PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

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

Authors

Xu, Chao-Yue; Zou, Ping; Xi, CHEN; Li, Shu-Lin; You, Jia-Chun; He, Zhi-Qing; Huang, Yan-Jin

VERSION 1 - REVIEW

Reviewer	**1**
Name	**Schwertfeger, Julie Lynn**
Affiliation	**Rosalind Franklin University of Medicine and Science, Psychiatry and Behavioral Medicine, Chicago Medical School**
Date	**07-Oct-2024**
COI	**None**

Thank you for this exciting study. In reviewing the protocol, there are many strengths to the study. To strengthen the rigor and replicability, the following protocol clarifications and additions are noted in comments in the attached manuscript pdf. Here are the concerns to address in the protocol publication:

1) Qualitative methods, coding, and integration in the analysis are not clear in the current protocol manuscript. Your description of the interview questions and the use of the qualitative data to supplement the quantitative data seems to be concurrent embedded design, though your protocol states early in methods that you will use concurrent triangulation.

2) Bias, 2-independent data transcription coders, and a process for resolving disagreements needs to be clarified in the qualitative methods portion of the protocol. Citing a methodological guideline that will be followed and stating so can satisfy this need succinctly.

3) The protocol figure is unclear regarding time ranges across participants at the 3-assessment time points, and a description of the figure shapes is needed to explain what currently appears to be repeated steps in different shapes in the figure.

4) Inclusion/Exclusion and identification and initial contact protocol of potential participants needs to be clarified. The exclusion criteria does not include time in caregiving role currently, and yet the protocol indicates that T0 is within 30 days of the person being cared for by the caregiver having had a stroke. Also, it is not indicated if only first ever stroke caregivers are being included or what other pre-stroke conditions and functional limitations would exclude a caregiver from the study. Lastly for inclusion/exclusion, please indicate what screening tool will be used to identify the exclusion items: psychiatric disorders, comorbid major diseases (will this be self-report or other verification methods)?

5) Discussion identifies nursing care planning and maladjustment, which are not in the aims nor in the protocol. The aims, methods, data analysis, and discussion should align. Support anticipated result discussion points in existing related study results in similar populations and the implications that positive results supporting your hypotheses will contribute in light of existing study results.

6) Data collection modes and timing for quantitative surveys and qualitative interviews are unclear. Because both are listed in parallel in the protocol for each time point, it is unclear whether the postdoc research staff who does the interviews will also collect the quantitative survey data or interact about the quantitative data under any circumstance. Please make it clear when, how, and by whom the quantitative data will/has been collected.

7) Study aims should match statistical analyses, which currently include latent class analyses and growth analysis. The data analysis and collection methods indicate that an aim regarding factors that correlate with differences in SRF and symptomology exists but is not stated currently.

The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

Reviewer	**2**
Name	**Jaracz, Krystyna**
Affiliation	**Poznan University of Medical Sciences**
Date	**17-Oct-2024**
COI	**None**

The research project presented in the manuscript is promising. It merits attention since informal caregivers of stroke survivors play an essential role in the recovery process and overall well-being of the patients. The outcome of this process largely depends on various resources, including the psychological health of caregivers. Consequently, the investigation of self-regulatory fatigue (SRF) within this population can be both valuable and a meaningful contribution to the existing literature.

The rationale for the study is quite clearly and convincingly articulated in the Introduction. The proposed mixed-methods approach, which integrates both quantitative and qualitative methodologies within a longitudinal study design, offers a more comprehensive understanding of the phenomenon under investigation, thus enhancing its potential practical relevance.

There are a few issues I would like to comment on:

1. In the Introduction, the authors provided comprehensive epidemiological data explaining the role of informal caregivers and emphasizing the importance of protecting and enhancing the caregivers' well-being. However, the explanation of the self-regulatory fatigue phenomenon, in my opinion, is too general. I would suggest providing a more specific definition and a broader explanation, as it is crucial for fully understanding the research subject and problem. This is especially needed given that there are few studies on this topic among informal caregivers. For example, helpful information can be found in the Encyclopedia of Behavioral Medicine.

2. It would also be valuable to explain briefly why SRF is so significant for caregivers.

3. Furthermore, it would be beneficial to explain the rationale for simultaneously studying the quality of life of caregivers (PROMIS 29) . Although the relationship between SRF and HRQoL seems logical, providing supporting arguments with scientific evidence (appropriate references) would be needed.

4. The information regarding the research aims on page 5 (lines 39–55) and that in the Research objectives section differ slightly, which may be confusing. Therefore, I suggest refining these parts or considering whether it is necessary to present the information about research aims in two separate places. I found it a little bit confusing and unclear.

5. For the sentences: “Longitudinal phenomenological inquiry:...” – lines 43-44, and “Self-regulatory fatigue ….” (lines 39-41), please add appropriate references so that the readers would be able to find the source information supporting your sentences.

In summary, The research project presented to me is very promising. As I mentioned above, the study will provide valuable information, especially for researchers and others interested in the broad topic of the consequences of stroke and informal caregiving for stroke survivors. After incorporating these suggested corrections, the research protocol will be more comprehensible, and a rationale for the study, in my opinion, will be more convincing. I wish the Authors success in conducting their research.

Reviewer	**3**

Name **Merriman, Niamh A.**

Affiliation **University College Dublin, School of Public Health, Physiotherapy and Sports Science**

Date **01-Nov-2024**

COI **None**

The authors present a protocol for a mixed methods study of the trajectory of self-regulatory fatigue in family caregivers of stroke survivors over a 6-month period. They include a 'Good Reporting of a Mixed Methods Study' checklist; however, they should also include the 'Consolidated Criteria for Reporting Qualitative Research (COREQ)' checklist. There are a number of points in the protocol which require revision. I have some comments for clarification on some aspects of the methodology.

Abstract – Methods and Analysis

The authors present the software packages used for analysis rather than the methods to be used for the analyses. This should be amended.

Introduction

The Introduction itself could be streamlined to focus more on outcomes for caregivers of stroke survivors rather than including general statements on the need for 'targeted interventions to address risk factors and enhance healthcare infrastructure for stroke treatment and rehabilitation'. What percentage of caregivers of stroke survivors have been found to experience self-regulatory fatigue? It would be better to have an idea of how widespread this aspect of caregiver burden is rather than incidence of stroke.

