randomly allocated to receive either the enhanced stroke self-management programme (Coaching Ongoing Momentum Building On stroKe rEcovery journeY [COMBO-KEY]) plus usual care or usual care only. COMBO-KEY is an 8-week programme underpinned by Bandura's principles of self-efficacy and outcome expectation. It consists of four home visits and five phone-coaching sessions delivered by trained health coaches. Each participant will receive a resource package containing a workbook, a quick reference guide, a planning toolkit and 15 videos of peer survivors' stroke survival experience. Survivors' outcomes include self-efficacy, outcome expectation and satisfaction with performance of self-management behaviours, HRQoL, depressive symptoms and community reintegration. Assessment will be conducted at baseline and immediately after completing the programme. Generalised estimating equations' model will be used to analyse the data.

Discussion It is anticipated that the programme will build community capacity in supporting stroke survivors. The results will shed light on integrating the programme into the current stroke rehabilitation services.

Ethics and dissemination The Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee has approved this protocol (CREC Ref. No.: 2018.009). Written informed consent will be obtained from all participants. Study results will be disseminated through peer-reviewed journals and presentations at local and international conferences.

Trial registration number ClinicalTrials.gov Identifier: NCT03741842; Pre-results

Strengths and limitations of this study

- This study evaluates an enhanced version of a stroke self-management programme (Coaching Ongoing Momentum Building On stroKe rEcovery journeY ['COMBO-KEY']) featuring the integration of a health coaching approach with home visits and phone coaching, and enriched theory-driven self-efficacy and outcome expectation enhancing strategies to build community-dwelling stroke survivors' confidence and positive expectations of recovery outcomes, and enable their engagement in self-management behaviours.
- Due to the nature of the intervention, only the assessors of the baseline and follow-up assessments are masked from the participants' group allocation, and blinding is not possible for participants, the person who will deliver the programme and persons who will conduct postprogramme interviews with participants for their feedback.
- Collection of both quantitative and qualitative data will enable more comprehensive interpretation of changes in the outcome measures.

INTRODUCTION

Stroke has remained the second leading cause of deaths globally since 2000 and a major cause of disability. It caused about 6.24 million deaths worldwide in 2015.[1] Statistics in Hong Kong also shows stroke has been the fourth leading cause of death since 2003.[2] Its prevalence is projected to increase with the world's ageing population.[3 4] Stroke constitutes a significant cause of disability. Even survivors with a mild stroke always experience chronic symptoms and hardship in regaining optimal independence after stroke.[5] The poststroke physical and psychosocial challenges may be complicated by ageing or comorbid conditions such as diabetes.[6–8] Significant decrease in survivors' health-related quality of life (HRQoL) beyond 2 years after stroke was reported.[9]

The poststroke recovery journey extends far beyond the discharge from the hospitals or community services. The support required to address the daily challenges encountered by stroke survivors can be long-term and demanding.[10] Studies reported that survivors might rely on healthcare providers or their caregivers for managing their health and doubt the likelihood of improving. It hence might hinder their motivation and engagement in continued rehabilitation.[11]

A priority need for survivors is to learn the knowledge and skills in managing poststroke challenges and reducing stroke risks, and to incorporate it into lifestyle-workable strategies to solve struggles and make choices for changing their health behaviours.[12] Furthermore, facilitating survivors to learn to build self-confidence, set short-term goals of recovery and accumulate mastery experience are important to maintain their determination and a sense of momentum in recovery.[12]

International evidence-based guidelines recommend self-management support to survivors for improved health outcomes and utilisation of healthcare services.[13] Stroke self-management is a person's capability to manage stroke-related changes including symptoms, treatment, and physical and psychosocial challenges.[14] To attain effective self-management, survivors need to learn core self-management skills including setting goals, planning actions, solving problems, making decisions, communicating with healthcare providers and using community resources. Underpinning these skills is survivors' acceptance of responsibility for their self-management behaviours such as exercise and managing psychological distress.[14]

A recent meta-review of 13 systematic reviews (SRs) found stroke self-management interventions were associated with significant improvements in activities of daily living (ADLs), and reduced dependence and death. However, it was inconclusive about the best theoretical frameworks to underpin the design and evaluation of such complex interventions.[15] Another SR reviewed three randomised controlled trials (RCTs) examining the effectiveness of theory-based stroke self-management programmes. The results showed potential benefits of the programmes on survivors' self-efficacy and HRQoL. However, the included studies were conducted in Western countries. Applicability of the programme to the Chinese population is not known.[16]

The SR also found that the most common theoretical premise underpinning the stroke self-management programme was Bandura's construct of self-efficacy.[16] Self-efficacy is a person's judgement of his or her ability to perform a behaviour.[17] Three SRs consistently found a significant positive association between survivors' self-efficacy and HRQoL.[12 18 19] Outcome expectation, a construct closely related to self-efficacy, is suggested to play an important role in a person's behavioural change. It refers to a person's belief in the likelihood of the outcome to occur after performing a behaviour.[17] A study showed that improved self-efficacy and outcome expectation was significantly associated with increased exercise behaviours in older stroke survivors.[20] Therefore, integrating both constructs in designing stroke self-management programmes could be worthwhile.

