

# Development and initial validation of a clinical measure to assess symptoms of post-stroke depression in the sequelae stage

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## Article

**Keywords:** stroke patients, post-stroke depression, instrument development, Delphi method, sequelae stage

**Posted Date:** April 14th, 2026

**DOI:** <https://doi.org/10.21203/rs.3.rs-8863622/v1>

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**Additional Declarations:** No competing interests reported.

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## Abstract

## Background

The high incidence of post-stroke depression (PSD) in the sequelae stage seriously affects the prognosis of patients. Due to the lack of specific measurements, it hasn't been effectively identified and intervened. This study aimed to develop a specific measure to assess symptoms of PSD in the sequelae stage.

## Methods

The initial item pool was obtained through literature review, semi-structured interviews of stroke patients, and group discussions. Following a survey of healthcare professional, Delphi expert consultation, and a patient pre-survey, the items were evaluated and screened.

## Results

The initial item pool included 50 items with 8 dimensions. The initial items pool was then screened through the evaluation of three panels of healthcare professionals (N = 30), experts (N = 18), and stroke patients in the sequelae stage (N = 30). After healthcare professional panel evaluation, 45 items were retained for Delphi expert panel evaluation. After two Delphi rounds, the item-level content validity index (I-CVI) of all items greater than 0.78, and the scale-level CVI /average was 0.941. A clinical measure for PSD in the sequelae stage with 8 dimensions (motivation, emotion, cognition, behavior, somatization, sleep, helplessness and guilt) and 33 items was formed. The participants panel didn't modify the items.

## Conclusion

This study developed a specific screening tool with good content validity to assess the symptoms of PSD in the sequelae stage.

### 1. Introduction

Globally, stroke ranks as the second leading cause of mortality and the foremost driver of long-term disability. The condition is defined by a constellation of five challenges: high rates of incidence, morbidity, mortality, and recurrence, alongside a staggering economic impact [1]. Despite therapeutic breakthroughs that have enhanced survival outcomes, survivors remain burdened by profound sequelae, among which depression represents a critical clinical concern. The life space of these stroke patients is primarily confined to the home environment, characterized by shrinking social networks and diminished participation in social activities, both of which may heighten the risk of depression [2]. Post-stroke depression (PSD) is a common complication after stroke. About one-third of stroke patients suffer from PSD at different stages after stroke [3, 4], among which PSD in the sequelae stage deserves special attention. PSD in sequelae stage refers to depression occurring 6 months after stroke [5]. Unlike PSD in the early and rehabilitation stage, PSD in the sequelae stage is more likely related to psychosocial function and cognitive dysfunction of stroke patients [6], which mainly manifested as insomnia, more irritable than usual and difficult to recover, and easy to fatigue [7]. Stroke patients in the sequelae stage frequently present with multiple comorbidities, which leads to a more protracted rehabilitation process and a lower degree of functional recovery. This, in turn, further intensifies the physical and psychological burden on these individuals. PSD in the sequelae stage brings serious mental and physical disorders to patients, greatly affects patients' prognosis and quality of life, and increases mortality and disability rates at the same time [7–9]. Firstly, the sequelae stage PSD may worsen the patient's cognitive and physical function [10, 11]. Secondly, PSD in the sequelae stage will significantly reduce the patient's willingness to actively recover, or even resist recovery, thereby affecting the patient's functional recovery in terms of language, movement, and walking. This makes it difficult for patients to return to work and society [12, 13]. Finally, compared to patients without PSD, patients with PSD in the sequelae stage were 1.6–1.9 times more likely to die, 2.2 times more likely to have long-term disability, and had an increased incidence of suicidal ideation [11]. Therefore, PSD in the sequelae stage urgently needs the attention of clinical medical workers. However, the sequelae stage PSD has not been currently identified and managed in a timely manner, which is related to the lack of the specific screening tools for sequelae stage PSD. This study tried to develop a specific screening tool for PSD in the sequelae stage, which aimed to provide an effective screening tool for medical staff and patients and to improve the detection rate of PSD in the sequelae stage.

### 2 Background

The tools currently used for PSD assessment in the sequelae stage fall into three main categories: mental disease diagnostic systems, ordinary depression rating scales and specific PSD screening scale.

## 2.1 The mental disease diagnostic systems

There are three main types of mental disease diagnostic systems for diagnosing PSD in the sequelae stage: Diagnostic and Statistical Manual of Mental Disorders-V (DSM-V), International Classification of diseases-10 (ICD-10) and Chinese Classification and Diagnostic Criteria of Mental Disorders-3 (CCMD-3). These diagnostic systems have certain deficiencies for screening the sequelae stage PSD: 1) DSM-V, ICD-10 and CCMD-3 don't clearly define the concept and diagnostic criteria of PSD [14]. 2) The above three diagnostic systems only have a severe depression rating, and the patient needs to use drug intervention as soon as the diagnosis is made, missing the best time for non-pharmacological intervention. 3) Attributions and symptoms of PSD and functional depression are different [15]. Therefore, the use of diagnostic criteria for functional depression to classify and diagnose PSD isn't applicable [15]. 4) It needs to be applied by a professional doctor, which limits the application of nursing staff [16].

## 2.2 The ordinary depression rating scales

The ordinary depression screening scale used for screening PSD in the sequelae stage is divided into examiner-rating scale and self-rating scale. The examiner-rating scale includes the Hamilton depression Rating Scale (HAMD) and the Montgomery and Asberg Depression Rating Scale (MADRS). The self-rating scale includes the Beck Depression Inventory-II (BDI-II), the Patient Health Questionnaire-9 (PHQ-9), the Zung Self-rating Depression Scale (SDS), the Center for Epidemiological Studies Depression Scale (CES-D), the Hospital Anxiety and Depression Scale (HADS) and the Geriatric Depression Scale (GDS). Though they were widely used in the stroke patients, none of the them are the best tools for screening PSD in the sequelae stage for the following reasons: 1) The above scales were not designed for PSD and therefore lack PSD-specific items [17–19], resulting in a lack of sensitivity. When these scales are used to screen for PSD in the sequelae stage, the reliability and validity of them need to be further confirmed [20–22]. 2) Some scales need to be assessed by professional raters, which greatly limits the widespread use of scales.

## 2.3 The specific PSD screening scale

The specific PSD screening scales used for screening PSD in sequelae stage mainly include: The Post-Stroke Depression Rating Scale (PSDRS) and Post-Stroke Depression Scale (PSDS). The above scales also have certain limitations in screening for PSD in the sequelae stage: 1) The PSDRS scale does not give an overall score, so it is unable to assess and classify the severity of PSD. Besides, its screening results are greatly affected by age [15]. 2) The PSDS has not verified its effectiveness in a large sample, and its reliability and validity need further evaluation [23].

