

# Development And Validation Of Questionnaire To Assess Sleep Disturbances, Mental Health And Quality Of Life In Subacute Stroke

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## ABSTRACT

**Background and purpose:** Stroke is a growing global health burden, leading to long-term complications such as physical disability, psychological distress, and sleep disorders. Existing assessment tools, mostly developed in Western contexts, may not align with Indian socio-cultural norms. This study aimed to develop and validate a culturally appropriate questionnaire to assess sleep disturbances, mental health, and quality of life (QoL) in subacute stroke patients.

**Methods:** Conducted at a tertiary healthcare centre in Belagavi, the study involved literature review, gap analysis, item generation, expert validation, and pilot testing. A panel of 15 experts evaluated the tool in two rounds, and content validity index (CVI-I) was calculated for each domain. A pilot study with 25 participants assessed reliability using Cronbach's Alpha, and data were analyzed using SPSS v29.0.10.

**Results:** In round one, CVI-I scores were 1.00 for sleep disturbances, 0.75 for mental health, and 0.87 for QoL. After revisions, all domains achieved a CVI-I of 1.00 in round two. The overall scale content validity index average (S-CVI/Ave) was 0.93, indicating strong content validity and expert agreement. Reliability analysis confirmed high internal consistency.

**Conclusions:** This study developed a valid and reliable tool for assessing sleep disturbances, mental health, and QoL in subacute stroke patients in India. Its culturally relevant design enhances clinical and research utility, supporting comprehensive evaluation and improved patient outcomes.

**Keywords:** Sleep disturbances, mental health, quality of life, subacute stroke, questionnaire development, validation, content validity, reliability.

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## INTRODUCTION –

Whenever the brain's blood supply is abruptly interrupted, brain function rapidly declines, leading to a stroke<sup>1</sup>. Stroke continues to rank as the second most common cause of mortality from non-communicable diseases, contributing to around 7 million fatalities, according to the most recent Global Burden of Disease (GBD) 2025 projections. It is the third leading cause of mortality and disability worldwide. Stroke is becoming more and more common, impacting not just people but also families and communities. Over 12.2 million individuals globally experience a stroke each year, and over 101 million people are currently dealing with the long-term consequences of this condition. Stroke is currently the fifth most common cause of disability and the fourth most common cause of death in India<sup>2,3</sup>.

Sleep is essential for preserving general health since it promotes immunity, heart health, metabolism, brain function, tissue repair, and even reproduction. It is also necessary for controlling emotions and memory. Many stroke survivors experience movement-related problems such as restless leg syndrome and periodic limb movements, as well as sleep disorders like insomnia and sleep-disordered breathing (including central and obstructive sleep apnea)<sup>4,5</sup>. Numerous complications might potentially result from a stroke. These include physical issues such as joint dislocations, pressure sores, spasticity, blood clots, muscle soreness, difficulty swallowing, urinary tract infections, and mental health issues. Stroke survivors may find it challenging to do daily duties due to disabilities, particularly those affecting the arms and hands, as well as cognitive impairments such as vascular dementia or minor memory problems.

These difficulties frequently result in less social interaction, raising the possibility of loneliness and mental health issues<sup>6,7</sup>. It's critical to evaluate and treat these problems thoroughly because many people have long-term difficulties during the subacute phase of stroke recovery, including emotional disorders, physical disabilities, and cognitive decline<sup>8</sup>. If ignored, they can impair mental health, sleep quality, and general quality of life. Healthcare providers can create more successful rehabilitation plans and support networks for stroke survivors by having a greater grasp of how these variables interact.<sup>9, 10, 11.</sup>

These elements have only been examined in earlier research, and those studies used a different questionnaire to measure them. The special requirements of stroke patients were not sufficiently addressed by the questionnaires that were in use at the time. Since many of the current stroke-specific assessment instruments were created in Western settings, they might not adequately take into consideration the sociocultural, economic, and medical variations that exist within the Indian community. For example, instruments intended to assess mental health or sleep disorders could contain questions that are difficult for Indian stroke survivors to comprehend or use<sup>12,13</sup>.

#### **METHODOLOGY:**

The study received approval of institutional ethical board(861) and was carried out in two phases.

Phase 1: The researcher created the SMQoL-SS questionnaire to assess quality of life, mental health, and sleep disorders in subacute stroke patients. There were two phases to the questionnaire development process: Item creation took place in Stage 1, and the questionnaire draft was reviewed by experts and finalized in Stage 2.

Stage 1: Identifying and defining the pertinent domains by identifying essential items and outlining their scope is the first phase, referred to as "item generation." The items were chosen after a review of the literature revealed a deficiency in some questions pertaining to the Indian population and their methods for addressing sleep difficulties, mental health, and quality of life after a stroke.

