

BMJ Open What are the symptom trajectories of self-regulatory fatigue among family caregivers of stroke survivors? A protocol of mixed-methods study in Chinese rehabilitation settings

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To cite: Xu C-Y, Zou P, Chen X, *et al.* What are the symptom trajectories of self-regulatory fatigue among family caregivers of stroke survivors? A protocol of mixed-methods study in Chinese rehabilitation settings. *BMJ Open* 2025;**15**:e092724. doi:10.1136/bmjopen-2024-092724

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<https://doi.org/10.1136/bmjopen-2024-092724>).

Received 21 August 2024
Accepted 12 February 2025



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ABSTRACT

Introduction Stroke presents a considerable burden not only to patients but also to their families and society at large. In many instances, stroke patients opt for home rehabilitation, relying on family caregivers for daily assistance. This dynamic significantly influences the physiological, psychological and social well-being of these caregivers. Despite its importance, the phenomenon of self-regulatory fatigue (SRF) among family caregivers has received insufficient attention in the literature. Therefore, the objective of this study is to investigate the levels of SRF, the characteristics of associated symptoms and the trajectories of symptom change experienced by family caregivers of stroke patients.

Methods and analysis This research employs a mixed-methods approach, combining a cross-sectional study with a prospective longitudinal quantitative and qualitative design. The Chinese version of the SRF Scale and the Chinese version of Patient-Reported Outcomes Measurement Information System profile-29 are used to assess SRF, psychological and physiological symptoms, and related functional outcomes among family caregivers of stroke patients. Latent class growth analysis will be employed to model the heterogeneous developmental trajectories of SRF-related symptoms among family caregivers of stroke patients. Reflexive thematic analysis will be employed to analyse, organise and summarise qualitative data, to identify the experiences and management needs related to SRF among family caregivers during home care. Through this comprehensive mixed-methods approach, the study aims to: investigate the levels of SRF experienced by family caregivers of stroke patients, identify patterns and trajectories of related symptoms. The integration of cross-sectional and longitudinal data allows for a thorough examination of both immediate and long-term aspects of caregiver experiences, providing valuable insights into the complex dynamics of SRF in this population.

Ethics and dissemination The study protocol was approved by the Medical Ethics Committee of the University of South China (approval number 2023-NHHL-051). Data collection was authorised by the ethics committees of the First Affiliated Hospital, Second

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study employs a mixed-methods approach, combining quantitative longitudinal surveys with qualitative interviews to understand caregiver experiences.
- ⇒ Semistructured interviews will provide insights into caregivers' experiences and coping strategies.
- ⇒ The key factors influencing self-regulatory fatigue identified in this study can inform the formulation and development of targeted interventions for family caregivers.
- ⇒ This proposed study tracking period only lasts 6 months; longer-term tracking is recommended.
- ⇒ The primary indicators used in the quantitative research section are largely self-reported by participants, which may lack the support of objective measures.

Affiliated Hospital and Nanhua Affiliated Hospital of the University of South China. The results of this study will be disseminated through publication in pertinent peer-reviewed journals, presentation at local and international conferences, and communication with all relevant stakeholders.

Trial registration number ChiCTR2400082717.

INTRODUCTION

Stroke remains a significant and growing health concern in China, with alarming trends in mortality and economic burden. A 20-year monitoring report reveals that stroke-related deaths among middle-aged individuals in China exceed 2 million, with an annual growth rate of 8.7%.¹ This rate far outpaces the country's population growth, which averaged only 0.53% annually between 2010 and 2020, according to the seventh national census.² The disparity between stroke mortality growth and population growth suggests that key risk factors for stroke have

not been effectively controlled. In recent years, China has experienced explosive growth in stroke incidence, with a concerning trend towards younger patients. The 'Annual Report on Cardiovascular Health and Diseases in China (2022 Edition)' highlights the substantial economic impact of stroke, reporting average annual growth rates of 16.81% and 12.79% in total hospitalisation costs for cerebral infarction and cerebral haemorrhage, respectively, since 2004.³ These statistics underscore the urgent need for improved stroke prevention and management strategies in China.

