Comprehensive Management of High-Risk Populations for Stroke Based on Social Networks in China: A Multicenter Randomized Clinical Trial (COMPLIANCE-MT)

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Statement of Confidentiality

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1 Protocol Summary

Comprehensive Management of High-Risk Population for Stroke Based on Social Network in china: A Multicenter Randomized Clinical Trial

1.1 Study Objectives

The objective of this study is to evaluate the effectiveness of social network-based interventions in improving medication adherence and risk factor management rates among high-risk stroke patients after hospital discharge.

1.2 Study Outcom

Primary Outcom：

The primary outcome is good Medication Adherence to all guideline-recommended vascular prevention medications at 12 months post-discharge

Adherence is assessed using self-reported data, with participants asked to indicate the number of days they missed taking a dose for each medication class during the preceding 30 days. This evaluation is conducted separately for each of the five evidence-based secondary prevention drug classes: antihypertensives, hypoglycemics, lipid-lowering agents, anticoagulants, and antiplatelets. Good adherence for each class is defined as taking the prescribed medication on more than 24 days out of the previous 30 days (corresponding to an adherence rate >80%). To meet the primary endpoint, a participant must achieve this >80% adherence threshold simultaneously across all five medication classes at the 12-month follow-up.

Any self-directed cessation or adjustment of the regimen without medical consultation is categorized as non-adherence. Conversely, patients who cease or adjust their medications according to medical advice will be considered adherent. For those who adjust their medications based on medical advice, adherence will be further assessed by inquiring about the number of days the medications were taken in the past month; if the number of days exceeds 24, they will be classified as adherent.

Secondary efficacy endpoints：

1) Proportion of good medication adherence to stroke prevention drugs at 1-, 3-, 6-, and 12-months post-discharge (assessed using the Morisky-8 Medication Adherence Scale [MMAS-8]). Good adherence is defined as an MMAS-8 score greater than 6.

2) Risk factor control, including blood glucose, blood pressure, lipid profile, body mass index (BMI), waist circumference, hip circumference, and smoking status, at 1-, 3-, 6-, and 12-months post-discharge.

3) Health-related quality of life (HRQoL) assessed using the EuroQol Five-Dimension Five-Level Scale (EQ-5D-5L) at 1-, 3-, 6-, and 12-months post-discharge.

4) Anxiety symptom severity assessed using the 7-item Generalized Anxiety Disorder Scale (GAD-7) at 1-, 3-, 6-, and 12-months post-discharge.

5) Depressive symptom severity assessed using the 9-item Patient Health Questionnaire (PHQ-9) at 1-, 3-, 6-, and 12-months post-discharge.

6) Stroke prevention knowledge scores assessed using the Stroke Prevention Knowledge Questionnaire at 1-, 3-, 6-, and 12-months post-discharge.

7) Personal motivation for stroke prevention assessed using the Stroke Attitude Questionnaire at 1-, 3-, 6-, and 12-months post-discharge.

8) Perceived social support assessed using the Perceived Social Support Scale (PSSS) at 1-, 3-, 6-, and 12-months post-discharge.

9) Stroke prevention-related health behavior scores assessed using the Stroke Prevention Health Behavior Scale at 1-, 3-, 6-, and 12-months post-discharge.

10) Self-efficacy for chronic disease management assessed using the Chronic Disease Self-Efficacy Scale at 1-, 3-, 6-, and 12-months post-discharge.

11) Intentions regarding prehospital delay in stroke emergency care assessed using the Prehospital Delay Behavior Intention Scale for Stroke at 1-, 3-, 6-, and 12-months post-discharge.

12) Incidence of major adverse cerebrovascular and cardiovascular events (MACCE), including stroke, acute coronary syndrome, and vascular death, at 1-, 3-, 6-, and 12-months post-discharge.

1.3 Study Design

COMPLIANCE-MT is a multicenter, prospective, parallel-group, randomized controlled superiority trial designed to evaluate the efficacy of a social network-based integrated management program compared with standard care for improving medication adherence and optimizing modifiable risk factor control in high-risk stroke populations during a 12-month follow-up period after discharge.Followed up would be conducted at 1, 3, 6, and 12 months after discharge.

Following the confirmation of participant eligibility according to pre-specified inclusion and exclusion criteria, formal informed consent will be obtained. All consenting procedures must be completed before the randomization process is initiated. The study is conducted in compliance with local and international regulatory and ethical requirements and was approved by was approved by ethics committee at each participating hospital prior any trial activities being undertaken.

1.4 Study Population

The population of this study is consisted of individuals at high risk for apoplexy. Participants were required to meet all inclusion and exclusion criteria for enrollment.

1.5 Inclusion Criteria

Patients must meet all of the following inclusion criteria and none of the subsequent exclusion criteria to be enrolled as subjects in this study:

1) Age ≥18 years.

2) Hospitalized patients at high risk of stroke are those who have at least three of the following risk factors: hypertension, dyslipidemia, diabetes, atrial fibrillation/valvular disease, smoking history, overweight/obesity, physical inactivity, or family stroke history; or those with a history of prior transient ischemic attack (TIA) or stroke.12

3) modified Rankin Scale (mRS) score ≤2.

4) Smartphone/WeChat access (patient or caregiver).

5) Informed consent obtained.

6) Active long-term therapy: ≥1 medication (antihypertensive, hypoglycemic, lipid-lowering, anticoagulant, antiplatelet).

1.6 Exclusion criteria

1) Inability to operate smartphones (patient or caregiver).

2) Comorbidities potentially confounding outcome assessments, including Advanced malignancies (life expectancy <12 months); Documented dementia; Severe psychiatric disorders (e.g., schizophrenia, major depressive disorder).

3) Residence in areas with unreliable internet access.

4) Concurrent participation in other clinical trials.

5) Any condition deemed by investigators to preclude safe trial participation.

1.7 Intervention

Eligible participants will be randomly assigned to either the conventional care group or social network-based intervention group.

