

# Impact of the Information-Motivation-Behavioral Skills Model Based Medication Literacy Intervention on Medication Self-Management Capacity in Stroke Patients: A Randomized Controlled Trial

Linlin Ma<sup>1,2,\*</sup>, Zhimin Liu<sup>3,\*</sup>, Xueru Chen<sup>2</sup>, Qian Zhang<sup>2</sup>, Tianyu Chu<sup>2</sup>, Xian Chen<sup>2</sup>, Jiajia Zhang<sup>2</sup>, Renjuan Sun<sup>1</sup>, Yibo Wu<sup>4</sup>

<sup>1</sup>Department of Neurology, Affiliated Hospital of Jiangnan University, Wuxi, People's Republic of China; <sup>2</sup>Wuxi School of Medicine, Jiangnan University, Wuxi, People's Republic of China; <sup>3</sup>Department of Neurology, Binzhou People's Hospital Affiliation to Shandong First Medical University, Binzhou, People's Republic of China; <sup>4</sup>Obstetrics, Gynecology and Reproduction Research Center, Affiliated Hospital of Jiangnan University, Wuxi, People's Republic of China

\*These authors contributed equally to this work

Correspondence: Renjuan Sun, Department of Neurology, Affiliated Hospital of Jiangnan University, Wuxi, People's Republic of China, Email 15061885987@163.com; Yibo Wu, Obstetrics, Gynecology and Reproduction Research Center, Affiliated Hospital of Jiangnan University, Wuxi, People's Republic of China, Email 9862016107@jiangnan.edu.cn

**Purpose:** This study aimed to evaluate the effectiveness of a multidisciplinary collaborative medication literacy intervention, grounded in the Information-Motivation-Behavioral Skills (IMB) model, on the medication self-management capacity, stroke-related knowledge, medication literacy, medication adherence, and health status of stroke patients.

**Patients and Methods:** This single-blind, two-arm RCT in a Wuxi tertiary hospital enrolled 127 participants, randomized into intervention (n = 63) and control groups (n = 64). The intervention group received a medication literacy intervention based on the Information-Motivation-Behavioral Skills (IMB) model through multidisciplinary collaboration, while the patients in the control group received standard care and follow-up after discharge. The primary outcome measure was medication self-management capacity, while secondary outcome measures included stroke-related knowledge, medication literacy, medication adherence, blood pressure, lipid levels, and unplanned readmission rates. The generalized estimating equation (GEE) model was employed to assess the effectiveness of the intervention.

**Results:** Compared with the control group, the intervention group showed significant improvement in medication self-management capacity ( $\beta_{day\ of\ discharge} = 1.41, p = 0.045$ , Cohen's d = 0.31;  $\beta_4\ weeks = 2.74, p = 0.003$ , Cohen's d = 0.52;  $\beta_{12\ weeks} = 3.46, p = 0.003$ , Cohen's d = 0.74). Significant improvements were also observed in stroke-related knowledge ( $\beta_4\ weeks = 2.67, p < 0.001$ ;  $\beta_{12\ weeks} = 3.97, p < 0.001$ ), medication literacy ( $\beta_4\ weeks = 1.22, p < 0.001$ ;  $\beta_{12\ weeks} = 1.18, p < 0.001$ ), medication compliance ( $\beta_4\ weeks = 1.07, p = 0.034$ ;  $\beta_{12\ weeks} = 1.45, p = 0.013$ ), and blood pressure reduction ( $p < 0.05$ ). The intervention did not significantly affect blood lipids or unplanned readmission rates ( $p > 0.05$ ). The sensitivity analysis using the PP method indicated that the obtained results were comparable to the ITT results, suggesting that the preliminary research results and conclusions of the medication literacy intervention based on multidisciplinary collaboration were reliable.

**Conclusion:** The medication literacy intervention based on the Information-Motivation-Behavioral Skills (IMB) model effectively enhances the medication self-management capacity of stroke patients. It positively influences several outcomes, including stroke-related knowledge, medication literacy, medication adherence, blood pressure.

**Keywords:** medication literacy, medication adherence, stroke, intervention studies

## Introduction

Stroke has long been recognized as a group of diseases arising from vascular lesions in the brain, primarily categorized into two types: ischemic stroke and hemorrhagic stroke.<sup>1</sup> The “Global Stroke Fact Sheet”, published by the World Stroke Organization (WSO) in 2022, revealed that stroke has become the second leading cause of death globally, with approximately 6.5 million fatalities attributed to it annually.<sup>2</sup> Currently, the treatment and prevention of predominantly depend on pharmacotherapy. However, due to the intrinsic nature of stroke and the various complications arising from brain tissue damage, patients predominantly require a prolonged regimen of multiple medications. Previous research has indicated that elderly commonly patients are typically administered a diverse array of drugs during hospitalization, with usage ranging from 5 to 34 different medications,<sup>3</sup> Furthermore, during the rehabilitation phase post-discharge, it has been reported that 60% of commonly patients continue to require more than five medications concurrently.<sup>4</sup> The combination of multiple medications commonly complicates the treatment regimen,<sup>5</sup> thereby increasing the challenges associated with long-term medication management. Consequently, ensuring the safe and continuous administration of medications for stroke patients remains a significant challenge for healthcare professionals.

The World Health Organization (WHO) has long emphasized that medication self-management is an indispensable component of health management,<sup>6</sup> which is recognized as crucial for disease control, reducing complications, improving quality of life, and minimizing the risk of recurrence in stroke patients.<sup>7</sup> However, the current state of medication self-management in stroke patients presents numerous challenges. A study examining the self-management capabilities of stroke patients revealed that particularly poor medication self-management abilities were present,<sup>8</sup> with missed medications or medication errors being prevalent.<sup>9</sup> Intermittent medication adherence was identified as the most common issue during the home rehabilitation phase. Various factors may limit medication self-management in stroke patients, including advanced age,<sup>10</sup> insufficient and biased medication knowledge,<sup>11,12</sup> inadequate social support,<sup>13</sup> and poor medication adherence. Clearly, inadequate medication self-management can lead not only to poor medication adherence and an increased risk of adverse medication reactions but also to the recurrence or exacerbation of the disease, such as subsequent strokes and worsening neurological deficits. Therefore, healthcare professionals must prioritize the medication self-management of stroke patients and implement targeted intervention strategies.

Numerous existing studies have demonstrated that enhancing medication literacy can improve medication adherence<sup>14</sup> and reduce adverse medication reactions,<sup>15</sup> thereby standardizing patients’ medication self-management behaviors regarding medication. Specifically, medication literacy is defined as the ability of individuals to effectively obtain, evaluate and apply medication-related information throughout the medication process, enabling them to make informed health decisions and maintain or promote their health.<sup>16</sup> For stroke patients, medication literacy encompasses not only the understanding of fundamental information such as medication names, dosages, and timing of administration, but also awareness of side effects, medication interactions, and necessary adjustments to medications during recovery. Currently, medication literacy interventions including health education and technical guidance have a positive impact on the outcome of medication self-management. For instance, Smith<sup>17</sup> conducted five lectures on health behavior skill changes for stroke patients, integrating individual assessments with group interventions, which resulted in significant improvements in medication adherence and patients’ self-efficacy. Similarly, Solmaz<sup>18</sup> found that, with the assistance of intelligent auxiliary tools, patients’ disease-related knowledge levels could be enhanced, leading to significant improvements in medication adherence and an overall elevation in medication self-management. Although most current intervention studies on medication literacy focus on elderly patients with chronic diseases, such as myocardial infarction,<sup>19</sup> there is a notable lack of intervention studies addressing medication literacy specifically for stroke patients.

Medication literacy interventions aimed at enhancing medication self-management are more likely to succeed when grounded in a theoretical framework. The Information-Motivation-Behavioral Skills Model, proposed by Fisher<sup>20</sup> in 1992, is widely acknowledged as a robust behavior change theory. This model underscores the causal relationships among information, motivation, and behavioral skills, positing that these three factors interact to collectively influence individual behavior change. Specifically, accurate information provides a rationale for behavior change, motivation propels individuals to take action, and behavioral skills facilitate the effective implementation of that action. When these three components reach a sufficient level, individuals are more inclined to experience behavior change. To date,

interventions based on the IMB model have demonstrated efficacy in improving patients' health behaviors, including adherence to treatment in chronic obstructive pulmonary disease,<sup>21</sup> coronary heart disease,<sup>22</sup> diabetes,<sup>23</sup> and other chronic diseases. However, there is a notable absence of such applications aimed at enhancing medication self-management among stroke patients.

To fill the research gap in this field, we have identified medication literacy as a pivotal focus. Utilizing the IMB model as the theoretical framework, we have established a multidisciplinary team comprising nurses, doctors and pharmacists. This team will provide medication literacy interventions for patients, aiming to effectively enhance the medication literacy levels of stroke patients through this program. Our objective is to standardize their medication self-management behaviors, thereby improve health-related outcomes.

