Trials

STUDY PROTOCOL

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Effects of a nurse-led motor function rehabilitation training program for patients with ischemic stroke and family caregivers: study protocol for a randomized controlled trial

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Abstract

Background Both individuals and society bear a considerable burden from ischemic stroke (IS), not only do patients continue suffering from motor dysfunction after discharge from hospital, but their caregivers also undertake the principal responsibility of assisting them in reintegrating into the family and society. To better improve the IS patients' limb function and daily life activities, their caregivers should also be involved in the training of the motor function rehabilitation during the period transitioning from hospital back home. This study mainly aims to investigate the effects of a nurse-led training for IS patients and their family caregivers on the improvement of the patients' physical function and the burden of caregivers.

Methods/design A randomized controlled trial with blind assessment will be conducted in hospitals and during the follow-ups at home. Fifty-eight pairs of adults diagnosed with ischemic stroke and their primary caregivers will be included. Participants will be randomly given with (1) a nurse-led, home-based motor rehabilitation training participated by caregivers (intervention group) or (2) routine self-care (control group). Both groups will receive assessment and health guidance on the day of discharge, and the intervention group will receive an additional home-based training program and supervision. These two groups will be followed up every week after discharge. The primary results are drawn from the evaluation of physical function and caregiver-related burden, and the secondary results derived from statistics of the modified Barthel index, stroke-specific quality of life, and National Institutes of Health Stroke Scale. Differences between the two groups will be measured by two-way repeated measures ANOVA, considering the data at baseline and at 1-week and 4-week follow-up after training.

Discussion Results may provide novel and valuable information on the effects of this culturally appropriate, caregiver-involved, and home-based rehabilitation training on the physical function of IS patients and caregiver-related burden.

Trial registration Chinese Clinical Trial Registry (chictr.org.cn) ChiCTR2300078798. Registered on December 19, 2023.

Keywords Ischemic stroke, Rehabilitation, Home nursing, Caregiver, Physical function, Caregiver burden

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Introduction

Background and rationale

Ischemic stroke (IS) refers to the ischemic and hypoxic necrosis of local brain tissues, which is an irreversible damage caused by disorder of cerebral blood supply resulting from various factors [1]. According to the Global Burden of Diseases Study (GBD) [2], from 1990 to 2019, the incidence of stroke and stroke-related deaths has escalated annually, reaching 12.2 million cases globally in 2019. Among 143 million cases of stroke, there are 101 million cases of stroke-related disability and 6.55 million stroke-related deaths. Accounting for 11.6% of total deaths worldwide, stroke has been the second leading cause, among which 62.5% are attributed to ischemic stroke. Since 2015, stroke has been the leading cause of death and disability in China, with an estimated 17.8 million adults having experienced a stroke in 2020 [3].

Hemiplegia is a primary sequela following the acute phase of IS [4], manifested by limb motor dysfunction [5], which diminishes patients' daily self-care capabilities and adversely affects their physical and mental health [6]. Throughout the lengthy period of recovery from hemiplegia, the first 3 months after the onset of IS are considered as the most optimal time for rehabilitation exercise [7].

In China, most IS survivors returned home after receiving acute phase treatment in hospitals [8, 9], while only a small number of IS patients continued motor function rehabilitation at clinics or community hospitals after discharge. Most IS patients chose to rely on themselves managing their post-stroke life at home due to the considerable cost of long-term rehabilitation and the underdevelopment of the primary healthcare system [10]. Currently, a well-prepared rehabilitation program providing direct guidance for both IS patients and caregivers has not yet been established, which hinder patients' self-assessment, intervention, and management of physical function at home post-discharge. Therefore, a scientific, individualized, and affordable rehabilitation exercise program is essential to promote the recovery of IS patients, who have limited access to receive high-quality rehabilitation training and therapeutic support.