Stage 2: A panel of 15(fifteen) professional volunteers, all of whom were neuro physiotherapists, validated and assessed the content. Eight of the fifteen experts took part in the first round of content validation, and seven more experts received questionnaires for validation in the second round. Each domain's components were scored using a Likert scale. To determine if each domain and the entire questionnaire appropriately reflected the targeted areas of interest, expert validation was conducted after the first questionnaire design was developed. The items were changed based on A Not pertinent, B Relevant to some extent, C Very pertinent, D Very pertinent. The assigned scores were arranged and analyzed with C, D, and A, B, as 1 and 0, respectively, to determine the content validity. The Content Validity Index (CVI) was calculated using the scale average method. Based on the results, the questionnaire was revised accordingly,

leading to the development of the final draft<sup>14,15.</sup>

Phase 2: After the SMQoL-SS questionnaire was finalized, a pilot research was carried out on 25(twenty five) participants at Belgavi City's tertiary health care center to confirm its efficacy. Convenience sampling was the method of choice. The goal of the study was explained to participants prior to its start, and each subject provided signed informed consent. Subjects with subacute stroke who are willing to participate and are between the ages of 18 and 60 are eligible to apply. Patients with recurrent stroke episodes who have previously been diagnosed with sleep disorders, depression, psychological disorders, epilepsy, or head trauma are excluded.

#### **STATISTICAL ANALYSIS:**

Based on expert input, we examined the content validity index using Microsoft Excel. This involved figuring out the average scores, the scale-level index using the universal agreement approach (S-CVI/UA), and the item-level content validity index (I-CVI). We then used these values to interpret the overall results. Descriptive statistics such as frequency, percentage, mean, and SD were used to summarize the data that was gathered. The reliability of the questionnaire was determined using Cronbach's Alpha. Version 29.0.10 of the SPSS software was used to analyze the data.

#### **RESULTS:**

The validity of the questionnaire domains was evaluated using content validity index for individual items(CVI-I). After the first round of questionnaire validation from 8(eight) experts the CVI-I score for Domain 1, which focused on sleep disturbances, was determined to be 1(one). For domain 2 (Mental health ), the CVI-I score was 0.75(zero point seven five) and for domain 3 (quality of life ), the CVI-I scores were 0.87(zero point eight seven) (table 1), indicating a good level of agreement, albeit slightly lower relevance than that observed for domain 1. (table 1)

Based on the feedback received from experts during the first round, the questionnaire was revised to incorporate the recommended corrections. The revised version then underwent a second round of validation, during which seven experts assessed the relevance of each item within the respective domains. The content validity index for individual items (CVI-I) reached a perfect score of 1 for domain 2 (Mental health) and domain 3 (QoL), indicating unanimous expert agreement on item relevance (table 2). The CVI-I score domain 1 (sleep disturbances) remained unchanged during both round of validation. These results demonstrate that the revisions led to an overall improvement in the questionnaire's validity. (table 2)

The S-CVI/Ave was calculated by averaging the I-CVI scores across all items, while the S-CVI/UA was determined by dividing the number of items that received full agreement (100%) from all experts by the total number of items. Based on evaluations from all 15(fifteen) experts, the questionnaire achieved an impressive S-CVI/Ave score of 0.95(zero point nine five).

After the validation process, a pilot study was carried out to

assess the reliability of the questionnaire. It involved 25 participants, whose ages ranged from 32 to 63 years, with an average age of  $49.56 \pm 9.42$  years. The duration since stroke onset ranged from 9 to 28 days, with a mean of  $18.20 \pm 5.06$  days

Among the 25 participants; the majority were affected with severe sleep disturbances (88%); and the 12% with moderate sleep disturbances. The 76% of the cases were found to have severe mental health disturbance; followed by moderate mental health disturbance (24%). Regarding quality of life; the 56% had Moderate QOL disturbances; and 44% with Severe QOL disturbances.(table 3)

The obtained reliability coefficients are  $> 0.70$  and hence the questionnaire is reliable (table 4).

## DISCUSSION:

In order to have an assessment tool that takes into account Indian customs that stroke survivors follow after their stroke, the SMQoL-SS Questionnaire was created. A measure that captures the interaction between sleep, mental health, and quality of life during the crucial subacute phase is desperately needed, given the complex nature of stroke recovery. Two separate stages of this study were carried out to guarantee a methodical and thorough approach to questionnaire preparation. The investigator conducted a thorough literature search, gap analysis, and item development throughout phase I. Psychometric testing was taken into consideration after generation. Fifteen professionals shared their opinions on the questionnaire's applicability. The Content Validity Index (CVI) of the questionnaire was calculated and found to be satisfactory, indicating a strong level of agreement among experts regarding the relevance of the items. The cronbach's alpha for the domains 1,2,3 were 0.96, 0.88, 0.95 respectively.