Informed by the SR results,[16] we developed a 4-week nurse-led stroke self-management programme (SESSMP) underpinned by Bandura's constructs of self-efficacy and outcome expectation.[21] It included a home visit for individualised assessment and education, two community group sessions for peer modelling, and three follow-up phone calls for sustaining goal attainment. Each participant received two DVDs sharing about 15 survivors' experiences of successful self-management.[21] An RCT testing the effectiveness of SESSMP showed that, among 128 community-dwelling stroke survivors after hospital discharge, those who received the SESSMP were associated with significantly greater improvements in their levels of self-efficacy, outcome expectation and satisfaction with performance of self-management behaviours, HRQoL and community reintegration at 1 month after the programme completion. However, transportation problems and carer unavailability were two major barriers that limited the survivors', with greater physical impairment or risks of adverse events, joining the programme.[22] Strategies to address these health needs are warranted.

A review suggested health coaching was an emerging innovative care model with potential benefits in reducing rates and morbidity of chronic diseases. Health coaches were new allied healthcare providers with expertise in supporting individuals' health behavioural change.[23] Our previous SESSMP revealed that some participants had low motivation in changing behaviours, or low health literacy in setting goals or solving problems. The nurse facilitator helped integrate strategies into participants' lifestyle and guided them to appreciate their potentials in accomplishing it. It mirrored the health coaching approach, which a health coach discusses with the person being coached, on goals and action plans for optimising health, and facilitating them to achieve the goals by exploring and motivating them to implement strategies that suit their health needs.[23] A recent SR[24] corroborated that trained community-based health workers who delivered health interventions, with or without partnering with healthcare providers, were potentially effective and cost-effective in reducing cardiovascular risks. One included study reinforced that trained lay volunteers who delivered coaching in three home visits and five phone calls significantly improved medication safety behaviours among older adults with chronic diseases.[25]

Previous studies advocated coaching via visits and phone calls. A pretest and post-test study incorporating phone calls and coaching to clinic visits showed 48% reduction in 30-day readmission among stroke survivors.[26] Another study reported 80% medication adherence among stroke survivors after receiving coaching (predischarge education and phone calls by a nurse coach; clinic visits to a nurse practitioner).[27] A study using process evaluation found survivors were very satisfied with an average

3.8 (SD 1.4) nurse-led home visits after discharge from hospitals.[28]

In this study, we will develop an enhanced version of SESSMP (Coaching Ongoing Momentum Building On stroKe rEcovery journeY ['COMBO-KEY']) featuring enriched programme content and resources to enhance survivors' self-efficacy and outcome expectation; strengthening doses of home visits and phone calls; adopting a health coaching approach to build survivors' confidence and positive expectations of recovery outcomes; and enabling their engagement in self-management behaviours.

Aim and hypothesis

We aimed to investigate the effectiveness of COMBO-KEY for improving stroke survivors' self-management behaviours and recovery outcomes.

It is hypothesised that, compared with those receiving usual care at 8 weeks after baseline, stroke survivors receiving COMBO-KEY will have significantly greater:

- Increase in levels of self-efficacy, outcome expectation and satisfaction with performance of self-management.
- Increase in HRQoL and community reintegration.
- Reduction in depressive symptoms.
- Satisfaction with the programme.

METHODS AND ANALYSIS

Design

An assessor-blinded two-arm RCT will be conducted. Figure 1 shows the study flow.

Settings

Participants will be recruited through the Community Rehabilitation Network (CRN) in Hong Kong. CRN is one of the largest non-government organisations in Hong Kong which provides various rehabilitative, social care and vocational services for community-dwelling people with chronic conditions including stroke.

Participants

Stroke survivors will be recruited if they are/have: (1) Aged ≥18 years. (2) A clinical diagnosis of ischaemic or haemorrhagic first-ever or recurrent stroke. (3) Been discharged from hospital after a recent stroke. (4) Living at home. (5) A modified Rankin Scale Score ≥3. (6) A Montreal Cognitive Assessment (MoCA) Score >20. Survivors will be excluded if they have severe dysphasia or are diagnosed with a mental illness, or have received or are currently receiving a stroke self-management programme.

Sample size calculation

Based on our previous interventional study,[22] effect sizes of SESSMP on self-efficacy in stroke self-management and HRQoL were 0.55 and 0.56, respectively. Using a power analysis software PASS V.13.0 (NCSS, Kaysville, Utah, USA), an estimated sample size of 53 participants per arm would give the proposed two-arm RCT 80% power at two-sided 5% level of significance to detect an effect size of >0.55 on our outcomes after the programme. Considering an attrition rate of 20%, 134 participants (67 per arm) will be required.

Randomisation

Blocked randomisation with a block size of six will be used. An independent statistician will prepare a computer-generated, random sequence of grouping identifiers. According to this sequence, we will randomly allocate the participants to either an intervention group or a control group in a 1:1 ratio after consenting and conducting baseline assessment. Concealed allocation using sealed, opaque and sequentially numbered envelopes will be performed.

Blinding

The research assistants who will conduct baseline and follow-up assessments will have no knowledge of the participants' group allocation. They will be involved in assessment and data entry only. Owing to the nature of the intervention, blinding is not possible for the participants, the person who will deliver the programme, the research assistants who will conduct interviews with the participants and the coaches about their feedback on the programme.

Intervention

Participants allocated to the intervention group will receive the enhanced stroke self-management programme ('COMBO-KEY') in addition to usual stroke care. The programme is aimed at building survivors' confidence and positive expectations of recovery outcomes, and enabling their engagement in self-management behaviours. It is underpinned by Bandura's principles of self-efficacy and outcome expectation.[21] Strategies to enhance self-efficacy and outcome expectations of the participants will be adopted (table 1).[17 21] The programme will consist of four home visits (1.5–2 hours each) and five phone-coaching sessions over 8 weeks. A trained coach leader who is either a registered nurse or a social care provider will deliver home visits. A coach who is a trained lay volunteer who is studying or has obtained a bachelor's degree in health or social sciences will conduct phone coaching. Both the coach leader and the coach will work as facilitators with the participants in a collaborative helping relationship. The purpose of coaching is to facilitate the participants to establish and attain the goals set through active listening, and supporting them to develop new ways of performing self-management behaviours to address their health needs. Each participant will be coached by the same coach leader and coach throughout the programme to promote better rapport and ensure consistency in care.

During weeks 1–3, a coach leader will conduct three weekly home visits. In home visit 1, the coach leader will assess the participant's current health condition and physical and psychosocial challenges such as mobility, use of assistive devices and role changes after stroke. The coach leader will also assess the participant's current level

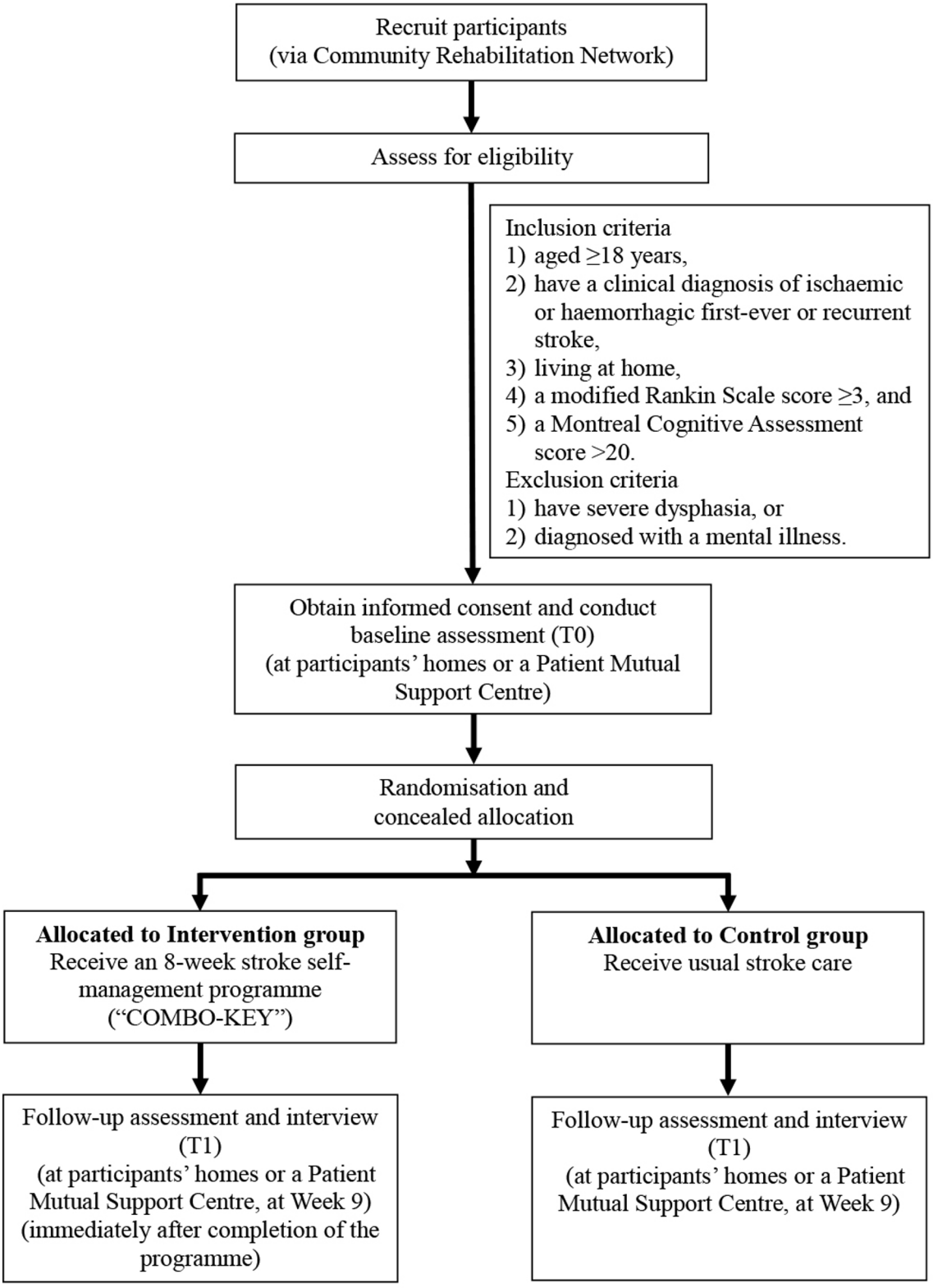

Figure 1 Flow of participants in the study. COMBO-KEY, Coaching Ongoing Momentum Building On stroKe rEcovery journeY.

of self-efficacy, outcome expectation and capabilities of performing self-management behaviours. The assessment findings will be documented on a record form specifically designed for home visits. Importance of stroke self-management will be discussed. A resource package specifically designed for the programme will be given to the participant. The coach leader will review the resource package with the participant and highlight important information. Based on the assessment findings, the coach leader will facilitate the participant to establish one self-selected

Table 1 Strategies adopted in the programme ('COMBO-KEY') to enhance stroke survivors' self-efficacy and outcome expectation of performing stroke self-management behaviours

Sources of information of self-efficacy	Strategies adopted	Programme components
Mastery experience	Establish a self-selected short-term goal of recovery	HV
	Develop an action plan with strategies that fit the participants' lifestyle	HV
	Facilitate to practice core self-management skills	HV, PF
	Encourage to record implementation of the plan	HV, PF
	Encourage the use of the resource package	HV, PF
	Facilitate the reflection of own resources, strengths and challenges	HV, PF
Vicarious experience	Review videos about peer survivors' experience sharing	HV
	Guide the reflection of own strengths and challenges	HV
Verbal persuasion	Acknowledge incremental successes	HV, PF
	Provide positive reinforcement	HV, PF
	Reinforce the importance of 'taking an active role'	HV, PF
Physiological and emotional states	Facilitate reinterpretation of negative physiological and emotional states using the resource package	HV, PF
Outcome expectation	Assess and reinforce positive outcomes valued by the participants after performing stroke self-management behaviours	HV, PF

COMBO-KEY, Coaching Ongoing Momentum Building On stroKe rEcovery journeY; HV, home visit; PF, follow-up phone calls.

short-term goal of recovery and action plan for the coming 3 weeks. The goal and action plan will be recorded on the coach leader's record form and the participant's resource package. During the home visit, developing strategies that fit the participant's lifestyle and preferences will be emphasised.[17 21]

The coach leader will assess the participant's condition and reinforce strategies for goal attainment in home visits 2 and 3. Practical tips for managing poststroke challenges will be discussed. The participant will also be encouraged to reflect on their goal attainment, and explore alternative lifestyle-workable strategies to better implement the action plan if needed. The use of the resource package will be reinforced. In home visit 3 (week 3), the coach leader will summarise the participant's progress and revise action plans if needed. The coach leader will then inform the coach about the participant's goal and action plans, and the assessment findings. Instructions about how to facilitate the participant's goal attainment will be provided to the coach.

During weeks 4–8, a coach will conduct five phone-coaching sessions followed by a final home visit (home visit 4) by a coach leader in week 8. The phone coaching sessions are aimed at facilitating the participant to accomplish the goal set. Each participant will be coached on applying self-management skills to solve the barriers or struggles encountered. Integration of their valued positive outcomes and pragmatic strategies into their lifestyle will be reinforced to enable behavioural changes.[17 21] Participants will also be encouraged to use the resource package to maintain their determination and momentum in accomplishing the goal. The coach will discuss with the coach leader about the participants' progress regularly. During week 8, the coach leader will conduct the last home visit to summarise goal attainment and discuss future planning with the participant.

All participants will receive a multimodal resource package which contains four items: (1) A stroke self-management and self-discovery workbook: provides information about self-management and guides survivors to develop strategies that are pragmatic to their lifestyle to manage poststroke challenges. (2) Health and life planning toolkit: contains six practical tools to facilitate day-by-day health planning and implementation related to managing physical and psychosocial challenges such as tailored printed reminders or text messages. (3) Fifteen videos in two DVDs: record experiences and tips about self-management by survivors who managed their stroke successfully. (4) A quick reference guide: provides easy reference to self-management, self-discovery and health planning.

A telephone hotline will be established for the participants and their caregivers to direct their queries about stroke self-management. The hotline will be operated 5 days per week during the programme. A research nurse will be responsible for responding to the calls after gathering queries and consulting the study team members.

We will develop a programme protocol and a training manual for coach leaders and coaches to ensure the consistent delivery of the programme. An expert panel of two nurse academics, one nurse consultant, one physician, two advanced practice nurses and two social workers will review the resource package, programme protocol and coach training manuals. Revisions will be made as appropriate on the panels' comments.

We aim to recruit a team of five coach leaders and 18 coaches. All coaches will be required to receive a prior 4-day training conducted by the principal investigator on core topics including self-management, self-efficacy and outcome expectation, care of survivors, health planning, phone coaching and safety precautions. Coach leaders will

Table 2 Outcome measures and data collection time points

Outcome measures	Instruments	Participants	Data collection time points	
			T0	T1
Primary outcomes				
Self-efficacy	SSEQ	X	X	X
Outcome expectation	SSOES	X	X	X
Secondary outcomes				
Satisfaction with performance of stroke self-management behaviours	SSBPS	X	X	X
Health-related quality of life	SSQOL	X	X	X
Depressive symptoms	GDS	X	X	X
Social participation	RNLI	X	X	X
Satisfaction with the programme -interview	–	X		X
Adherence to the programme sessions	–	X		X
Demographic and clinical information	–	X	X	X

T0: baseline.
T1: immediately after completing the intervention.
GDS, Geriatric Depression Scale; RNLI, Reintegration to Normal Living Index; SSBPS, Stroke Self-Management Behaviours Performance Scale; SSEQ, Stroke Self-Efficacy Questionnaire; SSOES, Stroke Self-management Outcome Expectation Scale; SSQOL, Stroke Specific Quality of Life Scale.

receive an additional 14 hours training on skills in home visiting, leadership and management skills, and care coordination. On satisfactory completion of a knowledge quiz and scenario-based practice sessions, the coaches will be allowed to deliver the programme sessions independently. Both coach leaders and coaches are required to report to the principal investigator on a regular basis or as needed during the implementation of the programme.

Control group

Participants in the control group will be instructed to continue to receive the stroke care services that they are receiving or planning to receive. It includes but is not limited to rehabilitation services offered by CRN or stroke support groups such as exercise or cognitive training, or psychosocial support interventions; or other health or medical services offered to the participants by the hospitals or health organisations such as health education or consultations.

Outcome measures

Survivors' outcomes will be measured at baseline before randomisation (T0) and immediately after completion of the programme (T1) (table 2).

Primary outcome measures include

Self-efficacy

Participants' self-efficacy in performing self-management behaviours will be measured by a 13-item Chinese version of the Stroke Self-Efficacy Questionnaire (SSEQ-C).[29 30] Participants will be asked to rate their level of confidence in performing daily functional activities and self-management. It contains two subscales including live with new challenges, and activity and exercise engagement. Each item is rated on an 11-point Likert Scale from 0-no confidence to 10-very confident. All item scores are summed (total 0–130). A higher score indicates higher self-efficacy. SSEQ-C demonstrated a high internal consistency (Cronbach's α=0.92). There were positive correlations between the total scores of SSEQ-C, General Self-Efficacy Scale, Frenchay Activities Index (FAI), and Stroke Specific Quality of Life Scale (Spearman's ρ: 0.48–0.68, $p<0.01$). Acceptable convergent validity was reported.[29]

Outcome expectation

Participants' outcome expectation of performing self-management behaviours will be measured by an 11-item Chinese version of the Stroke Self-management Outcome Expectation Scale (SSOES-C). Each item, rated on an 11-point Likert Scale from 0-strongly disagree to 10-strongly agree, assesses participants' confidence in the likelihood of the expected outcomes to occur after performing a self-management behaviour. All item scores are summed (total 0–110). A higher score indicates higher confidence in likelihood of the positive outcomes to occur. SSOES-C demonstrated a high internal consistency (Cronbach's α=0.94).[21]

Secondary outcome measures include

Self-management behaviours

The 11-item Chinese version of the Stroke Self-management Behaviours Performance Scale (SSBPS-C) will be adopted to assess participants' satisfaction with their performance of self-management behaviours such as exercising regularly. Each item is rated on an 11-point Likert Scale from 0-very dissatisfied to 10-very satisfied. All item scores are summed (total 0–110). A higher score indicates

higher satisfaction with own performance of self-management behaviours. SSBPS-C demonstrated high internal consistency (Cronbach's α=0.93).[21]

Health-related quality of life

Participants' HRQoL will be measured by the Chinese version of the Stroke Specific Quality of Life Scale (SSQOL-C).[31–33] It consists of 47 items with 11 domains including activities; mood, energy and family role; language; upper extremity function; relationships; thinking; vision; basic needs; personality; leisure and work; and transfer. Participants will be asked to indicate their level of agreement to each item describing their health conditions and their level of difficulty in performing self-care and daily tasks (1-strongly disagree/couldn't do it to 5-strongly agree/no trouble). All item scores are summed (total 47–235). A higher score indicates higher HRQoL. SSQOL-C showed high internal consistency (Cronbach's α of the total and domain scores: 0.63–0.93) and acceptable convergent validity. Correlations between the domains and Short Form (36) Health Survey (SF-36), SSEQ-C, FAI and Barthel ADL Index total scores were moderate to high (Spearman's ρ: 0.40–0.77, p<0.01).[33]

Depressive symptoms

The 15-item Chinese version of the Geriatric Depression Scale (GDS) will be used to measure participants' psychological well-being.[34 35] Participants will be asked for their agreement to the descriptions of each item based on their condition (Yes-1 score or No-0 score). All item scores are summed (total 0–15). A score of 5–8 indicates mild depression, 9–11 moderate depression and 12–15 severe depression. GDS showed high internal consistency (Cronbach's α=0.78) and acceptable convergent validity.[18] A significant correlation between the total scores of the scale and the London Handicap Scale (r=−0.30, p<0.01) was reported.[35]

Community reintegration

The 11-item Chinese version of the Reintegration to Normal Living Index (RNLI) will be adopted to assess participants' level of community reintegration.[36 37] RNLI contains six domains including mobility, self-care, activities, role within the family, comfort with relationships and ability to handle life events. The participants will be asked to indicate the extent to which each item of the index describes their situation on a 4-point scale (1-a small extent to 5-a great extent). There are two subscale scores: 'daily functioning' and 'perception of self', and a total score which will be summed and normalised to 100 (range 25–100). A higher score indicates better extent of community reintegration. The index has high internal consistency (Cronbach's α=0.92) and good convergent validity. There were significant associations between the index and FAI (r=0.44, p<0.001), and the Personal Well-being Index (r=0.25, p=0.033).[37]

The following outcomes will be collected at post-test:

Usage

Participants will be asked about their (1) Comments on the programme including ease of use and relevance of the programme contents and resource package, arrangement, and satisfaction with the coaches' performance (5-point Likert Scale, 1-very dissatisfied to 5-very satisfied). (2) Frequency (minutes) of using the resource package per week. (3) Level of goal attainment (0-not attained, 1-partially attained, 2-completely attained). The pattern of usage of the hotline will be recorded. It will include the number, frequency and duration of calls received, types of enquiries, and persons (survivors or caregivers) who use the hotline.

Qualitative feedback

All participants of the intervention group will be interviewed over phone about their feedback on the programme, the contents of the programme that are most helpful and areas for enhancement. All coach leaders and coaches will be interviewed in focus groups about their experience and satisfaction with conducting the programme, barriers and facilitators of conducting the programme, and areas for enhancement. Semistructured interview guides will be developed.

Demographic and clinical information

Participants' age, gender, educational level, marital status, financial support, accommodation and living condition, past and current health history, stroke history and severity, and assistive devices used will be collected. Scales including MoCA, Barthel ADL Index, modified Rankin Scale and National Institutes of Health Stroke Scale will be administered.

Data collection

A research assistant will visit the CRN Patient Mutual Support Centres (Centre) regularly to recruit the potential stroke participants. Advertisements will be posted in the CRN newsletters and website, and newsletters of a stroke support group to recruit participants. Participants will also be recruited via referrals by the CRN social workers. The research assistant will contact the potential participants by phone and perform a preliminary eligibility assessment. Eligible participants will be scheduled to attend a face-to-face eligibility assessment and informed about the study aim, schedule, intervention and data collection procedure, and rights to confidentiality. Participants' informed written consent will be obtained before commencing data collection. Consented participants will be scheduled for baseline and follow-up assessment by a research assistant at their home or the Centre. Another research assistant will conduct phone interviews (about 15 min) with the participants in the intervention group, and focus group interviews at the Centre with all coaches after completion of the programme.

Patient and public involvement

The feedback of stroke survivors who participated in a self-management programme examined in a previous

study[22] was incorporated in the design of this study protocol. Patients (community-dwelling stroke survivors) will be recruited and involved in the conduct of the study. The study participants' comments on the programme including ease of use and relevance of the programme contents will be collected quantitatively using a 5-point Likert Scale from 1-very dissatisfied to 5-very satisfied and qualitatively via phone interviews. The results of the study will be disseminated to the study participants on request.

Statistical analyses

Participants' baseline demographic and clinical characteristics, and outcome measures will be presented using appropriate descriptive statistics. Normal-like distributed and skewed continuous variables will be presented by their means (SD) and medians (IQR), respectively. Categorical variables will be presented by their frequencies and percentages. A generalised estimating equations model will be used to assess the differential changes in outcome variables from pretest to post-test between the intervention and control groups with adjustment for their baseline levels. All statistical analyses will be performed using IBM SPSS V.24.0 (IBM Corporation, Armonk, New York, USA). All statistical tests are two-sided with level of significance set at 0.05. Qualitative data will be recorded and transcribed verbatim. Thematic analysis will be performed to generate themes and codes related to satisfaction with the programme.

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 ICH-GCP. Agreement was made with CRN on the arrangement of recruiting stroke participants. Eligible participants including the stroke survivors and coaches who agree to participate in the study will be required to provide written consent. All information collected will be kept strictly confidential. Only the principal applicant will have access to the final trial data set.

DISCUSSION

COMBO-KEY is a novel programme aimed at enhancing stroke survivors' self-efficacy, outcome expectation and engagement in self-management behaviours for optimal poststroke health outcomes. The programme targets stroke survivors with moderate-to-severe disability who often have difficulties in applying rehabilitation knowledge and skills, and low confidence in performing stroke self-management behaviours such as rehabilitative exercise. It is theory-driven and adopts evidence-based strategies to enhance survivors' self-efficacy and outcome expectation of self-management behaviours. The video sharing would provide valuable role modelling experience for participants to learn from other stroke survivors.[21 22] The study integrates home visits and phone coaching in the self-management programme supplemented by a multimodal resource package. It is anticipated that this flexible mode of programme delivery will consolidate the benefits from hospital-based services, and enable survivors' capabilities in transferring knowledge and skills learnt into their lifestyle-workable strategies for sustaining their health behavioural change. Furthermore, it is expected to optimise programme benefits by addressing individual differences, and mobility or transportation problems. We expect survivors participating in the programme will be motivated to engage in a positive lifestyle to maintain determination and momentum in recovery.

This study innovatively involved trained coaches who are either healthcare or social care providers to deliver home visits, or lay volunteers to deliver phone-coaching sessions of the programme. We believe that this approach is significant in building the community capacity in promoting health. It is because the coaches can play an important role in propagating the messages of stroke self-management through their network or practice, and adopting the approach learnt from the programme to support stroke survivors whom they encounter in the community or practice. In addition, the resource package serves as a useful tool for stroke survivors, health and social care providers, students of health or social sciences-related programmes, and caregivers to learn more about self-management for supporting stroke survivors. The training manuals for coaches may also be adopted by health or other rehabilitative institutions to train more healthcare and social care providers and lay volunteers to support the delivery of the programme in future. It is anticipated that the ripple effect will continue to strengthen community capacity in adopting this approach to support and enable stroke survivors' participation in self-management behaviours for optimal recovery outcomes.

The results of the study would provide evidence to inform decisions for integrating the programme into the current rehabilitative service pathway for community-dwelling stroke survivors.

Contributors SHSL, JPCC and AMC contributed to the conception and design of the study. SHSL, JPCC, AMC and KCC wrote the first draft of the manuscript. JCYK and RYMW are coapplicants of the grant submission and contributed to the development of the programme intervention. All authors approved the final version of the manuscript.

Funding This protocol is supported by the Health Care and Promotion Scheme (Grant Ref. No.: 01170718) funded by the Food and Health Bureau, the Government of the Hong Kong Special Administrative Region.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This protocol was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No.: 2018.009).

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. World Health Organization. The top 10 causes of death. 2018 http://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death (accessed 15 Sep 2018).
2. Centre for Health Protection, Department of Health. Number of deaths by leading causes of death, 2001-2017. 2018 https://www.chp.gov.hk/en/statistics/data/10/27/380.html (accessed 15 Sep 2018).
3. Benjamin EJ, Virani SS, Callaway CW, *et al*. Heart disease and stroke statistics-2018 update: a report from the American Heart Association. *Circulation* 2018;137:e67–e492.
4. Yu R, Chau PH, McGhee SM, *et al*. *Trends of disease burden consequent to stroke in older persons in Hong Kong: implications of population ageing*. Hong Kong: The Hong Kong Jockey Club, 2012.
5. Taule T, Råheim M. Life changed existentially: a qualitative study of experiences at 6-8 months after mild stroke. *Disabil Rehabil* 2014;36:2107–19.
6. Chau JP, Thompson DR, Twinn S, *et al*. Determinants of participation restriction among community dwelling stroke survivors: a path analysis. *BMC Neurol* 2009;9:49.
7. Simeone S, Savini S, Cohen MZ, *et al*. The experience of stroke survivors three months after being discharged home: a phenomenological investigation. *Eur J Cardiovasc Nurs* 2015;14:162–9.
8. Woodman P, Riazi A, Pereira C, *et al*. Social participation post stroke: a meta-ethnographic review of the experiences and views of community-dwelling stroke survivors. *Disabil Rehabil* 2014;36:2031–43.
9. Godwin KM, Ostwald SK, Cron SG, *et al*. Long-term health-related quality of life of stroke survivors and their spousal caregivers. *J Neurosci Nurs* 2013;45:147–54.
10. Walsh ME, Galvin R, Loughnane C, *et al*. Community re-integration and long-term need in the first five years after stroke: results from a national survey. *Disabil Rehabil* 2015;37:1834–8.
11. Brown M, Levack W, McPherson KM, *et al*. Survival, momentum, and things that make me "me": patients' perceptions of goal setting after stroke. *Disabil Rehabil* 2014;36:1020–6.
12 Jones F, Riazi A. Self-efficacy and self-management after stroke: a systematic review. *Disabil Rehabil* 2011;33:797–810.
13. National Institute for Health and Care Excellence. Stroke rehabilitation: NICE guideline. 2011 http://guidance.nice.org.uk/CG/Wave21/4/Development/Consultation/DraftNICEGuidance/pdf/English (accessed 15 Sep 2018).
14. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. *Ann Behav Med* 2003;26:1–7.
15. Parke HL, Epiphaniou E, Pearce G, *et al*. Self-management support interventions for stroke survivors: a systematic meta-review. *PLoS One* 2015;10:e0131448.
16. SH L, Chau JPC, Chau JP, *et al*. Theory-based self-management programs for promoting recovery in community-dwelling stroke survivors: a systematic review. *JBI Database of Systematic Reviews and Implementation Reports* 2013;11:157–215.
17. Bandura A. *Self-efficacy: the exercise of control*. New York: W. H. Freeman, 1997.
18. Korpershoek C, van der Bijl J, Hafsteinsdóttir TB. Self-efficacy and its influence on recovery of patients with stroke: a systematic review. *J Adv Nurs* 2011;67:1876–94.
19. van Mierlo ML, Schröder C, van Heugten CM, *et al*. The influence of psychological factors on health-related quality of life after stroke: a systematic review. *Int J Stroke* 2014;9:341–8.
20. Shaughnessy M, Michael K, Resnick B. Impact of treadmill exercise on efficacy expectations, physical activity, and stroke recovery. *J Neurosci Nurs* 2012;44:27–35.
21. Lo SH, Chang AM, Chau JP. Study protocol: a randomised controlled trial of a nurse-led community-based self-management programme for improving recovery among community-residing stroke survivors. *BMC Health Serv Res* 2016;16:387.
22. Lo SHS, Chang AM, Chau JPC. Stroke self-management support improves survivors' self-efficacy and outcome expectation of self-management behaviors. *Stroke* 2018;49:758–60.
23. Smith LL, Lake NH, Simmons LA, *et al*. Integrative health coach training: a model for shifting the paradigm toward patient-centricity and meeting new national prevention goals. *Glob Adv Health Med* 2013;2:66–74.
24. Kim K, Choi JS, Choi E, *et al*. Effects of community-based health worker interventions to improve chronic disease management and care among vulnerable populations: a systematic review. *Am J Public Health* 2016;106:e3–28.
25. Wang CJ, Fetzer SJ, Yang YC, *et al*. The impacts of using community health volunteers to coach medication safety behaviors among rural elders with chronic illnesses. *Geriatr Nurs* 2013;34:138–45.
26. Condon C, Lycan S, Duncan P, *et al*. Reducing readmissions after stroke with a structured nurse practitioner/registered nurse transitional stroke program. *Stroke* 2016;47:1599–604.
27. Bushnell C, Arnan M, Han S. A new model for secondary prevention of stroke: transition coaching for stroke. *Front Neurol* 2014;5:219.
28. Fens M, Beusmans G, Limburg M, *et al*. A process evaluation of a stroke-specific follow-up care model for stroke patients and caregivers; a longitudinal study. *BMC Nurs* 2015;14:3.
29. Jones F, Partridge C, Reid F. The Stroke Self-Efficacy Questionnaire: measuring individual confidence in functional performance after stroke. *J Clin Nurs* 2008;17:244–52.
30. Lo SH, Chang AM, Chau JP. Translation and validation of a chinese version of the stroke self-efficacy questionnaire in community-dwelling stroke survivors. *Top Stroke Rehabil* 2016;23:163–9.
31. Williams LS, Weinberger M, Harris LE, *et al*. Development of a stroke-specific quality of life scale. *Stroke* 1999;30:1362–9.
32. Williams LS, Weinberger M, Harris LE, *et al*. Measuring quality of life in a way that is meaningful to stroke patients. *Neurology* 1999;53:1839–43.
33. Lo SH, Chang AM, Chau JP. Establishing equivalence of a Chinese version of the stroke specific quality of life measure for stroke survivors. *Disabil Rehabil* 2017;39:1079–86.
34. Yesavage JA, Brink TL, Rose TL, *et al*. Development and validation of a geriatric depression screening scale: a preliminary report. *J Psychiatr Res* 1983;17:37–49.
35. Chau J, Martin CR, Thompson DR, *et al*. Factor structure of the Chinese version of the Geriatric Depression Scale. *Psychol Health Med* 2006;11:48–59.
36. Wood-Dauphinee SL, Opzoomer MA, Williams JI, *et al*. Assessment of global function: the reintegration to Normal Living Index. *Arch Phys Med Rehabil* 1988;69:583–90.
37. Pang MY, Lau RW, Yeung PK, *et al*. Development and validation of the Chinese version of the Reintegration to Normal Living Index for use with stroke patients. *J Rehabil Med* 2011;43:243–50.