Page 4, line 12: The authors state that: 'The interconnection between caregiver well-being and patient outcomes is evident in recent studies'. It would be useful to be explicit about the direction of the association in statements like these and being careful to avoid repetition.

Page 4, line 29: The sentence beginning with 'In conclusion' does not belong in the introduction section.

Page 4, line 39 and 52: The authors state that: 'Self-regulatory fatigue has emerged as a significant factor potentially compromising the health of family caregivers'. Has SRF been shown to be a significant factor or a potential factor?

Page 5, line 18: Does survey administration really encourage active engagement of caregivers and promote health literacy? If so, there should be a reference for each of these claims.

Page 5, line 31: The study is described as documenting the trajectory of self-regulatory fatigue in caregivers of stroke survivors. If the goal is actually to develop an intervention to provide targeted guidance for caregivers, then this should be reflected in the title and the methodology.

Page 5, line 47-55: Again, the authors list a number of objectives that are not reflected in the methodology.

Research objectives

The development of an intervention to provide targeted guidance for caregivers of stroke survivors is not listed as an objective. Therefore, this should be not listed as a goal of the study in the introduction. If there is a plan to develop an intervention that is informed by this mixed methods study, then that should be made explicit throughout and it should be included as a research objective.

Methods and analysis – Study design

Page 7, line 11: The timeline for the entire study is from Nov 2024 to April 2025. This seems very optimistic and does not allow for any issues with recruitment or potential attrition of participants, let alone analysis of qualitative data, which the authors state will only occur once all data are collected.

Methods – settings and sample recruitment for quantitative data

It would be useful to have an idea of how many stroke survivors are treated annually across the two included institutions to give an idea of how feasible it will be to recruit and retain 200 participants.

Is a statistician included in the research team?

Methods – data collection method

Will participants also be recruited from rehabilitation settings?

Methods – research instruments

Have the PROMIS-29 and SRF-S been validated in caregivers of stroke survivors? If so, it is important to include this information. If not, do the authors plan to validate these tools in their target population?

Again, there are some statements in the methods section that are better suited to the discussion. For example: ‘This tool demonstrates strong reliability and validity, providing valuable health information that can assist healthcare providers and researchers in developing more effective treatment plans’.

Methods – data analysis

Why use two statistical software packages and not conduct all the analyses in R?

Methods – settings and sample recruitment for qualitative data

In recent years, there has been a move away from the notion of ‘data saturation’ and more of a focus on ‘information power’. See https://doi.org/10.1177/1049732315617444

For the qualitative research methods, the COREQ checklist should be followed and adhered to during reporting.

Methods – qualitative data analysis

It would be good to have more details on the planned within-case analyses and the cross-case analyses of the longitudinal qualitative interviews.

Also, the authors state they will be analysing data with the aim of 'identifying the experiences and management needs related to self-regulated fatigue among family caregivers during home care'. However, on examining the interview guide, there are no questions explicitly asking the caregivers for their perspective on what would be useful for them to manage their self-regulatory fatigue symptoms (if they report having them).

Discussion

Page 17, line 22: The authors state that the principles of precision nursing are reflected in the study. This is the first mention of this concept. If the design of the study is influenced by these principles, then that should be make clear and defined in the methods section. Same comment is relevant for line 29.

Page 17, line 23: Again, what is the evidence to support the statement that partaking in a survey will encourage active engagement and health literacy?

VERSION 1 - AUTHOR RESPONSE

Reviewer 1:
1. Comment "Qualitative methods, coding, and integration in the analysis are not clear in the current protocol manuscript. Your description of the interview questions and the use of the qualitative data to supplement the quantitative data seems to be concurrent embedded design, though your protocol states early in methods that you will use concurrent triangulation."
RE: Thank you for your valuable feedback regarding the clarity of qualitative methods, coding, and integration in our protocol manuscript. We appreciate your insights and more detailed statement about qualitative methods has been added.
[Familiarization with the Data (step 1): CX, JY, SL, and ZH 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): CX, JY, SL, and ZH 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, CX, JY, SL, and ZH 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 finalize the definitions and names of the themes. Writing the Report (step 6): CX will be responsible for drafting the final section of the qualitative research report. (page 21, line 19-23, and page 22, line 1-10]
[employs a concurrent embedded design, comprising two primary components(page 9,line7-8)]
Reference 1. Braun V, Clarke V. Supporting best practice in reflexive thematic analysis reporting

in Palliative Medicine: A review of published research and introduction to the Reflexive Thematic Analysis Reporting Guidelines (RTARG). Palliative medicine. 2024;38(6):608-16.
Reference 2. Schoonenboom J, Johnson RB. How to Construct a Mixed Methods Research Design. Kolner Z Soz Sozpsychol. 2017;69(Suppl 2):107-31.

2. Comment "Bias, 2-independent data transcription coders, and a process for resolving disagreements needs to be clarified in the qualitative methods portion of the protocol. Citing a methodological guideline that will be followed and stating so can satisfy this need succinctly."
RE: Thank you for your valuable feedback regarding the qualitative methods section of our protocol. We appreciate your emphasis on clarity concerning bias, the use of independent coders, and the resolution of disagreements. We searched for relevant literature, added some statements, and made adjustments in the elaboration of this section.
[Familiarization with the Data (step 1): CX, JY, SL, and ZH 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): CX, JY, SL, and ZH 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, CX, JY, SL, and ZH 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 finalize the definitions and names of the themes. Writing the Report (step 6): CX will be responsible for drafting the final section of the qualitative research report. (page 21, line 19-23, and page 22, line 1-10]
Reference 1. Braun V, Clarke V. Supporting best practice in reflexive thematic analysis reporting in Palliative Medicine: A review of published research and introduction to the Reflexive Thematic Analysis Reporting Guidelines (RTARG). Palliative medicine. 2024;38(6):608-16.

3. Comment "The protocol figure is unclear regarding time ranges across participants at the 3-assessment time points, and a description of the figure shapes is needed to explain what currently appears to be repeated steps in different shapes in the figure."
RE: Thank you so much for your vigorous review. Based on your suggestion, we have made modifications to the protocol figure.

