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Effectiveness of a smartphone-enabled dyadic self-care programme (SDSCP) for stroke survivors and caregivers: study protocol for a randomised controlled trial

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ABSTRACT

Introduction The promotion of self-care has begun to serve as a central response strategy to the rising burden of stroke. In fact, stroke self-care can be recognised to be a dyad phenomenon having an effect on the health of stroke survivors and their caregivers. While studies have confirmed the effectiveness of smartphone-based interventions in improving self-care among stroke survivors, there remains a lack of evidence specifically regarding dyadic self-care interventions for both patients and caregivers.

Aim The present single-blinded, two-arm, randomised controlled trial aims to verify the effectiveness of a smartphone-enabled dyadic self-care programme (SDSCP) for stroke survivors and their caregivers.

Methods and analysis The estimated sample size is 152 stroke survivor–caregiver dyads. The participants will be randomly classified (1:1) into either a control (N=76) or an experimental group (N=76) through block randomisation. The participants classified into the experimental group will be provided with SDSCP, and during the initial home visit, the research team members will provide instructions to all patients and caregivers on how to download and use the smartphone application. While the participants in the control group will be given the existing stroke standard care. The main outcome measures of stroke survivors will consist of the Self-Care of Stroke Inventory and a short version of the Stroke Specific Quality of Life Scale. The outcome measures of stroke caregivers will primarily cover the Caregiver Contribution to Self-Care of Stroke Inventory and Zarit burden interview. The data of this study will be collected at three time points, including baseline, 1 month and 6 months from the baseline.

Ethics and dissemination This study has been approved by the Ethics Committee of Zhengzhou University (ZZUIRB 2021–115) in January 2021. The results achieved in this study will facilitate the clinical practice to improve self-care of stroke survivors and promote dyadic health outcomes for stroke patients and caregivers.

Trial registration number The study was registered with the Chinese Clinical Trial Registry and the registration number is ChiCTR2100053591.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Rigorous randomised control trial design ensures reliable assessment of intervention effectiveness.
⇒ Inclusion of both stroke survivors and caregivers provides comprehensive understanding of the intervention impact.
⇒ Usage of smartphone technology increases convenience and potential engagement.
⇒ Generalisability limited to the single study setting in Henan province.
⇒ Technology limitations and access to smartphones may pose barriers for some participants.

INTRODUCTION

Worldwide, stroke is prevalent, costly and disabling more than 80 million people.[1 2] As reported by the Global Burden of Disease Study, the total number of disability-adjusted life years caused by stroke has shown a steadily rising trend since 1990, which reached 143 million with 6.55 million deaths in 2019. Furthermore, the global prevalence of stroke exceeds 100 million cases, and the socioeconomic burden resulting from stroke is also increasing annually.[3] Stroke has become the leading cause of death and disability in China, posing a significant threat to the overall health of the population.[4 5] This highlights the urgent need for new and effective intervention strategies to improve health outcomes for stroke survivors, and promoting self-care of stroke survivors should be a priority.[6 7]

Definition of self-care and its importance for stroke survivors

As emphasised by the International Center for Self-Care Research, it is crucial for patients with chronic diseases, including stroke, to actively engage in self-care practices to enhance their health outcomes,

reduce morbidity and mortality rates and minimise medical expenses.[8 9] Self-care is defined as the process of maintaining health through health promotion practices and disease management for chronic diseases, which consists of three core dimensions, including self-care maintenance, self-care monitoring and self-care management.[10] In addition, self-care maintenance refers to those behaviours for enhancing well-being, preserving health or for maintaining physical and emotional stability, while self-care monitoring comprises a process of routine, vigilant body monitoring, surveillance or 'body listening'. According to self-care management, an assessment of changes in physical and emotional signs and symptoms is involved to verify whether action is required. During the inaugural session of the International Center for Self-Care Research in Rome, Italy, Jaarsma recommended the application of Riegel's definition of self-care for chronic diseases. Furthermore, she emphasised the need for refining the definition of self-care to cater to specific diseases and their unique requirements.[11] Studies have shown that self-care is of great significance to improve the physical and mental health outcomes (eg, preventing stroke recurrence, reducing readmission rates and improving quality of life) of stroke survivors.[12 13] And the improvement of self-care has progressively acted as the core response strategy of the global health system to the increasing burden of stroke.[14 15] While healthcare providers have the responsibility to educate and motivate patients who had a stroke to engage in self-care as part of their overall health management, post-stroke self-care remains challenging due to the multifaceted care needs and complex disabling consequences that often impede patients' efforts.[15 16] In a survey of 18 344 people with stroke in China, over 50% were reported not to adhere to medication.[17] Another study showed that participants experienced a medium level self-management in 1 month and 3 months post-stroke.[18] Accordingly it is of high practical significance to thoroughly investigate the vital factors of stroke self-care to innovate self-care intervention models.