The role of family caregivers in poststroke rehabilitation is crucial and deserves significant attention. Research indicates that home caregivers are associated with a reduced risk of hospitalisation for stroke patients compared with those without such support.⁴ van Dijk and Buijck emphasise that informal caregivers are often considered the ideal source of care for stroke survivors.⁵ In China, cultural traditions and family values influence care decisions, with nearly 90% of stroke patients opting for home-based rehabilitation after hospital discharge.⁶ This trend underscores the importance of integrating caregivers into the rehabilitation process as essential health partners for patients. Family caregivers often endure prolonged physical and emotional exhaustion, which adversely affects their overall physical and mental health.^{7 8} According to the results of a cross-sectional survey, 43.9% of family caregivers have anxiety symptoms, and 53.9% of family caregivers have varying degrees of depression symptoms. About 68.4% of family caregivers bear a moderate to severe burden from caregiving.⁹ Two studies emphasise that caregivers often exhibit signs of stress, isolation and depression.^{10 11} According to a meta-analysis, approximately 40% of caregivers of stroke survivors experienced depressive symptoms at different time points during the assessment process.¹² Moreover, 18% of caregivers reported such symptoms within the first 4 months of caring for patients.¹³ The decline in the well-being of family caregivers is closely associated with the deteriorating health outcomes of the patients they care for. Em *et al* found that the physical and mental health of caregivers correlates with the severity of physical dysfunction in stroke patients.¹⁴ Furthermore, Pucciarelli *et al* suggest that improving caregivers' health can positively impact the functional recovery and daily living activities of stroke survivors.¹⁵ Given these findings, healthcare professionals should prioritise interventions that support the physical and mental health of caregivers. Such interventions can indirectly enhance patients' functional status and overall recovery. Currently, there is a paucity of personalised care plans that adequately address the heterogeneity among family caregivers of stroke patients.¹⁶ Additionally, there is a limited body of literature exploring the incorporation of self-regulatory fatigue (SRF) as a more advanced indicator for assessing the symptoms, functional capacities and burdens experienced by family caregivers during the poststroke recovery process.¹⁷ This gap highlights the need for further research in understanding and fulfilling

the needs of family caregivers, which is essential for enhancing the health of these caregivers and improving rehabilitation outcomes for stroke patients.

SRF has emerged as a potential factor compromising the health of family caregivers. According to two surveys conducted in China, the average level of SRF among family caregivers is classified as moderate.^{18 19} Self-regulation encompasses the multidimensional regulation of an individual's self-awareness, emotions and behaviour.²⁰ It is recognised as a crucial element in maintaining psychological stability,²¹ facilitating personal and professional success,²² and enhancing the overall quality of life.²³ SRF, frequently linked to the notion of 'ego depletion', is defined as a temporary reduction in an individual's capacity to exert self-control and regulate behaviour following rapid self-control resources depletion.²⁴ The high dependence of stroke patients and prolonged caregiving durations are closely related to the heightened physical and mental burden experienced by family caregivers.^{25 26} Additionally, the absence of psychological and social support can lead to a rapid depletion of self-regulation resources among family caregivers within a short timeframe.^{27 28} This depletion is a critical factor contributing to the onset of SRF.²⁰ In confronting these challenges, family caregivers may experience diminished willpower, motivation and overall cognitive and emotional regulation capabilities.²⁹ Previous research has demonstrated that SRF significantly impacts self-management behaviours.³⁰ Consequently, this fatigue can impede family caregivers' ability to engage effectively in self-care plans.³¹ Despite its importance, the effects and contributing factors of SRF among family caregivers remain understudied.³⁰ According to a cross-sectional survey in China, the higher the level of SRF, the poorer the self-control ability and the lower the quality of life for each individual.¹⁷ A previous cross-sectional survey indicated that individuals residing in rural areas exhibit lower levels of self-efficacy, psychological resilience and perceived social support—factors that are associated with SRF.³² Using SRF as a focal point for observing caregiver health can provide indirect insights into their physical and mental well-being. Moreover, it can serve as an early warning system for healthcare professionals, alerting them to family caregivers who may be at risk of developing physical and mental health issues in the future.

Subjective report surveys are not only easy to administer and analyse, thereby saving time, but they also encourage the active engagement of family caregivers. Similar to the procedure of health assessment in health literacy empowerment programmes, self-report tools can encourage family caregivers to reflect on their health experiences.³³ By articulating their symptoms, concerns and overall well-being, patients gain insights into their health status. This process not only aids in self-awareness but also empowers patients to engage more actively in discussions with healthcare providers. Currently, there is a paucity of subjective reports on SRF in the existing literature, and tools specifically designed to measure SRF are

not widely used.^{32 34 35} This study will employ the Chinese version of the SRF Scale (SRF-S) and the Patient-Reported Outcomes Measurement Information System (PROMIS). These tools will enable us to accurately identify SRF and related symptoms in family caregivers. This, in turn, will allow us to provide guidance and references for future research on symptom improvement and enhance caregivers' understanding of disease processes and health management.