4. Comment "Inclusion/Exclusion and identification and initial contact protocol of potential participants needs to be clarified. The exclusion criteria does not include time in caregiving role currently, and yet the protocol indicates that T0 is within 30 days of the person being cared for by the caregiver having had a stroke. Also, it is not indicated if only first ever stroke caregivers are being included or what other pre-stroke conditions and functional limitations would exclude a caregiver from the study. Lastly for inclusion/exclusion, please indicate what screening tool will be used to identify the exclusion items: psychiatric disorders, comorbid major diseases (will this be self-report or other verification methods)?"
RE: Much appreciated your valuable comment regarding the need for clarity on the inclusion/exclusion criteria and the identification and initial contact protocols for potential

participants. We have made modifications to this section based on your suggestions and clarifications to some of your questions is provided below.

The study protocol specifies that the initial contact (T0) occurs within 30 days post-stroke for the individual being cared for. While the current exclusion criteria do not explicitly mention the duration of caregiving experience, it is implied that caregivers must be actively involved in the care of a stroke patient during this period. This timeframe ensures that caregivers are not only available but also likely to experience relevant burdens associated with recent caregiving responsibilities. The following literature has been identified for your reference.

The included family caregivers were in a healthy state before the onset of stroke.

The inclusion criteria focus on caregivers of individuals who have experienced a first-ever stroke. The presence of major diseases will be verified through a combination of self-reporting and medical records review, where feasible.

[After obtaining permission from the University of South China and the three tertiary hospitals, three post-graduate students will undergo research assistant (RA) training conducted by the first author (CX) and corresponding author (YH). 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. One week following the admission of the stroke patient, the responsible nurse, along with the head nurse, will assess the eligibility of 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 to ensure consistency and minimize bias. RA will provide standardized 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. Upon 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.(page 13, line1-20)]

[(i) with first-ever stroke.(page11,line21)]

[3) Personal history of psychiatric illness according to medical records review or assessment of Chinese Health Questionnaire (CHQ)(page12, line 13-14)]

Reference 1. Wang D, Rushton S, Ledbetter L, Graton M, Ramos K, Hendrix CC. Factors associated with memory of informal caregivers: A scoping review protocol. PloS one. 2024;19(1):e0295449.

Reference 2. Jaracz K, Grabowska-Fudala B, Jaracz J, Moczko J, Kleka P, Pawlicka A, et al. Caregiver burden after stroke: a 10-year follow-up study of Polish caregivers for stroke patients. BMC nursing. 2024;23(1):589.

5. Comment “Discussion identifies nursing care planning and maladjustment, which are not in the aims nor in the protocol. The aims, methods, data analysis, and discussion should align. Support anticipated result discussion points in existing related study results in similar populations and the implications that positive results supporting your hypotheses will contribute in light of existing study results.”

RE: Thanks for your suggestion. We conducted a thorough review of the research objectives and the discussion section, subsequently implementing appropriate modifications to the discussion section in alignment with the established research objectives.

[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 post-stroke recovery. (page23, line3-5)]

6. Comment "Data collection modes and timing for quantitative surveys and qualitative interviews are unclear. Because both are listed in parallel in the protocol for each time point, it is unclear whether the postdoc research staff who does the interviews will also collect the quantitative survey data or interact about the quantitative data under any circumstance. Please make it clear when, how, and by whom the quantitative data will/has been collected."
RE: Much appreciated your careful review. We have made appropriate enhancements to the data collection sections for both quantitative and qualitative research.
[The collection of quantitative data will be conducted at three time points between November 2024 and June 2025: T0 (1month post-cerebrovascular event), T1 (3 months post-cerebrovascular event), and T2 (6 months post-cerebrovascular event). (page 12, line 23-24 and page 13, line 1)]
[Between November 2024 and June 2025, qualitative interviews will be conducted at three time points for each stroke patient: T0 (1month post-cerebrovascular event), T1 (3 months post-cerebrovascular event), and T2 (6 months post-cerebrovascular event). All interviews will be scheduled with the participants at a time and location convenient for them, following the completion of quantitative data collection. (page 18, line12-14)]

7. Comment "Study aims should match statistical analyses, which currently include latent class analyses and growth analysis. The data analysis and collection methods indicate that an aim regarding factors that correlate with differences in SRF and symptomology exists but is not stated currently."
RE: Thank you for your insightful feedback regarding the alignment of our study aims with the statistical analyses we intend to employ. We appreciate your observation and would like to clarify the data analysis. To identify independent influencing factors Logistic Regression will be applied.
[Latent Class Analysis (LCA) will be performed to classify family caregivers into distinct latent groups based on the varying characteristics of symptoms associated with self-regulatory fatigue. For inter-group comparisons, t-tests, chi-square tests, and analysis of variance (ANOVA) will be utilized, 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 self-regulatory fatigue-related symptoms among family caregivers of stroke patients. (page 17, line 9-15)]

Reviewer: 2
1. Comment "In the Introduction, the authors provided comprehensive epidemiological data explaining the role of informal caregivers and emphasizing the importance of protecting and enhancing the caregivers' well-being. However, the explanation of the self-regulatory fatigue phenomenon, in my opinion, is too general. I would suggest providing a more specific definition and a broader explanation, as it is crucial for fully understanding the research subject and problem. This is especially needed given that there are few studies on this topic among informal caregivers. For example, helpful information can be found in the Encyclopedia of Behavioral Medicine."
RE: Thank you for your insightful feedback regarding the Introduction of our manuscript. We

appreciate your suggestion to reference the Encyclopedia of Behavioral Medicine and your recognition of the comprehensive epidemiological data we provided on informal caregivers and the emphasis on their well-being. Based on your feedback, we have refined the definition of self-regulatory fatigue. We have consulted other relevant literature, which may be helpful in supplementing the content of the paper.

[Self-regulatory fatigue, 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 behavior following rapid self-control resources depletion(24). (page 6,line 7-10)]

[According to two surveys conducted in China, the average level of self-regulatory fatigue among family caregivers is classified as moderate(18, 19). (page 6, line2-3)]

Referrence1. Cameron D, Webb T. Self-Regulatory Fatigue. In: Gellman MD, Turner JR, editors. Encyclopedia of Behavioral Medicine. New York, NY: Springer New York; 2013. p. 1760-2.

Referrence 2. Ling Qian JS, She Wangling, Liu Liujun. Analysis of Self-regulatory Fatigue Status and Influencing Factors in Parents of Children with Asthma. Journal of clinical nursing. 2024;23(4):6-10.