Stroke self-care can be considered a dyadic phenomenon

Research conducted over the past two decades has revealed the intricacies of self-care, highlighting the impact of various factors such as experience, skills, disease knowledge, self-efficacy and depression on the self-care decision-making process of stroke survivors.[15] The influence of others, particularly family caregivers, has been identified as a significant challenge, as we increasingly recognise their impact on the barriers individuals face in self-care. Drawing from the transactive goal dynamics theory, patients and family caregivers, as a dyadic unit, operate within a self-regulating system, interacting and influencing each other's goals and pursuits.[19] Stroke self-care can be considered a dyadic phenomenon that patient self-care and the caregiver contribution to self-care are inter-related in predictors and outcomes.[20 21] As revealed by several qualitative research results, the contributions of caregiver to self-care of stroke survivors are of high significance to self-care and the health outcomes of patients.[20 22] In addition, stroke caregivers' care skills, confidence and mutual relationships were significantly correlated with patient health outcomes.[23] It showed that stroke caregiver and dyad interventions have underscored the importance of interventions focused on psychoeducation, peer support and skill building (eg, problem solving and goal setting).[24] However, few interventions explicitly aimed to improve dyadic self-care behaviours or relational outcomes and demonstrated positive effects for both members of the dyad.[25] Hence, it is urgent to develop effective dyadic self-care interventions to support stroke survivors and caregivers.

Information and communication technology has advantages in self-care interventions

Information and communication technologies (ICT), which have been revolutionising healthcare delivery, offer a way forward. ICT are expected to serve as the most powerful enabler to reduce the burden of stroke disease.[8 26] Arising from the rapid evolution of ICT over the past few decades, mobile health (mHealth), comprising web-based and smartphone applications (APPs), has been employed increasingly to manage self-care of patients with chronic diseases, including those suffering from stroke.[27 28] Nearly 80% of adults seek health information on the internet, with 62% suffering from chronic diseases; over three out of four respondents said internet experience has affected their decision-making on self-care.[29]

Numerous studies worldwide have confirmed the effectiveness of smartphone-based interventions in improving self-care among stroke patients.[30–32] For example, in 2020, Kamal *et al* conducted a single-centre randomised controlled trial that used a smartphone-based intervention to train patients in self-care skills, coping with emergencies, medication management and secondary stroke prevention. The results showed significant improvements in blood pressure, glycated haemoglobin levels and low-density lipoprotein levels in the intervention group. However, these studies did not specifically develop targeted interventions addressing the three core three components of stroke self-care (self-care maintenance, monitor and management).[32] According to our recent review, limited self-care interventions have been conducted in survivor–caregiver dyads and focus on both of their health outcomes, and many of them are ongoing and have achieved insufficient results.[21] Although some studies included stroke survivors and caregivers simultaneously, the contribution of caregivers to the self-care of patients who had a stroke remains unclear, and the intervention content has basically not considered dyadic relationship or goals.[33]

Smartphones have become the most widely used mode of communication, reaching 70% of the global population.[34] According to the China Internet Information Center report, as of June 2021, China has reached 1.007 billion internet users, with 99.6% of them using

smartphones. Preliminary investigation results from our research team indicate that there are approximately 20 or more stroke-related APPs available in the Chinese market. However, most of these APPs have limited functionality and content. There is a pressing need to develop personalised and comprehensive APPs in this field. Given the current technological landscape, the use of smartphone APP-based technological interventions for self-care has the potential to enable real-time monitoring and feedback, reaching a significant number of stroke survivors and caregivers to maintain and promote their dyadic health.

Conceptual framework

Research using behaviour change theories and methods will be critical to gain more insights into contextual effects on the success of self-care interventions.[9] A conceptual framework is developed in accordance with the Middle-Range Theory of Self-Care of Chronic Illness,[10] the Theory of Dyadic Illness Management,[35] the Unified Theory of Acceptance and Use of Technology (UTAUT)[36] and specific clinical practice of stroke. According to the Middle-Range Theory of Self-Care of Chronic Illness, self-care is a decision-making process aimed at achieving desired outcomes such as illness stability, health, well-being and quality of life. Furthermore, there exist feedback loops among self-care maintenance, self-care monitoring and self-care management components.[37] Self-care is considered an extremely challenging and complex process, so the programme on stroke self-care should primarily investigate the major factors as barriers and facilitators to self-care to improve stroke outcomes. The Theory of Dyadic Illness Management follows the basic principle that illness management is a dyadic phenomenon.[35] In this study, stroke survivor–caregiver dyads carry out self-care behaviours to manage illness together in a recursive fashion that influences dyadic health. Moreover, the contextual factors, including individual (either patient or caregiver) factors, dyad factors or social/cultural factors, will have an effect on the process of stroke self-care behaviours. Thus, stroke caregivers should be integrated into self-care programme, and dyadic interventions should be conducted. UTAUT has been frequently used to explain the use of information technology (eg, smartphone APPs). It consists of several constructs (eg, performance expectancy, effort expectancy, social influence, facilitating conditions and behavioural intention to use).[36] UTAUT is capable of guiding the programme of this study in the design and development stage of stroke dyadic self-care APP. It can help improve the actual usage rate of APP by highlighting the expectation and demand of stroke survivors and caregivers on the function, interface and ease of operation of APP, as well as by increasing the technical support of APP. Furthermore, the final conceptual framework of the programme of this study comprises four essential elements, that is, factors of self-care, smartphone APP, dyadic self-care (self-care of stroke and caregiver contribution to self-care of stroke) and dyadic health (figure 1). And the conceptual framework can provide theoretical support and guidance for the development in the current study.