Therefore, this study will investigate the aetiology and categorise the manifestations of SRF-related symptoms among family caregivers of stroke patients. We will examine the phenomenology of SRF-related symptoms experienced by primary family caregivers throughout various stages of the caregiving continuum. A prospective longitudinal analysis will be conducted to assess the temporal dynamics of SRF-related symptoms among these caregivers. The findings from this research will provide a reference for the development of a comprehensive management plan addressing SRF for family caregivers during the continuity of care process for stroke patients in the future.

Research objectives

1. To investigate the aetiology and categorise the manifestations of SRF-related symptoms among family caregivers of stroke patients.
2. To examine the phenomenology of SRF-related symptoms experienced by primary family caregivers of stroke patients across various stages of the caregiving continuum.
3. To conduct a prospective longitudinal analysis of the temporal dynamics of SRF-related symptoms among family caregivers.

METHODOLOGY

Study design

This study adheres rigorously to the Good Reporting of A Mixed Methods Study checklist (online supplemental material 1), ensuring comprehensive and transparent reporting of our mixed-methods approach.³⁶ The qualitative research section of this article will adhere to the Consolidated Criteria for Reporting Qualitative Studies checklist (online supplemental material 2) designed to enhance the quality and transparency of qualitative research, particularly in the context of interviews and focus groups.³⁷ The focus of this study is to analyse the temporal dynamics and influencing factors of SRF-related symptoms among family caregivers of stroke patients through longitudinal observation. To enhance this analysis, longitudinal qualitative research will simultaneously capture the emotional experiences of family caregivers at various stages of caregiving. Consequently, an embedded design was selected for this study, allowing for the integration of qualitative insights within the predominantly quantitative framework.³⁸ This mixed-methods study employs a concurrent embedded design, comprising

two primary components.³⁹ Quantitative component: (a) cross-sectional survey—to elucidate the typology of SRF-related symptoms among primary caregivers of stroke patients. (b) Prospective longitudinal study: to delineate the trajectory of SRF-related symptoms among primary caregivers over time. Qualitative component: longitudinal phenomenological inquiry⁴⁰—to explore the lived experiences of SRF symptoms among family caregivers of stroke patients with long-term functional impairments and self-care deficits. The study will employ a multiphase data collection strategy. T0 (baseline): cross-sectional survey administration and first qualitative interview within 1 month of the postcerebrovascular event. T1 (3 month follow-up): quantitative assessments and second qualitative interview. T2 (6 month follow-up): quantitative assessments—final quantitative assessments and third qualitative interview. The entire study will last from November 2024 to August 2025. The diagram of the study is presented in figure 1.

Qualitative data will be used to contextualise and expand on quantitative findings, particularly in interpreting symptom scores and extreme values. This integration aims to provide a comprehensive understanding of SRF among family caregivers that neither method could achieve independently. The findings from this study will inform the development of evidence-based interventions for managing SRF among family caregivers of stroke patients in subsequent research.

Quantitative research section

Sample size

When using Bayesian Information Criteria as the primary consideration for model selection, a minimum sample size of 200 cases is recommended.⁴¹ The robustness of latent class models for analysing variable trajectory categories is also influenced by sample size, with larger sample sizes (up to 500 cases) providing more reliable results. Therefore, considering both statistical requirements and the practical feasibility of data collection, this study has determined a minimum sample size of 200 cases.

Settings and sample recruitment

A cluster sampling method will be employed to recruit participants. The study will include all family caregivers of stroke patients who meet the inclusion and exclusion criteria from the rehabilitation and neurology departments of three tertiary hospitals in Hengyang City, Hunan Province. Preliminary estimates suggest that, on average, the neurology department at each hospital admits approximately 4000 patients annually, while the rehabilitation department admits about 400 patients per year. This patient volume provides a robust foundation for our recruitment efforts. The participants will be initially recruited in the ward, and subsequent follow-ups will be expected to be completed in rehabilitation settings. This approach ensures a representative sample and facilitates the practical implementation of the study.