Referrence3. Xiang Jing CC. Analysis of the current status and influencing factors of self-regulatory fatigue in parents of premature infants. Modern Nurse. 2023;30(9):120-3.

2. Comment “It would also be valuable to explain briefly why SRF is so significant for caregivers.”

RE: Thank you for your valuable comment regarding the significance of self-regulatory fatigue (SRF) for caregivers. We have consulted other relevant literature and supplemented certain content.

[The high dependence of stroke patients, 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 self-regulatory fatigue(20). (page 6, line10-15)]

Referrence3. Eriku GA, Bekele G, Yitayal MM, Belete Y, Girma Y. Depressive Symptoms and Its Associated Factors Among Primary Caregivers of Stroke Survivors at Amhara Regional State Tertiary Hospitals: Multicenter Study. Neuropsychiatric disease and treatment. 2023;19:1675-84.

Referrence 4. Kumar A, Yadav AK, Singh VK, Pathak A, Chaurasia RN, Mishra VN, et al. Caregiver Burden in Caregivers of Stroke Survivors: A Hospital-Based Study. Annals of Indian Academy of Neurology. 2022;25(6):1092-8.

Referrence 5. Ou PR, Wu MH, Tsai ST, Ma YC. The Relationship Between Social Support and Stress in Family Caregivers of Stroke Patients. The Journal of neuroscience nursing : journal of the American Association of Neuroscience Nurses. 2024;56(6):209-13.

Referrence6. Tyagi S, Luo N, Tan CS, Tan KB, Tan BY, Menon E, et al. Support system diversity among family caregivers of stroke survivors: a qualitative study exploring Asian perspectives. BMC geriatrics. 2021;21(1):594.

3. Comment “Furthermore, it would be beneficial to explain the rationale for simultaneously studying the quality of life of caregivers (PROMIS 29). Although the relationship between SRF and HRQoL seems logical, providing supporting arguments with scientific evidence (appropriate references) would be needed.”

RE: Thank you for your comment regarding the rationale for simultaneously studying the quality

of life of caregivers using the PROMIS profile-29. The rationale for utilizing PROMIS-29 to assess the quality of life of nursing staff, as well as the references pertaining to the relationship between self-reported fatigue (SRF) and health-related quality of life (HRQoL), have been included in the revised version of the article.
[The PROMIS-29 is a self-reported tool developed by the National Institutes of Health (NIH) to evaluate health-related quality of life (HRQoL) and functional status across various diseases. It assesses the impact of health conditions on patients' lives through 29 items covering multiple health dimensions, including physical health, mental health, social function. (page14, line14-18)]
[Additionally, the research findings by Sikorskii et al. (46) suggest that PROMIS 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. (page 15, line 7-12)]
[The six-month period following a stroke is recognized 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(47). By including caregivers in this assessment, we gain a holistic view of the healthcare experience. (page 15, line 23-24 and page 16, line 1-2)]
[According to a cross-sectional survey in China, the higher the level of self-regulatory fatigue, the poorer the self-control ability, and the lower the quality of life for each individual(17). (page 6, line 21-23)]

4. Comment “The information regarding the research aims on page 5 (lines 39–55) and that in the Research objectives section differ slightly, which may be confusing. Therefore, I suggest refining these parts or considering whether it is necessary to present the information about research aims in two separate places. I found it a little bit confusing and unclear.”
RE: Much appreciated your careful comment. We have made some modifications to this section.
[Therefore, this study will investigate the etiology and categorize the manifestations of self-regulatory fatigue (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 self-regulatory fatigue for family caregivers during the continuity of care process for stroke patients in the future. (page 7, line 24 and page 8, line 1-8)]

5. Comment “For the sentences: “Longitudinal phenomenological inquiry:...” – lines 43-44, and “Self-regulatory fatigue ....” (lines 39-41), please add appropriate references so that the readers would be able to find the source information supporting your sentences.”
RE: Much appreciated your careful comment and appropriate references have been added.
[This mixed-methods study employs a concurrent embedded design, comprising two primary components(39) (page 9, line 7-8)]
[Qualitative Component: Longitudinal phenomenological inquiry(40) (page 9, line 12-13)]
Reference 1. Wang Q, Xu C, He Z, Zou P, Yang J, Huang Y. An exploration of proactive health

oriented symptom patterns in patients undergoing percutaneous coronary intervention with stent implantation: A mixed-methods study protocol. PloS one. 2023;18(10):e0292285.
Reference 2. Lu Q, Mårtensson J, Zhao Y, Johansson L. Living on the edge: Family caregivers' experiences of caring for post-stroke family members in China: A qualitative study. International journal of nursing studies. 2019;94:1-8.

Reviewer: 3
1. Comment "The authors present a protocol for a mixed methods study of the trajectory of self-regulatory fatigue in family caregivers of stroke survivors over a 6-month period. They include a 'Good Reporting of a Mixed Methods Study' checklist; however, they should also include the 'Consolidated Criteria for Reporting Qualitative Research (COREQ)' checklist. "
RE: Thank you for your valuable feedback regarding the reporting standards for our mixed methods study on self-regulatory fatigue in family caregivers of stroke survivors. We appreciate your suggestion to include the COREQ checklist alongside our existing Good Reporting of a Mixed Methods Study checklist.
[The qualitative research section of this article will adhere to the Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist (Supplementary Material 2) designed to enhance the quality and transparency of qualitative research, particularly in the context of interviews and focus groups(37). (page 8, line 21-24 and page 9, line 1)]
Reference 1. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349-57.

2. Comment "Abstract – Methods and Analysis: The authors present the software packages used for analysis rather than the methods to be used for the analyses. This should be amended."
RE: Thanks for your suggestion. We have implemented modifications and enhancements to the data analysis methodology in accordance with your recommendations.
[Latent Class Growth Analysis (LCGA) will be employed to model the heterogeneous developmental trajectories of self-regulatory fatigue-related symptoms among family caregivers of stroke patients. Reflective thematic analysis (RTA) will be employed to analyze, organize, and summarize qualitative data, with the aim of identifying the experiences and management needs related to self-regulated fatigue among family caregivers during home care. (page 1, line 18-24)]

3. Commmet " The Introduction itself could be streamlined to focus more on outcomes for caregivers of stroke survivors rather than including general statements on the need for 'targeted interventions to address risk factors and enhance healthcare infrastructure for stroke treatment and rehabilitation'. What percentage of caregivers of stroke survivors have been found to experience self-regulatory fatigue? It would be better to have an idea of how widespread this aspect of caregiver burden is rather than incidence of stroke.
RE: Thank you for your insightful comment regarding the introduction. We appreciate your suggestion to streamline the focus toward outcomes specifically for caregivers of stroke survivors. In the revised introduction section, we have appropriately abbreviated the relevant descriptions of stroke and added pertinent descriptions. After a thorough review of the available literature, it appears that there is currently a lack of specific studies addressing the incidence of self-regulated fatigue. However, two cross-sectional surveys indicated that the average level of self-regulatory fatigue among family caregivers was moderate.
[Two studies emphasize 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). (page 5, line 4-9)]

[According to two surveys conducted in China, the average level of self-regulatory fatigue among family caregivers is classified as moderate(18, 19). (page 6, line 2-3)]

Reference 1. Greenwood N, Habibi R, Mackenzie A. Respite: carers' experiences and perceptions of respite at home. BMC geriatrics. 2012;12:42.

Reference 2. Haley WE, Roth DL, Hovater M, Clay OJ. Long-term impact of stroke on family caregiver well-being: a population-based case-control study. Neurology. 2015;84(13):1323-9.

Reference 3. Loh AZ, Tan JS, Zhang MW, Ho RC. The Global Prevalence of Anxiety and Depressive Symptoms Among Caregivers of Stroke Survivors. Journal of the American Medical Directors Association. 2017;18(2):111-6.

Reference 4. Byun E, Evans L, Sommers M, Tkacs N, Riegel B. Depressive symptoms in caregivers immediately after stroke. Topics in stroke rehabilitation. 2019;26(3):187-94.

Reference 5. Ling Qian JS, She Wangling, Liu Liujun. Analysis of Self-regulatory Fatigue Status and Influencing Factors in Parents of Children with Asthma. Journal of clinical nursing. 2024;23(4):6-10.

Reference 6. Xiang Jing CC. Analysis of the current status and influencing factors of self-regulatory fatigue in parents of premature infants. Modern Nurse. 2023;30(9):120-3.

Page 4, line 12: The authors state that: 'The interconnection between caregiver well-being and patient outcomes is evident in recent studies'. It would be useful to be explicit about the direction of the association in statements like these and being careful to avoid repetition.

RE: Much appreciated your valuable comment and have reviewed the literature to incorporate the statement into the introduction section of the revised version.

[The decline in the well-being of family caregivers is closely associated with the deteriorating health outcomes of the patients they care for. (page 5, line 9-11)]

Page 4, line 29: The sentence beginning with 'In conclusion' does not belong in the introduction section.

RE: Thank you for your comment regarding the sentence beginning with "In conclusion." We have made careful revisions to this section.

[This gap highlights the need for further research in understanding and fulfilling the needs of family caregivers is essential for enhancing the health of these caregivers and improving rehabilitation outcomes for stroke patients. (page 5, line 22-24)]

Page 4, line 39 and 52: The authors state that: 'Self-regulatory fatigue has emerged as a significant factor potentially compromising the health of family caregivers'. Has SRF been shown to be a significant factor or a potential factor?

RE: Thank you so much for your vigorous review. Based on your recommendations, we have revised the ambiguous statements pertaining to self-regulated fatigue.

[Self-regulatory fatigue has emerged as a potential factor compromising the health of family caregivers. (page 6 , line 1-2)]

Page 5, line 18: Does survey administration really encourage active engagement of caregivers and promote health literacy? If so, there should be a reference for each of these claims.

RE: Much appreciated your careful comment and more detailed statement about , We have

reviewed pertinent literature and incorporated more detailed explanations regarding the role of self-report tools in enhancing health literacy within the introduction section.
[Similar to the procedure health assessment in health literacy empowerment programs, 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, thereby improving their health literacy. (page 7, line 9-14]
Reference1. Lu F, Wong CKH, Ng APP, Li L, Fong DYT, Ip P, et al. Effectiveness of a 5-year health empowerment programme on promoting cardiovascular health for adults from low-income families in Hong Kong. Patient Educ Couns. 2024;124:108240.

Page 5, line 31: The study is described as documenting the trajectory of self-regulatory fatigue in caregivers of stroke survivors. If the goal is actually to develop an intervention to provide targeted guidance for caregivers, then this should be reflected in the title and the methodology.
RE: Thanks for your suggestion. The primary objective of our study is to delineate the trajectory of self-regulated fatigue among family caregivers. The findings may serve as a valuable reference for developing future management strategies for the long-term care of family caregivers following a stroke. We have made appropriate modifications to clarify any ambiguities in this section.
[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, ultimately improving their health literacy. (page 7, line 20-23)]

Page 5, line 47-55: Again, the authors list a number of objectives that are not reflected in the methodology.
RE: We sincerely appreciate your thorough and meticulous review. We have made appropriate modifications to clarify any ambiguities in this section.
[The findings from this research will provide a reference for the development of a comprehensive management plan addressing self-regulatory fatigue for family caregivers during the continuity of care process for stroke patients in the future. (page 8, line 5-6)]

Research objectives
The development of an intervention to provide targeted guidance for caregivers of stroke survivors is not listed as an objective. Therefore, this should be not listed as a goal of the study in the introduction. If there is a plan to develop an intervention that is informed by this mixed methods study, then that should be made explicit throughout and it should be included as a research objective.
RE: Thank you very much for your excellent opinion. The primary objective of our study is to delineate the trajectory of self-regulated fatigue among family caregivers. The findings may serve as a valuable reference for developing future management strategies for the long-term care of family caregivers following a stroke. We have made appropriate modifications to clarify any ambiguities in this section.
[(1) To investigate the etiology and categorize the manifestations of self-regulatory fatigue (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. (page 8, line 11-16)]

Methods and analysis – Study design
Page 7, line 11: The timeline for the entire study is from Nov 2024 to April 2025. This seems very optimistic and does not allow for any issues with recruitment or potential attrition of participants, let alone analysis of qualitative data, which the authors state will only occur once all data are collected.
RE: Thank you for your insightful feedback regarding the timeline of our study. We appreciate your concerns about the potential challenges related to participant recruitment, attrition, and the analysis of qualitative data. Based on your recommendation, we have appropriately extended the duration of the research.
[The entire study will last from November 2024 to August 2025. (page 9, line 19-20)]

Methods – settings and sample recruitment for quantitative data
It would be useful to have an idea of how many stroke survivors are treated annually across the two included institutions to give an idea of how feasible it will be to recruit and retain 200 participants.
RE: Thank you for your insightful comment regarding the recruitment and retention of participants in our study. We greatly appreciate your insights and have reviewed the literature to incorporate the description into the settings and sample recruitment for quantitative data section of the revised version. To address this concern, we gathered data on the annual stroke survivor population at all rehabilitation and neurology departments of three tertiary hospitals. The relevant statement has been added to the revised version of Settings and Sample Recruitment.
[Preliminary estimates suggest that, on average, the neurology department at each hospital admits approximately 4,000 patients annually, while the rehabilitation department admits about 400 patients per year. This patient volume provides a robust foundation for our recruitment efforts. (page 11, line 13-16)]

Is a statistician included in the research team?
RE: Thank you for your inquiry regarding the involvement of a statistician in our research team. We are pleased to confirm that a statistician is indeed part of our research team. The relevant information regarding the statisticians has been incorporated into the acknowledgments section of the revised manuscript.
[We would like to express my sincere gratitude to Dr. Xiao Qiao for her invaluable assistance in the statistical analysis of this study. E-mail: xq.hnit@gmail.com. Her expertise in mathematic (statistics) / epidemiology and biostatistics will greatly enhance the quality of our research. (page 24, line 22-24 and page25, line 1)]

Methods – data collection method
Will participants also be recruited from rehabilitation settings?
RE: Thank you for your thorough and meticulous review. The participants will be initially recruited in the ward, and subsequent follow-ups will be expected to be completed in rehabilitation settings. Following discharge, based on our prior consultations, the majority of stroke patients receiving treatment at these three hospitals initiate rehabilitation programs during their hospitalization and subsequently elect to attend the rehabilitation department of their original hospital for further rehabilitation. Therefore, the follow-up will be completed when the participates in rehabilitation in the rehabilitation department. We have taken your valuable

suggestion and supplemented this section.
[The participants will be initially recruited in the ward, and subsequent follow-ups will be expected to be completed in rehabilitation settings. (page 11, line 16-18)]

Methods – research instruments
Have the PROMIS-29 and SRF-S been validated in caregivers of stroke survivors? If so, it is important to include this information. If not, do the authors plan to validate these tools in their target population?
RE: Thank you for your insightful question regarding the validation of the PROMIS-29 and Self-Regulatory Fatigue Scale in caregivers of stroke survivors.
[Additionally, the research findings by Sikorskii et al. (46) suggest that PROMIS 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. (page 15, line 7-12)]
[The Chinese version of the SRF-S was translated and validated in young adults by Wang Li-Gang et al(48). Also validated in elderly maintenance hemodialysis patients and caregivers(17). (page 16, line 10-12)]

Again, there are some statements in the methods section that are better suited to the discussion. For example: 'This tool demonstrates strong reliability and validity, providing valuable health information that can assist healthcare providers and researchers in developing more effective treatment plans'.
RE: Thank you for your valuable feedback regarding the methods section of our manuscript. We have revised the methods section to ensure that it focuses solely on the procedural aspects of our study.
[The PROMIS-29 is a self-reported tool developed by the National Institutes of Health (NIH) to evaluate health-related quality of life (HRQoL) and functional status across various diseases. It assesses the impact of health conditions on patients' lives through 29 items covering multiple health dimensions, including physical health, mental health, social function. According to the validation study conducted by Evon et al. (43) on the Patient-Reported Outcomes Measurement Information System (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 randomized trial, Krohe et al. (44) 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. (45) , 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. (46) suggest that PROMIS 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. (page14, line

14-24 and page 15, line 1-12)]

Methods – data analysis
Why use two statistical software packages and not conduct all the analyses in R?
RE: Thank you for your question regarding the use of both IBM SPSS version 26.0 and R software packages for our analyses.
[IBM SPSS version 26.0 provides a user-friendly interface that facilitates straightforward data management and basic statistical analyses, making it particularly effective for initial exploratory analyses and descriptive statistics. While R version 4.2.1 excels in handling large datasets and implementing cutting-edge statistical methods. The use of both software packages for data analysis will allow us to capitalize on their complementary strengths, thereby enhancing the efficiency of our analytical processes. Additionally, employing both IBM SPSS version 26.0 and R version 4.2.1 facilitates cross-validation of results, which serves to strengthen the robustness of our findings. (page 16, line 18-24 and page 17, line 1-2)]

Methods – settings and sample recruitment for qualitative data
In recent years, there has been a move away from the notion of 'data saturation' and more of a focus on 'information power'. See https://doi.org/10.1177/1049732315617444
RE: Thank you for your insightful comment regarding the shift from the concept of "data saturation" to "information power." We appreciate your reference to the relevant literature, which highlights this evolving perspective in qualitative research.
[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(49). The size of a sample with adequate informational capacity is contingent upon the research objectives, the specificity of the sample, the application of established theories, the quality of dialogues, and the analytical strategies employed. (page 17, line 18-23)]
Reference 1. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2016;26(13):1753-60.

For the qualitative research methods, the COREQ checklist should be followed and adhered to during reporting.
RE: Thank you very much for your suggestion to include the COREQ checklist alongside our existing Good Reporting of a Mixed Methods Study checklist.
[The qualitative research section of this article will adhere to the Consolidated Criteria for Reporting Qualitative Studies (COREQ) checklist (Supplementary Material 2) designed to enhance the quality and transparency of qualitative research, particularly in the context of interviews and focus groups(37). (page 8, line 21-24 and page 9, line 1)]
Reference 1. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349-57.