Study purpose

This study aims to develop a smartphone-enabled dyadic self-care programme (SDSCP) to help patients suffering from stroke and their caregivers to effectively manage their conditions. The objective of this study is to assess the effectiveness of SDSCP on: (1) dyadic self-care behaviours (self-care of stroke and caregiver contribution to self-care of stroke); (2) health-related quality of life (HRQoL) and caregiver burden; (3) knowledge of stroke, self-efficacy and mutual relationship. The hypotheses formulated are as follows: H_1: There will be a significant difference in the pretest and post-test scores of self-care of stroke survivors and caregiver contribution to stroke self-care between the intervention and control groups. H_2: There will be

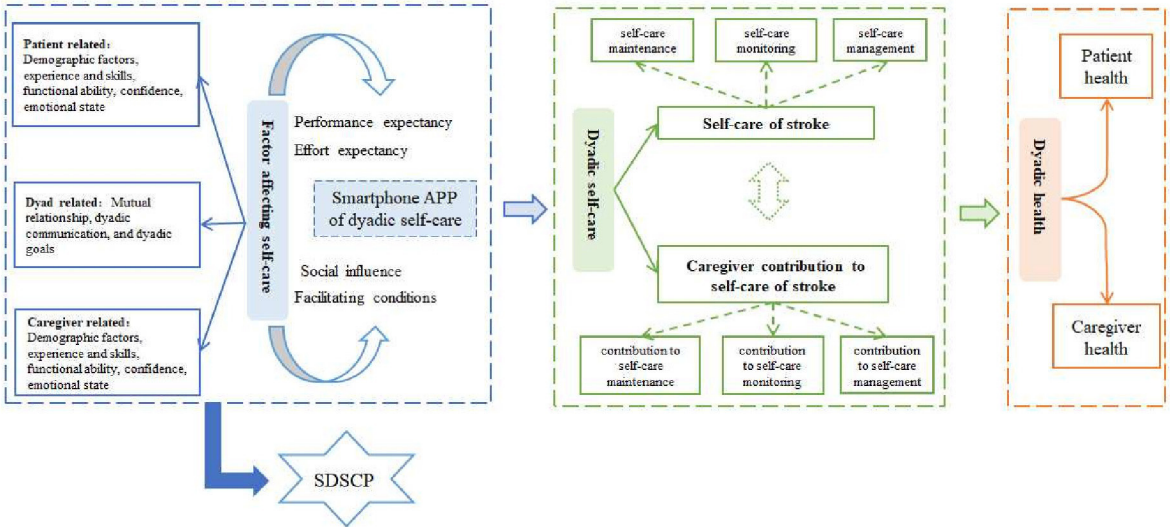

Figure 1 Conceptual framework. APP, application; SDSCP, smartphone-enabled dyadic self-care programme.

a significant difference in the clinical outcomes such as HRQoL of stroke survivors, caregiver burden of stroke caregivers between the intervention and the control groups. H_3: There will be a significant difference in the scores of the pretest and post-test of knowledge of stroke, self-efficacy and mutual relationship in patients suffering from stroke and their caregivers between the intervention and the control groups.

METHODS

Study design

The programme of this study is a prospective, two-arm, outcome assessor–blinded, randomised control trial. And the participants will be randomly classified to either the experimental group or the control group. Participants will be assessed at the baseline prior to the intervention and at 1 month and 6 months from the baseline, respectively.

Study setting and participants

The participants will be recruited from a tertiary referral hospital in Henan province. Approximately 10–12 individuals are admitted to this hospital each week due to stroke. Based on recent hospital statistics, the cumulative number of stroke survivors discharged last year exceeded 500 individuals. Stroke survivors and their caregivers will be invited to participate in this study on the day they discharge, and the eligibility screening will be conducted by the research team members.

The inclusion criteria for stroke survivors are as follows: (1) Confirmed medical diagnosis of stroke (including ischaemic and haemorrhagic). (2) Age ≥18 years. (3) Absence of moderate or severe cognitive impairment (Mini-Mental State Examination ≥21 points) and ability to cooperate with the investigation. (4) Presenting with mild-to-moderate stroke (scoring 1–15 on the National Institute of Health stroke scale). (5) Ownership and regular use of mobile phones in daily life. (6) Willingness to participate in the study. Patients will be excluded if they are participating in another intervention.