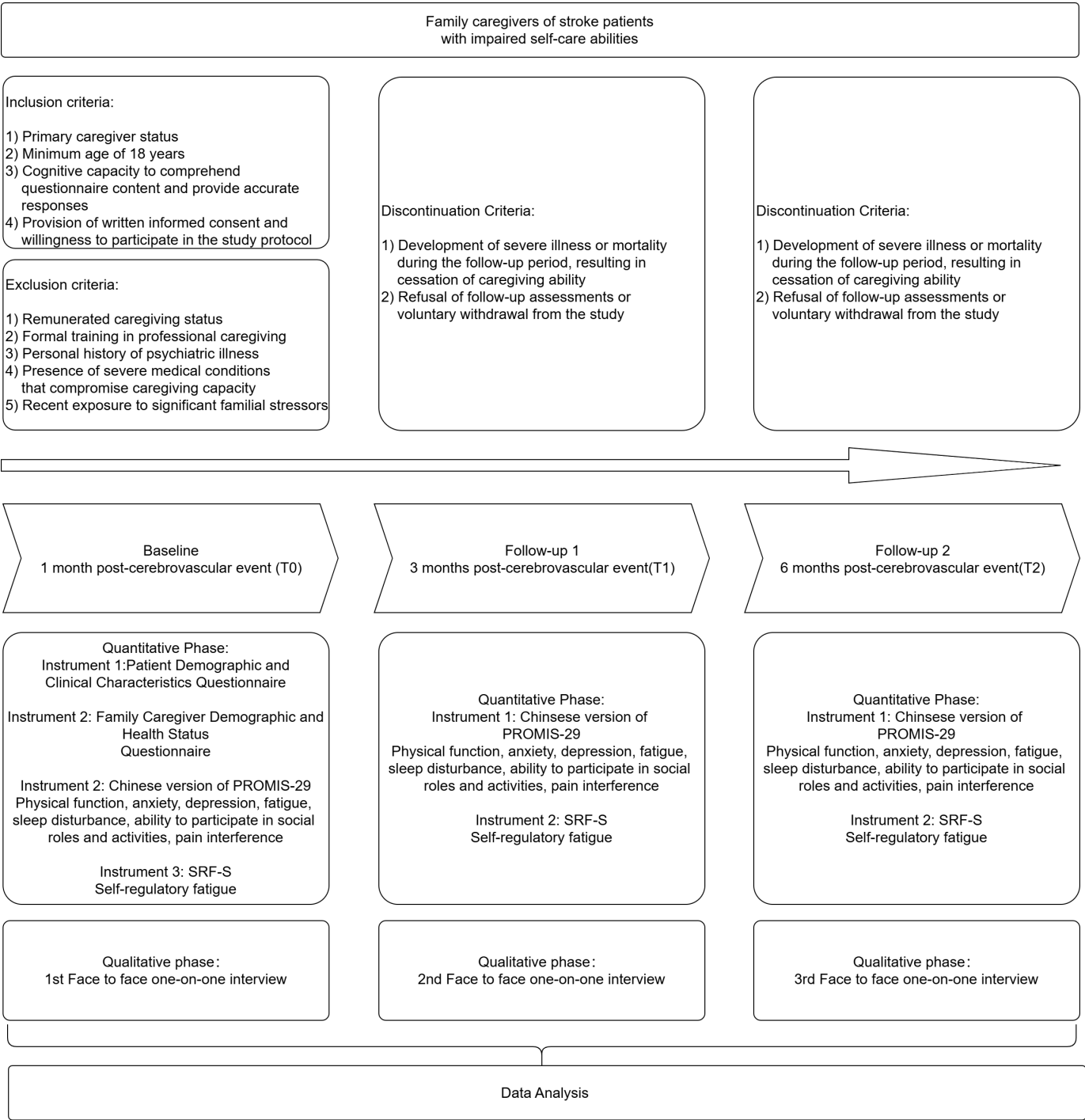


Figure 1 Research diagram. PROMIS-29, Patient-Reported Outcomes Measurement Information System profile-29; SRF-S, Self-Regulatory Fatigue Scale.

Eligibility criteria for samples

The conditions that stroke patients meet include: (1) with first-ever stroke; (2) impaired self-care ability, defined as a Modified Barthel Index score <60 (26), assessed weekly during hospitalisation; (3) residence within Hengyang city limits; (4) absence of comorbid major diseases, malignancies, end-stage conditions or need for dialysis and (5) no history of intermittent psychiatric disorders.