After discharge, IS patients are faced with multifaceted challenges during the process of adapting to substantial changes in post-stroke life, such as re-entering the community and assuming new social role [11]. In addition to IS patients, their family caregivers are also confronted with considerable challenges [12, 13]. Caregivers need to learn proper method to care for stroke survivors at home, effectively utilizing information and resources to not only improve their nursing efficacy, but also strike a balance between their work, personal life, and caregiving duties. If these problems remain unresolved, IS patients' quality of life may continue to decline, the risk of accidental rehospitalization may increase, and the burden and distress on caregivers may intensify. Patients have strong rehabilitation needs, and their primary caregivers also have obligations to assist with rehabilitation exercises [14]. Previous researches have investigated [15, 16] the home-based rehabilitation for IS patients; however, healthcare providers are typically the main implementers. To date, caregiver-implemented rehabilitation for IS patients at home has seldom mentioned.

Impacted by the ethos of Confucianism in China, family members of the discharged IS patients are usually considered as the main caregivers, namely, their spouses, offspring, siblings, and other immediate relatives; however, the knowledge and skill trainings of rehabilitation they received are limited. Researches have acknowledged the effectiveness of direct rehabilitation trainings provided by professionals. To better implement rehabilitation, professionals should focus more on patient empowerment [17–19]. Patient empowerment, defined as the process by which individuals gain confidence and power in decisions and actions that affect their health, requires patients to participate actively, to possess knowledge, self-efficacy, and health literacy. This means that healthcare workers should focus on enhancing patients' independence, boosting their self-confidence, empowering them to make decisions, and teaching them self-assessment, rehabilitation training method selection, and self-management throughout the rehabilitation process. Caregivers should also encourage patients to participate as actively as possible in rehabilitation training. The crucial time for IS patients and their caregivers to master the skills in managing rehabilitation and nursing care is the post-discharge period transitioning from hospital to home [14], during which healthcare providers should offer knowledge, skills, information, and emotional support to these patients and their caregivers to ensure the continuity of rehabilitation. To date, evidence-based programs and procedures that are culturally integrated with Chinese characteristics have not been established, resulting in the lack of a reference for nurses to empower the discharged IS patients and their caregivers and to provide them with education related to physical function rehabilitation. Our study aims to explore whether a nurse-led, caregiver-involved, home-based rehabilitation education program can improve the motor function outcomes of IS patients. This work also seeks to answer the following questions: Can this program improve patients' ability to perform daily activities? Can it enhance patients' quality of life? Can it alleviate the caregiver-related burdens?

The program comprises five steps, offering a reference for healthcare providers to leverage caregivers' initiative and encourage patient participation in limb function

rehabilitation. This program aims to (1) help patients identify their problems; (2) identify factors affecting patients' rehabilitation behavior; (3) assist patients in setting long-term goals; (4) involve patients in developing a home-based rehabilitation program; and (5) evaluate the outcomes.

This nurse-led, caregiver-participated interventional study will be conducted in collaboration with experts from multidisciplines to cover all areas of the topic.

Objectives

This study aims to conduct a randomized controlled trial of a rehabilitation education program that is nursing team-led, caregiver-involved, and features shared decision-making among healthcare providers, patients, and caregivers. The effectiveness of the program will be evaluated using the Motor Assessment Scale (MAS), the Brunnstrom Assessment (BRS), and the NIHSS, to determine its superiority over conventional rehabilitation in improving motor function recovery in homebound IS patients.

Methods

Trial design

This study is a two-arm, open-label randomized-controlled superiority trial of an individual limb function rehabilitation intervention (Table 1) mediated by caregivers for IS survivors at home. Participants will be allocated 1:1 to either intervention group or to control group by using a random number table (Fig. 1). The intervention group will be named as nurse-led home-based limb function rehabilitation participated by caregivers (NHLRC). The patients' physical function will be used as the main indicator to measure the effect of intervention. This randomized controlled trial has been registered in China Clinical Trial Registration Centre (registration number: ChiCTR2300078798) and approved by the Institutional Review Board of the First Affiliated Hospital of Shantou University (B-2023–213). The conduct of this study will follow the Declaration of Helsinki principles and has been designed in accordance with the SPIRIT 2013 statement [20].

Study setting

Participants will be recruited from multiple neurology departments and rehabilitation medicine wards of hospitals to achieve the target sample size. The study will be carried out in inpatient wards for face-to-face intervention and in patients' family and community environment for online intervention in Shantou, Guangdong Province, China.