Conventional care group: Patients in conventional care group will receive standardized education based on ASA/AHA2021 guidelines prior to discharge,2 delivered verbally by a certified Brain-Heart Health Manager (BHHM) and supplemented with an expert-reviewed booklet. Content will cover medication adherence, risk factor control, stroke recognition, emergency response, and follow-up plans. A contact number will be provided for post-discharge support. A baseline archive will document demographics, lifestyle, and cardiovascular risk factors.

Social network-based intervention group: Prior to discharge, participants in Social network-based intervention group are onboard to the integrated digital platform in addition to conventional care. BHHMs facilitate the activation of the digital interface via a unique QR code, assist in the creation of a comprehensive electronic health record (EHR), and guide participants through an interactive tutorial to ensure technical proficiency in data entry and communication features. Post-discharge, participants in intervention group will receive comprehensive management via the social network-integrated digital platform, including pharmacotherapy support(automated, dose-specific push notifications for medication reminders and timestamped adherence verification), precision education(weekly multimedia content tailored to the participant's dynamic risk profile, derived from AHA/ASA guidelines),

biometric surveillance(real-time clinical alerts for abnormal biometric data[e.g., SBP >140mmHg]), telehealth access(on-demand secure messaging and video consultations with BHHMs, with a guaranteed response time within 24 hours.)

2 Protocol Text

Enhancing patients' adherence to medications for stroke prevention—including antihypertensive, hypoglycemic, lipid-lowering, anticoagulant, and antiplatelet agents—and modifying unhealthy lifestyle habits play a crucial role in preventing stroke.[1,2] However, how to scientifically and effectively implement comprehensive post-discharge management for stroke patients, improve their medication adherence, and optimize patient education remains a key challenge in stroke prevention and control. In recent years, telemedicine interventions based on social networking platforms have been applied in clinical practice, with relevant studies demonstrating their significant efficacy in improving medication adherence and controlling modifiable risk factors among patients.[3] Therefore, we intend to further evaluate the effectiveness of this approach in stroke high-risk populations.

2.1 Study Background

Stroke is the second leading cause of death globally and the primary cause of death among urban and rural residents in China.[4,5] In recent years, it has exhibited epidemiological characteristics of "four highs": high incidence, mortality, disability, and recurrence rates, imposing a substantial economic burden on society. In 2017, the global prevalence of stroke was 104 million people, with 11.931 million new cases.[6] Among stroke patients, 70% of survivors are left with varying degrees of disability, the one-year recurrence rate is 13.2%, and 60% of patients with a first-ever stroke are at high risk of recurrence.[7]

Individuals at high risk of stroke are defined as those who have three or more of the following eight stroke risk factors: hypertension, dyslipidemia, diabetes mellitus, atrial fibrillation or valvular heart disease, smoking history, marked overweight or obesity, physical inactivity, and family history of stroke. Additionally, those with a history of transient ischemic attack (TIA) or previous stroke are also categorized into this high-risk group.[8] Comprehensive management of high-risk stroke patients — including improving adherence to stroke preventive medications, controlling risk factors, and modifying unhealthy lifestyles—plays a pivotal role in reducing stroke risk. The Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) randomized controlled trial demonstrated that controlling stroke risk factors can significantly reduce the recurrence

rate of stroke.[9] Meanwhile, with the continuous advancement of ischemic stroke treatment and the widespread application of thrombolysis and thrombectomy techniques, adequate knowledge of stroke and timely medical seeking are also particularly crucial for lowering post-stroke disability and mortality rates.

However, how to scientifically and effectively implement comprehensive patient management, improve medication adherence, and strengthen patient education remains a major challenge in stroke care. A registry study conducted across 106 hospitals in the United States—the Paul Coverdell National Acute Stroke Registry (PCNASR)—showed that only 75.5% of patients persisted with secondary preventive medications after discharge.[10] A follow-up study involving 25,018 Chinese patients with acute ischemic stroke or TIA at 3, 6, and 12 months found that the overall medication adherence rates for secondary prevention among ischemic stroke patients were 47.0%, 44.5%, and 34.9%, respectively.[11] Adherence rates exhibited a declining trend as the follow-up duration extended. Similar findings have been reported in South Korea, South Africa, and other European countries.[12,13,14] Beyond medication adherence, interventions targeting hypertension, dyslipidemia, hyperglycemia, and unhealthy lifestyles are far from optimal.

Some overseas institutions have attempted to leverage modern communication technologies — such as regular short message service (SMS) reminders, telephone consultations, or computer software notifications — to enhance patients' medication adherence and control of stroke risk factors,[15-18] and these approaches have achieved certain positive effects. Nevertheless, these methods are associated with drawbacks including inconvenience of communication and high time and labor costs. Meanwhile, comprehensive patient management in modern healthcare requires bidirectional communication between patients and healthcare providers, rather than a one-way information flow from medical staff to patients— a limitation inherent to traditional communication technologies.

In recent years, mobile-based patient management and education have been introduced into clinical practice. Existing studies have shown that this novel approach improves patients' medication adherence,[19] enhances the quality of bowel preparation, and optimizes blood pressure control, among other benefits. However, the application of this technology in stroke prevention remains limited. In our preliminary study, we attempted to implement comprehensive patient management using the mobile application BAMA Doctor (Philips). Propensity score analysis revealed that patients' 3-month medication adherence rate increased from 82.9% to 93.8% (P=0.036), and their stroke awareness rate rose from 72.4%

to 87.7% (P=0.016), demonstrating the effectiveness of mobile app-based comprehensive patient management.[3] Despite these promising results, this approach still faces potential challenges such as high system costs and poor patient usage compliance. Therefore, we intend to further verify the efficacy of social networking software-based comprehensive patient management in populations at high risk of stroke.

2.2 Study Objective

Evaluate the effectiveness of using social networks in improving the medication adherence and the control rate of risk factors among high-risk stroke populations after discharge.

2.3 Study Design

This study was a multicenter randomized clinical trial designed as a superiority study. Patients from 33 participating hospitals ,subjects will be randomized via an Internet-based randomization system in a 1:1 manner to treatment with social network-based intervention group or standard care group. Stratified randomization with permuted blocks will be performed to ensure balance across key prognostic factors, including prevention Type (Primary vs. Secondary Prevention)

Both patients and treating physicians will be aware of the treatment assignment. But primary outcome evaluation would be blinded. Information about medication adherence will be accessed through standardized forms and procedures, by trained investigators blinded for treatment allocation.