Family caregivers inclusion criteria:

1. Primary caregiver status, defined as the individual providing the most time-intensive care and assuming the majority of caregiving responsibilities.
 2. Minimum age of 18 years.
 3. Cognitive capacity to comprehend questionnaire content and provide accurate responses.
 4. Provision of written informed consent and willingness to participate in the study protocol.
- Family caregivers exclusion criteria:

1. Remunerated caregiving status.
 2. Formal training in professional caregiving.
 3. Personal history of psychiatric illness according to medical records review or assessment of the Chinese Health Questionnaire (CHQ).⁴²
 4. Presence of severe medical conditions that compromise caregiving capacity.
 5. Recent exposure to significant familial stressors.
- Family caregivers discontinuation criteria:

1. Development of severe illness or mortality during the follow-up period, resulting in cessation of caregiving ability.
2. Refusal of follow-up assessments or voluntary withdrawal from the study.

Data collection method

The collection of quantitative data will be conducted at three-time points between November 2024 and June 2025: T0 (1 month postcerebrovascular event), T1 (3 months postcerebrovascular event) and T2 (6 months postcerebrovascular event). After obtaining permission from the University of South China and the three tertiary hospitals, three postgraduate students will undergo research assistant (RA) training conducted by the first author (C-YX) and corresponding author (Y-JH). This training will encompass all research procedures, including participant recruitment based on the established inclusion and exclusion criteria, management of informed consent forms and techniques for administering questionnaires. 1 week following the admission of the stroke patient, the responsible nurse, along with the head nurse, will assess the eligibility of the family caregiver. They will provide a comprehensive explanation of the research objectives and procedures to the caregiver and subsequently obtain their written informed consent. The survey questionnaire will be administered on-site by RA (J-CY, S-LL and Z-QH) to ensure consistency and minimise bias. RA will provide standardised instructions on how to complete the questionnaire, ensuring uniformity in the data collection process across different researchers. All participants will be required to complete the questionnaire independently. In cases where participants are unable to read or write, RA will offer oral assistance to facilitate the completion of the questionnaire. If participants have any questions during the process, RA will provide immediate clarification. On completion, RA will review the questionnaires on-site to ensure they are fully completed. If any items are missing, participants will be asked to fill them in immediately. The questionnaires will be rechecked for completeness before being collected.

Research instruments

Patient Demographic and Clinical Characteristics Questionnaire

This instrument will collect comprehensive sociodemographic and clinical data, including: (a) sociodemographic variables: age, gender, anthropometric measures (height and weight), residential status, marital status, educational attainment, occupational status and

classification, socioeconomic indicators (average monthly income), health insurance coverage and lifestyle factors (smoking status and alcohol consumption). (b) Clinical variables: comorbidities, stroke classification, stroke incidence and time since onset, associated complications and rehabilitation parameters (duration, modalities and frequency).

Family Caregiver Demographic and Health Status Questionnaire

This instrument will assess key characteristics of the primary family caregiver, including: (a) sociodemographic variables: age, gender, marital status, educational attainment, occupational status and classification, socioeconomic indicators (average monthly income) and relationship to the patient. (b) Health-related variables: presence of chronic conditions and current medication regimen.

Chinese Health Questionnaire-12 (CHQ-12)

The CHQ-12 was meticulously developed by Cheng Tai'an, drawing on the widely recognised GHQ-12 (General Health Questionnaire) used internationally.⁴² GHQ-12 was originally developed by David Goldberg with the aim to assess an individual's mental health status, particularly identifying potential mental health issues such as anxiety and depression.⁴³ Yang *et al* verified CHQ-12 in the Chinese Mainland population, and Cronbach's alpha coefficient was 0.79.⁴⁴

Chinese version of the PROMIS-29 profile

The PROMIS-29 is a self-reported tool developed by the National Institutes of Health to evaluate health-related quality of life and functional status across various diseases. It assesses the impact of health conditions on patients' lives through 29 items covering multiple health dimensions, including seven health and function domains: physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference and pain intensity. All domains consist of four items, with the exception of pain interference and pain intensity, which include four items for pain interference and one item for pain intensity. According to the validation study conducted by Evon *et al*⁴⁵ on the (PROMIS in patients with chronic hepatitis C, the PROMIS scales for fatigue, depression, anxiety and sleep disorders exhibited strong reliability, with Cronbach's alpha values exceeding 0.87. In a randomised trial, Krohe *et al*⁴⁶ evaluated the content validity of the PROMIS Body Function Profile in comparison to the National Comprehensive Cancer Network—Functional Assessment of Cancer Therapy—Breast Cancer Symptom Index (NFBSI-16) in capturing symptoms and physical functions among patients with advanced breast cancer. Notably, over 70% of participants demonstrated an expected understanding of each item, and all patients reported that the questionnaire was easy to complete. According to the research findings by Huang *et al*,⁴⁷ the Chinese version of the PROMIS-29 has been demonstrated to be a valid and reliable tool

following an evaluation conducted in patients with aortic dissection, with a Cronbach's alpha greater than 0.90. Additionally, the research findings by Sikorskii *et al*⁴⁸ suggest that PROMIS-29 and traditional legacy tools yield comparable conclusions regarding the effects of interventions on pain, fatigue, sleep disturbances, anxiety, as well as physical and social functioning. Furthermore, due to its brevity and minimal response burden, the PROMIS 4-item form is an excellent choice for assessing patient-reported outcomes while both measurement systems are valuable for assessing caregiver outcomes.