The inclusion criteria for stroke caregivers are as follows: (1) Not being paid for the care provided. (2) Undertaking primary care tasks for over 4 hours per day and 3 days per week. (3) Absence of cognitive dysfunction and ability to cooperate with the investigation. (4) Ownership and regular use of mobile phones in daily life. (5) Willingness to participate in the study. Caregivers with documented cognitive impairment, as well as those involved in another interventional study, will be excluded.

Sample size determination

The sample size is determined in accordance with Cohen's recommendation on the expected differences between groups. Power analysis will be employed to determine the sample size of this study. G*Power software was used to calculate the sample size required in this study. Assuming a power of 80%, level of significance of 5% and a small Cohen's d effect size (d=0.3) from a previous study concerned with a stroke self-care intervention to improve HRQoL of stroke survivors,[38] the required sample size is 64 stroke survivors per group. In the same manner, assuming a power of 80%, level of significance of 5% and a large Cohen's d effect size (d=0.8) from a previous study concerned with an intervention to improve caregiver burden of stroke caregivers,[39] the required sample size is 26 stroke caregivers per group. Therefore, with reference to a 20% drop-out rate, the sample size required is 76 patient–caregiver dyads per group.

Randomisation

All eligible patients and caregivers will be informed about the study, and written consent will be obtained from those who are willing to participate. A research team member not involved in either participant recruitment or the intervention will prepare the random assignment schedule, generated by the computer software Research Randomizer. Block randomisation will be adopted using random block size and 1:1 ratio. Group assignments will be placed in sealed envelopes, and the envelope in line with the patient's ID will be opened on site. Moreover, patients will be classified into either one of the two groups based on the randomisation list the treatment indicated.

Study intervention

SDSCP for the experimental group

The participants of the experimental group will undergo the 6-month SDSCP. SDSCP is dyadic self-care programme covering the use of the internet and communication technologies and a smartphone to assist patients and caregivers in managing stroke at home or in communities. The participants will be introduced to the intervention during initial home visit. Besides installing a smartphone APP of dyadic self-care and a structured training session concerned with how to use APP, participants will also receive a stroke self-care manual and the self-monitoring sheets (eg, symptom monitoring sheet, blood pressure monitoring sheet, medication monitoring sheet and exercise monitoring sheet).

The composition the APP of dyadic self-care

The developed APP for this study consists of three terminals: the patient–caregiver dyads terminal, the healthcare provider terminal and the back-stage management terminal. After registering and logging into the APP, patient–caregiver dyads can access and engage with specific modules, following prompts and facilitating interaction. In case of any difficulties, timely communication and discussion with healthcare providers and back-stage management team members are possible. The clinical and community healthcare providers from the research team can access participants' data through a web-connected portal, enabling targeted care guidance and advice through scheduled telephone or video conferences. The back-stage management team, comprising software engineers, community nurses and graduate

students, provides online and offline technical support to ensure the smooth functioning of the APP.

Development and testing of the APP of dyadic self-care

The APP of dyadic self-care is developed by the research interdisciplinary team that consists of information and communication technologies engineers from a professional software development company, clinical and community healthcare providers, public health researchers, stroke survivors and caregivers to ensure both the data security of APP and the usability of the APP. This APP content integrates text and voice/video. The text information is designed in accordance with the reading level ≤grade 6 to ensure language smoothness and adapt to participants exhibiting limited literacy ability. In addition, this study intends to increase the knowledge map system of intelligent question answering in this APP using artificial intelligence technology to realise that participants can obtain timely and accurate self-care related feedback (eg, text, cartoon, video and story) by sending text/voice messages. The proposed functions of the patient–caregiver dyads terminal covered in the APP are elucidated below: (1) General information module: Collection and collation of general data of stroke patients and caregivers. (2) Positive mind training module: Carry out cognitive assessment training and improve the self-efficacy of patients and caregivers; Help patients and caregivers build social support networks to improve their sense of benefit. (3) Self-care knowledge and skills learning module: Introduction of self-care monitoring knowledge; Guidance of self-care maintenance behaviour; Demonstration of self-care management skills. (4) Dyadic management training module: Dyadic intimacy training; Management of dyadic negative emotions; Formulation of dyadic self-care objectives; Participation in significant dyadic interactive activities. (5) Personalised reminder module: Reminder of medication, eating and rehabilitation exercise time. (6) Dynamic assessment module: Monitoring and assessment of blood pressure, blood glucose, medication, eating and rehabilitation exercise. (7) Intelligent knowledge question and answer module. (8) Voice and video interaction module: Telephone/video conference between participants and the healthcare providers. The general structure of SDSCP for the experimental group is illustrated in figure 2. This study will use the purpose sampling method to select 10 stroke patient–caregiver dyads who meet the inclusion and exclusion criteria to test the APP. The researchers will instruct them to instal the APP in their smartphone and train them to operate the APP until they master it. After 2 weeks, the researchers will have an interview with the dyads to collect participants' feelings and suggestions to further update and improve the APP technology and contents.