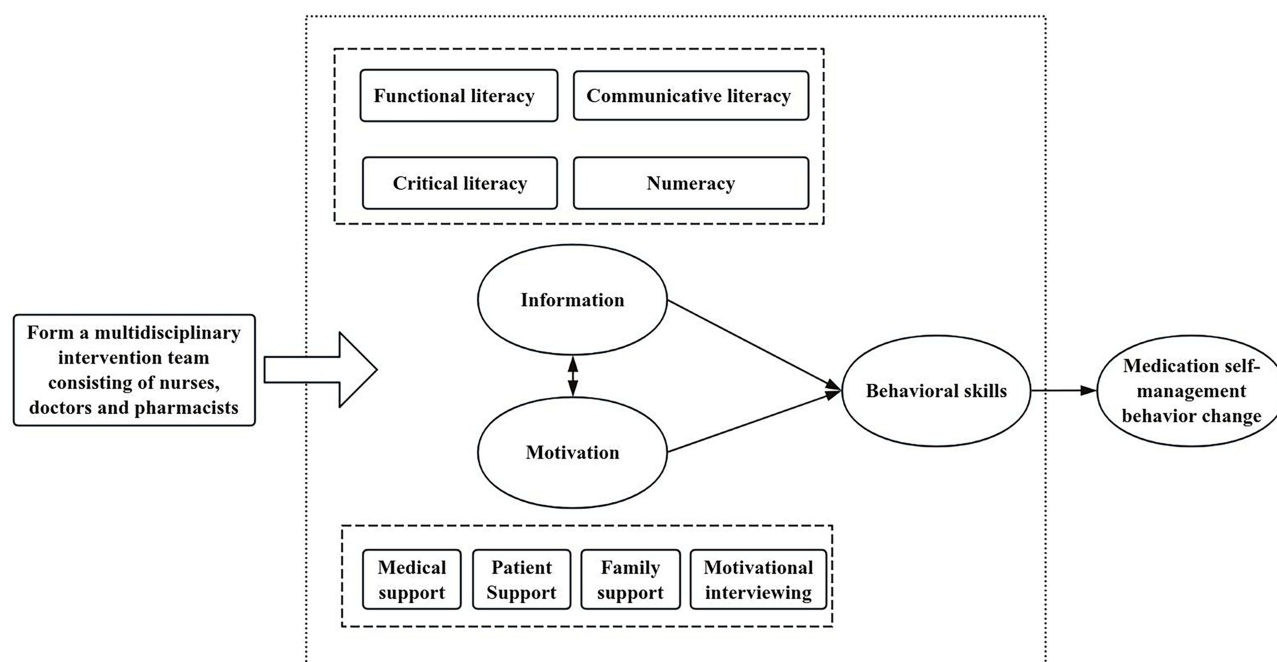
## Materials and Methods

### Theoretical Framework

The IMB model provided the theoretical basis for this study (Figure 1). Specifically, a multidisciplinary collaboration team, consisting of nurses, physicians, and pharmacists, was established. Utilizing the IMB model as the intervention framework, the team aimed to provide patients with a comprehensive four-dimensional medication literacy intervention. This research framework was proposed based on the findings from a literature review and an investigation of the current situation.

### Study Design and Setting

This study was conducted as a three-month, single-blind, two-arm randomized controlled trial to compare the effects of an IMB model-based medication literacy intervention with those of usual care on medication self-management in stroke patients. This study was carried out in a tertiary hospital located in Wuxi, Jiangsu Province. The study protocol received approval from the Research Ethics Committee of the Affiliated Hospital of Jiangnan University (LS2023063) and was registered with the Chinese Clinical Trial Registry (ChiCTR2400084673). Informed consent was obtained from all participants.



**Figure 1** Information-Motivation-Behavioral Skills (IMB) model (adaptation to our research).

## Participants

From June 2024 to August 2024, inpatients diagnosed with stroke were recruited from the Department of Neurology at a Class III Grade A hospital in Wuxi using convenience sampling. Participants were eligible for the study if they met specific inclusion and exclusion criteria. The inclusion criteria were as follows: ① age  $\geq 60$  years old; ② patients who met the diagnostic criteria for stroke and were confirmed by head CT or MRI; ③ Barthel Index (BI)  $> 60$  points,<sup>24</sup> indicating a certain level of self-care ability; ④ hospital stay of  $\geq 7$  days; ⑤ clear cognitive status with adequate communication skills; ⑥ voluntary participation. The exclusion criteria were: ① patients with hearing impairment, speech impairment, dementia, or cognitive impairment who could not cooperate with the researchers; ② severe dysfunction of lungs, heart, liver, or kidneys; ③ participation in other similar studies.

## Sample Size

Sample size estimation was conducted based on the results of a previous randomized controlled trial,<sup>25</sup> which identified an effect size (Cohen's *d*) of 0.58 for the difference in medication self-management levels between the two groups. A minimum of 48 participants per group was determined to be necessary, as calculated with G\*Power 3.1 software (Germany), to ensure that the study achieved at least 80% power to reject the null hypothesis at a significance level of 0.05. Furthermore, accounting for a 20% sample dropout rate, the final required sample size was adjusted to 127 participants, comprising 63 individuals in the intervention group and 64 in the control group.

## Interventions

### Intervention Group

Prior to the intervention, a multi-professional team comprising nurses, physicians, and pharmacists was established. Stroke specialist nurses served as the primary executioner of the intervention program, delivering comprehensive medication care services. They also acted as a communication bridge between physicians and pharmacists, accurately conveying physicians' treatment intentions and pharmacists' medication recommendations, thereby facilitating effective communication. Similarly, cardiovascular specialist nurses provided patients with health education regarding hypertension, hyperlipidemia, hyperglycemia, and other prevalent conditions. They offered personalized medication education and guided patients in regularly monitoring blood pressure, blood glucose and other relevant indicators. Concurrently, physicians conducted comprehensive assessments of stroke patients, developed individualized treatment plans, and selected the most appropriate medications and treatment strategies based on the patients' specific conditions, complications, and overall health status. As key experts in medication therapy management, pharmacists were tasked with reviewing the patient's medication regimens to ensure the rationality, safety, and efficacy of medication selection. Furthermore, pharmacists provide patients with detailed medication counseling, including information on medication of action, potential side effects, and possible interactions, to enhance patients' understanding of their treatment.

**Development of the intervention:** The initial draft of the intervention program was developed based on findings from a comprehensive literature review and a cross-sectional survey. This draft was further refined in alignment with the theoretical framework of the IMB model. Subsequently, two rounds of Delphi expert consultations were conducted to revise and enhance the preliminary plan. Prior to the formal implementation of the intervention, the final draft of the medication literacy intervention plan, grounded in the IMB model, was formulated based on feedback from the pre-experiment. This plan encompasses a total of seven themes: (1) build relationships to assess needs, (2) access and exchange of disease information, (3) application of medication information understanding, (4) medication management skills were improved, (5) medication guidance at discharge, (6) medication management behaviors were strengthened, and (7) follow-up.

**Implementation of the intervention:** The intervention was implemented over a total duration of 12 weeks, consisting of four inpatient group sessions, two individual sessions. Additionally, three follow-up telephone calls were conducted to reinforce the intervention. Each group session lasted between 30 to 40 minutes and was conducted in the neurology training room, while the one-to-one intervention lasted was 15 to 20 minutes, conducted either at the patient's bedside or in the outpatient department.

The theme of the first session was to build relationships to assess needs. Aimed to build a trusting relationship with the patient and evaluate their needs. The researchers first provided a comprehensive explanation of the research's purpose, process, expected benefits, and potential risks to the participants, who then signed a written informed consent form after fully understanding the information. Subsequently, the researchers guided the patients in describing their medication experiences to gain insights into their medication usage and any associated problems.

The theme of the second session focused on the access and exchange of disease information. The stroke specialist nurse educated the patients about stroke-related knowledge to help them develop an accurate perception of their condition.

The theme of the third session focused on the application of medication information understanding. The objective was to educate the patient about the relevant knowledge concerning stroke medications and to enhance family support in fostering accurate medication beliefs. The stroke specialist nurse provided informational guidance, and the intervention's primary content was integrated with QR code health education videos and cards detailing common stroke medications. Additionally, the head nurse of the neurology department developed a family system assessment form for the patient. The neurology doctor introduced available community resources, such as community pharmacy clinics and family-contracted doctors, to assist the patient in establishing a social support network. Furthermore, the pharmacist offered behavioral skills guidance through scenario simulation and role-playing.

The theme of the fourth session was the enhancement of medication management skills. The head nurse of the neurology department emphasized the importance of adhering to medication for secondary stroke prevention. Concurrently, the cardiovascular specialist nurse instructed the patient on the safe use of medication aids and guided them in accurately measuring blood pressure, monitoring blood sugar, and administering insulin, thereby improving the patient's communication skills.