Methods – qualitative data analysis
It would be good to have more details on the planned within-case analyses and the cross-case analyses of the longitudinal qualitative interviews.
RE: Thank you for your valuable feedback. Based on your suggestion, we have added detailed qualitative research data analysis methods to the data analysis section.
[The recorded interview content will be transcribed verbatim into written documents, and an

archive file will be established by CX and double checked by YH. 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. Reflective thematic analysis (RTA) will be employed to analyze, organize, and summarize the data, with the aim of identifying the experiences and management needs related to self-regulated fatigue among family caregivers during home care(50). The entire process was conducted under the guidance of three nursing PhD authors—PZ, XC, and YH—who possess extensive qualitative research experience in Reflexive Thematic Analysis (RTA) methods for analyzing qualitative data. All authors has completed at least four 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, YH, will organize 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:
Familiarization with the Data (step 1): CX, JY, SL, and ZH 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): CX, JY, SL, and ZH 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, CX, JY, SL, and ZH 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 finalize the definitions and names of the themes. Writing the Report (step 6): CX will be responsible for drafting the final section of the qualitative research report. (page 21, line 3-24 and page 22, line 1-10)]

Also, the authors state they will be analysing data with the aim of 'identifying the experiences and management needs related to self-regulated fatigue among family caregivers during home care'. However, on examining the interview guide, there are no questions explicitly asking the caregivers for their perspective on what would be useful for them to manage their self-regulatory fatigue symptoms (if they report having them).
RE: Thank you for your insightful feedback regarding the interview guide. We have considered your suggestion and have enhanced the interview outline accordingly.
[7. 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?"
8. 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?" (page 20, line 11- 19)]

Discussion
Page 17, line 22: The authors state that the principles of precision nursing are reflected in the

study. This is the first mention of this concept. If the design of the study is influenced by these principles, then that should be make clear and defined in the methods section. Same comment is relevant for line 29.
RE: Thank you for your valuable feedback regarding the mention of precision nursing in our study. We greatly appreciate your insights and have removed these descriptions from the revised version of the discussion.
[By focusing on individuals and their authentic feelings, the study enhances communication between family caregivers and nursing staff, thereby fostering social support for stroke patients. (page 23, line 8-10)]

Page 17, line 23: Again, what is the evidence to support the statement that partaking in a survey will encourage active engagement and health literacy?
RE: Thank you for your question regarding the evidence supporting the assertion that participation in a survey can encourage active engagement and enhance health literacy. Pertinent statements in the revised introduction section pertaining to this aspect have been incorporated.
[Similar to the procedure health assessment in health literacy empowerment programs, 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, thereby improving their health literacy. (page 7, line 9-14)]

VERSION 2 - REVIEW

Reviewer	**2**
Name	**Jaracz, Krystyna**
Affiliation	**Poznan University of Medical Sciences**
Date	**07-Dec-2024**
COI	

The authors addressed all my comments comprehensively. I have no more comments or questions.

Reviewer	**3**
Name	**Merriman, Niamh A.**
Affiliation	**University College Dublin, School of Public Health, Physiotherapy and Sports Science**
Date	**06-Jan-2025**
COI	

The authors present a protocol for a mixed methods study of the trajectory of self-regulatory fatigue in family caregivers of stroke survivors over a 6-month period and have put great effort into addressing the reviewers' comments. I have a few minor comments based on the authors' amended protocol.

Introduction

Page 7, line 43: The authors discuss the impact of self-report surveys on health literacy. Is it an objective of the study to increase health literacy among caregivers? How will this be measured? If not, recommend removing.

Methodology - Eligibility criteria for samples

Page 11, line 49: The authors state that history of psychiatric illness in caregivers will be identified through medical records review or through the Chinese Health Questionnaire (CHQ), however, in the Research Instruments section, the CHQ is not specifically mentioned. Will a bespoke instrument (Family Caregiver Demographic and Health Status Questionnaire) be used or will the CHQ be used?

Methodology – Research Instruments

Page 13, line 51: The authors provide many examples of the use of the PROMIS-29 across different patient populations, though not in caregivers or stroke survivors; however, my question remains - has the PROMIS-29 been validated in caregivers of stroke survivors? If so, it is important to include this information. If not, do the authors plan to validate these tools in their target population? Same question applies to the SRF questionnaire.

Page 14, line 45: The authors discuss the ease of use of the PROMIS 4-item form, but they are using the 29 item version. This is confusing for the reader.

Methodology – data analysis

Page 1, lines 19-37: The amount of detail around the justification for using two statistical software packages is overly long.

Patient and Public Involvement

Page 22, line 27: The authors state that they did not incorporate patient input into the relevance and acceptability of the intervention. This is not an intervention study.

Discussion

Page 23, line 13: The authors state that the study will enhance communication between family caregivers and nursing staff. Is this an objective of the study? How will this be measured?

VERSION 2 - AUTHOR RESPONSE

Reviewer: 2

1. Comment "The authors addressed all my comments comprehensively. I have no more

comments or questions."

RE: Thank you very much for your kind words and for taking the time to review our work. We are delighted to hear that we addressed all your comments comprehensively. Your feedback has been invaluable in enhancing the quality of our manuscript.

Reviewer: 3

1. Comment "Introduction - Page 7, line 43: The authors discuss the impact of self-report surveys on health literacy. Is it an objective of the study to increase health literacy among caregivers? How will this be measured? If not, recommend removing."

RE: Thank you for your insightful comment regarding the discussion of health literacy in our introduction. Following your valuable suggestion, we have removed the section pertaining to health literacy to improve the clarity and focus of our manuscript.

[Subjective report surveys are not only easy to administer and analyze, thereby saving time, but they also encourage the active engagement of family caregivers. Similar to the procedure health assessment in health literacy empowerment programs, 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 self-regulatory fatigue in the existing literature, and tools specifically designed to measure self-regulatory fatigue are not widely utilized[32, 34, 35]. This study will employ the Chinese version of the Self-Regulatory Fatigue Scale (SRF-S) and the Patient-Reported Outcome Measurement Information System (PROMIS). These tools will enable us to accurately identify self-regulatory fatigue 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. (page 7, line 7-21)]

[The quantitative component of the study utilizes self-report data collection, which encourages the active engagement of family caregivers and fosters their participation in maintaining the health of stroke patients. (page 22, line 14- 17)]

2. Comment "Methodology - Eligibility criteria for samples

Page 11, line 49: The authors state that history of psychiatric illness in caregivers will be identified through medical records review or through the Chinese Health Questionnaire (CHQ), however, in the Research Instruments section, the CHQ is not specifically mentioned. Will a bespoke instrument (Family Caregiver Demographic and Health Status Questionnaire) be used or will the CHQ be used?"