APP installation and training sessions

APP installation and a face-to-face training session will be presented to the participants in the SDSCP group after participant recruitment and allocation to the experimental group. The members of the research team will present the main contents of each module of the APP to all patients and caregivers during initial home visit, while conducting on-site demonstration and operation to ensure that the patients and the caregivers can use the mobile APP independently. After the training course, participants are allowed to ask questions and discuss

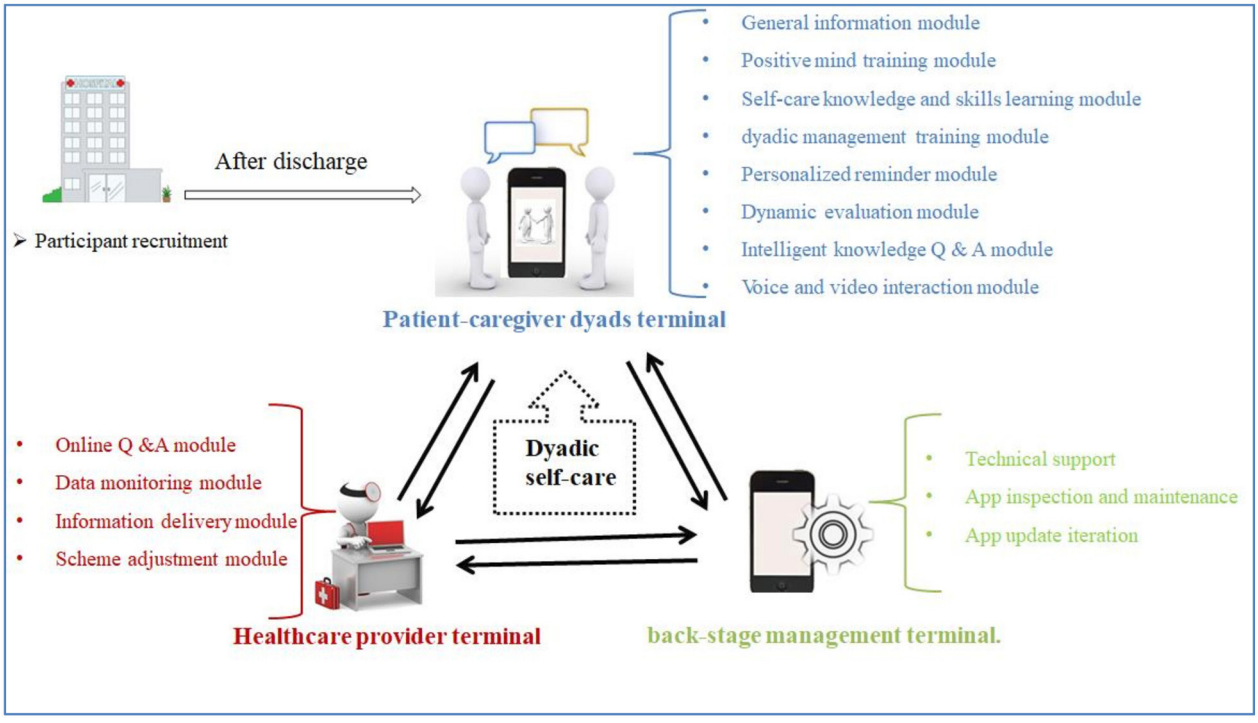

Figure 2 The general structure of SDSCP. SDSCP, smartphone-enabled dyadic self-care programme.

freely, and the researchers will answer questions. In addition, a copy of the finalised smartphone APP of dyadic self-care operation manual will also be provided to the study participants for use at home. Furthermore, participants will be informed that technical telephone/video/door-to-door service support will be available during this trial.

ESSC for the control group

The participants in the control group will receive the existing stroke standard care (ESSC) offered by the hospital and the community, comprising a health education based on the stroke self-care manual and regular telephone follow-up. Before discharge, the responsible nurse will negotiate with the patient for health education relating to stroke and issue a stroke self-care manual. The nurse will provide the patient or his family members with education and guidance on lifestyle management, symptom management, medication and rehabilitation management. After returning to the community, participants will receive bimonthly follow-up calls from hospital and community medical staff (eg, health status inquiry and lifestyle guidance).

Outcome measures

Primary outcomes for stroke survivors

Self-Care of Stroke Inventory

Stroke self-care behaviours will be measured with the use of the 23-item Self-Care of Stroke Inventory (SCSI) comprising three subscales which are called self-care maintenance, self-care monitor and self-care management.[40] SCSI was developed by members of our research team based on existing studies and semi-structured interviews. Cronbach's αs were 0.830, 0.930 and 0.831 of the three subscales. Test–retest reliability of the SCSI was excellent, with an intraclass correlation coefficient of 0.945, 0.907 and 0.837 of the three subscales. Higher scores will indicate better self-care behaviour of the stroke survivors.