The theme of the fifth session centered on medication guidance at discharge. The aim was to educate the patient about home medication practices, provide discharge medication instructions, and enhance the patient's self-efficacy. The stroke specialist nurse delivered guidance on medication safety and conducted motivational sessions to encourage the patient to express their genuine thoughts and feelings regarding medication use and the challenges they faced. The neurology doctor assisted in identifying the types and causes of the patient's medication issues and provided tailored solutions based on the patient's specific circumstances, incorporating physical demonstrations and medication logs for behavioral skills training.

The theme of the sixth session focused on reinforcing medication management behaviors, with the objective of standardizing patients' medication self-management during their home stay. Stroke specialist nurses and cardiovascular specialist nurses regularly shared approximately 10-minute health education videos about stroke health in the "Stroke Medication Management WeChat Group". Additionally, doctors and pharmacists addressed questions within the group to clarify doubts raised by patients and their caregivers. During outpatient follow-ups, pharmacists reviewed patients' medication logs and provided scientifically-based recommendations for any missed doses or adverse reactions.

The theme of the seventh session was follow-up, aimed at assessing patients' home medication management subsequent to the completion of the medication literacy intervention based on the IMB model. Researchers conducted monthly telephone follow-ups and provided corrective guidance for any medication issues that arose during the patients' home stay.

Before the study commenced, the intervention personnel underwent training on implementing the intervention measures. Following each intervention, the personnel responsible for the corresponding topic were required to submit an intervention checklist to ensure the thoroughness of the intervention content. If the completion rate of the intervention checklist reached 20%, additional training for the intervention personnel would be considered. Detailed information is provided in [Table 1](#).

### Control Group

Patients in the control group received standard nursing care and discharge follow-up. The specific nursing interventions encompassed the diagnosis and treatment of stroke-related conditions, which primarily included: (1) medication observation and condition monitoring; (2) nursing care for stroke symptoms; (3) daily living assistance; (4) discharge health education, along with consultation services regarding the patient's condition and medication management. Following discharge, two follow-up visits were conducted at one and three months.

**Table I** Details of Medication Literacy Intervention Based on the IMB Model

Topic	Time and Forms of Intervention	Theoretical Framework	Content of the Intervention
Build relationships to assess needs	Day of admission One to one, bedside (15–20 min)	Assessment	The content of the intervention was introduced, and informed consent was obtained. Patients were guided to articulate their medication experiences, and their medication self-management abilities were evaluated using the SAM scale, the Stroke Knowledge Questionnaire, the Chinese version of the Med Lit Rx SE scale, and the MARS-5 scale.
Access and exchange of disease information	The hospital stay was 2–3 days Group sessions, ward activity room (30–40 min)	Information guidance	This study aimed to enhance patient understanding of stroke-related knowledge through a structured educational approach. (1) Patients were provided with a stroke health brochure and an explanation of the content using simple language. (2) Following this explanation, patients were encouraged to articulate what they had learned in their own words. (3) Educators then clarified any misunderstandings and reinforced key information. This iterative process of explanation, feedback, and correction was designed to ensure that patients thoroughly comprehended the material.
		Guidance of motivation	(1) A multidisciplinary team, comprising neurologists, pharmacists, and nurses, provided comprehensive drug management and psychological support for patients. (2) The researchers conducted regular evaluations of the patients' medication usage and understanding, offering corrective guidance on aspects such as drug names, colors, shapes, administration methods, frequency, dosages, and overall medication management comprehension. (3) Patients and their caregivers were encouraged to join a WeChat group dedicated to medication management for stroke patients, with guidance provided to ensure caregivers actively participated in the intervention, thereby facilitating its effective implementation.
		Behavioral Skills Instruction	(1) Taking aspirin, a common medication for stroke, as an example, illustrates how patients can effectively extract critical information from medication instructions. This includes understanding the medication's name, dosage, expiration date, storage method, effects, and common adverse reactions, followed by practical application and assessment. (2) Two-dimensional code video education cards for common stroke medications were distributed, and patients were instructed on their usage. The educational video content encompassed the medication's name, dosage, effects, common adverse reactions, and medication precautions. The medication instructions were derived from official medication guidelines and were simplified by pharmacists to ensure both accuracy and comprehensibility of the medication information.
Application of medication information understanding	The hospital stay was 4–5 days Group sessions, ward activity room (30–40 min)	Information guidance	The intervention method employed was consistent with the "information guidance" approach within the theme of "disease information acquisition and communication". The primary focus of the intervention involved integrating the content of a two-dimensional code health education video card that addresses common medications for stroke.
		Guidance of motivation	(1) A family system assessment table was developed to evaluate the needs of patients for family support. (2) Main caregivers were required to participate in the intervention, and the advantages of family support in patient treatment were communicated to them. (3) To gain insight into the psychological experiences of caregivers while caring for patients, they were encouraged to express both positive and negative emotions actively, and effective strategies were implemented to assist them in coping with and regulating these emotions. (4) Family members were encouraged to enhance communication with patients, supervise medication adherence, and support patients in building confidence in managing their medications. (5) Available community resources, such as community pharmaceutical clinics and family doctors, were introduced to patients and their primary caregivers to foster social support.
		Behavioral Skills Instruction	(1) The scenarios of missed medication that patients may encounter in daily life were simulated, including forgetting to take medication on time and missing scheduled doses. By reproducing real-life situations, patients can more easily understand and remember effective coping strategies. (2) Through role-play, patients assume the role of individuals in need of care, while medical staff or pharmacists act as mentors. This simulation includes the response process following the identification of adverse reactions, encompassing symptom recognition, emergency treatment, and methods for contacting medical personnel.
Medication management skills were improved	The hospital stay was 6–7 days Group sessions, ward activity room (30–40 min)	Information guidance	(1) This paper discusses the consequences of non-adherence to medication following a stroke, as well as the benefits associated with adherence. (2) It is crucial to explain to patients the common units of drug dosage, including milligrams (mg), grams (g), and micrograms (µg), along with the conversion relationships between these units. (3) Teaching patients simple drug calculation methods, such as weight measurement, is essential for their understanding and management of medication.
		Guidance of motivation	A stroke experience exchange and sharing meeting was convened, inviting pharmacists to participate. Patients were encouraged to share their individual experiences and feelings regarding their conditions, discuss their medication experiences, exchange strategies for coping with medication side effects, and deliberate on methods for ensuring timely medication adherence.
		Behavioral Skills Instruction	(1) Patients will be provided with medication kits for one week, and staff will demonstrate on-site how to repackaging medications into these kits according to the doctor's orders. (2) Assistance will be offered to help patients select appropriate medication reminder tools, including family reminders, mobile phone alarms, and memos. (3) Patients will receive instruction on how to correctly measure blood pressure, monitor blood glucose levels, and administer insulin injections.

Medication guidance at discharge	1 day before discharge Group sessions, ward activity room (30–40 min)	Information guidance	<ol style="list-style-type: none"> <li>(1) The intervention method employed in this study mirrored the “information guidance” approach within the theme of “disease information acquisition and communication”. The primary content of the intervention integrated the “5 Moments of Medication Safety” proposed by the World Health Organization (WHO), which includes recognizing, taking, adding, checking, and stopping medications, tailored to the specific characteristics of discharged stroke patients.</li> <li>(2) It is crucial to emphasize the significance of regular follow-up appointments, enabling physicians to adjust the medication regimen in accordance with the patient’s recovery progress.</li> </ol>
		Guidance of motivation	<ol style="list-style-type: none"> <li>(1) Encouraging patients to openly express their genuine thoughts and feelings, as well as the challenges they encounter in their use of medications—particularly their concerns regarding adverse medication reactions—is essential.</li> <li>(2) It is important to systematically categorize the types and causes of patients’ medication-related issues. By aligning with the actual circumstances, healthcare providers can address these problems individually to resolve patients’ medication challenges, ensuring that they feel respected and understood.</li> <li>(3) Establishing both short-term and long-term health objectives with patients, while connecting their medication behaviors to these goals, can significantly enhance their intrinsic motivation to adhere to their medication regimens.</li> </ol>
		Behavioral Skills Instruction	<ol style="list-style-type: none"> <li>(1) The fundamental principles and precautions regarding medication storage were thoroughly explained to patients.</li> <li>(2) Patients were assisted in selecting fixed daily activities to serve as reminders for medication intake, thereby linking medication adherence with their daily routines.</li> <li>(3) A medication log template was provided to patients, advising them to document their daily medication, including the drug name, dosage, time of administration, bodily reactions, and other relevant information, along with guidance on how to accurately complete the log.</li> </ol>
Medication management behaviors were strengthened	4 weeks after discharge One to one, bedside (10–20 min)	Information guidance	Health education videos about stroke were pushed regularly in the WeChat group of stroke medication management every week.
		Guidance of motivation	<ol style="list-style-type: none"> <li>(1) Following the dissemination of the video, medical staff were assigned to address inquiries within the group, providing answers to questions posed by patients and their families.</li> <li>(2) Reminders for patients and caregivers to view the video were communicated through group announcements or messages, and feedback was collected regularly to gauge the needs and suggestions of both patients and caregivers.</li> </ol>
		Behavioral Skills Instruction	At the outpatient return visit, the writing of the patient’s medication log was checked, and scientific treatment suggestions were provided for the patients with missed medication and adverse reactions.
Follow-up	12 weeks after discharge		<ol style="list-style-type: none"> <li>(1) Patients were followed up via telephone on a monthly basis, during which any medication-related issues encountered at home were addressed.</li> <li>(2) In the third month post-discharge, the SAM scale, the Stroke Knowledge Questionnaire, the Chinese version of the Med Lit Rx SE scale, and the MARS-5 scale were utilized to assess patients’ medication self-management abilities following the intervention. Additionally, patients’ blood pressure and blood lipid levels were measured, and inquiries were made regarding any unplanned readmissions within three months post-discharge.</li> </ol>