To sum up, although there are many instruments for screening PSD in the sequelae stage, they all have certain limitations. Therefore, this study tried to develop a specific screening tool for PSD in sequelae stage by series of phases, such as building up conceptual framework, establishing the item pool, healthcare professional panel evaluation, Delphi expert panel evaluation and stroke patient panel evaluation. Such a development represents a critical clinical imperative within the landscape of stroke recovery.

## 3 Methods

### 3.1 Instrument development phase 1: Building up conceptual framework

The theory of learned helplessness was used as the theoretical basis for tool development. This theory was developed by Seligman in the 1960s [24, 25]. Learned helplessness is when people display cognitive, motivational, and emotional deficits after experiencing an event beyond their control [26]. Abramson et al. supplemented the original theory by adding explanatory style as a mediator between events and symptoms of helplessness (Fig. 1) [27]. Explanatory styles are divided into optimistic explanatory style and pessimistic explanatory style. Those with a pessimistic explanatory style tend to become depressed [26]. For stroke patients in the sequelae stage, rehabilitation treatment has not significantly improved their function and the rehabilitation result and future life are uncontrollable events for the patient, which will prompt the stroke patients to use pessimistic explanatory style. Symptoms of helplessness occur when a stroke patient who has a pessimistic explanatory style. Based on the theoretical basis of this study, the research group built up a conceptual framework combining the helpless symptoms in the theory of learned helplessness and the clinical manifestations of PSD patients in the sequelae stage. In the conceptual framework, taking stroke as a stimulating event, and constructing the items of the sequelae stage PSD screening tool from six dimensions of motivation, emotion, cognition, behavior, somatization and sleep (Fig. 2).

### 3.2 Instrument development phase 2: Establishment of the initial item pool

Based on the theory of learned helplessness, this study constructed an initial item pool of the PSD screening tool in the sequelae stage through literature review, semi-structured interviews, and group discussions. The literature review was performed by searching PubMed, Web of Science, Cochrane, CNKI and WanFang Database. The search terms were stroke, post-stroke depression, scale, measurement, etc. The semi-structured interviews were conducted on post-stroke patients with PHQ-9  $\geq 5$  in the sequelae stage. The interview outline are as follows: 1) What are your thoughts on the current environment? 2) Do you currently have a rehabilitation program? Can you elaborate on your recovery plan? 3) Please talk about the impact of stroke on your life. 4) How does your family treat you? 5) Please talk about your recent emotional changes. Do you feel down, when and why? 6) How is your sleep? 7) Under what circumstances do you feel tense and anxious? 8) Are you satisfied with your current state? Why? 9) Do you still have confidence in recovery? Specifically in what aspects? The interview location is in the doctor's office, the surrounding environment is quiet during the interview, and the interview time is 25–30 minutes. After the researcher explained the purpose to the patient and obtained consent, the interview was started and the whole process was recorded. Interview recordings and notes were transcribed within the day and analyzed using the Colaizzi seven-step analysis method [28]. The item was formed through the discussion of the results of the literature review and semi-structured interviews by the research group.

### **3.3 Instrument development phase 3: Healthcare professional panel evaluation**

Healthcare professionals in stroke rehabilitation units who had primary professional titles or above, worked for 3 years or more, were proficient in the treatment and nursing of stroke patients, and voluntarily participated were included in the panel. Healthcare professionals who met the criteria were recruited, and questionnaires were distributed and collected on the spot. Healthcare professionals independently rated the commonness of symptoms in the initial item pool based on their clinical experience. Each item was sorted according to 5 levels of “very common”, “common”, “uncommon”, “very uncommon”, and “unfamiliar with this item”. In this phase, the items considered very common and common by more than 50% of healthcare professionals are reserved [29].

### **3.4 Instrument development phase 4: Delphi expert panel evaluation**

#### **3.4.1 Expert Inclusion Criteria**

At this phase, experts with a bachelor's degree or above, work experience in related fields, and professional and technical titles above associate senior level are selected. In the end, 18 experts who volunteered to participate in the research were included in the first Delphi round, and 15 experts were included in the second Delphi round.

#### **3.4.2 Delphi expert panel evaluation questionnaire**

According to the results of healthcare professional panel evaluation, the expert consultation form is designed, which included 4 parts: 1) questionnaire guidance; 2) demographic of experts; 3) consultation questionnaire: experts rate items according to their importance; 4) the expert authority evaluation form. The research members explained the purpose and significance of the research to the experts and obtained their consent before consultation. The expert consultation forms were emailed to each expert. And they were asked to respond within two weeks. The second round consultation form was based on the results of the first round expert opinions. And related items were modified, deleted, and supplemented.

#### **3.4.3 The Delphi consultation indicators**

The indicators of Delphi consultation adopted in this study are as follows: 1) Initiative coefficient: the initiative coefficient of experts is expressed by the response rate of experts, and it is generally considered that the effect of Delphi consultation is good if the initiative coefficient reaches 70% or above [30]. 2) Authority coefficient (Cr): The Cr of experts is mainly determined by the experts' familiarity with the topic (Cs) and the judgment basis (Ca) of the experts' self-assessment. Cr is calculated as  $(Cs + Ca)/2$ . The experts' familiarity with the topic is divided into very familiar, familiar, general, unfamiliar, and very unfamiliar, with assignments of 1.0, 0.8, 0.6, 0.4, 0.2 respectively. Ca is calculated by theoretical analysis, practical experience, learned from peers and intuitive feeling (Table 1).  $Cr \geq 0.7$  is considered acceptable [29]. 3) Coordination coefficient: the coordination coefficient refers to the degree of consensus among experts, and is described by Kendall's W. The Kendall's W value is between 0 and 1, with larger values indicating greater consensus among experts. When there are more than 7 evaluation items, the criterion is whether the significance level is reached [31]. 4) The concentration of the experts' opinion: the mean score, full score ratio, and coefficient of variation (CV) are used to describe the concentration of expert opinion and also item inclusion indicators. The higher the mean score, the higher the importance of the corresponding indicator. The full score ratio is the ratio of the number of experts who give full marks to the item and the total number of experts. The full score ratio ranges from 0 to 1. The larger the value, the more people who give full scores, and the more important the indicator is. The smaller the CV value, the higher the concentration of expert opinions [32]. The expert opinion can be considered to be in agreement with  $CV \leq 0.20$  [33]. The item inclusion

criteria was:  $CV \leq 0.2$ , mean score  $\geq 4$  and full score ratio  $\geq 0.5$ . Notably, some items might be retained according to expert opinions. 5) Content validity: the content validity index includes the item-level content validity index (I-CVI) and the scale-level content validity index (S-CVI). When the number of experts exceeds 6, the I-CVI should be greater than 0.78 [34]. This study used the scale content validity index average (S-CVI/Ave) to represent the S-CVI. S-CVI/Ave is the mean of all items I-CVI of the scale. The S-CVI/Ave reaching 0.90 indicates good content validity [35].