An independent DSMB statistician will combine data on treatment allocation with the clinical data to report to the Data and Safety Monitoring Board (DSMB). The Steering Committee remains blinded to all analyses throughout the trial duration.

2.4 Study Population

2.4.1 Population

The study population consisted of individuals at high risk for apoplexy. Participants were required to meet all inclusion and exclusion criteria for enrollment.

2.4.2 Participating Centers
33 Branch Centers Nationwide

2.4.3 Inclusion Criteria

Patients must meet all of the following inclusion criteria and none of the subsequent exclusion criteria to be enrolled as subjects in this study:

1) Age ⩾18 years.

2) Hospitalized patients at high risk of stroke are those who have at least three of the following risk factors: hypertension, dyslipidemia, diabetes, atrial fibrillation/valvular disease, smoking history, overweight/obesity, physical inactivity, or family stroke history; or those with a history of prior transient ischemic attack (TIA) or stroke.12

3) modified Rankin Scale (mRS) score≤2.

4) Smartphone/WeChat access (patient or caregiver).

5) Informed consent obtained.

6)Active long-term therapy: ≥1 medication (antihypertensive, hypoglycemic, lipid-lowering, anticoagulant, antiplatelet).

2.4.4 Exclusion Criteria

During case screening, patients meeting any of the following conditions were excluded from the study：

1) Inability to operate smartphones (patient or caregiver).

2) Comorbidities potentially confounding outcome assessments, including Advanced malignancies (life expectancy <12 months); Documented dementia; Severe psychiatric disorders (e.g., schizophrenia, major depressive disorder).

3)Residence in areas with unreliable internet access.

4)Concurrent participation in other clinical trials.

5)Any condition deemed by investigators to preclude safe trial participation.

2.4.5 Withdrawal (Dropout) Criteria

All subjects who have signed the informed consent form, passed screening, and entered the study shall be considered dropout cases if they withdraw from the trial at any time and for any reason without completing the observation period specified in the protocol.

1) The subject voluntarily withdraws from the trial for any reason；

2) Due to adverse events, particularly serious adverse reactions, the subject, principal investigator, ethics committee, monitor, and/or head of the clinical pharmacology unit, or competent personnel from the national or local drug regulatory authority decide to discontinue the study based on ethical considerations；

3) The investigator deems it medically necessary for the subject to terminate the study；

4) The sponsor considers it necessary to discontinue the study because the investigator fails to conduct the clinical trial in accordance with the validation protocol；

5) The subject violates the trial protocol；

6) The subject is lost to follow-up due to changes in work or living environment or due to an accident. However, in the event of an unexpected incident such as a traffic accident, death, or fracture, timely follow-up should be conducted to determine the causal relationship with the investigational device；

7）The informed consent process is incomplete or absent；

8) Other reasons necessitating the termination of the trial.

If a subject withdraws from the study, the investigator should make every effort to contact the subject using various methods, such as home visits, scheduled follow-up appointments, telephone calls, or letters, to ascertain the reason for withdrawal. For subjects who withdraw due to an adverse event, if follow-up ultimately determines a causal relationship with the investigational device, this must be recorded in the case report form and the sponsor must be notified. All subjects who have been enrolled and have entered the study, regardless of whether they withdraw, must have all source data and source documents retained.

2.5 Sample size of the study

The sample size was determined based on a pre-trial feasibility survey involving 3702 similar patients across 26 centers in China, which revealed a composite medication adherence rate of 77.3% among high-risk stroke patients under conventional care.We hypothesized a clinically meaningful absolute improvement of 10% in adherence rates with a social network-based coordinated care intervention (from 77.3% in the control group to 87.3% in the intervention group), an effect size consistent with recent cardiovascular digital health trials showing moderate improvements in adherence through remote or community-based strategies.[3,20] Using PASS 11.0 software and Fisher’ s exact test, a sample of 648 patients (324 per group) was calculated to provide 90% power to detect this difference at a two-sided significance level of 0.05. To account for an anticipated 10% attrition rate over the 12-month follow-up in this high-risk stroke population, the target recruitment was inflated to 720 participants (360 per group).

To ensure the study's robustness, a sensitivity analysis was performed. This analysis confirmed that even if the control group adherence rate is lower than our survey's findings (ranging from 65.1% to 71.6%, as reported in previous literature),[21] a sample size of 720 remains sufficient to detect a 10% improvement with a statistical power between 84% and

89%.

2.6 Intervention

Eligible participants will be randomly assigned to either the conventional care group or social network-based intervention group.

Conventional care group: Patients in conventional care group will receive standardized education based on ASA/AHA 2021 guidelines prior to discharge, 2 delivered verbally by a certified Brain-Heart Health Manager (BHHM) and supplemented with an expert-reviewed booklet. Content will cover medication adherence, risk factor control, stroke recognition, emergency response, and follow-up plans. A contact number will be provided for post-discharge support. A baseline archive will document demographics, lifestyle, and cardiovascular risk factors.

Social network-based intervention group: Prior to discharge, participants in Social network-based intervention group are onboard to the integrated digital platform in addition to conventional care. BHHMs facilitate the activation of the digital interface via a unique QR code, assist in the creation of a comprehensive electronic health record (EHR), and guide participants through an interactive tutorial to ensure technical proficiency in data entry and communication features. Post-discharge, participants in intervention group will receive comprehensive management via the social network-integrated digital platform, including pharmacotherapy support(automated, dose-specific push notifications for medication reminders and timestamped adherence verification), precision education(weekly multimedia content tailored to the participant's dynamic risk profile, derived from AHA/ASA guidelines), biometric surveillance(real-time clinical alerts for abnormal biometric data[e.g., SBP >140mmHg]), telehealth access(on-demand secure messaging and video consultations with BHHMs, with a guaranteed response time within 24 hours.)

BHHMs conduct structured follow-ups at 1, 3, 6, and 12 months via telephone or clinic visits for participants in both groups. These sessions involve standardized assessments of medication adherence, physiological parameters, and psychological status, alongside individualized health counseling.