Eligibility criteria

The inclusion criteria for patients are as follows: (1) diagnosis of ischemic cerebral apoplexy according to the international classification of diseases (ICD) definition and in conformance to the guidelines of diagnosis and treatment of acute IS in China 2018 and confirmed by craniocerebral CT or MRI; (2) NIHSS score of 15 points or less on the day of discharge; (3) with no neurological impairment or motor dysfunction prior to this stroke; (4) stable vital signs and clear consciousness; and (5) willingness of patients and their families to cooperate.

The exclusion criteria for patients include the following: (1) inability to express language correctly due to aphasia or dysarthria; (2) presence of other serious chronic or malignant diseases; (3) previous stroke; and (4) with recurrent neurological disorders leading to impaired motor function during follow-up.

The inclusion criteria for caregivers are as follows: (1) adult (18 years old or older); (2) physically healthy and normal cognitive ability, living ability, language communication ability, and learning ability; and (3) primary caregiver.

The exclusion criteria for caregivers are as follows: (1) presence of tumor and history of major surgery and severe trauma and (2) with mental illness.

Recruitment

Basing on our defined sample size, we will recruit 58 patients from the neurology inpatient ward for a period of 3–5 months. Firstly, assessors will screen newly admitted patients with a diagnosis of IS daily through the electronic medical record system to initially identify patients for enrolment based on the inclusion and exclusion criteria. An independent research coordinator will review the information of patient and determine whether the patient meets the inclusion criteria, communicate with the patient to confirm, and have the patient sign an informed consent form. Weekly meetings among study members will be organized to report on recruitment and discuss the progress to make adjustments accordingly. Recruitment time may be shortened or lengthened as appropriate depending on the recruitment situation. Recruitment will be stopped when the desired target has been reached.

Participant withdrawal

Participants may withdraw from the trial for any reason at any time. The researcher can withdraw participants from the study for safety purposes.

Randomization

We will allocate eligible participants to the intervention or control group in a 1:1 ratio through simple

Table 1 Description of the intervention

Stage	Limb functional stage	Program	Delivery of intervention
Stage 1	Motor function was assessed by Brunnstrom: at stage I–II Manual muscle strength assessment: grade 1–2 Body position: mainly in bed, unable to sit and stand balance	Educating patients on appropriate antispasmodic positioning Guiding the caregivers how to correctly assist the patient to turn over to meet the basic position change of the patient at home Educating the caregivers to implement standard passive range of motion exercises for the shoulder, elbow, wrist, finger, hip, knee, and ankle joints	Members of the rehabilitation nursing team educate patients face to face Distribute education manuals to patients (illustrated) Provide patients with specific rehabilitation training videos (for patients/caregivers to review when needed)
Stage 2	Motor function was assessed by Brunnstrom: at stage III Manual muscle strength assessment: grade 3 Body position: patient can sit up with assistance but was unable to maintain sitting and standing balance	Teaching patients to turn actively to the left and right and carry out repeated training Guiding patients in the skills of moving in bed Teaching patients to carry out passive-active movement step by step, gradually transition to active exercise Ensuring that patients master torso training (gradually transition from the hip lifting activity of both legs to the hip lifting activity of the affected side)	Members of the rehabilitation nursing team educate patients face to face Distribute education manuals to patients (illustrated) Provide patients with specific rehabilitation training videos (for patients/caregivers to review when needed) Establish contact with patients/caregivers through WeChat App (members of the rehabilitation nursing team can timely answer patients' questions and obstacles in home implementation during the intervention)
Stage 3	Motor function was assessed by Brunnstrom: at stage IV Manual muscle strength assessment: grade 4 Body position: patient can maintain a balanced sitting position	Instructing caregivers to carry out resistance training for patients with various repetitive tasks to increase muscle strength Carrying out appropriate rehabilitation training related to the control of muscle spasm based on the evaluation content Members of rehabilitation nursing team should guide patients to carry out clothing training to help patients adapt to the needs of daily life	Members of the rehabilitation nursing team educate patients face to face Distribute education manuals to patients (illustrated) Provide patients with specific rehabilitation training videos (for patients/caregivers to review when needed) Establish contact with patients/caregivers through WeChat App (members of the rehabilitation nursing team can timely answer patients' questions and obstacles in home implementation during the intervention)
Stage 4	Motor function was assessed by Brunnstrom: at stage V–VI Manual muscle strength assessment: grade 5, close to the standard muscle strength level Body position: mainly in bed, unable to sit and stand balance	Considering the patients' ability of daily life, instruct the patients to carry out some fine motor training to adapt to daily activities, such as grasping, grasping, buttoning, and so on Guiding patients to carry out walking training in accordance with the current activity function	Members of the rehabilitation nursing team educate patients face to face Distribute education manuals to patients (illustrated) Provide patients with specific rehabilitation training videos (for patients/caregivers to review when needed) Establish contact with patients/caregivers through WeChat App (members of the rehabilitation nursing team can timely answer patients' questions and obstacles in home implementation during the intervention) Part of the daily living ability training and repetitive task walking training programs are designed as game projects to enhance the interest of the patient training process