RE: Thank you for your thoughtful observation regarding the eligibility criteria and the instruments used in our study. We appreciate your attention to detail. The Chinese Health Questionnaire (CHQ) will indeed be utilized to assess the mental health status of caregivers. The description of the scale has been incorporated into the Research Instruments section for enhanced clarity and understanding.

[The CHQ-12 (Chinese Health Questionnaire) was meticulously developed by Cheng Tai'an, drawing upon the widely recognized GHQ-12 (General Health Questionnaire) used internationally[42]. GHQ-12 was originally developed by David Goldberg with the aim of assessing an individual's mental health status, particularly identifying potential mental health issues such as anxiety and depression[43]. Yang Tingzhong and others verified CHQ-12 in Chinese Mainland population, and Cronbach's alpha coefficient was 0.79[44]. (page 13, line 15-21)]

3. Comment "Methodology – Research Instruments

Page 13, line 51: The authors provide many examples of the use of the PROMIS-29 across different patient populations, though not in caregivers or stroke survivors; however, my question remains - has the PROMIS-29 been validated in caregivers of stroke survivors? If so, it is important to include this information. If not, do the authors plan to validate these tools in their target population? Same question applies to the SRF questionnaire."

RE: Thank you for your valuable feedback regarding the limited direct evidence indicating that the PROMIS-29 has been specifically validated for caregivers of stroke survivors. We appreciate your insights and we would like to explain to you that it can still be used in this population based on the following reasons:

1. *Strong Psychometric Properties*: The PROMIS-29 is a scale used to evaluate health-related quality of life. It has shown high reliability and validity across various populations, including caregivers of other health conditions [1,2].
2. *Relevance of Domains*: The domains assessed by the PROMIS-29— physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles, and pain intensity —are pertinent to the challenges faced by family caregivers [3-5]. This design allows the PROMIS-29 to be broadly applicable across diverse diseases and populations, ensuring its versatility and relevance in a wide range of clinical and research settings.
3. *Feasibility and Utility*: The PROMIS-29 is practical for clinical settings, offering quick assessments that can help identify caregiver needs.

Meanwhile, we are would like to outline the reasons why Self-Regulatory Fatigue Scale can be applied to family caregivers of stroke patients without the need for further validation.

1. *Universality and basic research of the scale*: SRF-S is a universally applicable tool, meticulously developed through a robust foundation of psychological theories and comprehensive empirical research. As a result, the scale's established theoretical universality negates the necessity for additional validation when applied to family caregivers of stroke patients.
2. *Cultural adaptability and previous verification*: The SRF-S scale has undergone cultural adaptation and translation, previous study have demonstrated that it possesses strong reliability and validity across patients with various chronic conditions, showing a high Cronbach's alpha coefficient (e.g. 0.84), indicating good internal consistency. This previous validation provides support for its application in new specific populations.

Reference:

1. Sikorskii A, Victorson D, O'Connor P, Hankin V, Safikhani A, Crane T, et al. PROMIS and legacy measures compared in a supportive care intervention for breast cancer patients and caregivers: Experience from a randomized trial. Psychooncology. 2018;27(9):2265-73.
2. Kent ML, Jannace K, Highland KB, Dimarzio M, Tran J, Gonzalez S, et al. Caregiver Patient Reported Outcomes Measurement Information System (PROMIS) profiles in patients undergoing total joint arthroplasty and spine surgery: a prospective observational cohort study. Reg Anesth Pain Med. 2019.
3. Hu P, Yang Q, Kong L, Hu L, Zeng L. Relationship between the anxiety/depression and care burden of the major caregiver of stroke patients. Medicine. 2018;97(40):e12638.
4. Em S, Bozkurt M, Caglayan M, Ceylan Cevik F, Kaya C, Oktayoglu P, et al. Psychological health of caregivers and association with functional status of stroke patients. Topics in stroke rehabilitation. 2017;24(5):323-9.
5. Pucciarelli G, Vellone E, Savini S, Simeone S, Ausili D, Alvaro R, et al. Roles of Changing Physical Function and Caregiver Burden on Quality of Life in Stroke: A Longitudinal Dyadic Analysis. Stroke. 2017;48(3):733-9.
6. WANG Li-Gang ZJ-Y, WANG Jia, TAO Ting, FAN Chun-Lei, GAO Wen-bin. Validity and reliability of the Chinese version of the Self-Regulatory Fatigue Scale in young adults. Chinese Mental Health Journal. 2015;29(04):290-4.
7. Ji X, Yu H. Factors Associated with Self-Regulatory Fatigue in Chinese Older Patients with Coronary Heart Disease: A Cross-Sectional Survey. Patient preference and adherence.

2023;17:941-9.
8. Wang L, Yu Y, Tao T, Zhang J, Gao W. The self-care dilemma of type 2 diabetic patients: The mechanism of self-regulation resource depletion. PloS one. 2018;13(12):e0208690.

4. Comment "Page 14, line 45: The authors discuss the ease of use of the PROMIS 4-item form, but they are using the 29 item version. This is confusing for the reader.
Methodology – data analysis"

RE: We sincerely appreciate your insightful feedback concerning the reference to the PROMIS-4 item form in connection with our utilization of the PROMIS-29. Your meticulous attention to detail is invaluable, and we recognize how this could potentially create confusion for our readers. Thank you for helping us enhance clarity in our work.

[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. (page 14, line 2-7)]

5. Comment "Page 1, lines 19-37: The amount of detail around the justification for using two statistical software packages is overly long."

RE: We appreciate your observation that the level of detail provided may be overly lengthy. To enhance clarity and conciseness, we have revised this section to streamline our justification while retaining the essential information that highlights the rationale behind our choice of software.

[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. (page 16, line 7-11)]

6. Comment "Patient and Public Involvement
Page 22, line 27: The authors state that they did not incorporate patient input into the relevance and acceptability of the intervention. This is not an intervention study."

RE: Thank you so much for your vigorous review. Based on your suggestion, we have made modifications to the Patient and Public Involvement section.

[However, we acknowledge the limitations of not incorporating patient input, particularly in ensuring the relevance and acceptability of the qualitative data collection. (page 21, line 23-24 and page 22, line 1)]

7. Comment "Discussion
Page 23, line 13: The authors state that the study will enhance communication between family caregivers and nursing staff. Is this an objective of the study? How will this be measured?"

RE: Much appreciated your careful comment. We have made some modifications to this section.

[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. (page 22, line 17-21)]