Table 1  
Calculated expert judgement used in authority coefficient

| Judgement based on   | Impact on experts' evaluation |          |     |
|----------------------|-------------------------------|----------|-----|
|                      | High                          | Moderate | Low |
| Practical experience | 0.5                           | 0.4      | 0.3 |
| Theoretical analysis | 0.3                           | 0.2      | 0.1 |
| Learned from peers   | 0.1                           | 0.1      | 0.1 |
| Intuitive feeling    | 0.1                           | 0.1      | 0.1 |
| Total                | 1.0                           | 0.8      | 0.6 |

### 3.5 Instrument development phase 5: Stroke patient panel evaluation

A total of 30 participants with stroke in the sequelae stage were included through purposeful sampling to evaluate the items. Inclusion criteria of participants: 1) who diagnosed with stroke and meet CT and MRI diagnostic criteria; 2) who have stable vital signs and clear consciousness; 3) who were more than 6 months after stroke; 4) who are able to communicate in writing or language and give informed consent. The exclusion criteria were participants: 1) with subarachnoid hemorrhage; 2) with severe heart, liver, renal insufficiency, respiratory failure, malignant tumor and other major diseases; 3) with cognitive dysfunction.

### 3.6 Statistical Analysis

SPSS24.0 was used for data analysis. Descriptive statistics, such as frequency and percentage, mean and standard deviation (SD) were used to describe the results of healthcare professional panel and stroke patient panel evaluation, initiative coefficient, Cr, full score ratio, CV, content validity, and general information of healthcare professionals, experts and participants. Using Kendall's W test to calculate coordination coefficient.

## 4 Result

### 4.1 Establishment of the initial item pool

The initial item pool included 50 items which were divided into 8 dimensions: motivation, emotion, cognition, behavior, somatization, sleep, helplessness and guilt. Of the 50 items in the pool, 7 items were obtained through the literature; 29 were obtained from the existing depression scales, such as the DSM-V, HAMD, SDS, CES-D, GDS, MADRS, BDI-II, HADS, and PHQ-9; 14 items were obtained from semi-structured interviews. Of the 8 dimensions, 2 of them (helplessness and guilt) were obtained from the semi-structured interviews.

### 4.2 Healthcare professional evaluation

Thirty healthcare professionals participated in this phase, including 20 nurses, 8 doctors, and 2 rehabilitation specialists. Among them, 15 have primary titles, 14 have intermediate titles, and 1 have senior titles. Their working years ranged from 3–30 years. After the healthcare professional evaluation, a total of 5 items were deleted, and 45 items were finally obtained. There were 44 items that were considered very common + common  $\geq 50\%$  by healthcare professionals, all of which were reserved. Six items did not meet the inclusion criteria. Among them, 5 items from the ordinary depression rating scales were finally deleted after discussion by the research group. One of them was retained, namely item 29 (Table 2). Since this item was derived from semi-structured interviews with participants, it was reserved for Delphi expert consultation.

Table 2  
Development and initial validation of post-stroke depression measure for the sequelae stage patients

| Phase 1: Literature review                                                                                                        |              |                        |    | Phase 2:<br>Healthcare<br>professional<br>evaluation | Phase 3: Delphi expert panel evaluation |              |                        |              |           |                   |      | Selected<br>tems |      |          |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------|------------------------|----|------------------------------------------------------|-----------------------------------------|--------------|------------------------|--------------|-----------|-------------------|------|------------------|------|----------|
|                                                                                                                                   |              |                        |    |                                                      | First round                             |              |                        | Second round |           |                   |      |                  |      |          |
| Sum of very<br>common and<br>common (%)                                                                                           | M<br>±<br>SD | Full<br>score<br>ratio | CV |                                                      | I-CVI                                   | M<br>±<br>SD | Full<br>score<br>ratio | CV           | I-<br>CVI |                   |      |                  |      |          |
| Domain and items                                                                                                                  |              |                        |    |                                                      |                                         |              |                        |              |           |                   |      |                  |      |          |
| Motivation                                                                                                                        |              |                        |    |                                                      |                                         |              |                        |              |           |                   |      |                  |      |          |
| 1. I don't do things on my own initiative. (revised to "I don't want to take the initiative to do things." after the first round) |              |                        |    | 86.67                                                | 4.33 ± 0.77                             |              | 0.50                   | 0.18         | 0.83      | 4.80<br>±<br>0.56 | 0.87 | 0.12             | 0.93 | Selected |
| 2. I don't want to go out.                                                                                                        |              |                        |    | 66.67                                                | 4.17 ± 0.79                             |              | 0.39                   | 0.19         | 0.78      | 4.73<br>±<br>0.70 | 0.87 | 0.15             | 0.87 | Selected |
| 3. I don't want to try new things. <sup>b</sup>                                                                                   |              |                        |    | 80.00                                                | 3.94 ± 1.05                             |              | 0.39                   | 0.27         | 0.67      |                   |      |                  |      | Deleted  |
| 4. I don't think I can go back to work. <sup>b</sup>                                                                              |              |                        |    | 76.67                                                | 4.00 ± 0.26                             |              | 0.39                   | 0.26         | 0.72      |                   |      |                  |      | Deleted  |
| Emotion                                                                                                                           |              |                        |    |                                                      |                                         |              |                        |              |           |                   |      |                  |      |          |
| 5. I feel down.                                                                                                                   |              |                        |    | 90.00                                                | 4.83 ± 0.38                             |              | 0.83                   | 0.08         | 1.00      | 5.00<br>±<br>0.00 | 1.00 | 0.00             | 1.00 | Selected |
| 6. I feel hopeless.<br>(revised to "I feel hopeless in life."<br>after the first round)                                           |              |                        |    | 66.67                                                | 4.89 ± 0.32                             |              | 0.89                   | 0.07         | 1.00      | 5.00<br>±<br>0.00 | 1.00 | 0.00             | 1.00 | Selected |
| 7. I think I'm so useless.<br>(moved to guilt dimension after the<br>first round)                                                 |              |                        |    | 70.00                                                | 4.50 ± 0.86                             |              | 0.67                   | 0.19         | 0.89      | 4.93<br>±<br>0.26 | 0.93 | 0.05             | 1.00 | Selected |
| 8. I think life is meaningless. <sup>a</sup>                                                                                      |              |                        |    | 46.67                                                |                                         |              |                        |              |           |                   |      |                  |      | Deleted  |
| 9. I worry about little things. <sup>b</sup>                                                                                      |              |                        |    | 73.33                                                | 4.00 ± 1.07                             |              | 0.39                   | 0.27         | 0.67      |                   |      |                  |      | Deleted  |
| 10. I am not satisfied with my<br>current life. <sup>b</sup>                                                                      |              |                        |    | 86.67                                                | 4.00 ± 0.14                             |              | 0.39                   | 0.28         | 0.78      |                   |      |                  |      | Deleted  |
| 11. I feel isolated.<br>(moved to helplessness dimension<br>after the first round)                                                |              |                        |    | 70.00                                                | 4.22 ± 1.06                             |              | 0.56                   | 0.25         | 0.78      | 4.87<br>±<br>0.51 | 0.93 | 0.11             | 0.93 | Selected |
| 12. I feel anxious.                                                                                                               |              |                        |    | 90.00                                                | 4.67 ± 0.59                             |              | 0.72                   | 0.13         | 0.94      | 4.73<br>±<br>0.59 | 0.80 | 0.13             | 0.93 | Selected |
| 13. I feel irritable. <sup>b</sup>                                                                                                |              |                        |    | 60.00                                                | 4.11 ± 1.18                             |              | 0.50                   | 0.29         | 0.78      |                   |      |                  |      | Deleted  |
| I worry about the future.                                                                                                         |              |                        |    |                                                      |                                         |              |                        |              |           | 4.27<br>±<br>0.70 | 0.40 | 0.16             | 0.87 | Selected |
| 14. I lose interest in things around<br>me.                                                                                       |              |                        |    | 70.00                                                | 4.72 ± 0.46                             |              | 0.72                   | 0.10         | 1.00      | 4.93<br>±<br>0.26 | 0.93 | 0.05             | 1.00 | Selected |