**Abbreviations:** SAM, Self-Administration of Medication; Med Lit Rx SE, Medication Literacy in Spanish and English; MARS-5, Medication Adherence Self Report Scale.

This study implemented multi-dimensional preventive measures to mitigate the risks of cross-contamination associated with shared personnel and resources. Firstly, specialized training was conducted for the intervention personnel, and data collectors were instructed to standardize their data collection practices. The roles of the medical teams and researchers were clearly delineated between the intervention group and the control group, with specific personnel designated to implement the intervention for each group. Secondly, the intervention environment and teaching aids were thoroughly cleaned and organized after each intervention. Thirdly, access to the “Stroke Patient Medication Management WeChat Group” was restricted exclusively to the intervention group. Finally, the independence of the group-based intervention was emphasized to both patients and their primary caregivers prior to the intervention, as well as during each intervention and follow-up, with a strict prohibition on the communication of intervention-related content between the groups.

## Outcome Measures

Data were collected at four time points: baseline (T0), day of discharge (T1), week 4 (T2), week 12 (T3). The primary outcome was medication self-management capacity, which was assessed by the Self-Administration of Medication Tool (SAM). The secondary outcomes included stroke-related knowledge, medication literacy, medication adherence, blood pressure, blood lipid levels, and the rate of unplanned readmission.

### Medication Self-Management Capacity

The Self-Administration of Medication Tool (SAM) was developed by Manias et al<sup>26</sup> and subsequently translated into Chinese by Lin et al.<sup>27</sup> SAM is primarily designed to comprehensively evaluate patients’ capacity for self-managing their medications. It encompasses three dimensions: capable to self-medicate (11 items), knowledge about medications (7 items), and experience with self-medication (6 items), totaling 24 items. Each item is scored using a 5-point Likert scale, which includes responses such as “never”, “rarely”, “sometimes”, “often”, and “always”, with corresponding scores ranging from 0 to 4. Higher scores indicate better medication self-management. Scores equal to or greater than 60 are considered indicative of competent medication management, while scores below 60 suggest incompetence. The Cronbach’s  $\alpha$  coefficient of the scale is 0.913.

### Stroke-Related Knowledge

The stroke-knowledge questionnaire was developed by Yao Qiping,<sup>28</sup> a Chinese scholar, encompassing six dimensions: preemptive symptoms, emergency treatment, risk factors, safe medication, behavior, and rehabilitation knowledge, totaling 40 items. A dichotomous scoring system was utilized, assigning 1 point for a correct answer and 0 points for an incorrect answer or “do not know” response. The total score ranged from 0 to 40, with higher scores indicating a greater level of knowledge mastery. The Cronbach’s  $\alpha$  coefficient of the questionnaire is 0.893.

### Medication Literacy

The Medication Literacy in Spanish and English (Med Lit Rx SE) was developed by Saucedo et al<sup>29</sup> and adapted into Chinese by Zheng Feng et al<sup>30</sup> in 2016. This scale simulates four medication use scenarios and consists of 14 items, scored on a 2-point scale, with a maximum score of 14. The medication literacy level of the evaluated individual can be objectively assessed, with higher scores indicating greater levels of medication literacy. The specific evaluation criteria are as follows: a total score exceeding 10 points indicates a high level of medication literacy; a score between 4 and 10 points signifies a medium level; and a score below 4 points reflects poor medication literacy. The scale has been utilized in studies involving populations such as kidney transplant recipients<sup>31</sup> and individuals with coronary heart disease.<sup>32</sup> The Cronbach’s  $\alpha$  coefficient of the scale is 0.937.

### Medication Adherence

We used the five-item version of the Medication Adherence Self Report Scale (MARS) to evaluate adherence to stroke medication.<sup>33</sup> The MARS consists of five general statements about non-adherent behavior on a 5-point Likert scale (1 = always, 2 = often, 3 = sometimes, 4 = rarely, 5 = never). The total score is the sum of the five individual items. A high score indicates a high level of medication adherence. The Chinese version of MARS demonstrated good internal consistency (Cronbach’s  $\alpha$  coefficient was 0.870).<sup>34</sup>

## Blood Pressure, Blood Lipids

Systolic blood pressure (SBP), diastolic blood pressure (DBP), triglyceride (TG), and total cholesterol (TC) levels were obtained from the patients' electronic medical records at the time of admission and subsequently measured again 12 weeks after discharge for analysis.

## Unplanned Readmissions

The study defined unplanned readmissions within 12 weeks post-discharge as those resulting from patient deterioration, complications, or other health issues related to stroke. In this study, patients were primarily queried about readmissions through follow-up telephone calls, and their responses were subsequently verified against the hospital's electronic medical records (EMR) or hospitalization information system (HIS).

## Randomization, Allocation Concealment and Blinding

Participants were randomly assigned in a 1:1 ratio to either the intervention group or the control group through simple randomization. This process was conducted using computer-generated random numbers by a research assistant who was unaware of the study's details. The random numbers and group assignments were sealed in opaque envelopes, which were opened by research assistants after they had assessed the baseline data from participants who provided written informed consent. Given the nature of the intervention, intervention nurses and study participants could not be blinded. However, the outcome assessors and data analysts were blinded to the allocation.

## Statistical Analysis

All data were analyzed using IBM SPSS Statistics 27.0 software (IBM Corporation, Armonk, New York, USA). Prior to conducting the statistical analysis, an assessment of outliers and normality tests was performed on the research data. The sample size for this study comprised 127 participants. Given that a sample size of  $\geq 50$  makes the Kolmogorov–Smirnov test an appropriate method for normality testing,<sup>35</sup> this study utilized this test. Quantitative data exhibiting a normal distribution were presented as mean  $\pm$  standard deviation, while categorical data were reported as frequencies and percentages. Independent sample *t*-tests and chi-square tests were employed for comparisons between groups. Both primary and secondary outcomes were analyzed according to the intention-to-treat (ITT) principle. Little's Missing Completely at Random (MCAR) test was conducted to perform to evaluate the nature of missing data. The generalized estimating equation (GEE) model was utilized to evaluate the impact of the intervention on medication self-management capacity, stroke-related knowledge scores, medication literacy, and medication adherence scores. This model is capable of explaining repeated measurement data with internal correlations and is applicable to datasets with missing values due to loss to follow-up.<sup>36</sup> It can manage missing data using the quasi-likelihood method without requiring interpolation, under the assumption that the data are missing completely at random.<sup>37</sup> Thus, it is particularly suitable for intention-to-treat analysis. The control group (group = 0) and the baseline measurement group (T0) were designated as the reference categories for the GEE model. The interaction term between time and group (group \* time) was employed to measure differences and changes in each variable across time points among the groups. Given that we could not identify known prognostic factors for the main outcomes of this study in the target population from the literature, and considering that baseline characteristics were generally comparable among the different groups, we opted not to adjust the baseline covariates in the GEE analysis. Continuous outcome measures were assessed using Cohen's *d* (standardized mean difference) to estimate effect size.<sup>38</sup> A two-sided *p*-value  $< 0.05$  was considered statistically significant. To determine the robustness of the research findings, a sensitivity analysis (per-protocol analysis) was conducted in this study.<sup>39</sup>

## Results

### Participant Flow

A total of 219 stroke patients were screened prior to the commencement of the study, of which 127 eligible participants were included and randomly assigned to either the intervention group ( $n = 63$ ) or the control group ( $n = 64$ ). The CONSORT flowchart is shown in Figure 2. Data collection was completed for 119 participants at T1, 111 at T2, and 104 at T3, the reasons for the dropouts in the intervention group included being transferred to other hospitals, refusal to