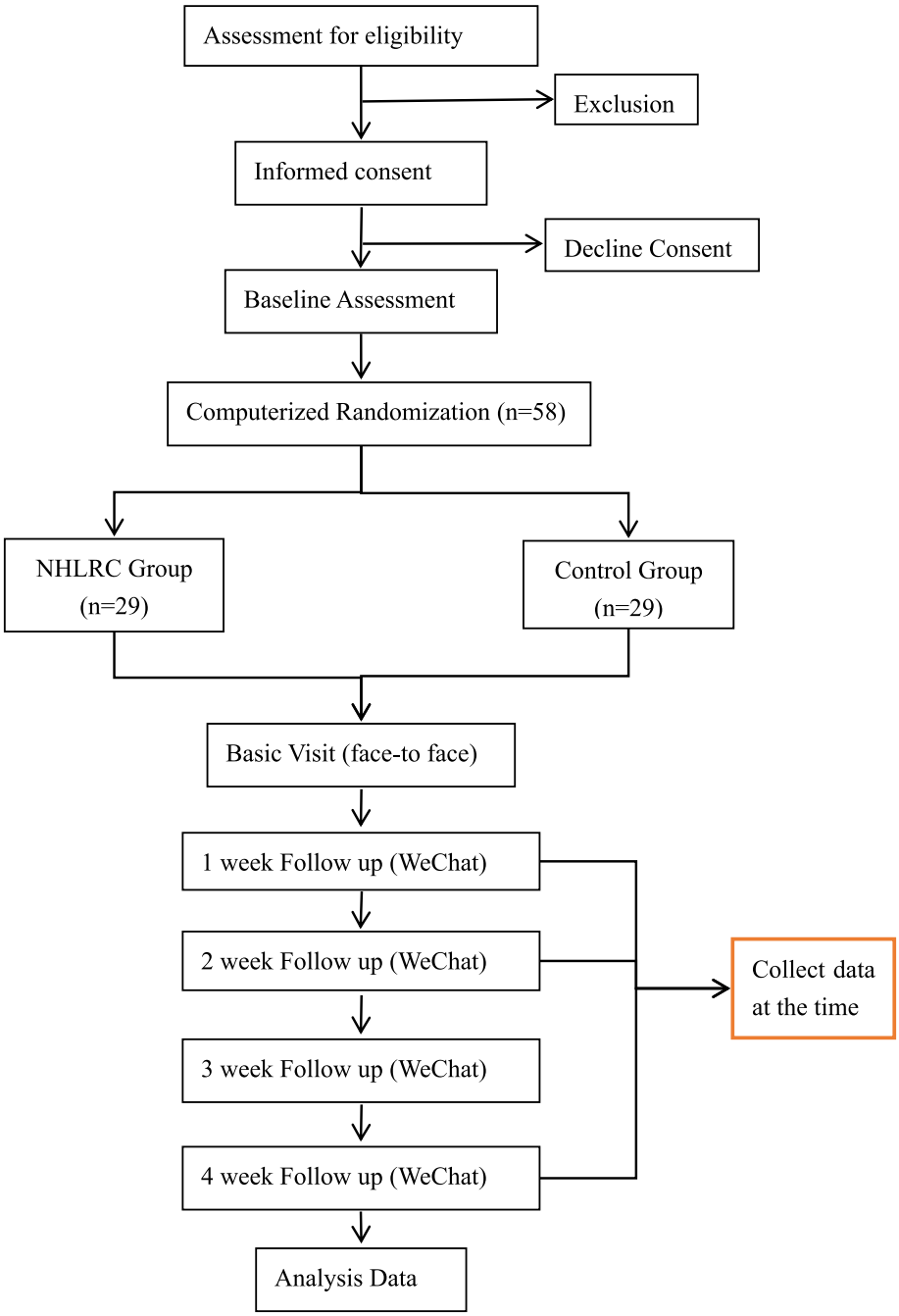

Fig. 1 Flow diagram of the study

randomization with IBM SPSS Statistics version 25. Random numbers will be generated by a research assistant who is not involved in recruitment, intervention allocation, or outcome assessment. After collecting baseline data for each group, the research assistant will place the subgroup data in sequentially numbered, opaque sealed envelopes to inform the intervention nurse.

Blinding

A researcher who is unaware of the intervention allocation will conduct outcome assessment and data entry and analysis. However, this study is not blinded due to the nature of the intervention; that is, the interventionist and carers of patients in the intervention group and the nurse in charge of the intervention will not be blinded because they will need to update participants and maintain the

intervention and services. The design is open label with only outcome assessors being blinded so unblinding will not occur.

Interventions

Participants will be required to complete the discharge assessment form before the day of discharge. After completing the discharge assessment, the participants will be randomly assigned to receive post-discharge NHLRC and standard primary care in their families. The intervention period will start immediately following randomization and will last for a month.

Patients in the NHLRC group will receive face-to-face learning of rehabilitation skills when they are discharged from the hospital. The knowledge provider is a multi-disciplinary home-based rehabilitation nursing team that is composed of advanced practice nurse (APN) engaged in professional rehabilitation of stroke, neurologists, rehabilitation doctors, and physical therapists. APN will mainly conduct and supervise family rehabilitation education. Neurophysicians, rehabilitation doctors, and physical therapists are mainly involved in the construction of home rehabilitation intervention content plan. All members are responsible for the adjustment and optimization of the program content. After the assessment is completed, the patient's current functional status will be confirmed. Based on the results, team members will recommend home-exercise items that match the patient's motor function state. The intervention program was based on the Brunnstrom theory. We combined Brunnstrom's assessment method with limb function assessment methods such as muscle strength assessment to determine the physical function stage of the patient, and then formulated the corresponding training content based on the physical function