Numbers in italics indicate unqualified index. Wording in italics indicate item is new. Mandarin to English translation preserves original Mandarin phrasing. <sup>a</sup> Indicates items deleted after the healthcare professional evaluation. <sup>b</sup> Indicates items deleted after the first round of Delphi. <sup>c</sup> Indicates items deleted after the second round of Delphi.

| Phase 1: Literature review                                                                                                                                                                                                                                                                                                                                                                    |              |                        |    | Phase 2:<br>Healthcare<br>professional<br>evaluation | Phase 3: Delphi expert panel evaluation |                        |      |              |                   |      |      | Selected<br>tems |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------------|----|------------------------------------------------------|-----------------------------------------|------------------------|------|--------------|-------------------|------|------|------------------|----------|
|                                                                                                                                                                                                                                                                                                                                                                                               |              |                        |    |                                                      | First round                             |                        |      | Second round |                   |      |      |                  |          |
| Sum of very<br>common and<br>common (%)                                                                                                                                                                                                                                                                                                                                                       | M<br>±<br>SD | Full<br>score<br>ratio | CV | I-CVI                                                | M<br>±<br>SD                            | Full<br>score<br>ratio | CV   | I-<br>CVI    |                   |      |      |                  |          |
| (moved to motivation dimension after the first round)                                                                                                                                                                                                                                                                                                                                         |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| (revised to “I lost interest in things that I used to be interested in.” after the second round)                                                                                                                                                                                                                                                                                              |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| 15. I want to cry.                                                                                                                                                                                                                                                                                                                                                                            |              |                        |    | 53.33                                                | 4.44 ± 0.98                             | 0.61                   | 0.22 | 0.94         | 4.67<br>±<br>0.62 | 0.73 | 0.13 | 0.93             | Selected |
| (moved to behavior and revised to “I cry or want to cry e” after the first round)                                                                                                                                                                                                                                                                                                             |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| <i>I can hardly be happy.</i>                                                                                                                                                                                                                                                                                                                                                                 |              |                        |    |                                                      |                                         |                        |      |              | 4.67<br>±<br>0.62 | 0.73 | 0.13 | 0.93             | Selected |
| Cognition                                                                                                                                                                                                                                                                                                                                                                                     |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| 16. My memory has deteriorated.                                                                                                                                                                                                                                                                                                                                                               |              |                        |    | 96.67                                                | 4.50 ± 0.71                             | 0.61                   | 0.16 | 0.89         | 4.60<br>±<br>0.63 | 0.67 | 0.14 | 0.93             | Selected |
| 17. My ability to think about problems has declined.                                                                                                                                                                                                                                                                                                                                          |              |                        |    | 93.33                                                | 4.50 ± 0.71                             | 0.61                   | 0.16 | 0.89         | 4.67<br>±<br>0.90 | 0.87 | 0.19 | 0.87             | Selected |
| 18. I can’t express my thoughts <sup>c</sup>                                                                                                                                                                                                                                                                                                                                                  |              |                        |    | 80.00                                                | 4.28 ± 0.89                             | 0.50                   | 0.21 | 0.83         | 4.20<br>±<br>1.15 | 0.53 | 0.27 | 0.80             | Deleted  |
| (revised to “I can’t express my thoughts properly.” after the first round)                                                                                                                                                                                                                                                                                                                    |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| 19. My mind has become dull.                                                                                                                                                                                                                                                                                                                                                                  |              |                        |    | 90.00                                                | 4.44 ± 0.62                             | 0.50                   | 0.14 | 0.94         | 4.67<br>±<br>0.49 | 0.67 | 0.10 | 1.00             | Selected |
| 20. I have a hard time concentrating. <sup>b</sup>                                                                                                                                                                                                                                                                                                                                            |              |                        |    | 80.00                                                | 4.28 ± 0.96                             | 0.50                   | 0.22 | 0.89         |                   |      |      |                  | Deleted  |
| 21. I see myself as a failure. <sup>a</sup>                                                                                                                                                                                                                                                                                                                                                   |              |                        |    | 40.00                                                |                                         |                        |      |              |                   |      |      |                  | Deleted  |
| 22. I became hesitant to make decisions. <sup>b</sup>                                                                                                                                                                                                                                                                                                                                         |              |                        |    | 66.67                                                | 3.89 ± 1.02                             | 0.28                   | 0.26 | 0.78         |                   |      |      |                  | Deleted  |
| Behavior                                                                                                                                                                                                                                                                                                                                                                                      |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| 23. I like being alone. <sup>a</sup>                                                                                                                                                                                                                                                                                                                                                          |              |                        |    | 46.67                                                | Deleted                                 |                        |      |              |                   |      |      |                  |          |
| 24. I will cry. <sup>a</sup>                                                                                                                                                                                                                                                                                                                                                                  |              |                        |    | 30.00                                                | Deleted                                 |                        |      |              |                   |      |      |                  |          |
| 25. I am very concerned about my health. <sup>c</sup>                                                                                                                                                                                                                                                                                                                                         |              |                        |    | 73.33                                                | 3.83 ± 1.34                             | 0.44                   | 0.35 | 0.67         | 4.27<br>±<br>0.96 | 0.53 | 0.23 | 0.80             | Deleted  |
| (revised to “I was overly concerned with my health.” after the first round)                                                                                                                                                                                                                                                                                                                   |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| 26. I don’t like to communicate with people.                                                                                                                                                                                                                                                                                                                                                  |              |                        |    | 66.67                                                | 4.33 ± 0.91                             | 0.61                   | 0.21 | 0.72         | 4.87<br>±<br>0.35 | 0.87 | 0.07 | 1.00             | Selected |
| (moved to motivation and revised to “I don’t want to communicate                                                                                                                                                                                                                                                                                                                              |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| Numbers in italics indicate unqualified index. Wording in italics indicate item is new. Mandarin to English translation preserves original Mandarin phrasing. <sup>a</sup> Indicates items deleted after the healthcare professional evaluation. <sup>b</sup> Indicates items deleted after the first round of Delphi. <sup>c</sup> Indicates items deleted after the second round of Delphi. |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |

| Phase 1: Literature review                                                                                                              |              |                        |    | Phase 2:<br>Healthcare<br>professional<br>evaluation | Phase 3: Delphi expert panel evaluation |                        |      |              |                   |      | Selected<br>tems |      |          |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------------|----|------------------------------------------------------|-----------------------------------------|------------------------|------|--------------|-------------------|------|------------------|------|----------|
|                                                                                                                                         |              |                        |    |                                                      | First round                             |                        |      | Second round |                   |      |                  |      |          |
| Sum of very<br>common and<br>common (%)                                                                                                 | M<br>±<br>SD | Full<br>score<br>ratio | CV | I-CVI                                                | M<br>±<br>SD                            | Full<br>score<br>ratio | CV   | I-<br>CVI    |                   |      |                  |      |          |
| with people” after the first round)                                                                                                     |              |                        |    |                                                      |                                         |                        |      |              |                   |      |                  |      |          |
| 27. I blame myself. <sup>a</sup>                                                                                                        |              |                        |    | 26.67                                                |                                         |                        |      |              |                   |      | Deleted          |      |          |
| 28. I have fewer social activities.                                                                                                     |              |                        |    | 66.67                                                | 4.33 ± 0.77                             | 0.50                   | 0.18 | 0.83         | 4.67<br>±<br>0.72 | 0.80 | 0.16             | 0.87 | Selected |
| 29. I have cut down on recovery time. (revised to “I have reduced recovery time than usual.” after the first round) <sup>c</sup>        |              |                        |    | 30.00                                                | 3.89 ± 0.90                             | 0.28                   | 0.24 | 0.67         | 4.07<br>±<br>0.88 | 0.40 | 0.22             | 0.67 | Deleted  |
| I think a lot.                                                                                                                          |              |                        |    |                                                      |                                         |                        |      |              | 4.13<br>±<br>1.06 | 0.47 | 0.26             | 0.80 | Selected |
| Somatization                                                                                                                            |              |                        |    |                                                      |                                         |                        |      |              |                   |      |                  |      |          |
| 30. I feel tired.                                                                                                                       |              |                        |    | 86.67                                                | 4.72 ± 0.57                             | 0.78                   | 0.12 | 0.94         | 4.73<br>±<br>0.59 | 0.80 | 0.13             | 0.93 | Selected |
| 31. I eat less than usual. <sup>c</sup>                                                                                                 |              |                        |    | 66.67                                                | 4.17 ± 0.86                             | 0.44                   | 0.21 | 0.72         | 3.93<br>±<br>1.28 | 0.47 | 0.33             | 0.67 | Deleted  |
| 32. I find it difficult to complete daily activities. (revised to “I find it difficult to manage everyday life.” after the first round) |              |                        |    | 83.33                                                | 4.44 ± 0.70                             | 0.56                   | 0.16 | 0.89         | 4.87<br>±<br>0.35 | 0.87 | 0.07             | 1.00 | Selected |
| 33. I am not satisfied with my current physical condition.                                                                              |              |                        |    | 96.67                                                | 4.22 ± 1.06                             | 0.50                   | 0.25 | 0.83         | 4.87<br>±<br>0.49 | 0.67 | 0.10             | 1.00 | Selected |
| Sleep                                                                                                                                   |              |                        |    |                                                      |                                         |                        |      |              |                   |      |                  |      |          |
| 34. I woke up in the middle of the night.                                                                                               |              |                        |    | 73.33                                                | 4.72 ± 0.57                             | 0.78                   | 0.12 | 0.94         | 4.80<br>±<br>0.56 | 0.87 | 0.12             | 0.93 | Selected |
| 35. I don’t fall asleep easily.                                                                                                         |              |                        |    | 83.33                                                | 4.61 ± 0.61                             | 0.67                   | 0.13 | 0.94         | 4.73<br>±<br>0.59 | 0.80 | 0.13             | 0.93 | Selected |
| 36. I have trouble falling asleep after waking up in the middle of the night.                                                           |              |                        |    | 80.00                                                | 4.61 ± 0.50                             | 0.61                   | 0.11 | 1.00         | 4.80<br>±<br>0.56 | 0.87 | 0.12             | 0.93 | Selected |
| 37. I get less sleep.                                                                                                                   |              |                        |    | 76.67                                                | 4.44 ± 0.86                             | 0.61                   | 0.20 | 0.89         | 4.67<br>±<br>0.72 | 0.80 | 0.16             | 0.87 | Selected |
| 38. I think a lot when I can’t sleep.                                                                                                   |              |                        |    | 80.00                                                | 3.83 ± 1.38                             | 0.44                   | 0.36 | 0.67         |                   |      |                  |      | Deleted  |
| I have a lot of dreams at night. (revised to “I dream a lot while I sleep.” after the second round)                                     |              |                        |    |                                                      |                                         |                        |      |              | 4.53<br>±<br>0.64 | 0.60 | 0.14             | 0.93 | Selected |
| Helplessness                                                                                                                            |              |                        |    |                                                      |                                         |                        |      |              |                   |      |                  |      |          |
| 39. I think the recovery effect is much lower than I expected.                                                                          |              |                        |    | 70.00                                                | 4.44 ± 0.78                             | 0.61                   | 0.18 | 0.83         | 4.80<br>±         | 0.87 | 0.12             | 0.93 | Selected |

Numbers in italics indicate unqualified index. Wording in italics indicate item is new. Mandarin to English translation preserves original Mandarin phrasing. <sup>a</sup> Indicates items deleted after the healthcare professional evaluation. <sup>b</sup> Indicates items deleted after the first round of Delphi. <sup>c</sup> Indicates items deleted after the second round of Delphi.