A short version of the Stroke Specific Quality of Life Scale

The 12-item short version of the Stroke Specific Quality of Life Scale (SS-QoL-12) will be used to measure patients' HRQoL. The SS-QoL-12 has high internal consistency and the higher the total score, the better the HRQoL will be. The measurement properties of the Chinese version of SS-QoL-12 was examined of patients with mild-to-moderate upper extremity dysfunction and the reliability of the subscales and the whole scale ranged from 0.67 to 0.99.[41]

Secondary outcomes for stroke survivors

Stroke Self-Efficacy Questionnaire

The 13-item Stroke Self-Efficacy Questionnaire (SSEQ)[42] will be used to measure self-efficacy of stroke survivors. The Chinese version of SSEQ has 11 items after cultural adaptation and it exhibits a high internal consistency (Cronbach's alpha=0.92).[43] The higher the score, the higher the self-efficacy in performing daily functional activities and self-management will be.

The Mutuality Scale

Mutuality Scale (MS) will be exploited to measure mutuality in patients suffering from stroke and their caregivers and a higher score represents higher mutuality. MS exhibits a four-factor structure (ie, love, shared pleasurable activities, shared values, as well as reciprocity) in its patient and caregiver version. Cronbach's αs and model-based internal consistency index is >0.90, and intraclass correlations range from 0.66 to 0.93 in MS patient and caregiver version.[44] The Chinese version of MS has a high internal consistency (Cronbach's alpha=0.96) in 120 Chinese caregivers.[45]

Stroke Knowledge Questionnaire

The Stroke Knowledge Questionnaire (SKQ) will be applied to assess the patients' knowledge of stroke. There are eight items in the questionnaire (eg, daily life, diet, medication and premonition symptoms of stroke). SKQ was developed by Liao *et al* in China and it has an acceptable Cronbach's alpha of 0.87.[46] The higher the score, the higher the patient's knowledge of stroke health will be.

Primary outcomes for stroke caregivers

Caregiver Contribution to Self-Care of Stroke Inventory

Stroke caregivers' contribution to self-care will be measured based on the 23-item Caregiver Contribution to Self-Care of Stroke Inventory (CCSCSI) comprising three subscales which called caregiver contribution to self-care maintenance, caregiver contribution to self-care monitor and caregiver contribution to self-care management. CCSCSI was also developed by members of our research team based on existing studies and semi-structured interviews. The Cronbach's α of the three subscales were 0.893, 0.973 and 0.867, respectively. The test–retest reliability after 2 weeks was 0.834, 0.829 and 0.887, respectively.[47] The higher the scores, the better the contribution to self-care of the stroke caregivers will be.

Zarit burden interview

The Zarit burden interview (ZBI-22 will be used to measure caregiver burden in this study. It consists of 22 items scored on a 5-point Likert scale from 0 (never) to 4 (nearly always), except for the final item on global burden, rated from 0 (not at all) to 4 (extremely). The total score ranges from 0 to 88 with higher scores indicating higher burden.[48] The ZBI-22 has been widely used and the Chinese version of ZBI showed acceptable internal consistency with a Cronbach's α of 0.89 in previous study.[49]

Secondary outcomes for stroke caregivers

General Self-Efficacy Scale

The 10-item General Self-Efficacy Scale (GSES) will be used to measure Self-Efficacy of stroke survivors in this study. This 4-point Likert scale has a high internal consistency with a Cronbach's alpha of 0.92.[50] The higher

the scores, the higher the competence in coping with demanding situations will be. The Chinese version of GSES was widely used in China and it has an acceptable Cronbach's α of 0.85.[51]

will be also used to assess the knowledge of stroke and mutuality of stroke caregivers.

Sociodemographic data and health service use

Sociodemographic data (eg, age, gender, marital status, education level, financial status, occupation of the dyads, type and number of stroke, days post stroke, ability to perform daily living activities for stroke survivor and type of caregiver, days of care for stroke caregivers) will be collected by the general data questionnaire developed by the researcher team at the baseline. And outcome measures on health service use (eg, direct medical costs of emergency admissions and length of hospital stay during readmissions, number of unplanned medical consultations) will be employed to verify the potential cost-effectiveness of the programme. The number of emergency admissions and the total length of readmission hospital stay will be retrieved from the hospital clinical management system. The number of unplanned medical consultations will be measured by self-reports of the participants.

Data collection and analysis

Demographic and baseline data of participants will be obtained after participant recruitment. The research associate accounting for outcome assessments and data processing will be unaware of the group allocation. The researchers will contact all participants in advance and make appointments, and acquire the post-trial data via telephone/face-to-face/video conference during the follow-up of 1 month and 6 months after baseline. Participants are expected to take 20–30 min to complete the questionnaire. Figure 3 illustrates the data collection protocol.