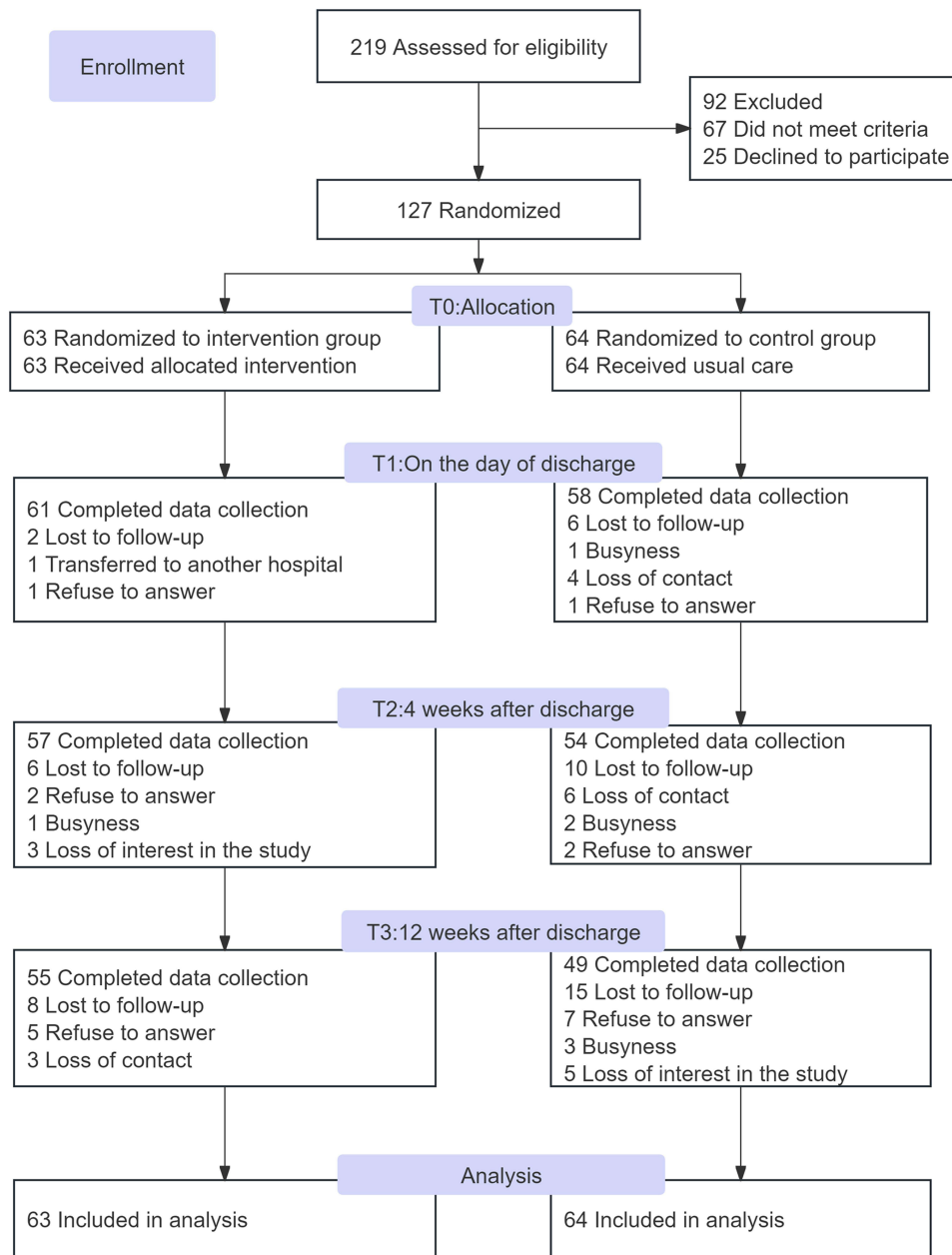


Figure 2 The CONSORT flowchart.

answer, work commitments, and loss of interest in the study. For the control group, the main reasons for dropout were refusal to answer and loss of contact.

The attrition rate at T3 was 18.1%. In No statistically significant differences were observed in baseline characteristics regarding socio-demographic features and outcome variables between participants who completed the study and those who dropped out (as shown in [Supplementary Material Table 1](#)), implying the attrition bias is minimal.

### Baseline Characteristics

The mean age of the 127 participants was 67.47 years, with more than half being female (52.0%). Additionally, 70.9% of the participants had received junior high school education or higher. A significant majority, 88.2%, lived with their families, while a minor proportion were unemployed, and the per capita monthly household income was below 3000 yuan. All participants were covered by health insurance. In terms of medical characteristics, the majority of participants had ischemic stroke

(89.8%), and 52.8% reported no family history of stroke. Most participants had a disease duration exceeding one year (61.4%) and were prescribed fewer than five types of medication (55.1%). Furthermore, 62.2% of participants took medication twice or more per day without guidance. All patients demonstrated certain self-care abilities. Overall, the mean systolic blood pressure was elevated at 152.07 mmHg, while the mean diastolic blood pressure was 83.51 mmHg. The mean triglyceride level was 1.39 mmol/L, and the total cholesterol level was 3.89 mmol/L, both of which fell within normal ranges. There were no statistically significant differences in baseline characteristics between the two groups (Table 2).

**Table 2** Baseline Socio-Demographic and Clinical Characteristics for the Intervention and Control Groups

Characteristics	Control Group (n=64) Mean (SD)	Intervention Group (n=63) Mean (SD)	t/ $\chi^2$ -value
Age	68.33(6.88)	66.60(4.87)	7.662 <sup>a</sup>
Gender, n (%)			0.069 <sup>b</sup>
Female	30(46.9)	31(49.2)	
Male	34(53.1)	32(50.8)	
Education level, n (%)			0.790 <sup>b</sup>
Elementary school and below	17(26.6)	20(31.7)	
Junior high school	17(26.6)	17(27.0)	
Senior high school	20(31.3)	19(30.2)	
Technical school or college	10(15.5)	7(11.1)	
Status of residence, n (%)			0.735 <sup>b</sup>
Live alone	6(9.4)	9(14.3)	
Cohabitation	58(90.6)	54(85.7)	
Monthly income (Chinese Yuan), n (%)			0.022 <sup>b</sup>
<3000	17(26.6)	17(27.0)	
3000-6000	30(46.8)	30(47.6)	
>6000	17(26.6)	16(25.4)	
Employment status, n (%)			0.944 <sup>b</sup>
In-service staff	21(32.8)	16(25.4)	
Retiree	27(42.2)	31(49.2)	
Unemployed	16(25.0)	16(25.4)	
Medical insurance, n (%)			2.271 <sup>b</sup>
Basic medical insurance for urban employees	27(42.2)	35(55.6)	
Basic medical insurance for rural and non-working urban residents	37(57.8)	28(44.4)	
Stroke type, n (%)			0.720 <sup>b</sup>
Ischemic stroke	56(87.5)	58(92.1)	
Hemorrhagic stroke	8(12.5)	5(7.9)	
Family history of stroke, n (%)			1.790 <sup>b</sup>
Yes	34(53.1)	26(41.3)	
No	30(46.9)	37(58.7)	
Course of disease, n (%)			0.622 <sup>b</sup>
<1	26(40.6)	23(36.5)	
1-6	29(45.3)	28(44.4)	
>6	9(14.1)	12(19.1)	
Types of medication, n (%)			0.379 <sup>b</sup>
<5	37(57.8)	33(52.4)	
≥5	27(42.2)	30(47.6)	
Frequency of medication use, n (%)			0.195 <sup>b</sup>
1	25(39.1)	23(36.5)	
2	10(15.6)	9(14.3)	
≥3	29(45.3)	31(49.2)	

(Continued)

**Table 2** (Continued).

Characteristics	Control Group (n=64) Mean (SD)	Intervention Group (n=63) Mean (SD)	t/ $\chi^2$ -value
Medication guide, n (%)			0.088 <sup>b</sup>
Yes	25(39.1)	23(36.5)	
No	39(60.9)	40(63.5)	
Self-care ability, n (%)			0.207 <sup>b</sup>
Mild dependence	34(53.1)	36(57.1)	
Independent living	30(46.9)	15(42.9)	
Medication self-management capacity (SAM)	59.17(5.34)	59.71(5.36)	-0.571 <sup>a</sup>
Capable to self-medicate	22.92(2.95)	23.32(3.30)	-0.712 <sup>a</sup>
Knowledge about medications	21.50(1.78)	21.76(1.88)	-0.806 <sup>a</sup>
Experience with self-medication	14.75(1.38)	14.36(1.14)	0.512 <sup>a</sup>
Stroke-related knowledge	24.53(1.54)	24.29(1.53)	0.901 <sup>a</sup>
Medication literacy (Med Lit Rx SE)	5.48(1.22)	5.63(1.32)	-0.694 <sup>a</sup>
Medication adherence (MARS-5)	15.48(2.02)	15.22(1.59)	0.811 <sup>a</sup>
Systolic blood pressure (mmHg)	153.59(22.76)	150.52(19.36)	0.818 <sup>a</sup>
Diastolic blood pressure (mmHg)	84.25(11.84)	82.76(11.32)	0.724 <sup>a</sup>
Triglyceride (mmol/L)	1.46(0.77)	1.31(0.49)	1.214 <sup>a</sup>
Total Cholesterol (mmol/L)	3.87(1.03)	3.91(1.06)	-0.242 <sup>a</sup>

Notes: <sup>a</sup> Independent-test; <sup>b</sup> Chi-square test.

Abbreviations: SD, Standard Deviation; SAM, Self-Administration of Medication; Med Lit Rx SE, Medication Literacy in Spanish and English; MARS-5, Medication Adherence Self Report Scale.

## Outcomes

### Effects of the Intervention on Medication Self-Management Capacity

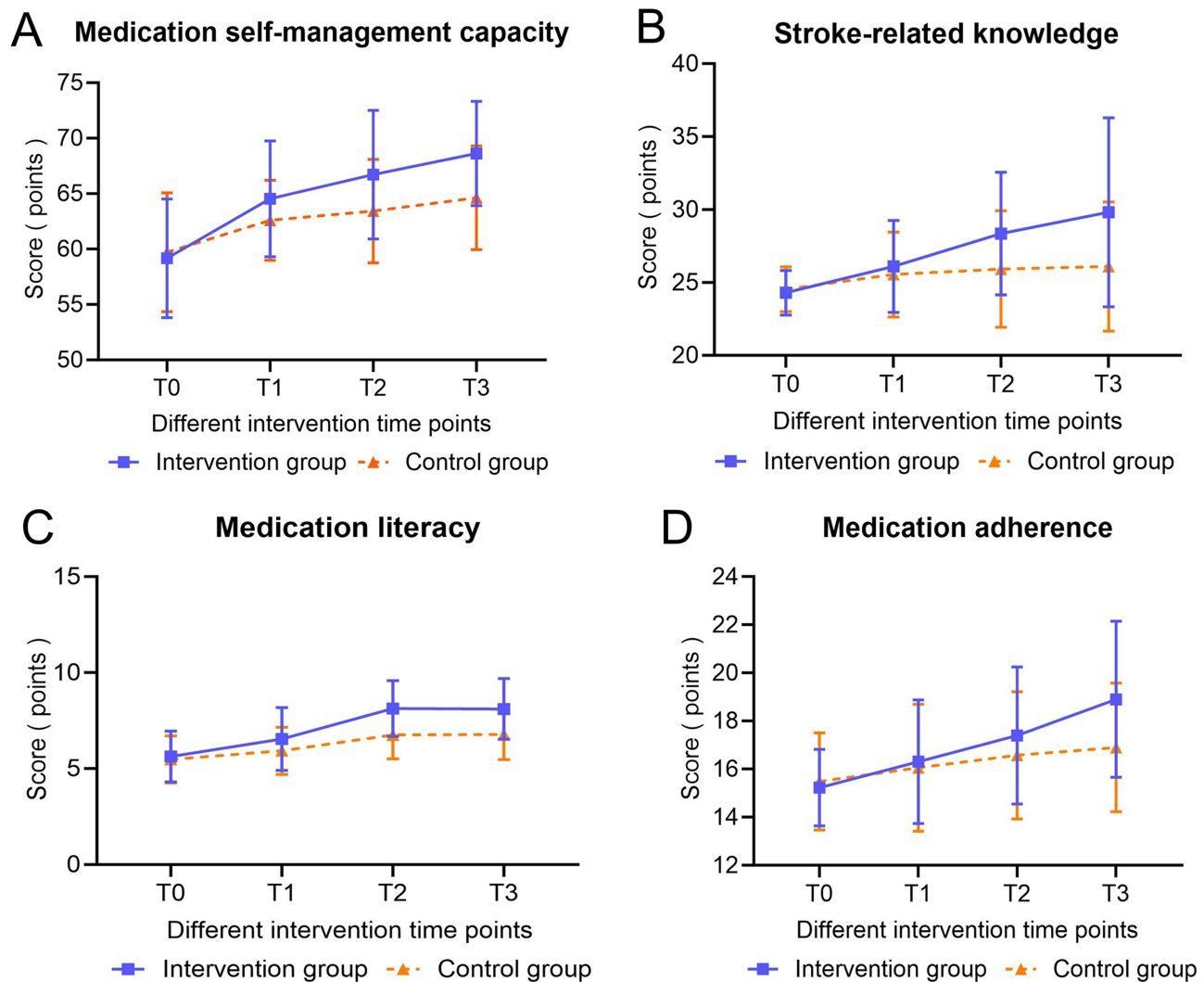
Table 3 and Figure 3A present the research results of the primary outcomes. Little's test for completely random missingness indicated a non-significant result ( $p = 0.101$ ), suggesting that the data were missing completely at random. In comparison to the control group, the intervention group demonstrated a significant improvement in medication self-management ability, as measured by the SAM scale at T1 ( $\beta = 1.41, p = 0.045$ ). This positive effect was sustained at T2 and T3 (T2:  $\beta = 2.74, p = 0.003$ ; T3:  $\beta = 3.46, p = 0.003$ ). The effect sizes at T1, T2, and T3 were 0.31, 0.52, and 0.74, respectively, indicating that the medication literacy intervention had a small to moderate effect on enhancing medication self-management. The Generalized Estimating Equations (GEE) results revealed significant interaction effects between the groups and time for the ability to self-medicate (T2:  $\beta = 0.98, p = 0.034$ ; T3:  $\beta = 1.78, p = 0.010$ ) and experience with self-medication (T2:  $\beta = 1.19, p = 0.021$ ; T3:  $\beta = 1.14, p = 0.048$ ) at T2 and T3, but no interaction effect was observed at T1. Notably, there were no significant differences in medication-related cognition scores between the two groups at T1, T2, or T3. Figure 3A illustrates the changes in medication self-management capacity scores for the two groups across different intervention time points.

### Effects of the Intervention on the Level of Stroke-Related Knowledge, Medication Literacy and Medication Adherence

Compared to routine care, the medication literacy intervention significantly enhanced medication literacy (T2: Cohen's  $d = 0.89$ ; T3: Cohen's  $d = 0.81$ ), demonstrated a moderate effect in improving stroke-related knowledge (T2: Cohen's  $d = 0.65$ ; T3: Cohen's  $d = 0.71$ ), and showed a small to medium effect on medication adherence (T2: Cohen's  $d = 0.39$ ; T3: Cohen's  $d = 0.49$ ). At T2 and T3, the intervention group exhibited statistically significant differences in stroke-related knowledge (T2:  $\beta = 2.67, p < 0.001$ ; T3:  $\beta = 3.97, p < 0.001$ ), medication literacy (T2:  $\beta = 1.22, p < 0.001$ ; T3:  $\beta = 1.18, p < 0.001$ ), and medication adherence (T2:  $\beta = 1.07, p = 0.034$ ; T3:  $\beta = 1.45, p = 0.013$ ) when compared to the control group. At T1, the effect sizes for stroke-related knowledge, medication literacy, and medication adherence were minimal, measuring 0.27, 0.32, and 0.19, respectively. Generalized estimating equation (GEE) analysis in Table 4 indicated no significant interaction between group and time for stroke-related knowledge ( $\beta =$

**Table 3** Generalized Estimating Equation Models of the Comparison of Medication Self-Management Capacity Between the Intervention and Control Groups

Outcome Variables	Intervention Group Mean (SD)	Control Group Mean (SD)	Time Effect		Group Effect		Group*Time Effect		Cohen' d
			$\beta$ (95%CI)	p	$\beta$ (95%CI)	p	$\beta$ (95%CI)	p	
Medication self-management capacity					0.54 (-1.30, 2.39)	0.565			
Time 1	64.53 (5.22)	62.59 (3.61)	3.42 (2.48, 4.35)	<0.001			1.41 (0.03, 2.78)	0.045	0.31
Time 2	66.71 (5.81)	63.42 (4.66)	4.25 (3.08, 5.42)	<0.001			2.74 (0.96, 4.53)	0.003	0.52
Time 3	68.62 (4.70)	64.62 (4.68)	5.45 (4.11, 6.78)	<0.001			3.46 (1.18, 5.73)	0.003	0.74
Capable to self-medicate					0.40 (-0.69, 1.48)	0.474			
Time 1	24.24 (3.58)	23.39 (2.57)	0.47 (-0.05, 0.10)	0.078			0.45 (-0.70, 3.51)	0.270	0.14
Time 2	25.14 (3.75)	23.76 (2.65)	0.84 (0.25, 1.43)	0.005			0.98 (0.97, 7.37)	0.034	0.30
Time 3	26.94 (3.36)	24.77 (3.20)	1.85 (1.01, 2.69)	<0.001			1.78 (1.54, 22.80)	0.010	0.54
Knowledge about medications					0.26 (-0.37, 0.90)	0.417			
Time 1	22.17 (2.24)	21.48 (1.40)	-0.02 (-0.47, 0.44)	0.941			0.42 (-0.33, 1.17)	0.270	0.22
Time 2	23.67 (2.42)	22.29 (1.52)	0.79 (0.42, 1.16)	<0.001			0.52 (-0.28, 1.32)	0.203	0.26
Time 3	23.50 (2.26)	22.77 (1.11)	1.28 (0.82, 1.73)	<0.001			0.46 (-0.46, 1.38)	0.330	0.14
Experience with self-medication					-0.12(-0.55, 0.32)	0.605			
Time 1	18.12 (2.42)	17.71 (1.40)	2.96 (2.55, 3.37)	<0.001			0.52 (-0.32, 1.37)	0.225	0.26
Time 2	18.46 (2.44)	17.38 (2.82)	2.63 (1.87, 3.40)	<0.001			1.19 (2.20, 5.34)	0.021	0.45
Time 3	18.12 (3.05)	17.10 (2.52)	2.35 (1.61, 3.08)	<0.001			1.14 (0.01, 2.27)	0.048	0.41



**Figure 3** Changes in the scores of the medication (A) self-management capacity, (B) stroke-related knowledge, (C) medication literacy and (D) medication adherence of patients were observed.

0.81,  $p = 0.172$ ), medication literacy ( $\beta = 0.46$ ,  $p = 0.082$ ), and medication adherence scores ( $\beta = 0.50$ ,  $p = 0.278$ ) at T1. Figure 3B–D respectively illustrate the changes in stroke-related knowledge, medication literacy and medication adherence scores for the two groups at different intervention time points.

### Effects of the Intervention on Blood Pressure, Blood Lipids, and Unplanned Readmission Rates

The effects of the intervention on blood pressure, blood lipids, and unplanned readmission rates are presented in Table 5 and Table 6. Compared to the control group, both SBP and DBP were significantly lower in the intervention group at T3, with effect sizes of 0.16 and 0.37, respectively. This indicates that the intervention had a mild to moderate effect on blood pressure. However, no significant changes were observed in the levels of TG, TC, or the rate of unplanned readmission in the intervention group ( $p > 0.05$ ).

### Sensitivity Analysis

Sensitivity analysis is essential for evaluating the robustness of research findings derived from the original data.<sup>40</sup> The sensitivity analysis performed using the per-protocol (PP) approach demonstrated that both the primary and secondary outcome indicators yielded results comparable to those obtained from the main analysis based on ITT. This confirmed

**Table 4** Generalized Estimating Equation Models of the Comparison of Stroke-Related Knowledge, Medication Literacy and Medication Adherence Between the Intervention and Control Groups

Outcome Variables	Intervention Group Mean (SD)	Control Group Mean (SD)	Time Effect		Group Effect		Group*Time Effect		Cohen' d
			$\beta$ (95%CI)	p	$\beta$ (95%CI)	p	$\beta$ (95%CI)	p	
Stroke-related knowledge					-0.25 (-0.78-0.28)	0.364			
Time 1	26.10 (3.15)	25.54 (2.91)	1.01 (0.23, 1.79)	0.011			0.81 (-0.35, 1.97)	0.172	0.27
Time 2	28.35 (4.20)	25.92 (3.99)	1.39 (0.33, 2.45)	0.010			2.67 (1.11, 4.24)	<0.001	0.65
Time 3	29.81 (6.48)	26.09 (4.43)	1.56 (0.26, 2.86)	0.019			3.97 (1.77, 6.17)	<0.001	0.71
Medication literacy					0.15 (-0.27-0.57)	0.484			
Time 1	6.54 (1.64)	5.93 (1.23)	0.45 (0.13, 0.77)	0.006			0.46 (-0.06, 0.98)	0.082	0.32
Time 2	8.13 (1.45)	6.76 (1.26)	1.28 (0.89, 1.66)	<0.001			1.22 (0.68, 1.77)	<0.001	0.89
Time 3	8.11 (1.58)	6.78 (1.31)	1.29 (0.89, 1.70)	<0.001			1.18 (0.57, 1.79)	<0.001	0.81
Medication adherence					-0.26 (-0.89-0.37)	0.413			
Time 1	16.30 (2.57)	16.06 (2.64)	0.58 (-0.15, 1.30)	0.117			0.50 (-0.40, 1.41)	0.278	0.19
Time 2	17.39 (2.85)	16.57 (2.65)	1.09 (0.34, 1.83)	0.004			1.07 (0.08, 2.06)	0.034	0.39
Time 3	18.90 (3.24)	16.90 (2.67)	1.41 (0.66, 2.17)	<0.001			1.45 (0.31, 2.60)	0.013	0.49

**Table 5** Pairwise Comparison of Blood Pressure and Blood Lipids Between the Two Groups After Intervention

Variable	Control Group (n=64) Mean (SD)	Intervention Group (n=63) Mean (SD)	t-value	p-value	Cohen' d
SBP	145.70(12.10)	141.16(10.40)	2.269	0.025	0.16
DBP	82.28(7.83)	79.56(6.81)	2.092	0.038	0.37
TG	1.37(0.50)	1.25(0.41)	1.421	0.158	0.25
TC	3.76(0.83)	3.59(0.64)	1.298	0.197	0.23

**Table 6** Pairwise Comparison of Unplanned Hospital Readmission Rates Between the Two Groups After Intervention

Variable	Number of Unplanned Hospital Readmissions	Occurrence Rate	Z-value	p-value
Control group (n=64)	5	7.8%	0.501	0.479
Intervention group (n=63)	3	4.8%		

that the research results and conclusions regarding initial effectiveness of the medication literacy intervention, grounded in multidisciplinary collaboration, were reliable ([Supplementary Table 2](#)).

## Discussion

The effectiveness of a medication literacy intervention program based on the IMB model for patients with stroke was evaluated in terms of medication-related and health-related outcomes. We found that the intervention produced statistically significant positive effects on enhancing patients' short-term medication self-management capacity. Additionally, improvements were observed in stroke-related knowledge, medication literacy, medication adherence, and blood pressure. However, the intervention did not yield statistically significant effects on blood lipid levels, including triglycerides and total cholesterol, nor did it affect the rate of unplanned readmission.

The medication literacy intervention based on the IMB model significantly enhanced the participants' capacity for medication self-management. From the time of admission to 12 weeks post-discharge, the medication self-management levels of stroke patients exhibited a continuous upward trend following the intervention, aligning with the findings of Van.<sup>41</sup> Studies have shown that low memory and executive function are linked to inadequate medication self-management.<sup>42</sup> Due to the neurological dysfunction associated with the condition, 30% to 60% of stroke patients experience varying degrees of memory decline, attention deficits, and executive dysfunction,<sup>43</sup> which severely impairs their ability to manage medications effectively. Consequently, effective medication self-management necessitates a series of cognitive processes, particularly memory and executive functions.

Our study provided patients with essential information about medications through health education. Additionally, we delivered educational videos featuring QR codes for common medications used in stroke management, allowing patients to scan the codes and watch the videos multiple times to reinforce their understanding and facilitate long-term memory retention. Furthermore, we conducted motivational interviews and offered behavioral skills guidance, including training patients to utilize medication reminder tools. This approach enabled patients to acquire specific medication management skills, while their executive functioning improved through simulated scenarios and case analyses. Moreover, a retrospective study examining the correlation between pharmacist-provided medication guidance and medication self-management revealed that the success of medication self-management remains closely tied to the guidance provided by pharmacists, particularly among hospitalized older adults undergoing rehabilitation.<sup>44</sup> Ernawati et al<sup>45</sup> further illustrated that pharmacist involvement significantly enhances patients' medication adherence and self-management capabilities, while also reducing

the incidence of medication-related problems. Collectively, these findings, along with our current study, underscore the effectiveness of a multidisciplinary intervention team, including pharmacists, in enhancing medication self-management.

The current study highlights that at both the 4th and 12th weeks following the intervention, there was a significant increase in stroke related knowledge among stroke patients, aligning with the findings of previous research.<sup>46</sup> This effect can be attributed to several potential mechanisms: our study utilized a feedback method<sup>47</sup> to provide informational guidance to patients, coupled with motivational interviewing. This approach empowered patients to better recognize their own abilities and potential, thereby enhancing their self-efficacy in disease management. Consequently, the improvement in self-efficacy encourages patients to engage more actively in learning and rehabilitation activities, continuously strengthening their health awareness and maintaining focus on disease knowledge post-intervention, which facilitates effective self-management of their conditions. It is anticipated that this increase in knowledge will positively influence patients' attitudes towards medication, foster a scientific understanding of "active medication", and subsequently enhance medication literacy and adherence.