| Phase 1: Literature review                                                                                                                                                                                                                                                                                                                                                                    |              |                        |    | Phase 2:<br>Healthcare<br>professional<br>evaluation | Phase 3: Delphi expert panel evaluation |                        |      |              |                   |      |      | Selected<br>tems |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------------|----|------------------------------------------------------|-----------------------------------------|------------------------|------|--------------|-------------------|------|------|------------------|----------|
|                                                                                                                                                                                                                                                                                                                                                                                               |              |                        |    |                                                      | First round                             |                        |      | Second round |                   |      |      |                  |          |
| Sum of very<br>common and<br>common (%)                                                                                                                                                                                                                                                                                                                                                       | M<br>±<br>SD | Full<br>score<br>ratio | CV | I-CVI                                                | M<br>±<br>SD                            | Full<br>score<br>ratio | CV   | I-<br>CVI    |                   |      |      |                  |          |
|                                                                                                                                                                                                                                                                                                                                                                                               |              |                        |    |                                                      |                                         |                        |      |              |                   | 0.56 |      |                  |          |
| 40. I don't think friends and family fully understand me.                                                                                                                                                                                                                                                                                                                                     |              |                        |    | 60.00                                                | 4.50 ± 0.79                             | 0.61                   | 0.17 | 0.94         | 4.80<br>±<br>0.56 | 0.87 | 0.12 | 0.93             | Selected |
| 41. I have no confidence in recovery. (revised to "I don't feel like my body is getting better" after the first round)                                                                                                                                                                                                                                                                        |              |                        |    | 70.00                                                | 4.22 ± 0.94                             | 0.50                   | 0.22 | 0.78         | 4.73<br>±<br>0.46 | 0.73 | 0.10 | 1.00             | Selected |
| 42. I feel powerless about a lot of things.                                                                                                                                                                                                                                                                                                                                                   |              |                        |    | 80.00                                                | 4.89 ± 0.32                             | 0.89                   | 0.07 | 1.00         | 4.86<br>±<br>0.35 | 0.87 | 0.07 | 1.00             | Selected |
| 43. I feel like I've lost control of my body. <sup>c</sup>                                                                                                                                                                                                                                                                                                                                    |              |                        |    | 90.00                                                | 4.44 ± 0.78                             | 0.61                   | 0.18 | 0.83         | 4.60<br>±<br>1.05 | 0.80 | 0.23 | 0.93             | Deleted  |
| 44. I don't think I am who I used to be. <sup>b</sup>                                                                                                                                                                                                                                                                                                                                         |              |                        |    | 86.67                                                | 4.22 ± 1.06                             | 0.50                   | 0.25 | 0.83         |                   |      |      |                  | Deleted  |
| 45. I don't think I can change my current status.                                                                                                                                                                                                                                                                                                                                             |              |                        |    | 76.67                                                | 4.33 ± 0.97                             | 0.50                   | 0.22 | 0.94         | 4.87<br>±<br>0.35 | 0.87 | 0.07 | 1.00             | Selected |
| Guilt                                                                                                                                                                                                                                                                                                                                                                                         |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |
| 46. I think I am a financial burden on the family.                                                                                                                                                                                                                                                                                                                                            |              |                        |    | 76.67                                                | 4.61 ± 0.70                             | 0.72                   | 0.15 | 0.89         |                   |      |      |                  | Combined |
| I think I'm a burden on the family. (revised to "I consider myself a burden on the family" after the second round)                                                                                                                                                                                                                                                                            |              |                        |    |                                                      | Combined by items 46, 50                |                        |      |              | 5.00<br>±<br>0.00 | 1.00 | 0.00 | 1.00             | Selected |
| 47. I feel like I'm dragging down my family.                                                                                                                                                                                                                                                                                                                                                  |              |                        |    | 83.33                                                | 4.78 ± 0.43                             | 0.78                   | 0.09 | 1.00         |                   |      |      |                  | Combined |
| 48. I feel guilty.                                                                                                                                                                                                                                                                                                                                                                            |              |                        |    | 53.33                                                | 4.61 ± 0.61                             | 0.67                   | 0.13 | 0.94         |                   |      |      |                  | Combined |
| I feel guilty for dragging down my family                                                                                                                                                                                                                                                                                                                                                     |              |                        |    |                                                      | Combined by items 47, 48                |                        |      |              | 5.00<br>±<br>0.00 | 1.00 | 0.00 | 1.00             | Selected |
| 49. I feel like I have had an impact on my family's life. (experts considered that repeat with 47) <sup>b</sup>                                                                                                                                                                                                                                                                               |              |                        |    | 76.67                                                | 4.56 ± 0.51                             | 0.56                   | 0.11 | 1.00         |                   |      |      |                  | Deleted  |
| I feel that my existence reduces the quality of life of the family (experts considered that repeat with "I feel guilty for dragging down my family") <sup>c</sup>                                                                                                                                                                                                                             |              |                        |    |                                                      |                                         |                        |      |              | 4.73<br>±<br>0.59 | 0.80 | 0.13 | 0.93             | Deleted  |
| 50. I feel that my family has the burden of taking care of me.                                                                                                                                                                                                                                                                                                                                |              |                        |    | 86.67                                                | 4.50 ± 0.71                             | 0.61                   | 0.15 | 0.89         |                   |      |      |                  | Combined |
| I have thoughts of hurting myself. (revised to "I don't want to live" after the second round)                                                                                                                                                                                                                                                                                                 |              |                        |    |                                                      |                                         |                        |      |              | 4.40<br>±<br>0.99 | 0.67 | 0.22 | 0.80             | Selected |
| Total items retained                                                                                                                                                                                                                                                                                                                                                                          |              |                        |    | 45items                                              | 49items                                 |                        |      |              | 33items           |      |      |                  |          |
| Numbers in italics indicate unqualified index. Wording in italics indicate item is new. Mandarin to English translation preserves original Mandarin phrasing. <sup>a</sup> Indicates items deleted after the healthcare professional evaluation. <sup>b</sup> Indicates items deleted after the first round of Delphi. <sup>c</sup> Indicates items deleted after the second round of Delphi. |              |                        |    |                                                      |                                         |                        |      |              |                   |      |      |                  |          |

## 4.3 Delphi expert panel evaluation

### 4.3.1 Demographics of Experts

For the two round Delphi consultation, 18 experts were responded in the first round, and 15 experts were responded in the second round. Their areas of expertise include applied psychology, psychiatric nursing, community and aged care, stroke nursing, stroke rehabilitation and depression treatment. There are 4 nurses, 3 doctors, 10 nursing teachers and 1 psychological worker in the first round, with a working experience of 13–40 years. There are 4 nurses, 2 doctors, 8 nursing teachers and 1 psychological worker in the second round, with a working experience of 13–40 years.

### 4.3.2 The Delphi consultation indicators

The initiative coefficient of the two round Delphi consultation were 81.81% and 83.33%, both greater than 70%. The Cr values of the two Delphi rounds were 0.90 and 0.89, both of which were  $> 0.70$ , indicating a high degree of authority of experts. The coordination coefficient, which was expressed by the Kendall's W, were 0.135 ( $P < 0.01$ ) and 0.223 ( $P < 0.01$ ) respectively for the first and second round Delphi consultation. With respect to the concentration of expert opinions, the mean scores of the first and second round is 4.89–3.83 and 3.93–5.00 respectively; the full score ratio of the first and second round is 0.28–0.89 and 0.47–1.00, respectively; the CV of the first and second round is 0.07–0.36 and 0.00–0.33. Items with mean score  $\geq 4.00$ , full score ratio  $\geq 0.50$  and  $CV \leq 0.2$  were reserved. In the first Delphi round, 26 items met the inclusion criteria and were retained. There were 19 items that did not meet the criteria, of which 9 items were removed and the remaining 10 items were reserved for the next round. In the second Delphi round, there were 8 items that didn't meet the item retention criteria and of which 5 items were deleted. See Table 2 for details. For the content validity, the I-CVIs ranged from 0.56–1.00 and 0.67–1.00 in the first and second rounds consultation. After two rounds of expert consultation, the I-CVI of the scale items was greater than 0.78, and the S-CVI/Ave was 0.941.