All items are scored using a 5-point Likert scale, with variations in the descriptions of the response options for each item. Each domain is scored separately, resulting in scores across three primary domains. Furthermore, scores can be converted into standardised T-scores, where the mean is set at 50 with a SD of 10. Higher T-scores indicate a greater degree of the measured construct. For instance, a T-score of 70 in social role functioning suggests that the individual's ability to engage socially is above the average for the general population, reflecting better social functioning. Conversely, a T-score of 70 in depression indicates a higher level of depressive symptoms compared with the general population. The PROMIS tools have been translated into over 40 languages and are widely used in various healthcare settings.

The 6-month period following a stroke is recognised as the optimal timeframe for patient recovery. Concurrently, this period is critical for family caregivers, who may experience substantial impacts on their quality of life during this time.⁴⁹ By including caregivers in this assessment, we gain a holistic view of the healthcare experience.

Chinese version of the SRF-S

The SRF-S was developed by Nes *et al*.⁵⁰ and consists of 18 items specifically designed to assess SRF in individuals with chronic diseases. The scale has demonstrated good reliability and validity, effectively distinguishing SRF from self-control and physical fatigue, thereby providing a more direct and accurate assessment of an individual's state of self-depletion.

The Chinese version of the SRF-S was translated and validated in young adults by Wang *et al*.⁵¹ Also validated in elderly maintenance haemodialysis patients and caregivers.¹⁷ It comprises three dimensions: cognitive control, emotional control and behavioural control, with a total of 16 items. Each item is scored using a 5-point Likert scale, ranging from 'strongly disagree' (1) to 'strongly agree' (5), yielding a total score between 16 and 80. Higher scores indicate greater severity of SRF.

Data analysis

Statistical analyses will be conducted using IBM SPSS V.26.0 and R statistical software V. 4.2.1. SPSS 26.0 provides a user-friendly interface for data management and basic statistical analyses, ideal for exploratory and descriptive statistics, while R 4.2.1 excels in handling large datasets and advanced statistical methods. Using both software

packages leverages their strengths, enhancing analytical efficiency and allowing for cross-validation of results to improve the robustness of findings. Quantitative data that conforms to a normal distribution will be summarised using mean $\pm$ SD, while data that do not follow a normal distribution will be described using median and IQR. Categorical data will be presented as frequency and percentage to characterise the general demographic features of the study participants.

To compare demographic differences between study subjects who were lost to follow-up and those who remained, independent sample t-tests and χ^2 tests will be employed. Latent class analysis will be performed to classify family caregivers into distinct latent groups based on the varying characteristics of symptoms associated with SRF. For intergroup comparisons, t-tests, χ^2 tests and analysis of variance will be used, while logistic regression will be applied to identify independent influencing factors. Additionally, latent class growth analysis (LCGA) will be employed to model the heterogeneous developmental trajectories of SRF-related symptoms among family caregivers of stroke patients.

Qualitative research section

Sample size

The sample size for qualitative research is determined by the informational power of the sample size, meaning that the more information the sample has that is relevant to the actual research, the fewer participants are required.⁵² The size of a sample with adequate informational capacity is contingent on the research objectives, the specificity of the sample, the application of established theories, the quality of dialogues and the analytical strategies employed. To ensure the collection of rich and relevant information, we will select participants who can provide valuable insights into the research topic. The anticipated sample size is approximately 10–15 individuals.

Settings and sample recruitment

In this study, a purposive sampling method will be used to select family caregivers of stroke patients as interview participants. For caregivers of hospitalised stroke patients, qualitative interviews will be conducted in conference rooms within the ward. This setting is chosen to accommodate the significant caregiving burden that many family caregivers experience, providing a supportive environment for the interviews. For caregivers of discharged stroke patients, interviews will take place in their homes or in community conference rooms, allowing for a comfortable and familiar atmosphere that may encourage open and candid discussions.