2.7 Study Outcomes

1) Primary Outcom：

The primary outcome is good Medication Adherence to all guideline-recommended vascular prevention medications at 12 months post-discharge

Adherence is assessed using self-reported data, with participants asked to indicate the number of days they missed taking a dose for each medication class during the preceding 30 days. This evaluation is conducted separately for each of the five evidence-based secondary prevention drug classes: antihypertensives, hypoglycemics, lipid-lowering agents, anticoagulants, and antiplatelets. Good adherence for each class is defined as taking the prescribed medication on more than 24 days out of the previous 30 days (corresponding to an adherence rate >80%). To meet the primary endpoint, a participant must achieve this >80% adherence threshold simultaneously across all five medication classes at the 12-month follow-up.

Any self-directed cessation or adjustment of the regimen without medical consultation is categorized as non-adherence. Conversely, patients who cease or adjust their medications according to medical advice will be considered adherent. For those who adjust their medications based on medical advice, adherence will be further assessed by inquiring about the number of days the medications were taken in the past month; if the number of days exceeds 24, they will be classified as adherent.

2）Secondary Outcomes：

- Proportion of good medication adherence to stroke prevention drugs at 1-, 3-, 6-, and 12-months post-discharge (assessed using the Morisky-8 Medication Adherence Scale [MMAS-8]). Good adherence is defined as an MMAS-8 score greater than 6.[21,22]
- Risk factor control, including blood glucose, blood pressure, lipid profile, body mass index (BMI), waist circumference, hip circumference, and smoking status, at 1-, 3-, 6-, and 12-months post-discharge.
- Health-related quality of life (HRQoL) assessed using the EuroQol Five-Dimension Five-Level Scale (EQ-5D-5L) at 1-, 3-, 6-, and 12-months post-discharge.[23]
- Anxiety symptom severity assessed using the 7-item Generalized Anxiety Disorder Scale (GAD-7) at 1-, 3-, 6-, and 12-months post-discharge.[24]
- Depressive symptom severity assessed using the 9-item Patient Health Questionnaire (PHQ-9) at 1-, 3-, 6-, and 12-months post-discharge.[25]
- Stroke prevention knowledge scores assessed using the Stroke Prevention Knowledge Questionnaire at 1-, 3-, 6-, and 12-months post-discharge.[26]
- Personal motivation for stroke prevention assessed using the Stroke Attitude Questionnaire at 1-, 3-, 6-, and 12-months post-discharge.[27]
- Perceived social support assessed using the Perceived Social Support Scale (PSSS) at 1-, 3-, 6-, and 12-months post-discharge.[28]

- Stroke prevention-related health behavior scores assessed using the Stroke Prevention Health Behavior Scale at 1-, 3-, 6-, and 12-months post-discharge.[29]
- Self-efficacy for chronic disease management assessed using the Chronic Disease Self-Efficacy Scale at 1-, 3-, 6-, and 12-months post-discharge.[30]
- Intentions regarding prehospital delay in stroke emergency care assessed using the Prehospital Delay Behavior Intention Scale for Stroke at 1-, 3-, 6-, and 12-months post-discharge.[31]
- Incidence of major adverse cerebrovascular and cardiovascular events (MACCE), including stroke, acute coronary syndrome, and vascular death, at 1-, 3-, 6-, and 12-months post-discharge.

2.8 Randomization, Blinding, and Allocation Management

The randomization procedure utilizes online randomization. Randomization is allowed to proceed once patients meet the study inclusion criteria. There is no fixed number of participants to be enrolled at each center; instead, a competitive enrollment approach is adopted. Recruitment of study subjects can be halted once the total sample size reaches 720 cases. During randomization, stratification is conducted based on center and population (stroke-free individuals, stroke patients). After randomization, both patients and health managers are informed of their allocation status, but the primary outcome assessment is conducted in a blinded manner. Primary outcome data are collected by researchers who have undergone standardized training and are unaware of the random allocation status, using standardized forms and procedures. The steering committee maintains blinding for all data analysis, and independent statisticians analyze follow-up and clinical data, reporting to the Data Safety Monitoring Board (DSMB).

2.9 Individual subject withdrawal

Subjects may withdraw from the study at any time for any reason without any impact. Researchers may decide to withdraw a subject from the study due to urgent medical reasons. Data from subjects who have not provided consent will be anonymized and used for baseline analysis to further describe this population. During analysis, missing data will be imputed, and key parts of personal data will be removed.

2.10 Premature Termination of Study

This study will be terminated prematurely only upon the recommendation of the Data Safety Monitoring Board. In the event of early termination, the database will be closed

after the 180-day assessment of the last enrolled patient is completed, and the study results will be reported.

2.11 Definition and Response Measures for Adverse Events

2.11.1 Adverse Event Definition

An adverse event refers to any unfavorable medical occurrence that arises during the course of a clinical trial, regardless of its relationship to the device.

2.11.2 Adverse Event Severity Assessment

- Grade I: No impact on daily activities；
- Grade II: Impact on daily activities；
- Grade III: Loss of ability to perform daily activities.

2.11.3 Mitigation Measures for Adverse Events

All adverse events occurring during the study period must be accurately recorded in the adverse event form. The investigator shall provide targeted treatment for each adverse event and conduct follow-up assessments until the symptoms resolve or stabilize.

2.11.4 Serious Adverse Events

A serious adverse event is any unfavorable medical occurrence or effect that results in the following outcomes

- results in death；
- Life-threatening (at the time of occurrence)；
- requires inpatient hospitalization or prolongs existing hospitalization；
- results in congenital anomaly or birth defect；
- results in permanent or significant disability or incapacity；
- requires pharmacologic or surgical intervention to prevent any of the above outcomes

As well as any other medically significant event that, although not resulting in any of the outcomes listed above due to drug or surgical intervention, could reasonably occur based on appropriate clinical judgment. Elective hospitalization is not considered a serious adverse event. Upon becoming aware of a serious adverse event, the investigator must immediately report it to the trial coordinator, who is available 24 hours a day, 7 days a week.