### 4.3.3 Expert Opinions

In the first Delphi round, experts proposed to modify 19 items and add 6 items. Based on experts' opinion, the expression and dimension placement of 14 items were revised. Items 46 and 50 were merged into the item "I think I'm a burden on the family", and items 47 and 48 were merged into the item "I feel guilty for dragging down my family". Item 49 was deleted because experts considered it to be a duplicate of item 47. In the second Delphi round, experts made comments on 4 items. According to the expert opinion, the expressions of 3 items were modified and the item "I feel that my existence reduces the quality of life of the family" was deleted as the expert thought that it was a duplicate of the item "I feel guilty for dragging down my family". Finally, 33 items and 8 dimensions reached consensus after the two rounds Delphi consultation (Table 2 and Table 3).

Table 3  
The post-stroke depression scale in the sequelae stage

|                                                                               |
|-------------------------------------------------------------------------------|
| <b>Domain and items</b>                                                       |
| <b>Motivation</b>                                                             |
| 1. I don't want to take the initiative to do things.                          |
| 2. I don't want to go out.                                                    |
| 3. I don't want to communicate with people.                                   |
| 4. I lost interest in things that I used to be interested in.                 |
| <b>Emotion</b>                                                                |
| 5. I feel down.                                                               |
| 6. I feel hopeless in life.                                                   |
| 7. I feel anxious.                                                            |
| 8. I worry about the future.                                                  |
| 9. I can hardly be happy.                                                     |
| <b>Cognition</b>                                                              |
| 10. My memory has deteriorated.                                               |
| 11. My ability to think about problems has declined.                          |
| 12. My mind has become dull.                                                  |
| <b>Behavior</b>                                                               |
| 13. I have fewer social activities.                                           |
| 14. I cry or want to cry.                                                     |
| 15. I think a lot.                                                            |
| <b>Somatization</b>                                                           |
| 16. I feel tired.                                                             |
| 17. I find it difficult to manage everyday life.                              |
| 18. I am not satisfied with my current physical condition.                    |
| <b>Sleep</b>                                                                  |
| 19. I woke up in the middle of the night.                                     |
| 20. I do not fall asleep easily.                                              |
| 21. I have trouble falling asleep after waking up in the middle of the night. |
| 22. I get less sleep.                                                         |
| 23. I dream a lot while I sleep.                                              |
| <b>Helplessness</b>                                                           |
| 24. I think the recovery effect is much lower than I expected.                |
| 25. I don't think friends and family fully understand me.                     |
| 26. I don't feel like my body is getting better.                              |
| 27. I feel powerless about a lot of things.                                   |
| 28. I feel isolated.                                                          |
| 29. I do not think I can change my current status.                            |

| Domain and items                               |
|------------------------------------------------|
| Motivation                                     |
| Guilt                                          |
| 30. I think I'm so useless.                    |
| 31. I consider myself a burden on the family.  |
| 32. I feel guilty for dragging down my family. |
| 33. I don't want to live.                      |

## 4.4 Stroke patient panel evaluation

Thirty stroke patients in the sequelae stage were invited for the patients panel, including 20 males and 10 females. The age range of participants was 44–85 years (mean = 60.97, SD = 9.66). Nearly half (43.33%) of the participants received more than 6 years of education, and their illness duration ranged from 6 to 12 months (mean = 6.96, SD = 1.36). The number of strokes of the participants ranged from 1 to 5 times, and 93.33% of them had their first stroke. Stroke patients didn't propose changes to the screening tool.

## 5 Discussion

Based on the theory of learned helplessness, this study constructed an initial item pool for PSD in the sequelae stage with 8 dimensions and 50 items through literature review, semi-structured interviews and group discussions. Then through the evaluation of the healthcare professional panel, the Delphi expert panel, and the stroke patient panel, a specific screening tool for PSD in the sequelae stage with 33 items and 8 dimensions was formulated. The screening tool may effectively identify the sequelae stage PSD, and provides a basis for early detection and targeted management of the sequelae stage PSD.

## 5.1 Healthcare professional evaluation

During the healthcare professional panel evaluation, the healthcare professionals believed that most of the items were common in stroke patients and they did not add new items. This indicated that the research team has comprehensively summarized the clinical manifestations of PSD patients in the sequelae stage when constructing the initial item pool. A total of 6 items were deemed uncommon by the healthcare professional panel, 5 of which were removed and 1 was retained. The item "I have cut down on recovery time" from the behavior dimension was retained. It was derived from qualitative interviews with PSD patients in the sequelae stage, as a self-reported instrument, we want to keep as more as items as possible from the stakeholders. Furthermore, previous studies had pointed out that the sequelae period PSD would reduce the willingness of patients to recover [12], which might also be a symptom of depression.

## 5.2 The Delphi expert panel evaluation

A Two-round Delphi expert consultation were conducted with 18 and 15 experts respectively. Two or three rounds of Delphi expert consultation are generally considered reasonable [36], and a stable consensus can be obtained with around 15 experts [34]. The initiative coefficient of the two Delphi rounds in this study were 81.8% and 83.3%, respectively. A high initiative coefficient indicates that experts have a good enthusiasm for participating and the consultation results are highly credible [37]. Regarding the authority coefficient, the Cr of experts in the two rounds were greater than 0.70. The high degree of authority coefficient indicates that the prediction accuracy of the items is high, and the consultation results have high reliability [29]. The Kendall's W of expert consultation were statistically significant and increased from 0.135 in the first round to 0.223 in the second round, which indicated that the opinions of the experts gradually tended to be consistent and the coordination was good after the 2 rounds Delphi consultation [38]. In addition, the coordination coefficient after the 2 rounds Delphi consultation is higher than other similar studies [38], which means that the opinions of experts in this study tend to be more consistent. After two Delphi rounds, the content validity of the scale has also been significantly improved. The values of I-CVIs and S-CVI/Ave both reach the acceptable standard, which indicates good content validity.

In this phase, the mean, full score ratio and CV were used as the criteria for items selection. In the first Delphi round, 19 items didn't meet the criteria, of which 9 were removed and 10 were retained. The items retained were as follows: the item 2, 31, 33, and 45 were well received by healthcare professionals and were reserved for their clinical relevance. The items 29, 11, 18, 25, 26 and 41 were reserved after revision according to expert opinions. In the second round, eight items did not meet the criteria, of which three were retained: "I worry about the future", "I think a lot" and "I don't want to live". These three items were added by experts in the first round and had good content

validity. In addition, according to expert opinion, one duplicate item was deleted and 4 related items were merged into 2 in the first round; one duplicate item is deleted in the second round. Finally, a screening scale with 33 items was formed.