A cross-sectional survey<sup>48</sup> has confirmed that medication literacy is a crucial factor influencing medication adherence, with a significant positive correlation between the two. Specifically, the intervention notably improved participants' medication literacy, which directly or indirectly enhanced the patients' medication adherence. Thus, the effectiveness of the intervention can be elucidated through the IMB model.<sup>49</sup> Our intervention significantly augmented patients' disease knowledge reserves. Building upon this foundation, we systematically enhanced patients' medication literacy levels through targeted guidance and scenario simulation training, alleviating the burden of medication use and ultimately improving adherence. Similarly, previous studies based on the IMB model have identified comparable intervention mechanisms. Mirzaei-Alavijeh et al<sup>50</sup> implemented an incentive education course grounded in the IMB model for elderly patients with type 2 diabetes, confirming that this intervention could enhance medication literacy by improving medication knowledge and self-efficacy, thus leading to better adherence. Jia et al<sup>51</sup> furthermore demonstrated that providing essential information, motivation, and behavioral skills during the intervention significantly improves patients' medication adherence, warranting clinical promotion and application. Furthermore, considering that polypharmacy and complex medication regimens are prevalent factors contributing to poor patient adherence,<sup>52</sup> this study suggests that introducing medication management auxiliary tools (such as smart reminder devices and dose-separated medicine boxes) can simplify the medication process, aiding patients in understanding and executing their treatment plans, thereby continuously enhancing medication adherence.

Blood pressure serves as a critical indicator for evaluating the health status of stroke patients, with its management directly impacting medication adherence<sup>53</sup> and treatment efficacy.<sup>54</sup> Consequently, standardized blood pressure monitoring and management can effectively prevent both the occurrence and recurrence of strokes, thereby enhancing patient prognosis. In our study, we observed that motivational information delivered through phone calls and brief standardized medication reminder messages can contribute to lowering blood pressure. These messages are crucial for stroke patients, as they facilitate positive changes in blood pressure when patients are adequately informed and motivated. However, it is noteworthy that, despite the observed reductions in both systolic and diastolic blood pressures among participants, the systolic blood pressure of some patients remained above the normal range. Relevant literature indicates that lifestyle management is a vital component of hypertension treatment.<sup>55</sup> Although medication literacy intervention can help patients recognize the detrimental effects of unhealthy lifestyles, the absence of comprehensive guidance and interventions addressing lifestyle factors - such as diet, exercise, and psychological well-being - poses challenges for achieving significant changes in short term, thereby impacting blood pressure control.

Dyslipidemia is a significant risk factor for stroke. Research indicates that for every 1 mmol/L increase in total cholesterol, the risk of stroke rises by 25%.<sup>56</sup> Unfortunately, during the follow-up period, although lipid levels decreased, no statistically significant differences were observed. This outcome may be attributed to the complexities involved in lipid management. The management of lipids in stroke patients relies not only on pharmacological treatment but is also influenced by various factors.<sup>57</sup> While medication literacy interventions can significantly enhance patients' self-management of medications, the control of lipid levels is closely related to patients' dietary, physical activity, genetic predispositions, and comorbidity. Consequently, it is challenging to comprehensively address all key aspects of lipid management through medication literacy interventions alone.

Readmission is one of the most frequently used indices of quality of care. Hospital readmissions, particularly unplanned ones, are regarded as unpredictable outcomes of care.<sup>58</sup> The readmission rate for stroke patients is notably elevated compared to restriction diseases,<sup>59</sup> with polypharmacy being a common reason for readmission among elderly stroke patients. A retrospective study<sup>60</sup> found that elderly patients aged 65 and older who were discharged experienced readmissions due to medication-related issues within 30 days post-discharge, accounting for approximately 20% to 40% of total readmissions during this period. Therefore, effective pre-discharge care planning and post-discharge medication management are essential to reduce the readmission rate among stroke patients. Unfortunately, while this study can enhance patients' medication self-management capacity and effectively reduce complications such as infections and thrombosis resulting from medication errors or poor control of risk factors, it fails to significantly decrease the unplanned readmission rate among stroke patients. This restriction is attributed to the complex health status of patients, the diversity of readmission incentives, and the integration challenges within the medical system. Future efforts should focus on developing a comprehensive intervention model that includes "medication literacy, psychological support, rehabilitation nursing, and multidisciplinary follow-up", as well as optimizing the allocation of medical resources to more comprehensively reduce the risk of readmission.

This study identified a differential dropout rate at the T3 stage, with the control group exhibiting a dropout rate of 23.4%, compared to 15.9% in the intervention group. This dropout pattern may either attenuate or exaggerate the intervention effect, potentially leading to a deviation of the research conclusions from the actual situation.<sup>61</sup> To assess the stability of the research findings, we conducted a sensitivity analysis. Initially, we employed ITT analysis as the primary method, adhering strictly to the principle of including all randomly assigned subjects in the analysis according to their original groups. This approach objectively reflects the intervention effect under varying dropout rates within the actual research context.<sup>62</sup> Subsequently, the PP analysis conducted as part of the sensitivity analysis corroborated the findings of the ITT analysis, with both approaches yielding consistent conclusions. Importantly, there were no significant differences in key baseline characteristics between the dropouts and the completers, suggesting that the dropout situation was not influenced by the observed confounding factors. In conclusion, despite the observed differential dropout phenomenon, the consistency of the sensitivity analysis results and the verification of the causes of dropout indicate that the main conclusions of this study are robust.

It is noteworthy that, despite the implementation of certain prevention and control measures in this study, potential risks of cross-contamination may still persist. Specifically, the direction of contamination is primarily evidenced by the control group receiving partial intervention-related information, which may diminish the observed outcome differences between the intervention and control groups, thereby leading to an underestimation of the true efficacy of the intervention measures. Nonetheless, an analysis of the actual prevention and control measures suggests that the extent of such impact is limited. On one hand, the control group did not engage in core intervention sessions, such as group guidance, role-playing, and WeChat group notifications, and could only access fragmented information, which hampers the achievement of a comprehensive intervention effect. On the other hand, the ITT analysis incorporated all randomized patients; thus, even if minor cross-contamination occurred, its influence on the overall results has been partially alleviated through the ITT principle. Furthermore, the consistency between the results of the PP analysis, conducted as a sensitivity analysis, and the ITT analysis further corroborates the robustness of the conclusions, indicating that potential cross-contamination did not systematically affect the core findings. Future multi-center studies could enhance prevention and control strategies by implementing grouping based on different hospitals and designating dedicated medical teams to assume full responsibility throughout the study, thereby reducing cross-contamination risks linked to shared resources and more accurately validating the efficacy of the intervention measures.<sup>63</sup>

## Limitations

Despite its strengths, this study has several limitations. Firstly, due to resource constraints, the research was conducted at a university-affiliated hospital in Wuxi City, which may limit the generalizability of the results. Conducting multi-center studies would enhance the robustness of our findings. Secondly, the 12-week follow-up period is relatively short; we believe that an endpoint exceeding six months would provide more conclusive evidence regarding the long-term benefits of the multidisciplinary drug literacy intervention based on the IMB model. Thirdly, the study's participant population

did not include patients with cognitive dysfunction or severe physical disabilities, meaning the applicability of the intervention plan to these groups remains unverified. Future research should consider designing stratified intervention strategies and formulating targeted measures based on the varying functional conditions of patients, such as implementing a family collaborative care model. Finally, the high dropout rate, particularly in the control group, may have compromised the study's ability to detect differences between the groups.

## Conclusion

This study has demonstrated that a medication literacy intervention based on the IMB model can effectively enhance the medication self-management capacity of stroke patients. Furthermore, these interventions positively influence the knowledge levels, medication literacy, and adherence of stroke patients, as well as their health conditions, including blood pressure. However, our research found no significant beneficial effects on blood lipid levels or unplanned readmission rates. Future research should focus on developing a comprehensive intervention model that integrates medication literacy, psychological support, rehabilitation care, and multidisciplinary follow-up. Additionally, long-term, multi-center studies are necessary to validate our findings and provide robust evidence regarding the effectiveness of IMB model-based medication literacy interventions for stroke patients supported by a multidisciplinary team.

## Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and received approval from the Research Ethics Committee of the Affiliated Hospital of Jiangnan University (No.LS2023063). Additionally, it was registered with the Chinese Clinical Trial Registry (ChiCTR2400084673).

## Data Sharing Statement

Upon reasonable request, communicating the correspondence author (Yibo Wu) may present data in favor of the results of this research.

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## Disclosure

All of the authors had no any personal, financial, commercial, or academic conflicts of interest separately for this work.

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