2.11.5 Follow-up of adverse events

All adverse events will be followed up until resolution or stabilization.

Depending on the nature of the event, additional diagnostic tests or medical procedures may be required during follow-up, guided by clinical indications and/or consultation with

the participant’s primary care physician or a specialist.
Serious adverse events must be reported until the study concludes in China, as defined in the study protocol.

2.11.6 Data and Safety Monitoring Board（DSMB）

To enhance the safety of patient management, the trial will be monitored by an independent Data Safety Monitoring Board (DSMB). The DSMB is chaired by a health management expert and includes a stroke medical expert and an independent methodologist/statistician. The DSMB organizes regular meetings, at least annually or after the enrollment of 50 patients, whichever occurs first, and evaluates the occurrence of adverse reactions according to the procedures. During the enrollment period of patients in the study, interim analysis results of mortality and all other information related to the primary outcomes (including serious adverse events deemed to be treatment-related) will be provided to the DSMB chair in strict confidentiality. All other analyses that may be required will also be provided to the DSMB. Based on these analyses, if the DSMB proposes reasonable evidence that may substantially affect patient management, it can make recommendations to the chair of the steering committee.

The recommendations of the DSMB will be sent to the study sponsor by the chair of the steering committee. If the sponsor decides not to fully adopt the DSMB's recommendations, the sponsor will send these recommendations to the EC, including an explanation justifying why some (or all) of the DSMB's recommendations will not be followed.

2.12 Statistical analysis

2.12.1 Statistical Software and Statistical Analysis Plan

After the research protocol is finalized, statistical professionals will be responsible for negotiating and formulating a statistical analysis plan with the principal investigator. All statistical analyses and data aggregation will be conducted using SAS® 9.4. If applicable, R software version 4.4.3 or higher will be used for plotting.

All analyses were conducted according to the intention-to-treat principle. Baseline data stratified by treatment group were summarized and reported descriptively. Missing values in baseline characteristics were explicitly documented, and missing baseline data were imputed using regression-based imputation methods.

2.12.2 Statistical methods

All statistical tests were conducted as two-sided tests, and a P value of $\leqslant$ 0.05 was considered to indicate statistical significance.

- Descriptive statistics for quantitative variables included the mean, standard deviation, median, minimum, maximum, first quartile (Q1), and third quartile (Q3); for categorical variables, frequencies and corresponding percentages were reported for each category.
- Comparisons of baseline characteristics between the two groups were performed using appropriate statistical methods according to variable type: for quantitative variables, independent samples t-tests were applied when data met assumptions of normality and homogeneity of variance; otherwise, the Wilcoxon rank-sum test was used; for categorical variables, the chi-square test was employed, with Fisher’s exact test substituted when the chi-square test was not applicable; for ordinal variables, the Wilcoxon rank-sum test or the Cochran–Mantel–Haenszel test was used.

2.13 Ethical Considerations and Informed Consent in Clinical Research

2.13.1 Ethical Standards and Regulations

This study was conducted in accordance with the Declaration of Helsinki (2000), the Regulations on Clinical Trials of Medical Devices, and other relevant national laws and regulations.

2.13.2 Institutional Review Board

Prior to initiating the clinical study, the investigator must submit the clinical study protocol, the informed consent form, and other relevant documents to the institutional review board (IRB) of the hospital where the clinical trial sponsor is located. The clinical study may commence only after receiving formal approval from the IRB. Any amendments to the study protocol must be reviewed and approved by the IRB prior to implementation. Serious adverse events occurring during the clinical study must be reported to the IRB in writing without delay.

2.13.3 Informed Consent Form

Prior to enrollment in this study, the investigator must provide the participant and their family members with comprehensive information about the clinical trial, including its objectives, methodology, anticipated benefits, potential adverse events, and corresponding management strategies. Enrollment may proceed only after the participant has fully

understood the nature of the study and has signed the informed consent form.

The informed consent form shall be signed jointly by the attending physician and the participant or the participant’s legally authorized representative, in duplicate; one copy shall be retained by the participant or their representative, and the other by the investigator.

2.13.4 Benefit and Risk Assessment

This study poses no risk to participants’ physical health. Compared with standard secondary prevention management for patients with apoplexy, a comprehensive secondary prevention strategy based on social networks may improve clinical outcomes, enhance medication adherence, and better control modifiable risk factors. Furthermore, this study may facilitate the dissemination of an efficient and practical health management program, thereby benefiting a broader population of patients with acute ischemic stroke.

2.13.5 Confidentiality Principle

Within the bounds of applicable laws and regulations, all feasible measures will be implemented to protect the privacy of study participants and ensure the confidentiality of their personal information. Participants’ health management records will be stored securely at the hospital, and access to these records will be restricted exclusively to the principal investigators, the research oversight authority, and the institutional ethics committee. No publicly disseminated reports of the study findings will include any information that could identify individual participants.

2.14.Data Management

Data management and statistical analysis were conducted by statisticians.

2.14.1 Case Report Form Completion and Transfer

The Case Report Form (CRF) is completed by the investigator, and a CRF must be completed for each enrolled subject. After review by the monitor, the original copy of the completed CRF is transferred to the data manager for data entry and management. No modifications to the CRF content are permitted after transfer of the original copy.

2.14.2 Data Entry and Modification

The data manager develops a data entry program using software to perform data entry and management. To ensure data accuracy, two data entry personnel must independently conduct duplicate data entry and cross-verify the entries.

For any queries identified in the case report forms, the data manager generates a query

form (QF) to request clarification from the investigators; the monitor then contacts the investigators to ensure timely response and return of the completed QF. Based on the investigators' responses, the data manager modifies, validates, and enters the data; if necessary, an additional QF may be issued.

2.14.3 Database lock

After data review and validation confirm that the database has been correctly established, the data manager, principal investigator, statistical analyst, sponsor, and monitoring manager jointly review the data and finalize the definition and classification of the analysis populations. Subsequently, the data manager locks the database.

Once locked, the database or associated files are generally not modified.

2.14.4 Data Processing

After the database is locked, the statistical analysis is submitted to the statistical analysts for execution.