Data collection

Between November 2024 and June 2025, qualitative interviews will be conducted at three-time points for each stroke patient: T0 (1 month postcerebrovascular event), T1 (3 months postcerebrovascular event) and T2 (6 months postcerebrovascular event). All interviews will

be scheduled with the participants at a time and location convenient for them, following the completion of quantitative data collection. All interviews will be conducted on a one-on-one basis, with only the family caregiver and the researcher present. A postgraduate student (C-YX) trained in qualitative interviewing will be responsible for face-to-face data collection. Prior to the interviews, the researcher will prepare all necessary materials and equipment, including informed consent forms, interview outlines, recording devices, notebooks, pens and thank you gifts. Before commencing the interview, the researcher will explain the purpose and significance of the study to the family caregiver. The interviewee will be informed that recording equipment will be used to ensure the completeness of the information gathered during the interview process. It will be emphasised that all content collected is for research purposes only, and the interviewee has the right to withdraw at any time if they experience any discomfort. The researcher will seek the interviewee's understanding and consent regarding these procedures.

Each interview is expected to last between 30 and 60 min. During the interview, the researcher will focus not only on capturing the verbal responses of the interviewee but also on carefully observing and recording non-verbal behaviours, such as facial expressions, tone of voice and body movements, which may reflect psychological changes. The researcher will conduct appropriate follow-ups on valuable information, providing timely responses and employing interview techniques such as repetition and probing questions to facilitate a deeper exploration of the information shared by the interviewee.

Interview content

The interview will focus on open-ended questions designed to elicit in-depth responses from participants. The questions will include:

Understanding of stroke:

"Can you talk about your understanding of stroke? What changes has the patient's illness brought to your life, and how do you respond to these changes?"

Patient care dynamics:

"What is the patient's response to your care while assisting with their daily activities and recovery? How did you feel during the caregiving process, and what changes has the caregiving responsibility brought to you?"

Health and well-being:

"How is your current health condition? How do you feel while caring for the patient? How do you balance the patient's health needs with your own? What is your perspective on the relationship between the patient's health and your health?"

Changes in personal time:

"Has your alone time changed since the patient's illness? How do you feel about these changes?"

Role of the family caregiver:

"How do you understand the role of a family caregiver? What changes do you believe you, as a family member, will bring to the patient's recovery?"

Challenges in caregiving:

"What are the current difficulties you face in caring for the patient and assisting in their rehabilitation process? What kind of support do you hope to receive?"

Definition and recognition of SRF:

"How would you define self-regulatory fatigue in your own words?"

"Have you noticed changes in your ability to manage stress or maintain routines since becoming a caregiver?"

Triggers and symptoms:

"What specific situations or tasks contribute most to your feelings of difficulty in maintaining emotional and physiological stability?"

"Can you describe any physical or emotional symptoms you experience that you believe are related to this difficulty?"

Data analysis

All qualitative data analysis will be conducted using NVivo 10 software. A diachronic approach will be adopted for data analysis, meaning that analysis will occur after the completion of all data collection. This approach allows for comprehensive consideration of all data waves, providing a deeper perspective on the changes over time that contribute to understanding the experiences and processes of family caregivers.

This structured approach ensures a rigorous analysis process while fostering collaboration among authors at each stage of reflexive thematic analysis (RTA) implementation. The recorded interview content will be transcribed verbatim into written documents, and an archive file will be established by C-YX and double-checked by Y-JH. This file will include essential information such as material number, basic information about the interviewee, and details regarding the method and location of data collection. RTA will be employed to analyse, organise and summarise the data, to identify the experiences and management needs related to SRF among family caregivers during home care.⁵³ The entire process was conducted under the guidance of three nursing PhD authors—PZ, XC and Y-JH—who possess extensive qualitative research experience in RTA methods for analysing qualitative data. All authors have completed at least 4 months of both theoretical and practical training related to RTA methodologies. In the event of disagreements arising before or during any stage of the process, the corresponding author, Y-JH, will organise a meeting to facilitate discussion on the key challenges and complexities encountered by the authors.

Each specific step will be carried out according to the following arrangement:

Familiarisation with the data (step 1): C-YX, J-CY, S-LL and Z-QH will engage in a thorough review of the interview-related documents to ensure comprehensive familiarity with the data. Each author will highlight sections that

align with the qualitative research objectives and will document relevant notes. Consensus will be achieved through discussions in subsequent meetings. Generating initial codes (step 2): C-YX, J-CY, S-LL and Z-QH will work in pairs to code the materials, take pertinent notes and export the codes from NVivo software in the form of charts. Consensus regarding the coding will be established during a collaborative meeting. Developing themes (step 3): following consensus on the initial coding, C-YX, J-CY, S-LL and Z-QH will collaboratively create an initial thematic map based on the codes to facilitate theme development through discussion. Reviewing themes (step 4): the identified themes will undergo a thorough review to ensure they accurately reflect the dataset. This review will be conducted collectively by all four authors. Defining and naming themes (step 5): during a dedicated meeting, all authors will engage in discussions to finalise the definitions and names of the themes. Writing the report (step 6): C-YX will be responsible for drafting the final section of the qualitative research report.