Statistical analyses will be conducted with the IBM SPSS Statistics V.24. Data will be double entered and compared, to detect and correct any errors that might have occurred during the data entry. Intention-to-treat analysis will be conducted to manage missing data. Descriptive statistics will be adopted to summarise participants' baseline characteristics and outcome variables. The normality in distribution of all continuous outcomes will be assessed. Appropriate transformation of skewed data will be conducted before analysis. The χ^2 and the independent sample t-test will be performed to compare the baseline variables of the intervention and the control groups. Repeated measures analysis of variance will be adopted to analyse the outcome variables across the time. For the use of multivariate repeated measures analysis of covariance, the above confounding variables will be considered as covariates in the model of analysis for any significant differences between the experimental and control group at baseline. The trial is designed to test the hypothesis at a 0.05 level of significance.

Reliability, validity and fidelity

The content of the stroke dyadic self-care programme will be validated by more than 10 experts from the study's related fields to ensure the validity of the intervention programme. All the survey tools used in this study have good reliability and validity, and the reliability of these tools will be verified again through the survey data of participants in this study. About whether the intervention will be delivered to stroke survivors and caregivers with fidelity, strategies within the Borelli framework[52] will be adopted in this study. This framework provides guidelines and strategies for assessing and monitoring treatment fidelity across five domains: study design, provider training, treatment delivery, treatment receipt and treatment enactment. It is worth mentioning that participants' compliance with the intervention will be ensured through the use of the daily clock system in the APP and bimonthly phone supervision.

Ethics and dissemination

This study has been approved by the Ethics Committee of Zhengzhou University in January 2021. All participants of the experimental group and the control group will gain a clear insight into the content, purpose, significance, methods and benefits of the study. Moreover, informed consent will be signed for all stroke survivors and caregivers participating in the study (please refer to online supplemental file 1 for the Informed Consent Form). If the intervention is effective, this study will plan to offer SDSCP intervention to participants in the control group after study. The findings of this study will be published in scientific journals and will be presented at scientific conferences. The original data set produced by this study will be available from the corresponding author on reasonable request.

Patient and public involvement

Stroke survivors and their caregivers were actively engaged during the development stage of the SDSCP, providing valuable feedback to enhance its effectiveness. However, the general public was not directly involved in the formulation of research questions, intervention designs and the writing of this protocol.

DISCUSSION

Our knowledge of optimal methods to promote self-care of stroke is evolving. Most health maintenance, body monitoring and symptom management activities have been carried out at home or community by stroke individuals and their caregivers as self-care activities, so the role played by caregivers in stroke self-care supported programme should be stressed.[53] Although considerable efforts have been made in stroke care and management by healthcare staff, the uptake and frequency of stroke self-care activities have been continuously low.[54] Therefore, more targeted, effective and cost-effective strategies should be formulated to empower and encourage