characteristics of the stage (Table 1). The specific content of the intervention program will be developed based on the recommendations of internationally published guidelines for rehabilitation of patients with IS [8, 21–24]. The content will have some adjustments to consider the cultural appropriateness of implementation in China. The main learning contents of patients/caregivers are as follows: how to carry out limb rehabilitation training at home?, when to carry out rehabilitation training?, and how to choose the most appropriate rehabilitation training content? Members of the rehabilitation nursing team should assist patients in setting rehabilitation goals and making weekly rehabilitation plans and distribute learning manuals and video learning materials to patients for review at home. The rehabilitation nursing team will conduct online follow-up of patients every other week to assess whether they have achieved short-term goals, adjust or add rehabilitation contents for patients, reconfirm the intensity of home-based training of patients, answer the questions raised by the patient during rehabilitation at home, and encourage the patient to maintain rehabilitation.

Patients in the two groups will receive the same basic nursing care in hospitals. In addition, the control group will be routinely given post-discharge health education, such as secondary prevention measures, medication adherence, universal guidance on the content of home care, and universal rehabilitation-related information such as correct limb positioning, post-discharge precautions, and medical referral-related assistance.

Implementing the intervention will not require alteration to usual care pathways (including the use of any medication) and these will continue for both trial arms. There are no restrictions regarding concomitant care during the trial.

Outcomes

Outcomes will be measured at baseline and at the end of intervention (4 weeks after randomization). The primary efficacy endpoint is patients' physical function.

Basic characteristics

Initial personal and sociodemographic variables include age, gender, monthly income (RMB), education level (illiteracy, primary education, junior high school education, high school education, college education or above), marital status (unmarried, married, divorced, widowed), primary caregivers (wife/husband, son/daughter, parents, grandparents, grandchildren, collateral relatives, hired babysitter), hemiplegic site (left limb, right limb, both sides), stroke duration (days), body mass index (BMI), and abdominal circumference.