Patient and public involvement

Patients and the public were not involved in the development of this research proposal or the conduct of the study. The research question and study design were informed by the review of existing evidence and discussions with clinical experts. However, we acknowledge the limitations of not incorporating patient input, particularly in ensuring the relevance and acceptability of the qualitative data collection. In future studies, we will seek patient involvement in refining the research question, selecting appropriate outcome measures and optimising the study design.

ETHICS AND DISSEMINATION

The study protocol was approved by the Medical Ethics Committee of the University of South China (Approval number 2023-NHHL-051). Data collection was authorised by the ethics committees of the First Affiliated Hospital, Second Affiliated Hospital and Nanhua Affiliated Hospital of the University of South China. The results of this study will be disseminated through publication in pertinent peer-reviewed journals, presentation at local and international conferences, and communication with all relevant stakeholders.

DISCUSSION

This study is expected to explore the patterns of SRF-related symptoms among family caregivers, establishing a foundation for developing management plans addressing maladjustment in family caregivers at different stages of the poststroke recovery. The quantitative component of the study uses self-report data collection, which encourages the active engagement of family caregivers and fosters their participation in maintaining the health of stroke patients. By focusing on individual experiences

and authentic emotions, this study fosters a deeper understanding among family caregivers regarding their own feelings. This awareness encourages them to take proactive steps in seeking appropriate assistance, ultimately enhancing the social support available for stroke patients. Additionally, the combination of reliable self-report tools and one-on-one face-to-face interviews allows for a comprehensive and nuanced understanding of the experiences and self-care situations faced by family caregivers following cerebrovascular events.

However, potential limitations of the proposed study include the relatively short tracking period of 6 months. Future research could benefit from longer-term tracking to provide a more comprehensive understanding of the long-term SRF experienced by caregivers of stroke patients. Furthermore, the primary indicators used in the quantitative research section are largely self-reported by participants, which may lack the support of objective measures.

CONCLUSION

This protocol outlines a comprehensive mixed-methods study designed to investigate the symptom trajectory of SRF-related symptoms in family caregivers of stroke survivors. By combining cross-sectional investigation, quantitative longitudinal surveys with qualitative in-depth interviews, this study aims to provide a nuanced understanding of how SRF develops, progresses and impacts caregivers over time.

The proposed research addresses a significant gap in the literature by focusing specifically on SRF, a critical yet understudied aspect of caregiver burden. By mapping the trajectory of SRF-related symptoms, we anticipate identifying key inflection points and contributing factors that could inform targeted interventions. The mixed-methods approach will allow for a rich, multifaceted exploration of caregivers' experiences, capturing both the measurable changes in fatigue levels and the lived experiences of managing this challenge.

Acknowledgements We would like to express our sincere gratitude to Dr. Qiao Xiao for her invaluable assistance in the statistical analysis of this study. E-mail: xq.hnit@gmail.com. Her expertise in mathematicmathematics (statistics)/epidemiology and biostatistics will greatly enhance the quality of our research. We extend our heartfelt appreciation to all the research participants who generously volunteered their time and shared their experiences. Your contributions were invaluable and form the cornerstone of this research.

Contributors C-YX: conceived and designed the study, developed the theoretical framework and wrote the initial draft of the manuscript. PZ, XC, S-LL, J-CY and Z-QH: assisted in the design of the methodology, contributed to drafting sections of the manuscript and contributed to the critical revision of the manuscript for important intellectual content. Y-JH: acted as guarantor. Assisted in the design of the methodology, and reviewed and provided feedback on all drafts of the manuscript, ensuring clarity and coherence.

Funding This work was supported by the Social Science Achievement Review Committee of Hunan Province under Grant number: XSP25YBZ054; the Natural Science Foundation of Hunan Province under Grant number: 2023JJ40558; and the Health Commission of Hunan Province under Grant number: B202314057822.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design or conduct or reporting or dissemination plans of this research.

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

Provenance and peer review Not commissioned; externally peer reviewed.

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