2.15 Management, Monitoring, and Publication

2.15.1 Data handling and storage

All data will be entered into a web-based database (OpenClinica) by local study staff. Participants will be assigned unique study identifiers for record coding. Local investigators will maintain a confidential list linking these identifiers to participant names. The master key file containing this identifier–name linkage will be stored separately from the study database in digital format, organized by study identifier within a secure drive system, with access restricted exclusively to the study coordinator.

2.15.2 Monitoring and Quality Assurance

Monitors will schedule site visits based on each center's enrollment rate and previously identified deviations; in principle, monitoring visits will occur within five business days following a center's first participant enrollment. Monitors will verify informed consent documentation and perform source data verification for all enrolled participants. Monitored data include, but are not limited to, inpatient medical records, outpatient medical records, follow-up medical records, imaging materials, and assessment forms. In addition, monitors will verify the completeness and consistency of data entered into OpenClinica.

2.15.3 Revision

A revision refers to any modification made to the study protocol after the ethics committee

(EC) has issued a favorable opinion. All revisions must be reported to the EC that issued the favorable opinion.

2.15.4 Annual Progress Report

The sponsor shall submit a summary of the trial progress to the Ethics Committee annually. The information provided shall include the date of enrollment of the first participant, the number of participants enrolled and the number of participants who have completed the trial, serious adverse events/serious adverse reactions, other issues, and protocol amendments.

2.15.5 Study Suspension and Early Termination Reporting

The investigator or sponsor shall notify the ethics committee (EC) of study termination within eight weeks; study termination is defined as the date of the last visit by the last enrolled participant.

The sponsor shall immediately inform the EC of any study suspension, including the rationale for implementing such a measure.

In the event of early study termination, the sponsor shall notify the EC within 15 days, specifying the reasons for premature discontinuation.

Within one year following study completion, the investigator or sponsor shall submit the final study report to both the EC and the competent authority, incorporating all peer-reviewed publications and conference abstracts arising from the study.

References：

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Scale Appendix

1.Morisky-8 Medication Adherence Scale

You indicated that you are taking medication(s) for your (identify health concern, such as "high blood pressure"). Individuals have identified several issues regarding their medication-taking behavior, and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication.		
	Yes	**No**
1. Do you sometimes forget to take your [health concern] medication(s)?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medication(s)?		
3. Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication(s)?		
5. Did you take your [health concern] medication(s) yesterday? (or the last time you were supposed to take it?)		
6. When you feel like your [health concern] is under control, do you sometimes stop taking your medication(s)?		
7. Taking medication(s) every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?		
8. How often do you have difficulty remembering to take all your medication(s)?		

(Please circle your answer below)

Never/Rarely……..a
Once in a while……..b
Sometimes……..c
Usually……d
All the time……..e

Codes:

No = 1; Yes = 0

Re-codes:

If Item8=b Item8r = .75 (high adherence)

If Item8=c Item8r = .50 (moderate adherence)

If Item8=d Item8r = .25 (low adherence)

Baseline Adherence: 3- Level Likert Scale

Low Adherence (< 6)

Medium Adherence (6 to <8)

High Adherence (= 8)

Morisky DE, Ang A, Krousel-Wood M, et al.Predictive validity of a medication adherence measure in an outpatient setting[J].J Clin Hypertens (Greenwich) , 2008, 10 (5) :348-354.

2.UK (English) EQ-5D-5L Paper Self-Complete

(sample version, v1.3)

Under each heading, please choose the ONE answer that

best describes your health TODAY

MOBILITY

I have no problems in walking about	❑
I have slight problems in walking about	❑
I have moderate problems in walking about	❑
I have severe problems in walking about	❑
I am unable to walk about	❑

SELF-CARE

I have no problems washing or dressing myself	❑
I have slight problems washing or dressing myself	❑
I have moderate problems washing or dressing myself	❑
I have severe problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

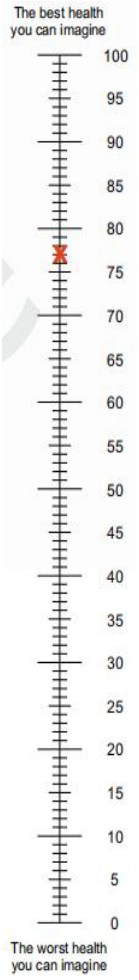
I have no problems doing my usual activities	❑
I have slight problems doing my usual activities	❑
I have moderate problems doing my usual activities	❑
I have severe problems doing my usual activities	❑
I am unable to do my usual activities	❑

PAIN/DISCOMFORT

I have no pain or discomfort	❑

I have slight pain or discomfort	❑
I have moderate pain or discomfort	❑
I have severe pain or discomfort	❑
I have extreme pain or discomfort	❑

This example from the EQ-5D-5L Paper Self-Complete version shows how the EQ VAS is scored.



We would like to know how good or bad your health is TODAY.

This line is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Please mark an X on the line to show how your health is TODAY.

Now, write the number you marked on the line in the box below.

YOUR HEALTH TODAY= ☐

EuroQol Research Foundation. EQ-5D-5L User Guide, Version 4.0[EB/OL]. (2025-08).

3.GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1.Feeling nervous, anxious or on edge	0	1	2	3
2.Not being able to stop or control worrying	0	1	2	3
3.Worrying too much about different things	0	1	2	3
4.Trouble relaxing	0	1	2	3
5.Being so restless that it is hard to sit still	0	1	2	3
6.Becoming easily annoyed or irritable	0	1	2	3
7.Feeling afraid as if something awful might happen	0	1	2	3

Total Score ____ = Add Columns____ + ____ + ____ + ____

Spitzer RL,Kroenke K,Williams JB,et al.A brief measure for assessing generalized anxiety disorder:The GAD-7[J].Arch Intern Med,2006,166(10):1092-1097.