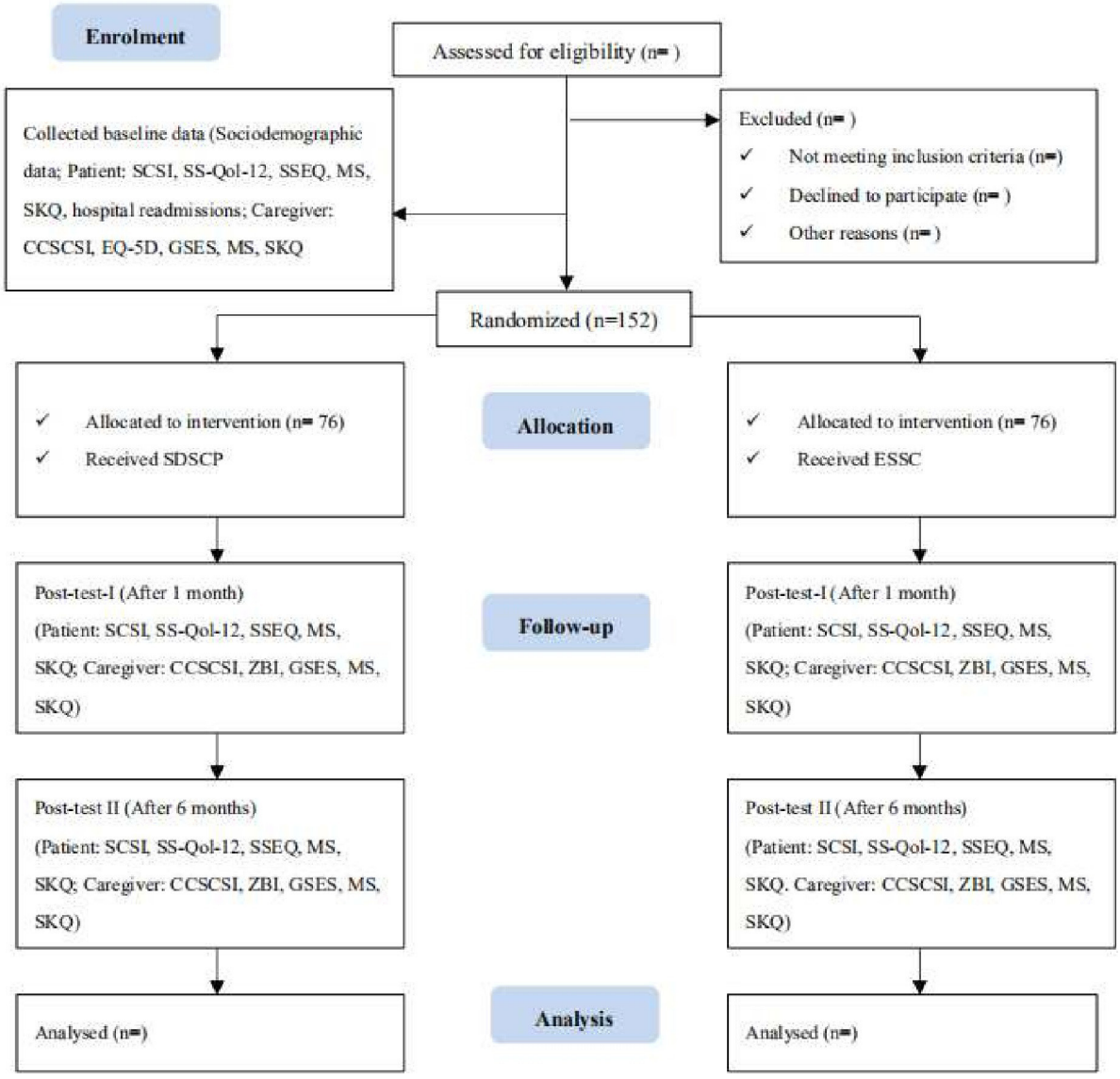

Figure 3 Consolidated Standards of Reporting Clinical Trial (CONSORT) flow diagram. CCSCSI, the Caregiver Contribution to Self-Care of Stroke Inventory; ESSC, the existing stroke standard nursing; GSES, the General Self-Efficacy Scale; MS, the Mutuality Scale; SCSI, Self-Care of Stroke Inventory; SDSCP, a smartphone-enabled dyadic self-care programme; SKQ, the Stroke Knowledge Questionnaire; SSEQ, the Stroke Self-Efficacy Questionnaire; SS-Qol-12, a short version of the Stroke Specific Quality of Life Scale; ZBI: Zarit burden interview.

individuals suffering from stroke and their caregivers to engage in self-care and improve their health outcomes.

The mHealth interventions administered via a smartphone can provide new feasible and effective rehabilitation options at home for stroke survivors and their caregivers. For example, as indicated by an intervention conducted in India called 'Care for Stroke' using smartphone technology to manage physical disabilities following a stroke. The intervention yielded positive outcomes, empowering stroke survivors to independently engage in their family and social roles, thereby addressing the resource limitations for stroke rehabilitation in low-income and middle-income countries.[55] However, this intervention was not evaluated through randomised clinical trials, which could provide more robust evidence for its feasibility and clinical impact.

Through a randomised control trial, SDSCP programme's effectiveness will be assessed in improving dyadic self-care behaviours, quality of life and caregiver burden. The study's design and comprehensive outcome measures contribute to advancing stroke care research and addressing the needs of both patients and caregivers. The usage of repeated measures at multiple time points allows for the evaluation of both short-term and long-term effects of the intervention, providing valuable insights into the sustainability and potential benefits over time. To the best of the authors' knowledge, SDSCP is the first randomised controlled trial examining the effectiveness of a smartphone-enabled dyadic self-care programme among Chinese stroke survivors and caregivers. To date, there are very few smartphone APPs in the market that are developed for patients suffering from

stroke and their caregivers. The proposed APP will incorporate the three aspects of self-care and serve as a dyadic self-care APP. This study is expected to be of high significance to subsequent self-care research since it pay attention to the contribution of caregivers to self-care of stroke survivors and formulate effective interventions from the three core elements of self-care. This study may be able to improve dyadic self-care behaviours, patient quality of life and caregiver burden, and to some extent increase stroke knowledge, self-efficacy and mutual relationship of the dyads. And the study results will also provide valuable evidence to inform future identification and assessment of optimal methods to deliver stroke self-care programmes to improve the health of stroke survivor–caregiver dyads and save medical resources such as stroke-related health service use. If SDSCP proves to be more effective in promoting the self-care of stroke survivor–caregiver dyads and the other health-related outcomes than usual care, this mHealth system would be considered a valuable treatment option for some stroke survivors and their caregivers. Even if SDSCP demonstrated similar effects to the current care provided by the hospital and community, advantages inherent to the mHealth (eg, saving healthcare costs and the possibility of rehabilitating from home) make it a complementary treatment to consider. In addition, the research results can further test and improve the conceptual framework of the research, and play a reference role in the development of dyadic self-care theory.

The major limitation of this clinical trial is that it is a single-centre study, and participants will be recruited in one single centre in China. In addition, the data submitted by patients and caregivers may not reflect all the challenges that they experience and because they can review contents of the dyadic self-care APP and not submit them, analysis and the ability to provide interventions may be limited.

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