Primary outcome variables

The primary outcome measure is the change in the Motor Assessment Scale (MAS) from baseline to the end of the 4-week intervention [25]. The scale has eight areas of motor function including supine to side lying, supine to sitting over side of bed, balanced sitting, sitting to standing, walking, upper arm function, hand movements, and advanced hand activities. Each item is scored from 0 to 6, and total scores range from 0 to 48, where a score of 48 indicates lack of motor symptoms. The scale is highly reliable, with an inter-rater correlation of 0.95 and a test–retest correlation of 0.98. This study will focus on exploring changes in patients' overall motor function before and after the intervention; therefore, total score will be used as the primary outcome measure.

Secondly outcome variables

Brunnstrom Scale (BRS)

This scale was developed by Swedish physiotherapist Signe Brunnstrom in the 1950s. The assessment method divides patients into three groups that will be evaluated for the upper limb, lower limb, and hand; each part will be divided into six stages: stage (1), flaccidity; stage (2), a little or no active movement; stage (3), movements through the synergy, no voluntary movement; stage (4), some movements out of synergy; stage (5), complex movement out of the synergy with voluntary movements; stage (6), synergy disappears and near normal [26]. The assessor will determine the current motor status of patients by observing them in completing specific movements. The scale is simple, easy to use, and operable. It is also a common tool in clinical assessment of motor function in stroke patients.

Modified Barthel index (MBI)

Barthel index is used to measure the activities of daily living (ADL) and was compiled by Mahoney and Barthel in 1965. Shah modified the index to improve the sensitivity of BI for stroke rehabilitation in 1989 and renamed it MBI—modified Barthel index [27]. This study will use the improved Chinese version of the MBI scale (C-MBI) [28]. The modified version is widely used in China and more in line with Chinese culture. It is a 10-item scale of basic ADL and focuses on self-care (personal hygiene, bathing, feeding, toilet, dressing, bowel control, bladder control) and transfer (ambulation, chair/bed transfers, stair climbing). Each item of the scale has five levels of scores, and each item is weighted differently. The total score ranges from 0 to 100. Lower scores indicate worse self-care ability and higher degree of need for care of patients. The internal consistency reliability coefficient for the MBI is 0.93.

Stroke-specific quality of life (SS-QOL)

In this study, we will use stroke-specific quality of life (SS-QOL) [29] to measure the quality of life of the participants. This scale is specifically designed for patients with stroke and has 12 domains: energy (three items), family role (three items), language use (five items), movement (six items), mood (five items), personal personality (three items), self-help activities (five items), social role (five items), thinking ability (three items), upper limb function (five items), vision (three items), and occupation–production activities (three items). It has a total of 49 items and uses a five-level scoring system (1–5 points), with the lowest score of 49 and the highest score of 245. Higher scores indicate higher quality of life. The reliability of this test is reported as a Cronbach's $\alpha \geq 0.73$ [29].

National Institutes of Health Stroke Scale (NIHSS)

NIHSS is one of the world's most common and easy-to-administer scales for assessing the degree of neurological deficits in stroke patients [30]. It consists of 12 items, namely, consciousness, gaze, visual field, facial palsy, upper limb muscle strength, lower limb muscle strength, ataxia, sensation, speech, dysarthria, neglect, and distal limb function. Each impairment is scored on an ordinal scale, ranging from 0 to 2, from 0 to 3, or from 0 to 4. Higher scores indicate more serious nerve damage, and the highest score possible is 42.

Chinese version of the Modified Caregiver Strain Index (C-M-CSI)

We will use the Chinese version of the Modified Caregiver Strain Index (C-M-CSI) [31] to measure caregiver-related burden. This scale contains 13 items, including financial, physical, psychological, social, and personal domains. Each item is rated from 0 (no) to 2 (yes). The total score ranges from 0 to 26 points, with higher scores indicating greater caregiver burden.

Data collection

Blinded assessors will collect the clinical and sociodemographic data in a case report form as well as outcome data at baseline (t0) and after the intervention (w4). The schedule of enrolment, intervention, and assessments is presented in Fig. 2.