4.Nine-symptom Checklist

Name _____ Date _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3

5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
(For office coding: Total Score ___ = ___ + ___ + ___)				

Kroenke K,Spitzer RL,Williams JB.The PHQ-9:validity of a brief depression severity measure.J Gen Intern Med,2001,16(9):606-613

5.Stroke Prevention and Treatment Knowledge Questionnaire

Category	Question	Yes	No
Daily Living	1. Should maintain regular bowel movements		
	2. Should maintain a positive and optimistic attitude		
	3. Should maintain regular daily routines and adequate sleep		
	4. Should avoid excessive fatigue		
	5. Should avoid extreme joy or sorrow		
	6. Cold weather can easily induce stroke; should replenish water in a timely manner		
	7. Hot weather can easily induce stroke; should replenish water in a timely manner		

	8. Should not take long hot baths or soak for extended periods		
Exercise	9.Maintaining appropriate physical activity can prevent stroke		
	10. Rehabilitation exercises can improve activities of daily living function		
	11. Should not exercise on an empty stomach in the morning or over-exercise		
	12. Should not move too quickly or suddenly; should get up slowly to avoid dizziness		
Diet	13. Should limit salt intake		
	14.Should reduce intake of fatty and high-sugar foods to prevent and control obesity		
	15. Should quit smoking		
	16.Should limit alcohol consumption		
Risk Factors	17.Effectively controlling stroke risk factors (hypertension, hyperlipidemia, diabetes mellitus) is an important measure for preventing stroke, among which hypertension is the most significant risk factor for stroke		
	18.The key for hypertensive patients to prevent and control stroke is to maintain long-term stable control of hypertension		
	19.Individuals with atherosclerosis who have normal or low blood pressure may also experience ischemic stroke		
	20.Stroke tends to occur in middle-aged and elderly people, but in recent years, there has been a trend of younger onset		
	21.Patients with a family history of cardiovascular and cerebrovascular diseases have a higher likelihood of experiencing stroke		
Medication	22.Should take antihypertensive drugs as prescribed by doctors; antihypertensive drugs should not be taken before bedtime to prevent excessively low blood pressure and bradycardia, which may lead to cerebral thrombosis formation		
	23.Blood pressure should not be lowered as quickly as possible		
	24.Most hypertensive patients need to take maintenance doses of antihypertensive drugs for a long time and should not stop, reduce or change medications arbitrarily		
	25.Taking additional antithrombotic drugs (such as Aspirin Enteric-coated Tablets) before bedtime can help prevent cerebral apoplexy		
	26.If suffering from diabetes, blood glucose should be controlled as prescribed by the doctor		

Blood pressure monitoring	27.The standard for blood pressure control is ≤140/90 mmHg (≤ 150/90 mmHg for elderly patients, and ≤130/90 mmHg for patients with diabetes, kidney disease, or a history of stroke)		
	28.Hypertensive patients cannot estimate blood pressure based on feelings and should monitor blood pressure regularly		
Precursors of stroke occurrence	29. Deviation of the corner of the mouth and drooling		
	30. Numbness on one side of the face, numbness, weakness or inflexible movement of one side of the limbs		
	31. Sudden inability to speak, slurred speech, or inability to express meaning correctly		
	32. Transient blackness in front of the eyes, blurred vision, visual field defect, or diplopia		
	33. Sudden onset of severe headache, dizziness of unknown cause, even accompanied by nausea and vomiting		
	34. Choking when eating or drinking, or even difficulty swallowing		
Management	35. Seek medical attention within 3 hours once any sign of stroke occurs		
	36. When a stroke is suspected, the patient should immediately rest in bed; if vomiting occurs, keep the head turned to one side and immediately call "120"		

Wan LH, Zhang XP, Hong H, et al. Health behaviors of stroke patients and their influencing factors[J]. Chinese Nursing Research, 2010, 24(1):1-4.

6.Stroke Attitude Questionnaire

Item	Strongly Necessary	Necessary	Unnecessary
1. Active control of hypertension is essential			
2. Active treatment of heart disease is required			
3. Active management of diabetes mellitus is necessary			
4. Personality modification should be considered for individuals prone to irritability and emotional outbursts			
5.A low-sodium diet should be adopted (e.g., daily salt			

intake < 6g)			
6.A low-fat diet is recommended (e.g., reducing consumption of fatty meats)			
7.Weight reduction and body weight control should be prioritized			
8.Smoking cessation and alcohol limitation are advisable			
9.Regular cholesterol monitoring should continue after hospital discharge			
10.Regular blood lipid testing should be maintained post-discharge			
11.Periodic medical follow-ups and physical examinations are important			
12.Prompt medical consultation is necessary when experiencing uncomfortable symptoms			
13.Continuous learning about stroke prevention and functional exercise knowledge is recommended			
14. Persisting in functional exercises after onset is equally important as receiving treatment			
15. Stroke patients should maintain light to moderate exercise (e.g., engaging in physical activity at least 3 times per week, with each session lasting more than 30-45 minutes)			
16.Exercise should be incorporated into daily life activities (e.g., practicing grocery shopping, climbing stairs, etc.)			

Lin, B. L. (2012). Current status and influencing factors of compliance with functional exercise among community-dwelling stroke patients (Master's thesis). Zhengzhou University, Zhengzhou.

7.The Multidimensional Scale of Perceived Social Support

Items	Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
1. There is a special person who is around when I am in need.	1	2	3	4	5	6	7

2. There is a special person with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
3. My family really tries to help me.	1	2	3	4	5	6	7
4. I get the emotional help and support I need from my family.	1	2	3	4	5	6	7
5. I have a special person who is a real source of comfort to me.	1	2	3	4	5	6	7
6.My friends really try to help me.	1	2	3	4	5	6	7
7.I can count on my friends when things go wrong.	1	2	3	4	5	6	7
8.I can talk about my problems with my family.	1	2	3	4	5	6	7
9. I have friends with whom I can share my joys and sorrows.	1	2	3	4	5	6	7
10.There is a special person in my life who cares about my feelings.	1	2	3	4	5	6	7
11.My family is willing to help	1	2	3	4	5	6	7

me make decisions.							
12. I can talk about my problems with my friends.	1	2	3	4	5	6	7

Zimet, G. D., Dahlem, N. W., Zimet, S. G., & Farley, G. K. (1988). The multidimensional scale of perceived social support. Journal of Personality Assessment, 52(1), 30 - 41.

8. The Stroke Prevention Health Behavior Scale

Below are statements regarding your lifestyle at home over the past month. Please answer each question accurately and mark " √ " in the corresponding box.

	Item	**Never**	**Sometimes**	**Often**	**Always**
Physical Activity	Exercise according to plan				
	Engage in moderate- to high-intensity exercise for at least 20 minutes, three or more times per week (e.g., brisk walking)				
	Participate in light or moderate physical activities (e.g., continuous walking for 30–40 minutes per session, more than five times per week)				
	Take part in recreational or leisure sports (e.g., dancing)				
	Perform stretching exercises at least three times per week				
	Incorporate physical activity into daily routines				
	Monitor pulse during exercise to reach target heart rate				
Low Fat	Choose low-fat, low-cholesterol foods; daily cooking oil intake < 25 g (about 30 ml, equivalent to 2.5 level tablespoons)				
Low Sugar	Limit consumption of sugar or sugary foods (e.g., candy)				
Nutrition	Consume 250-400 grams (5-8 liang) of				

	grains (e.g., rice, flour) daily				
	Eat at least 100 grams (2 liang) of fruit daily				
	Eat 400-500 grams (8 liang-1 jin) of vegetables daily				
	Consume 1 cup (250 grams) of dairy and 50 grams of soy products daily				
	Eat 125-200 grams (2.5-4 liang) of fish, poultry, meat, or eggs daily				
	Check nutrition, fat, and sodium content by reading food package labels				
	Eat breakfast every day				
Low Salt	Keep daily salt intake below 6 grams (about the amount of one mineral water bottle cap)				
Monitoring	Follow doctor's instructions to monitor blood pressure regularly				
Smoking	Smoking (averaging more than one cigarette per day)				
Alcohol	Excessive drinking (daily intake of ⩾50ml of liquor, or ⩾100ml of wine, or ⩾300ml of beer)				
Medication	Have you ever forgotten to take your medication?				
	Do you sometimes neglect to take your medication?				
	Have you ever stopped taking your medication when you felt your symptoms improved?				
	Have you ever stopped taking your medication when you felt your symptoms worsened?				

Wan, L. H., Xiong, X. N., Pan, J. H., et al. (2017). Development and reliability and validity test of the Health Behavior Scale for stroke patients. Journal of Nursing Science, 32(1), 25–29.

9. The Self Efficacy for Managing Chronic Disease Scale (SEMCD)

For each of the following questions, please ***circle*** the number that corresponds with your **confidence** that you can do the tasks regularly at the present time

How confident are you that you can...

1.Keep the fatigue caused by your disease from interfering with the things you want to do?

not at all Confident 1 2 3 4 5 6 7 8 9 10 totally confident

2. Keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all Confident 1 2 3 4 5 6 7 8 9 10 totally confident

3. Keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all Confident 1 2 3 4 5 6 7 8 9 10 totally confident

4. Keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all Confident 1 2 3 4 5 6 7 8 9 10 totally confident

5. Do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

6. Do things other than just taking medication to reduce how much your illness affects your everyday life?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

Stanford Patient Education Research Center (2011) Self-Efficacyfor Managing Chronic Disease 6-item Scale. Available at: http://patienteducation.stanford.edu/research/secd6.html (last accessed 7June 2011).

10. Stroke Pre-hospital Delay Behavior Intention Scale

No	When you (or you find someone) in the following situations, you think:	Very serious	Serious	Generally serious	Not too	Not hing
1	Inconsistent in thinking and language; answers to the problems such as time and place are unclear; restlessness	1	2	3	4	5
2	When asleep, intense stimulation is required to wake up; answers are irrelevant or vague; when stimulation is stopped, fall asleep quickly	1	2	3	4	5
3	Can be awakened and was able to answer simple questions, but slowly, then continued to sleep when stimulation stopped	1	2	3	4	5
4	Weakess, heaviness, or numbness on one side of the limb	1	2	3	4	5
5	Vertigo (see rotation), blacked out	1	2	3	4	5
6	Severe headache, vomiting, neck stiffness, neck pain	1	2	3	4	5
7	Double vision on one side of the eyes	1	2	3	4	5
8	Clear pronunciation, but of incorrect and ambiguous words	1	2	3	4	5
9	Blurred vision on one side of the eyes	1	2	3	4	5
No	If you observe the above symptoms, do you agree with the following ideas?	Agree very much	Agree	Don’t know	Agree less	Disagree
10	Don’t go to the hospital because the results are the same whether or not you go	5	4	3	2	1
11	Don't go to thehospital because it is too much trouble	5	4	3	2	1
12	Don't go to the hospital because worried about added burden	5	4	3	2	1
13	Don't go to the hospital because symptoms are from being old	5	4	3	2	1
14	Don't go to the hospital because body is usually ok and symptoms are no big deal	5	4	3	2	1
15	Patient will soon recover and symptoms are nothing important	5	4	3	2	1
16	Patient will first rest and see how they feel since the weather is	5	4	3	2	1
17	I will wait since there is no one around to help me	5	4	3	2	1
18	Sudden weakness, heaviness, or numbness on one side of the limb is just recent tiredness	5	4	3	2	1
19	Sudden blurred vision in one or both eyes is from excessive	5	4	3	2	1
20	Weakness, clumsiness on one side of the limb in the morning, because pressure to stay in bed	5	4	3	2	1
21	Sudden headache and dizziness are caused by a cold	5	4	3	2	1
22	My first thought is to have a rest at onset of symptoms	5	4	3	2	1
23	My first thought is to take some medicine at onset of	5	4	3	2	1

24	If my symptoms don't improve(or worsen),then I will go to the hospital	5	4	3	2	1
25	Don't call an ambulance because of the high cost	5	4	3	2	1
26	I can’t think to call an ambulance at first	5	4	3	2	1
27	I chose a Chinese medicine hospital suggested by an	5	4	3	2	1

ZHAO Q L,YANG L,ZUO Q,et al.Instrument development and validation of the Stroke Pre-hospital Delay Behavior Intention Scale in a Chinese urban population[J].Heal Qual Life Outc,2014,12:170.DOI:10.1186/s12955-014-0170-8.