## 5.3 The stroke patient's evaluation

The participants made no additional suggestions for items. This is because the initial item pool was built based on semi-structured interviews with PSD patients in the sequelae stage, and this step may effectively cover all possible symptoms of PSD patients. Notably, participants expressed more items on helplessness, confusion, passivity, and focused on their own feelings. Experts recommend more items on physical changes, loss of pleasure and extreme behavior.

## 6 Strengths and limitations

The principal merit of this research is the formulation of a targeted PSD screening instrument for the sequelae stage through a robust methodological framework. Having established favorable content validity, this tool serves as a critical foundation for timely identification and evidence-based interventions. Consequently, it holds significant potential to optimize clinical outcomes and enhance the overall quality of life for stroke patients. However, several limitations should be noted for this study. First, this study only developed and preliminarily validated the tool, and future research is needed to test the reliability and validity of the tool in a larger sample. Second, the screening tool was developed in a Chinese population, future studies are need to test its usefulness in different cultural contexts. Finally, longitudinal studies are needed to test its effectiveness over time.

## 7 Conclusion

This study developed and initially validated a PSD-specific screening tool in the sequelae stage. Through evaluation by the panel of healthcare professionals, Delphi experts, and the stroke patients, the screening tool demonstrated good content validity at both the item and scale level. It can be a potential tool for the effective assessment of sequelae stage PSD, which may help develop targeted interventions to improve the prognosis and quality of life of stroke patients.

## Declarations

### Ethics declarations

### Competing interests

The authors declare no competing interests.

### Ethical approval

This study was approved by the Ethics Committee of the First Affiliated Hospital of Wenzhou Medical University (Approval number: KY2022-070; Clinical trial number: not applicable) on 19 May 2022, and adhered to the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

### Informed consent

Participants were required to review and accept an informed consent form prior to their participation from May 2022 to June 2022. This form detailed the research objectives, the intended use of collected data (strictly for scientific research and academic publication, with no personally identifiable information retained), and the guarantee of confidentiality. It also outlined participant rights, specifically the right to withdraw at any stage without penalty, and clarified that the survey posed no foreseeable risks. Written informed consent was obtained via a paper document where participants selected the "I agree" option to signify their willingness to participate. This was a prerequisite for proceeding to the formal investigation phase.

## Author Contribution

Shishi Dong and Yawei Zeng: research design and manuscript writing, data analysis; Linchao Yu, Fengzhen Li, Liuqiao Ning and Yi Zhang: data collection; Jufang Li: manuscript revising; Gexin Gao: research design and manuscript revising. All authors have read and approved the manuscript.

# Acknowledgement

This research was supported by the Wenzhou Municipal Science and Technology Bureau (grant number: Y20220098). Thanks to all participants.

## Data Availability

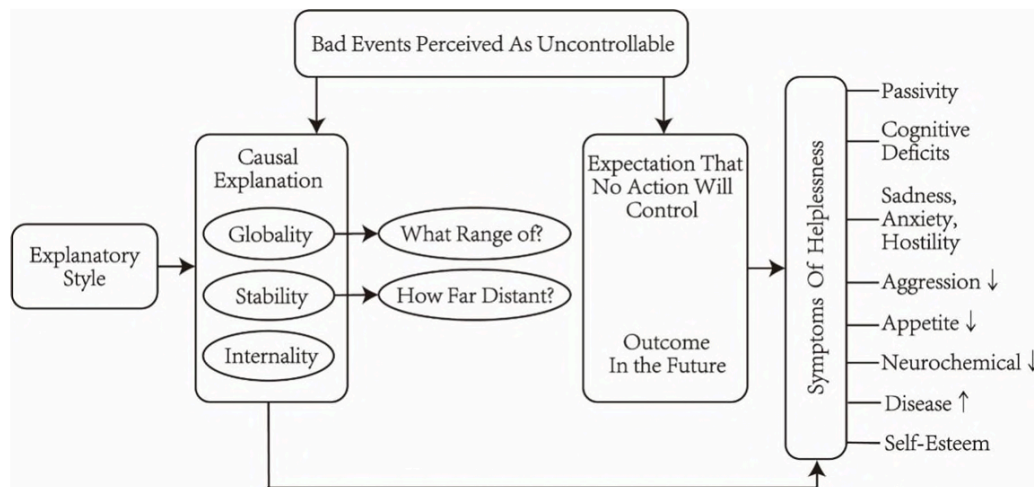
The datasets generated and analyzed during the current study are available in the supplementary materials provided with this manuscript.

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## Figures



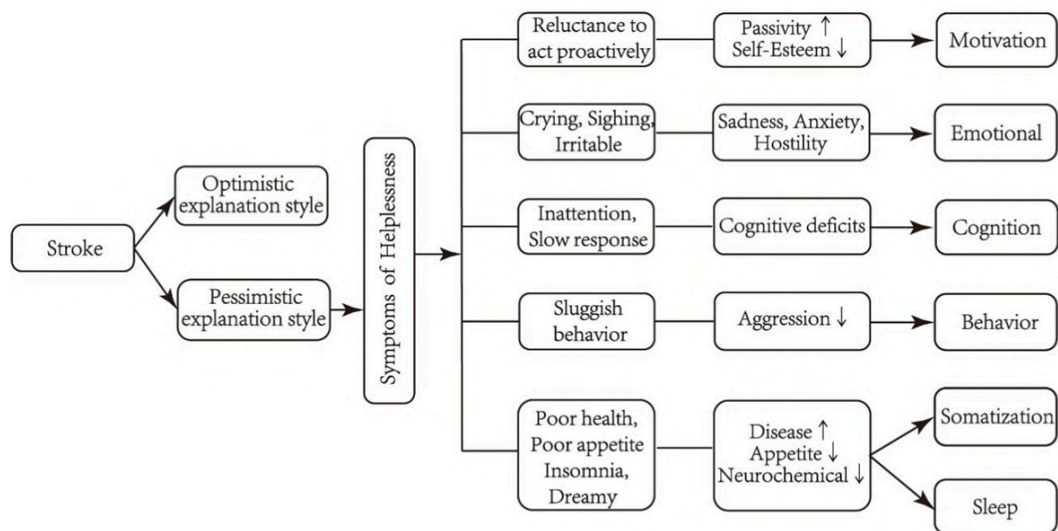
↑ means increase; ↓ means decrease.

**Figure 1: The theory Learned helplessness**

**Alt Text for Figure1:** Uncontrollable bad events bring about symptoms of helplessness through the concomitant cognition and the pessimistic explanatory style.

**Figure 1**

See image above for figure legend



↑ means increase; ↓ means decrease.

**Figure 2: Conceptual framework for the tool development**

**Alt Text for Figure2:** Through the theory of learned helplessness combined with literature review, semi-structured interview and research group discussion, eight dimensions of this clinical measurement were obtained.

## Figure 2

See image above for figure legend

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Delphi1.xlsx](#)
- [Delphi2.xlsx](#)