It is standard procedure in our study to describe the study in detail to participants at recruitment and answer all questions that may be encountered. After signing the consent form, patients were helped to set weekly goals and develop a home-based rehabilitation plan, and patients were given a rehabilitation implementation record sheet for documentation. In addition, to promote participant retention and to complete the follow-up, we encourage patients to send their home limb function rehabilitation videos to researchers through WeChat App, so that researchers can dynamically monitor the implementation of the intervention plan, so as to correct patients' irregular rehabilitation training actions in time. We insist on following up every week, answer patients' inquiries in time, check patients' implementation records regularly, and track their compliance with rehabilitation training.

Sample size

Sample size will be calculated using PASS software (15.0.5 version, USA) based on a previous randomized controlled trial [32] that measured changes in disability

	Study period						
	Enrolment	Allocation	Intervention (face-to-face)	Intervention (WeChat)			Close-out
Time point	-t0	t0	td	w1	w2	w3	w4
Enrolment							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
Intervention							
Experimental group			◆—	—	—	—	—◆
Control group			◆—	—	—	—	—◆
Assessments							
Clinical and sociodemographic data			X				
Motor assessment Scale			X				X
Brunnstrom assessment			X				X
Modified Barthel index			X				X
Stroke-specific quality of life			X				X
National Institutes of Health Stroke Scale			X				X
Chinese version of the Modified Caregiver Strain Index			X				X

Fig. 2 Schedule of enrolment, intervention, and assessments. Notes: -t0: admitted but not grouped; t0: baseline, day of enrollment; td: on the first day of intervention after allocation, baseline data were collected at this time; w1: 1 week after discharge; w2: 2 weeks after discharge; w3: 3 weeks after discharge; w4: 4 weeks after discharge, intervention outcome data were collected at this time

levels and quality of life in stroke patients undergoing home-based rehabilitation. The sample size calculation is approximated with two-sample *t*-test assuming equal variance. The MAS score of the study population, which serves as the primary outcome indicator, is expected to improve by 11 points in the home rehabilitation group. This expectation is based on prior research [32] indicating that similar home-based rehabilitation programs have led to average MAS score improvements of approximately 10 to 12 points. For comparison, the mean MAS score of the control group is 29 ± 9 points. A two-sided α of 0.05 with a desired power of 90% will be adopted. The sample size of the treatment group is calculated as $N1 = 23$, and the sample size of the control group is $N2 = 23$. Considering a 20% dropout rate,

the final minimum number of subjects needed for each group is 29, totaling at least 58 subjects.

Statistical analysis

The classification variable will be expressed as counts with percentages, such as *n* (%). Data with a normal distribution will be expressed as means with standard deviation, such as mean ± SDs, while data with a non-normal distribution will be represented as medians with interquartile ranges, such as medians (IQRs). The continuous variables of normal distribution will be analyzed by Student *t*-test.

Intention-to-treat analysis will be applied to include all randomized participants. Thus, the participants will be analyzed in the groups to which they will be allocated, even if they do not complete the intervention protocol. A multiple imputation model will be used to process the missing data. Additionally, statistical analyses of the baseline characteristics of participants who remain in the study and those who are lost to follow-up will also be performed to explore whether there is differential dropout. Group differences at baseline will be assessed using chi-square tests and independent *t*-tests for continuous variables. All statistical analyses will be conducted using the SPSS software (version 25.0). A two-sided p value < 0.05 will be considered significant.

Data management and confidentiality

All paper material will be store and locked in a designated cabinet, and the electronic data will be saved in the password-secured electronic case information system. Data will be input by dedicated research assistants and checked by supervisor. Any revisions to the original data will be documented in detail. The personal information of the participants will remain anonymous and be stored securely throughout the study. All staff in this study will always maintain the strict confidentiality of the information. No additional studies using the data collected in this trial are planned. Protocol amendments will be submitted to the local research ethics committee and modifications will be updated in ClinicalTrials.gov. Changes will be communicated to all investigators.

Data monitoring

A data monitoring committee (DMC) will be set up for on-site audits and quality control. The DMC will be independent from the sponsor with no conflicts of interest. Two audits will be executed: at the midpoint and at the end of the RCT. The focus was on whether enrolment, sampling, data collection, intervention, and follow-up were performed and documented in a timely manner in accordance with the study protocol. In terms of adverse events, the main adverse event of patients with motor dysfunction at home is falls [33]. This study will educate patients and caregivers on the prevention of falls in the course of family activities (if necessary, by optimizing family environmental equipment and auxiliary tools). Carry on the related drill of the fall emergency treatment to the patient and caregiver, once the fall occurs, instruct the patient to report immediately and seek medical treatment in time. According to the occurrence of adverse events, the study members met to discuss and decide whether to discontinue the participant's intervention.

Dissemination

The progress, completion, and publication of the results of the trial will be attributed to all the partners. The ultimate results of the trial will be reported to each participant through open access publications. To maximize dissemination, these findings will be reported in open access publications in high-impact journals; oral and poster demonstrations on home-based participatory family rehabilitation for patients with motor disorders after ischemic stroke will be conducted nationally and internationally.

Discussion

In China, a significant proportion of the population is afflicted with ischemic stroke, but the attention paid to rehabilitation is considerably overshadowed by that given to the disease, leading to suboptimal family-community rehabilitation participation and disability recovery. A systematic review [34] involving 1704 patients has indicated that the advantages of home-based combined exercise evidently outweigh those of other simple exercise, such as combined exercise and aerobic exercise, in promoting stroke survivors' long-term social participation. Given limited resources, this home-based rehabilitation exercise for IS patients are considered an efficient and cost-effective rehabilitation method that should receive sufficient attention and priority consideration. Although commonly neglected, tailoring individualized rehabilitation plans according to different stages of patients' motor function is one of the most pivotal steps. In various regions of China, the feasibility of the model which involves caregivers in family rehabilitation for IS patients has been demonstrated by numerous studies [35, 36]. The study results indicated that this model can improve patients' activities of daily living to varying degrees, but how to incorporate individualized rehabilitation into previous home-based rehabilitation programs remains unclear. The innovation of this study lies in the following: (1) the research team formulating a home-based rehabilitation program tailored to the stages of patients' motor function, helping them choose the proper program that reasonably matches their functional abilities at home, to

promote the implementation of individualized rehabilitation training; (2) under the cultural background of Chinese tradition, our study attaches importance to the vital role of caregivers in family-oriented nursing. Our team will impart knowledge and skills to both patients and caregivers simultaneously, encouraging them to make decisions that are beneficial for themselves. Previous studies [37] have explored various novel methods to intervene in IS patients' motor function at home, including artificial intelligence devices, interactive technology, and augmented reality. However, to extensively implement this type of rehabilitation in developing countries with vast population, two key considerations must be addressed. First, the high cost of equipment presents a financial obstacle for certain patients. Second, patients using new equipment require regular evaluation to assess the suitability, thereby increasing the demand for healthcare human resources. Within the cultural context of Chinese tradition, caregiver-implemented rehabilitation remains an indispensable resource for IS patients at home, especially for those who are financially constrained and reliant on family caregiver. Although continuously updated interventions for home-based rehabilitation are available, their practical application varies due to regional cultural differences as well as multicultural collision and integration. Therefore, a more comprehensive and internationalized model of self-initiated home-based rehabilitation care should be developed for patients with IS and even other chronic diseases.

Trial status

Recruitment will begin on January 25, 2024. Data collection aims to be completed in July 2024. Date and version identifier: 2023.12.19-version1.0.

Supplementary information.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08392-3.

Additional file 1. SPIRIT checklist

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Author's contributions
JS is the study sponsor; she conceived the study idea and supervised the trial process at the study site. YD and JX contributed to the study design. YD drafted the manuscript. JS, QYL, and YL revised the manuscript. YD, DYW, JX, and FW were responsible for participant recruitment and data collection. YD and JQZ will perform the data analysis. All authors critically reviewed the main text and approved the final manuscript.

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Availability of data and materials
The datasets analyzed during this trial are available from the corresponding author on reasonable request. The authors JS, YD, and JX will have access to the final test data set.

Declarations

Ethics approval and consent to participate
Ethical review approval was obtained from two centers: the Ethics Committee of Shantou University Medicine College (6 December 2023, SUMC-2023–061) and the Ethics Committee of the First Affiliated Hospital of Shantou University Medicine College (13 November 2023). All study designs will comply with the principles of the Declaration of Helsinki. All individuals will sign written informed consent forms before participating in the RCT.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no conflict of interest.

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