Effects of Kaiyin Xuanfei Manipulation Treatment on Patients with Dysarthria after Stroke: Study Protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background

Dysarthria is one of the most common stroke complications. It seriously affects the patient's ability to communicate with one another and their overall recovery. The priority therapeutic methods in treating dysarthria after stroke (DAS) are speech training, physical therapy, and traditional Chinese rehabilitation, but the overall outcomes are not optimal. This study combines proprioceptive neuromuscular facilitation (PNF) and traditional chinese medicine (TCM) theory to design a kaiyin xuanfei manipulation (KYXF), which may improve the physiological function of vocal organs and improve speech intelligibility. However, there is still a lack of high-quality, large-sample clinical studies. The objective of this study is to conduct a randomized controlled trial to evaluate KYXF's efficacy in the treatment of DAS.

Methods

Patients (N = 60) who meet the trial's inclusion criteria will be randomly divided into 2 groups in this prospective, single-blind, randomized controlled trial: speech training and speech training plus KYXF, with each group consisting of 30 patients. Both groups will undergo routine medical therapy, rehabilitation, and speech training. For 8 weeks, all treatments will be delivered 5 times per week. The Frenchay functional score will be used to evaluate all outcomes at baseline, week 4, week 8, and follow-up.

Discussion

This study will be the first prospective randomized controlled trial to evaluate the safety and preliminary efficacy of KYXF in patients with DAS. Furthermore, this trial is also expected to standardize and expand the clinical treatment of DAS using a combination of traditional chinese and western medicine.

Trial Registration

Chinese Clinical Trial Registry, identifier: ChiCTR2100050343. Registered on 26 August 2021.

Background

Stroke is a major global health issue with high morbidity, mortality, and disability rate that has significantly impacted the patient quality of life and increased social burden[1]. Dysarthria is a common stroke complication that also belongs to the category of "yin" in traditional Chinese medicine. The pathological mechanism is primarily due to the muscle movement disorder related to speech production caused by damage to the central or peripheral nerves, with clinical manifestations including slurred speech, not being fluent in the language, abnormal breathing, tone, and speed of speech[2, 3].

Epidemiological surveys have shown that the incidence of dysarthria is second only to hemiplegia, with an incidence rate as high as 69.5% at baseline in stroke, and 27% of patients still suffer from persistent dysarthria after 3 months[4, 5]. It significantly impairs the patient's ability to communicate in a language, reducing their social identity and causing psychological barriers[6, 7].

Currently, there is no specific medication for treating DAS in the world. The clinical practice of modern medicine mainly focuses on speech rehabilitation training and physical therapy, but its rehabilitation costs are high, the cycle is long, and the effect is insignificant[8]. Acupuncture is the main clinical practice in TCM[9]. However, some people find it difficult to accept it because of the numerous blood vessels and pain sensitivity in the anatomical structure of the head and face. Therefore, finding an alternative therapy with a significant impact, simple promotion, and high safety is crucial for treating DAS.

Acupressure, as a disease prevention and treatment method guided by the theory of TCM and based on meridians and acupoints, is favored by people because of its good therapeutic effect, easy operation, and high safety[10]. TCM research has discovered that applying acupressure to acupuncture points with high-density nerve endings[11]can adjust human body functions, dredge meridians and collaterals, and reproduce the effect of "De Qi" in TCM[12]. Modern medical research has also proved that acupressure can stimulate the nervous system, improve blood and lymphatic circulation[13], relax muscle adhesion[10], reduce pain[14], and alleviate joint movement restriction[15]. Based on the numerous benefits of acupressure, this study takes it as the theoretical basis of TCM while also incorporating proprioceptive neuromuscular facilitation (PNF) to conduct a new treatment method known as Kaiyin Xuanfei manipulation (KYXF). Fengchi (GB20), Renying (ST9), Lianquan (CV23), Shuitu (ST10), Tiyan [16](Extra, a new point. In the posterior border of the mandible and lower border of the mastoid process), and Tunyan [16](Extra, a new point. Between the hyoid and Adam’s apple, 0.5 cun lateral to the midline) are selected as the base points while performing acupressure, the patient's head and neck are allowed to do a spiral diagonal movement, and certain visual and auditory stimulation is given to the patient, which not only improves the limb motor function but also promotes the functional reconstruction of the central nervous system. However, the effectiveness and safety of KYXF in treating DAS are yet unknown due to the lack of large sample randomized controlled research. Therefore, we designed this prospective, large sample randomized controlled trial to explore the effect of KYXF on dysarthria and to obtain further data to standardize and expand the clinical application of DAS treatment. The outcomes will demonstrate whether the KYXF is a safe and effective treatment for DAS patients. The protocol could help provide an adequate DAS treatment and improve the rehabilitation outcomes between multidisciplinary treatment teams[8, 17].

Methods/design

Study design

This prospective, single-blind, randomized, controlled trial evaluated the therapeutic effectiveness and safety of KYXF in treating DAS. The patients will be recruited from the Rehabilitation Center of the First Affiliated Hospital of Henan University of Chinese Medicine. 60 patients who meet the inclusion and exclusion criteria will be randomly divided into 2 groups: the control group and the experimental group.

The control group will use routine speech training; the experimental group will use KYXF manipulation for 20 minutes based on the control group. Both groups will receive routine medical treatment, rehabilitation training, and speech training. All patients will be treated for 1 time/day, 5 days/week, and last for 8 weeks. Patients will be assessed at 5-time points: baseline (0 weeks), mid-treatment (4 weeks after treatment begins), end of treatment (8 weeks after treatment begins), and follow-up (12 weeks and 24 weeks after treatment finishes). The Frenchay score will be used to evaluate the efficacy of all patients[18]. The trial flow chart is shown in Fig. 1. The trial process chart is shown in Table 1.

Table 1
Timing of treatment assessments and data collection.

	STUDY PERIOD					
	Enrolment	**Baseline**	**Treatment phase**		**Follow-up phase**	
TIMEPOINT	**-1 Week**	**0 Week**	**4 Weeks**	**8 Weeks**	**12 weeks**	**24 weeks**
ENROLMENT						
Eligibility screen	x					
Informed consent	x					
Medical history	x					
Merger disease	x					
Randomization		x				
INTERVENTIONS						
Experimental-group		x	x	x		
Control group		x	x	x		
ASSESSMENTS						
Frenchay		x	x	x	x	x
Adverse events		x		x	x	x
Safety evaluation		x		x		

Patients

Diagnostic basis

(1) The diagnostic criteria of stroke in Western medicine refer to the "Clinical diagnosis of patients with cerebrovascular disease"[19].

(2) The diagnostic criteria of stroke in TCM refer to "From clinical appearance to accurate management in acute ischemic stroke patients: With the guidance of innovative traditional Chinese medicine diagnosis"[20].

Inclusion criteria

(1) Patients aged ≥ 18 years and ≤ 70 years.

(2) Patients who meet the diagnostic criteria of stroke by computed tomography (CT) or magnetic resonance imaging (MRI), and their basic vital signs (temperature, pulse, respiration, blood pressure) are stable and can cooperate with treatment.

(3) Patients with a stroke course 2 weeks to 6 months,1 point ≤ National Institute of Health stroke scale (NIHSS) score ≤ 20 points and with mild or moderate dysarthria (14 ≤ Frenchay score ≤ 26)[21].

(4) Patients who agree to participate in this study and sign an informed consent form.

Exclusion criteria

(1) Patients who don't meet the above inclusion criteria.

(2) Patients with severe heart, lung, liver, kidney disease, diabetes, osteoporosis, or severe bleeding tendency.

(3) Patients with systemic infection or severely unstable condition.

(4) Patients with aphasia, cognitive impairment, or severe dysphagia.

(5) Patients with severe dysarthria who cannot cooperate with treatment (Frenchay score ≤ 13)[21].

Suspension/Elimination/Shedding criteria

(1) Suspension criteria: Patients with severe adverse reactions; Due to problems in the study, patients' efficacy cannot be judged.

(2) Elimination criteria: Patients who fail to cooperate with treatment as required; patients who don't meet the inclusion criteria.

(3) