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Effects of a nurse-led peer support intervention for stroke survivors: protocol for a randomised controlled trial

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ABSTRACT

Introduction Many stroke survivors have unmet psychosocial needs during the recovery phase following a stroke. There is emerging evidence that peer support interventions may play a valuable role in managing stroke. However, evidence regarding the effectiveness of peer support interventions on the psychosocial outcomes of stroke survivors is uncertain. This study aims to develop a nurse-led peer support intervention for stroke survivors based on the Person–Environment–Occupation–Performance Model and evaluate its effects on the psychosocial outcomes of stroke survivors.

Methods and analysis This is an assessor-blinded two-arm randomised controlled trial. A convenience sample of 120 stroke survivors will be recruited from two community centres and one rehabilitation unit in Yangzhou, a medium-sized city in eastern China, with 60 participants each in the intervention and control groups. The participants allocated to the intervention group will receive the nurse-led peer support intervention, which includes 6 weekly peer support sessions facilitated by a nurse and at least one peer facilitator. Participants randomised to the control group will receive the same dose of interpersonal interaction as intervention participants, including weekly individual face-to-face session for 6 weeks. The primary outcomes are social participation and participation self-efficacy. The secondary outcomes are psychosocial distress, social support, stigma towards disease, self-efficacy in managing chronic conditions and quality of life. Data will be collected at baseline, immediately after the intervention and 3 months after the intervention. A process evaluation will be conducted qualitatively and quantitively to examine the mechanism by which the intervention impacts the psychosocial outcomes of stroke survivors. All outcomes will be analysed following the intention to treat principle. Generalised Estimation Equation models will be used to assess the intervention effect.

Ethics and dissemination This protocol was approved by the Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No.: 2021.196-T). All participants will be required to provide written informed consent. Results of the study will be disseminated through publication in peer-reviewed journals and presentation at local or international conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised clinical trial evaluates an evidence-based intervention theoretically grounded in the Person–Environment–Occupation–Performance Model.
⇒ Participants will be randomly assigned to intervention group and attention control group, which will disentangle the benefits of attention from the impacts of the intervention itself.
⇒ Process evaluation will be conducted qualitatively and quantitatively to understand the fidelity of intervention implementation and how the intervention impacts the psychosocial outcomes of stroke survivors.
⇒ Although outcome assessors will be blinded to reduce investigator bias, participants and the interveners will not be blinded to the group allocation due to the intervention nature.
⇒ There is a risk that some participants may drop out during the study period due to the longitudinal nature of the study, especially due to COVID-19 outbreak disruptions, which may contribute to the attrition bias.

Trial registration number ChiCTR2100050853.

INTRODUCTION

Stroke has high incidence, prevalence and mortality. Recent studies report this disease as the third leading cause of disability and the second leading cause of death globally.[1–3] In 2016, there were 13.7 million new stroke cases worldwide, of which 5.51 million cases were reported in China, which has the highest age-standardised incidence of stroke internationally.

Many stroke survivors face psychosocial challenges after hospital discharge. It is reported that one-third of stroke survivors suffer from post-stroke depression,[4] while 20% report the experience of anxiety symptoms post-stroke.[5] These emotional symptoms are associated with increased mortality, slow recovery and decreased quality of life.[6–8] In

addition, physical impairments after stroke pose different degrees of activity limitation and participation restriction.[9 10] Evidence suggests that participation restrictions are associated with social isolation, the occurrence of recurrent stroke and increased mortality.[11–14]

Despite efforts made to improve acute stroke care, less attention has been given to postdischarge care, especially in terms of psychosocial support.[15–17] Evidence regarding interventions aimed at improving psychosocial health, especially post-stroke social participation, is lacking. Studies about stroke rehabilitation often do not include outcomes to assess participation, and studies involving participation often do not adopt a theoretical framework to guide the development of interventions and the choice of outcome measures.[17 18] Therefore, more theory-based psychosocial intervention studies are needed.

Peer support interventions that enhance social support may potentially improve the psychosocial outcomes of stroke survivors. A systematic review showed that group self-management interventions involving peer support could facilitate experience-sharing, increase knowledge and communication, improve goal setting and problem solving, and boost motivation and self-efficacy among stroke survivors.[19]

Peer support is defined as assistance and encouragement from persons with a similar condition to an individual.[20] Peers may understand the target population's condition in a comprehensive way that healthcare professionals may not, thus the knowledge, coping strategies and experiences presented by peers could be more persuasive for individuals who share the same experience.[21] According to the concept analysis proposed by Dennis,[20] trained peer facilitators can provide informational, emotional and appraisal support to their partners (see figure 1). Through the direct, buffering or mediating effect, both peer partners and peer facilitators can attain better psychosocial outcomes, such as increased self-efficacy, enhanced effective coping, decreased emotional symptoms and increased social participation.[20]

However, evidence regarding the effectiveness of peer support interventions on the psychosocial outcomes of stroke survivors is still not very clear. We conducted a systematic review of 11 randomised controlled trials (RCTs) and non-RCTs and found that stroke survivors might benefit from peer support interventions, particularly in terms of improving their psychological outcomes. However, the evidence about the effects of peer support interventions on social outcomes was uncertain.[22] Most previous studies did not adopt a theory to guide the design of the intervention.[22] None of the studies conducted in China evaluated the psychosocial outcomes of stroke survivors.

Another systematic review found that interventions delivered by healthcare workers appeared to be more effective in improving chronic disease management among vulnerable community populations compared with alternatives including usual care, enhanced usual care or no intervention.[23] Thus, incorporating healthcare workers into peer support interventions may be a feasible option to ensure specialist knowledge of the disease when needed. Nurses are relatively accessible and less costly to employ,[24] and most importantly, patients express satisfaction with health services provided by nurses in the communities.[25 26] A study involving 390 stroke survivors after hospital discharge aimed at addressing psychosocial problems found that nurse-led stroke aftercare effectively addressed psychosocial problems and had a lower cost as compared with usual care.[27]

Aim and hypothesis

This study aims to develop a theory-driven nurse-led peer support intervention (NPSI) for stroke survivors based on the Person–Environment–Occupation–Performance Model (PEOP) and evaluate its effects on stroke survivors' psychosocial outcomes.

We hypothesise that, compared with stroke survivors receiving attention care in the control group, at 6 weeks after commencing the intervention and at 3 months after completion of the intervention, the stroke survivors receiving the NPSI will have: increased social participation and social support; greater participation self-efficacy; less psychological distress; higher self-efficacy in managing chronic conditions, less stigma towards disease and improved quality of life.

METHODS AND ANALYSIS

Design

An assessor-blinded two-arm RCT will be conducted (see figure 2 for the flow diagram of the study). This protocol will adhere to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.[28]

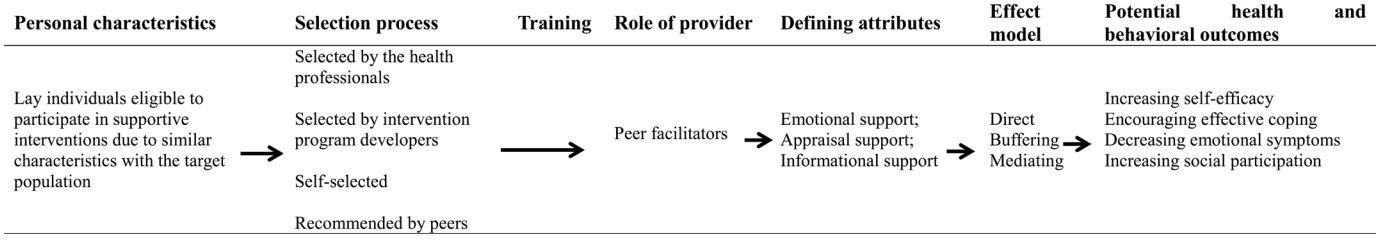

Figure 1 Effect mechanism of peer support interventions.

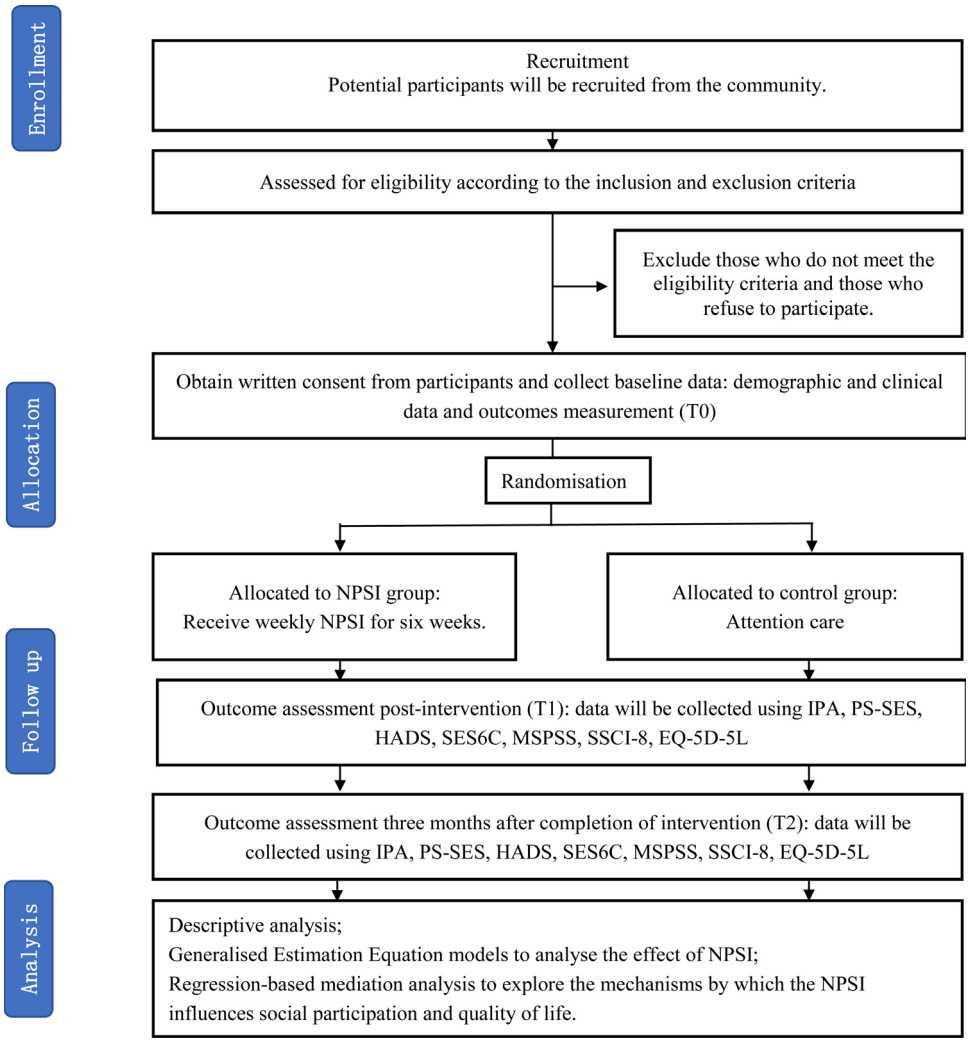

Figure 2 Study flow diagram. EQ-5D-5L, EuroQol 5D-5L; HADS, Hospital Anxiety and Depression Scale; IPA, Impact on Participation and Autonomy; MSPSS, Multidimensional Scale of Perceived Social Support; NPSI, nurse-led peer support intervention; PS-SES, Participation Strategies Self-Efficacy Scale; SES6C, Self-Efficacy for Managing Chronic Disease 6-Item Scale; SSCI-8, Stigma Scale for Chronic Illnesses-8 items.

Setting and participants

Participants will be recruited from two community centres and one rehabilitation unit near the two communities in Yangzhou, a medium-sized city in Jiangsu province, Eastern China. Recruitment posters will be distributed to community health centres, family physician centres, day rehabilitation units and a rehabilitation unit at the recruitment sites.

Inclusion criteria

Individuals who meet the following criteria will be recruited:

1. Have a clinical diagnosis of ischaemic or haemorrhagic first-ever or recurrent stroke before enrollment according to the diagnostic criteria of the Chinese Society of Neurology, Chinese Stroke Society.[29 30]
2. Aged ≥18 years old.
3. Able to communicate meaningfully in Mandarin and provide informed consent.

Exclusion criteria

1. Are not medically stable or have a terminal illness.
2. Diagnosed with a mental illness.
3. Have moderate or severe cognitive impairment and cannot participate meaningfully in the workshop sessions (eg, Mini-Mental State Examination ≤20)[31] or do not have the physical capacity to travel to the workshop site even with assistance.
4. Are participating in another intervention research programme.
5. Plan to move out of the area within 6 weeks, or do not have a reasonable expectation that they will attend a programme for 2 hours/week for up to 6 weeks.

Sample size

G*Power (V.3.1) was used to calculate the sample size. The power calculation is based on the primary outcomes of social participation and participation self-efficacy. In a multicentre randomised trial of 185 stroke survivors, the

effect size of peer support interventions on participation self-efficacy was 0.58.[32] In order to have 80% power to detect a significant difference at a significance level of 0.05, enrolling 48 participants in each group is needed. With an estimated attrition rate of 20%, enrolling 120 stroke survivors with 60 participants in each group is planned. This sample size is also enough for an effect size of 0.74 for the outcome of social participation, which was drawn from a systematic review and meta-analysis.[22]

Randomisation

After completing baseline assessments, participants will be randomly allocated to the NPSI or control group (1:1 ratio). Blocked randomisation[33] will be used with blocks of 4 or 6 via a computer-generated, random-number sequence. Sequentially numbered, opaque, sealed envelopes will be used to guarantee allocation concealment. Randomisation will be stratified by recruitment sites and residential areas to achieve balanced randomisation. Both randomisation and allocation procedures will be conducted by a researcher not involved in recruitment, intervention delivery and outcome assessment.

Blinding

Due to the nature of the intervention, the researchers who deliver the intervention and the participants themselves will know the group allocation. Only the two research assistants who assess the outcomes will be blinded from group assignments. The person conducting the data analysis will not be blinded.

Intervention

Components

The NPSI consists of six sessions, in which participants will discuss stroke-related topics in groups and support each other. The stroke-related topics include didactic education (eg, the pathophysiology of stroke, stroke prevention); self-management strategies (eg, use of problem-solving techniques, action planning); social participation (eg, home role attainment, community reintegration) and emotional management (see detailed content of each session in table 1). The content of the intervention was informed by findings from our previous systematic review on the effectiveness of peer support interventions.[22] The dose of the interventions varied across studies and the typical number of sessions was 6–8 sessions.[22] As such, we set 6 sessions for the NPSI based on the learning activities for each session.

Theoretical underpinning

The NPSI will be developed based on the PEOP model. This model is a client-centred model aiming to improve the performance and social participation of individuals.[34] It has four components: occupation (what people want or need to do in their daily lives); performance (the actual act of doing); person (intrinsic factors, eg, psychological, physiological, neurobehavioral, cognitive and spiritual factors) and environment (extrinsic factors, eg, health system; social supports; social & economic system; culture and value; natural environment). In the PEOP model, complex interactions exist between the person and the environment in which people carry out meaningful activities. The interaction of personal capacity, environmental factors and chosen activities leads to performance and participation. To achieve a desired level of participation, people and groups must overcome personal and environmental barriers that limit their participation in activities and attempt to make use of personal capacity and environment enablers which support them in doing meaningful activities. The peer support groups will discuss these barriers, facilitators and problem-solving strategies around the intervention topics during the peer support sessions. It is expected that through these discussions, the self-efficacy or social participation of the participants can be improved.

Intervention delivery

The NPSI will be conducted in groups (4–8 participants per group) and delivered weekly for 6 weeks. Each session will be conducted face-to-face and last around 1.5–2 hours. Participants in each group will discuss one or two topics per session (see table 1 for the detailed contents of each session). During the session, group members will discuss barriers, facilitators and possible problem-solving strategies for a meaningful goal (eg, community integration) proposed by each participant. At the end of each session, participants will make an action plan and then report any relevant progress to the group at the beginning of the next session. The location of the group sessions will be chosen according to the convenience of the group members. Participants will arrange their own transportation with costs reimbursed by the researchers. An information booklet that includes stroke-related knowledge and the intervention content will be provided to participants. Stroke survivors can attend the sessions with their caregiver or a friend. A participant will be considered to have completed the intervention if they attend four or more sessions.

To ensure participant adherence, the sessions will be fixed at the same time each week for a peer support group (eg, participants in group one gather on Tuesday afternoon every week) in case they forget the gathering time due to decreased memory ability. The peer facilitators will call the participants at least once each week to encourage them to implement their action plan and remind them to remember the time and place of the next session.

Facilitators and training

A nurse facilitator and at least one peer facilitator will administer each peer support session using the same verified workbook. At least four peer facilitators will be recruited and trained in this study. They should meet the following criteria[35]: (1) is a stroke survivor (or stroke survivor with caregiver); (2) stroke occurred at least 18 months previously; (3) have good communication and expression abilities.

Table 1 Content for scheduled NPSI sessions

Sessions	Contents
Session 1: Introduction, group norms, self-management strategy.	Activity 1: Self-introduction and identifying the problems of each group member. Activity 2: Introducing the course and responsibilities of the participants. Activity 3: Introducing self-management strategies. Activity 4: Introducing how to prevent stroke recurrence. Activity 5: Making an action plan for preventing stroke recurrence. Activity 6: Summary.
Session 2: Management of emotional changes after stroke.	Activity 1: Debriefing and problem-solving. Activity 2: Discussion about common thoughts, fears and other emotional changes after stroke. Activity 3: Introducing problem-solving strategies to address the emotional changes. Activity 4: Communication skills. Activity 5: Making an action plan to deal with emotional changes and facilitate effective communication. Activity 6: Summary.
Session 3: Participation at home.	Activity 1: Debriefing and problem-solving. Activity 2: Participation at home. Activity 3: Common symptoms after stroke and possible problem-solving strategies. Activity 4: Making an action plan for home participation. Activity 5: Summary.
Session 4: Community integration and leisure activities.	Activity 1: Debriefing and problem-solving. Activity 2: Community integration and leisure activities. Activity 3: Rehabilitation exercises and physical exercises. Activity 4: Making an action plan for community participation or leisure activities. Activity 5: Summary.
Session 5: Socialisation.	Activity 1: Debriefing and problem-solving. Activity 2: Socialisation. Activity 3: Maintaining a healthy diet. Activity 4: Making an action plan for social activities. Activity 5: Summary.
Session 6: Returning to work and summary.	Activity 1: Debriefing and problem-solving. Activity 2: Education, work and volunteer work. Activity 3. Guidelines for taking medication for stroke. Activity 4: Making an action plan for returning to work. Activity 5: Summary of the course.

NPSI, nurse-led peer support intervention.

A training programme will be provided to peer facilitators. The programme will be conducted face-to-face via four group sessions (2 hours per session, total 8 hours). It will be held two times a week for two weeks and will be facilitated by a nurse, an occupational therapist and a physical therapist. The training content includes stroke knowledge, communication and group facilitation skills, and self-management skills. A variety of training methods will be employed in the training sessions including verbal explanation, discussion, group brainstorming, case-based scenarios and group facilitation simulations.[36]

Patient and public involvement

In order to develop the patient-tailored intervention,[30] stroke survivors meeting the eligibility criteria were invited to provide insights regarding their rehabilitative experiences, the risk factors of post-stroke psychological distress and participation restriction, and their psychological and social needs to inform the development of the components of the NPSI. After intervention delivery, participants' satisfaction and comments on the intervention's usefulness and acceptability will be collected through an investigator-generated satisfaction questionnaire and in-depth interviews.

Control group

Participants randomised to the control group will receive attention care from the nurse facilitator. This will be individual face-to-face guidance scheduled weekly for 6 weeks. The contents and duration of the guidance will be the same as the intervention components included in the NPSI but will be delivered individually without support from peers.

Outcome measures

The following outcomes will be measured at baseline (T0), post-intervention (6 weeks later) (T1) and 3 months after the intervention (T2) for the stroke survivors in both groups (table 2).

Primary outcomes

Social participation

Social participation will be measured using the Impact on Participation and Autonomy (IPA).[37] The Chinese version

Table 2 Assessment schedule and measures for outcomes

Outcomes	Instruments	Baseline (T0)	Immediately after 6 weeks of NPSI (T1)	3 months post-intervention (T2)
Primary outcomes				
Social participation	The Impact on Participation and Autonomy (IPA)	×	×	×
Participation self-efficacy	Participation Strategies Self-Efficacy Scale- Chinese version (PS-SES-C)	×	×	×
Secondary outcomes				
Psychological distress	Hospital Anxiety and Depression Scale (HADS)	×	×	×
Social support	Multidimensional Scale of Perceived Social Support (MSPSS)	×	×	×
Stigma towards disease	Stigma Scale for Chronic Illnesses-8 items (SSCI-8 items)	×	×	×
Self-efficacy in managing chronic conditions	Self-efficacy for Managing Chronic Disease 6-item Scale (SECD6)	×	×	×
Quality of life	EuroQol-5D-5L	×	×	×
Satisfaction with the intervention				
Participants' satisfaction-survey	Investigator-generated satisfaction questionnaire (only for the intervention group)		×	
Participants' feedback-interview	/		×	

NPSI, nurse-led peer support intervention.

of the IPA (IPA-C) has been validated in Chinese stroke survivors.[38] The IPA-C comprises 25 items including four domains: autonomy indoors (7 items), social relations (6 items), family role (7 items) and autonomy outdoors (5 items). The Cronbach's α of IPA-C was 0.959, with each domain ranging 0.782–0.965. The test–retest reliability was 0.969, with each domain between 0.915 and 0.951.[38] Each item of the IPA-C is rated from 0 (excellent) to 4 (very poor). The total score range of IPA-C is 0–100, with a lower score indicating better self-perceived participation and autonomy.

Participation self-efficacy

Participation self-efficacy will be assessed using the Participation Strategies Self-Efficacy Scale-Chinese version (PS-SES-C).[39] It measures individuals' self-efficacy in using strategies to participate in home, community, work and social activities. It comprises 35 questions with six subscales: (1) managing home participation, (2) staying organised, (3) planning and managing community participation, (4) managing work/productivity, (5) managing communication and (6) advocating for resources. Each item is rated on a Likert scale of 1–10 with higher scores indicating greater self-efficacy. The PS-SES-C had good internal consistency and test–retest reliability, with a Cronbach's α of 0.98 and intraclass correlation coefficient of 0.79.[39]

Secondary outcomes

Psychological distress

Psychological distress will be assessed using a Chinese version of Hospital Anxiety and Depression Scale (HADS). HADS is a 14-item self-report questionnaire, with 7 items to assess severity of anxiety and 7 items to assess severity of depression.[40] It is a widely used instrument in research and has good psychometric properties in stroke patients.[41 42] A greater HADS score indicates a higher level of psychological distress.

Social support

Participants' perceived social support will be assessed using the 12-item Multidimensional Scale of Perceived Social Support (MSPSS).[43] It measures support from three sources: family (4 items), friends (4 items) and a significant other (4 items). Each item of the MSPSS is rated from 1 (totally disagree) to 7 (totally agree). The sum of the score represents the level of perceived social support, with a higher score indicating higher perceived social support. The Chinese version of MSPSS has been validated and used in various populations.[44 45]

Stigma towards disease

Participants' stigma toward disease will be measured using the Chinese version of the Stigma Scale for Chronic Illnesses-8 items. It was developed by Molina *et al* and is a simplified version of the 24-version stigma scale for chronic disease.[46] It has been demonstrated to have good validity and reliability with a Cronbach's α of 0.892 and test–retest interclass correlation of 0.809.[47]

Self-efficacy in managing chronic conditions

The Chinese version of Self-Efficacy for Managing Chronic Disease 6-Item Scale (SES6C) will be used to assess participant self-efficacy in managing chronic conditions. The SES6C had acceptable psychometric properties with a Cronbach's α of 0.88 in Chinese population.[48] It is scored with a 10-point Likert scale from 1 (not at all confident) to 10 (totally confident). The total score ranges from 6 to 60 and a higher score indicates higher level of self-efficacy.

Quality of life

The quality of life of the participants will be measured by using the Chinese version of EuroQol 5D (EQ-5D-5L).[49] The EQ-5D-5L includes five dimensions: mobility; self-care; usual activities; pain/discomfort and anxiety/depression. Each dimension has five levels (no problem, slight problem, moderate problem, severe problem and extreme problems, respectively). The total scores range from 5 to 25 and higher scores indicate lower quality of life. The EQ-5D-5L was reported to have good psychometric properties for measuring physical and social functioning and overall health after stroke.[50]

Satisfaction with the NPSI

Participants' satisfaction with the NPSI will be assessed using an investigator-generated 8-item satisfaction questionnaire. This questionnaire measures patients' level of satisfaction with the NPSI regarding the usefulness, acceptability and satisfaction with the intervention. Each item was rated from 1 (not satisfied) to 4 (very satisfied).

Data collection procedures

The researcher responsible for recruitment will contact potential participants by phone and conduct preliminary screening for eligibility. Eligible participants will be invited to participate in the study. Stroke survivors who consent to participate will sign a written consent form. Those who have consented will be scheduled for baseline assessment by two research assistants at their home, rehabilitation unit or community health centre. To aid any survivors with low health literacy, the research assistants will read all the materials to the participants. After randomisation, the intervention group will receive the 6 week NPSI. Participants in both groups will be invited back for post-intervention data collection (T1) within 1 week post-intervention. Follow-up data will be collected 3 months after the intervention for participants in both groups. The data that will be collected and the instruments that will be used at each time point are presented in table 2.

The two research assistants will receive standard training for data collection. Their skills will be evaluated before the data collection and the inter-rater reliability between the two research assistants will be assessed.

Data management

The data from participants will only be used for research purpose. The data will be entered into statistics software and double-checked by the two research assistants who are responsible for data collection. The hard copy of the data will be kept in a locked cabinet and the electronic data will be stored in a hard disk protected with passwords. Only the principal investigator will have access to the data. All the data will be destroyed 5 years after the completion of the study.

Process evaluation

Process evaluation will be conducted according to the recommendation of the Medical Research Council Framework.[51] An expert panel on stroke care will review the clarity, relevance and appropriateness of the workbook used by the facilitators and the information booklet. To ensure intervention consistency for every group, all the group sessions will be facilitated by the same nurse. All peer facilitators will receive training together using a standardised training manual and procedures. The nurse facilitator will conduct regular meetings with peer facilitators. The nurse facilitator will record the process of every session and make a summary after each session. The recruitment rate, attrition rate and completion rate will be recorded.

To understand the mechanism of the effect of the intervention, the mediating effect of social support, participation self-efficacy, stigma towards disease, self-efficacy in managing chronic conditions, psychological distress will be examined to explore the mechanism by which the NPSI influences social participation and quality of life.

Participants' satisfaction will be assessed using an investigator-generated 8-item satisfaction questionnaire. Semistructured interviews will be conducted to obtain their feedback on the intervention's acceptability and usefulness. A purposive sample of 20 participants in the intervention group will be invited from participants with low and high satisfaction. Content analysis will be used to analyse the qualitative data from the participants.

Data analysis

Data will be analysed using IBM SPSS Statistics V.23. Sociodemographic and clinical characteristics and the baseline outcome data will be described using means (SD), medians (IQR) or frequencies, where appropriate. Data between the two groups will be compared using the appropriate statistics according to their level of measurement. Continuous data will be analysed using independent t-tests or Mann-Whitney U tests.[52] Categorical data will be compared using χ^2 test or Fisher's exact tests.

The effects of NPSI on the primary and secondary outcomes will be evaluated following the intention to treat principle. Generalised Estimation Equation models will be used to assess the intervention effect over time by controlling other possible covariates even in the presence of randomly missing data.[53] Regression-based mediation analysis[54] will be used to explore the mechanisms by which the NPSI influences social participation and quality of life. The possible mediating effect of social support, self-efficacy, stigma towards disease, psychological distress will be determined.

Monitoring and trial management

Due to the type of intervention, a data monitoring committee was not organised. A study committee including the principal investigator, one research professional, one physical therapist, one occupational therapist and two professional nurses will supervise the conduct of the study and monitor any safety issues that arise. Adverse events related to the NPSI will be assessed and medical help will be suggested by

the committee when necessary. If problems that can affect the study's implementation emerge, the principal investigator may make relevant modifications to the study protocol after a committee meeting; the modifications of the study protocol will be submitted to the relevant ethics committee for approval before the implementation of the modified study protocol.

ETHICS AND DISSEMINATION

The research team will adhere to the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki. The protocol has obtained ethical approval from the Joint Chinese University of Hong Kong–New Territories East Cluster Clinical Research Ethics Committee (the Joint CUHK-NTEC CREC). An information sheet with details of the study, including research content, requirements, potential benefits and risks, will be provided to the participants before enrolment. Written consent will be obtained from each participant by the researcher conducting recruitment (see online supplemental material 1). The data and information collected from participants will be handled following the principles of confidentiality and anonymity and will only be used for research. Only the researchers have access to the data. Results of this study will be disseminated through local or international conference presentations and published in peer-reviewed journals.

DISCUSSION

There is emerging evidence that peer support interventions may play a valuable role in enhancing stroke recovery.[19 55] However, the evidence regarding the effectiveness of peer support interventions on the psychosocial outcomes of stroke survivors remains unclear. This is the first study conducted in China to evaluate the effectiveness of peer support interventions on the psychosocial outcomes of stroke survivors. This will also be a well-conducted RCT with sample sizes estimated using power analysis, which will be more robust in determining the value of peer support as an intervention. The results of this study can add to the body of knowledge regarding the usefulness of peer support interventions in stroke rehabilitation and provide evidence for future research on the effectiveness, delivery format, dosage and intervention components of peer support interventions, especially for Chinese stroke survivors.

Although the strengths of this study are substantial, there are also some limitations. First, due to the nature of the intervention, both the participants and the interventionists will not be blinded to the group allocation. To reduce the potential bias, participants will only be told that they will receive the nurse-led peer support intervention or the individual face-to-face guidance and they will remain unaware of which one may be better. The outcome assessors will be blinded to reduce detection bias. Second, similar to any other longitudinal study, there may be challenges in participation recruitment and retention especially during the COVID-19 pandemic. Stroke survivors may refuse to continue or drop out of the trial due to various reasons, which may contribute to the attrition bias. To address these challenges, the researchers will work closely with the staff in the recruitment sites to encourage participant recruitment and retention. In addition, the interventionists will try to develop a trusting relationship with the participants. Third, as the intervention will be facilitated by a nurse facilitator and at least one peer facilitator, it might be difficult to differentiate between the impact of peer or professional facilitators.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s)

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES

1 Feigin VL, Norrving B, Mensah GA. Global burden of stroke. *Circ Res* 2017;120:439–48.
2 Katan M, Luft A. Global burden of stroke. *Semin Neurol* 2018;38:208–11.
3 Johnson CO, Nguyen M, Roth GA, *et al*. Global, regional, and national burden of stroke, 1990-2016: a systematic analysis for the global burden of disease study 2016. *Lancet Neurol* 2019;18:439–58.
4 Hackett ML, Pickles K. Part I: frequency of depression after stroke: an updated systematic review and meta-analysis of observational studies. *Int J Stroke* 2014;9:1017–25.
5 Knapp P, Dunn-Roberts A, Sahib N, *et al*. Frequency of anxiety after stroke: an updated systematic review and meta-analysis of observational studies. *Int J Stroke* 2020;15:244–55.
6 Ayerbe L, Ayis S, Wolfe CDA, *et al*. Natural history, predictors and outcomes of depression after stroke: systematic review and meta-analysis. *Br J Psychiatry* 2013;202:14–21.
7 Astuti P, Kusnanto K, Dwi Novitasari F. Depression and functional disability in stroke patients. *J Public health Res* 2020;9:9.

8 Teoh V, Sims J, Milgrom J. Psychosocial predictors of quality of life in a sample of community-dwelling stroke survivors: a longitudinal study. *Top Stroke Rehabil* 2009;16:157–66.
9 Li Y, Li X, Zhou L. Participation profiles among Chinese stroke survivors: a latent profile analysis. *PLoS One* 2020;15:e0244461.
10 Palstam A, Sjödin A, Sunnerhagen KS. Participation and autonomy five years after stroke: a longitudinal observational study. *PLoS One* 2019;14:e0219513.
11 Yu B, Steptoe A, Niu K, *et al*. Prospective associations of social isolation and loneliness with poor sleep quality in older adults. *Qual Life Res* 2018;27:683–91.
12 Li C, Jiang S, Li N, *et al*. Influence of social participation on life satisfaction and depression among Chinese elderly: social support as a mediator. *J Community Psychol* 2018;46:345–55.
13 Misawa J, Kondo K. Social factors relating to depression among older people in Japan: analysis of longitudinal panel data from the ages project. *Aging Ment Health* 2019;23:1423–32.
14 Boden-Albala B, Litwak E, Elkind MSV, *et al*. Social isolation and outcomes post stroke. *Neurology* 2005;64:1888–92.
15 Wu S, Anderson CS. A need to re-focus efforts to improve long-term prognosis after stroke in China. *Lancet Glob Health* 2020;8:e468–9.
16 Zawawi NSM, Aziz NA, Fisher R, *et al*. The unmet needs of stroke survivors and stroke caregivers: a systematic narrative review. *J Stroke Cerebrovasc Dis* 2020;29:104875.
17 Teasell R, Mehta S, Pereira S, *et al*. Time to rethink long-term rehabilitation management of stroke patients. *Top Stroke Rehabil* 2012;19:457–62.
18 Engel-Yeger B, Tse T, Josman N, *et al*. Scoping review: the trajectory of recovery of participation outcomes following stroke. *Behav Neurol* 2018;2018:1–22.
19 Clark E, MacCrosain A, Ward NS, *et al*. The key features and role of peer support within group self-management interventions for stroke? a systematic review. *Disabil Rehabil* 2020;42:307–16.
20 Dennis C-L. Peer support within a health care context: a concept analysis. *Int J Nurs Stud* 2003;40:321–32.
21 Helgesson VS, Gottlieb B. Support groups. In: Cohen S, Underwood LG, Gottlieb B, eds. *Social Support Measurement and Intervention:A Guide for Health and Social Scientists*. Toronto: Oxford University Press, 2000: p 221.
22 Wan X, Chau JPC, Mou H, *et al*. Effects of peer support interventions on physical and psychosocial outcomes among stroke survivors: a systematic review and meta-analysis. *Int J Nurs Stud* 2021;121:104001.
23 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.
24 Yan P. Research on the distribution methods of performance salary between physicians and nurses within the department. *Contemporary accounting* 2020:113–4.
25 Pang S, Zhao H, Chen L. Long-Term care strategies for the elderly with disabilities in China. *Chinese Journal of Gerontology* 2016;36:4928–30.
26 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.
27 Verberne DPJ, van Mastrigt GAPG, Ponds RWHM, *et al*. Economic evaluation of nurse-led stroke aftercare addressing long-term psychosocial outcome: a comparison to care-as-usual. *BMJ Open* 2021;11:e039201.
28 Chan A-W, Tetzlaff JM, Gøtzsche PC, *et al*. Spirit 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346::e7586:e7586.
29 Chinese Society of Neurology, Chinese Stroke Society. Chinese guidelines for diagnosis and treatment of acute ischemic stroke 2018. *Chin J Neurol* 2018;51:666–82.
30 Chinese Society of Neurology, Chinese Stroke Society. Chinese guidelines for diagnosis and treatment of acute hemorrhagic stroke (2019). *Chin J Neurol* 2019;52:994–1005.
31 Cumming TB, Churilov L, Lindén T, *et al*. Montreal cognitive assessment and mini-mental state examination are both valid cognitive tools in stroke. *Acta Neurol Scand* 2013;128:122–9.
32 Wolf TJ, Baum CM, Lee D, *et al*. The development of the improving participation after stroke self-management program (IPASS): an exploratory randomized clinical study. *Top Stroke Rehabil* 2016;23:284–92.
33 Schulz KF, Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. *The Lancet* 2002;359:515–9.
34 Baum CM, Christiansen CH. Person-Environment-Occupation-Performance: An Occupation-Based Framework for Practice. In: Christiansen CH, Baum CM, eds. *Occupational therapy performance, participation, and well-being*. NJ: Slack incorporated, 2004: p 242.
35 Stamatakis CV. The Efficacy of Peer Support in Community Stroke Rehabilitation[PhD thesis]. Cardiff University, 2015.
36 Tang TS, Funnell MM, Gillard M, *et al*. The development of a pilot training program for peer leaders in diabetes: process and content. *Diabetes Educ* 2011;37:67–77.
37 Cardol M, de Haan RJ, van den Bos GA, *et al*. The development of a handicap assessment questionnaire: the impact on participation and autonomy (ipa). *Clin Rehabil* 1999;13:411–9.
38 Li H. Revise of Chinese version of Impact On Participation and Autonomy questionnaire and application in stroke patients[Master thesis]. Second Military Medical University, 2013.
39 Chau JPC, Lo SHS ZJ, *et al*, American Heart Association. *Self-efficacy after stroke: validation of psychometric properties of a translated Chinese version of participation strategies self-efficacy scale*. United States: International Stroke Conference, 2021.
40 Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361–70.
41 Bjelland I, Dahl AA, Haug TT, *et al*. The validity of the hospital anxiety and depression scale. an updated literature review. *J Psychosom Res* 2002;52:69–77.
42 Tang WK, Ungvari GS, Chiu HFK, *et al*. Screening post-stroke depression in Chinese older adults using the hospital anxiety and depression scale. *Aging Ment Health* 2004;8:397–9.
43 Zimet GD, Dahlem NW, Zimet SG, *et al*. The multidimensional scale of perceived social support. *J Pers Assess* 1988;52:30–41.
44 Zhou K, Li H, Wei X, *et al*. Reliability and validity of the multidimensional scale of perceived social support in Chinese mainland patients with methadone maintenance treatment. *Compr Psychiatry* 2015;60:182–8.
45 Wang X, Wang X, Ma H. *Manual of Mental Hygiene Rating Scale*. Beijing: Chinese Mental Health Magazine, 1999.
46 Molina Y, Choi SW, Cella D, *et al*. The stigma scale for chronic illnesses 8-item version (SSCI-8): development, validation and use across neurological conditions. *Int J Behav Med* 2013;20:450–60.
47 Cuiyu D, Liya L, Lili Z. A study of reliability and validity of the stigma scale for chronic illness 8-item version (SSCI-8) in stroke patients. *Tianjin Journal of Nursing* 2019;27:505–9.
48 Hu H, Li G, Arao T. Validation of a Chinese version of the self-efficacy for managing chronic disease 6-Item scale in patients with hypertension in primary care. *ISRN Public Health* 2013;2013:1–6.
49 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
50 Golicki D, Niewada M, Buczek J, *et al*. Validity of EQ-5D-5L in stroke. *Qual Life Res* 2015;24:845–50.
51 Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: medical research council guidance. *BMJ* 2015;350:h1258.
52 Garson GD. *Testing statistical assumptions*. USA: Statistical Publishing Associates, 2012.
53 Zeger SL, Liang KY, Albert PS. Models for longitudinal data: a generalized estimating equation approach. *Biometrics* 1988;44:1049–60.
54 Hayes AF, Preacher KJ. Statistical mediation analysis with a multicategorical independent variable. *Br J Math Stat Psychol* 2014;67:451–70.
55 Levy BB, Luong D, Perrier L, *et al*. Peer support interventions for individuals with acquired brain injury, cerebral palsy, and spina bifida: a systematic review. *BMC Health Serv Res* 2019;19:288.