The sleep disturbance and sleep apnea questionnaire has been used in studies conducted in the some countries to examine obstructive sleep apnea and sleep disturbances in stroke patients. The results showed that sleep problems affected 72% of stroke survivors. In a preliminary study using the SMQoL-SS, we discovered that 88% of stroke survivors are susceptible to sleep disruptions during their subacute period when using culturally relevant questions. Furthermore, it was determined that culturally particular practices—like using firm pillows and eating substantial meals right before bed—exacerbated these problems. These behaviors are typical among Indian stroke survivors. In order to improve its contextual relevance and overall robustness, our questionnaire incorporates these culturally significant aspects<sup>16,17</sup>.

Even in otherwise healthy people, sleep interruptions have been shown to induce mental exhaustion and mood disturbances. Persistent mental exhaustion and mood disturbances can also contribute to the beginning of numerous psychosocial difficulties in stroke patients, particularly during the subacute phase. Many stroke survivors experience mild to moderate mental health disorders, according to studies that use depression and anxiety questionnaires to examine depression in stroke survivors. Other important indicators like addiction,

suicidal thoughts, or thoughts of hurting other people were not examined in these research, though. In our study, addressing these issues revealed that they often act as triggers or primary indicators of psychosocial disturbances during the subacute phase of stroke recovery. It is important to evaluate and treat all of these issues together because symptoms such as addiction and suicidal ideation frequently worsen in tandem with anxiety<sup>17,18</sup>.

A person's lifestyle, which is influenced by both deliberate attempts to preserve their health and social contacts, is a major factor in determining their quality of life. It symbolizes a unique pattern of everyday actions that are significantly impacted by a person's overall well-being. Studies assessing health-related quality of life (HR-QoL) in stroke patients—using standardized questionnaires—have traditionally focused on domains such as physical functioning, social functioning, mental health, and general health. These studies have consistently concluded that stroke survivors experience a significant decline in quality of life. However, crucial factors such as financial burden, sources of financial support, ability to return to work, and support from family and friends were not included in the original questionnaires. Our pilot study, which incorporated these additional components, found that these socio-economic and psychosocial factors often exacerbate the decline in quality of life. In fact, results indicated that stroke survivors, particularly during the subacute phase, experience moderate to severe deterioration in their overall quality of life when these stressors are present. To enhance both reliability and contextual relevance, our revised questionnaire now integrates these critical elements, providing a more comprehensive understanding of the challenges faced by stroke survivors<sup>19,20</sup>.

With a Content Validity Index-Individual (CVI-I) of approximately 0.95 and Cronbach's alpha values above 0.80 in all three domains, the SMQoL-SS exhibits robust reliability and validity. The SMQoL-SS Questionnaire was developed to address the cultural and contextual needs of Indian stroke survivors, particularly during the subacute phase. By integrating sleep, mental health, and quality of life domains, along with culturally specific practices and psychosocial stressors, the tool offers a comprehensive assessment of post-stroke challenges. This makes it a highly effective instrument for evaluating sleep disturbances, mental health, and quality of life in individuals with subacute stroke, suitable for both diagnostic and prognostic purposes..

A key limitation of this study is that the questionnaire was validated within a single geographic region. To enhance its cross-cultural applicability, further validation across diverse cultural and linguistic settings is necessary.

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Tables -

Items	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	I-CVI
Domain 1	1	1	1	1	1	1	1	1	1
Domain 2	1	1	0	1	1	1	0	1	0.75
Domain 3	1	1	1	1	1	0	1	1	0.87
CVI average	0.86								

**Table 1:** the content validity index of round 1 based on rating of relevance of items from 8 experts.

Items	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	I-CVI
Domain 1	1	1	1	1	1	1	1	1
Domain 2	1	1	1	1	1	1	1	1
Domain 3	1	1	1	1	1	1	1	1
CVI average	0.95							

**Table 2 :** Content validity index for round 2 based on the rating of relevance of items by 7 experts

		Frequency	%
Sleep disturbances	Mild sleep disturbances (14-28)	0	0
	Moderate sleep disturbances (29-42)	3	12
	Severe sleep disturbances (43-70)	22	88
Mental health	Mild mental health disturbance (12-24)	0	0
	Moderate mental health disturbance (25-36)	6	24
	Severe mental health disturbance (37-60)	19	76
Quality of life	Mild QOL disturbances (14-28)	0	0
	Moderate QOL disturbances (29-42)	14	56
	Severe QOL disturbances (43-65)	11	44

**Table 3 :**Grades of sleep disturbances, mental health and quality of life

	Number of items	Cronbach's Alpha
Sleep disturbances	14	0.969
Mental health	12	0.883
Quality of life	14	0.956

**Table 4:** Reliability analysis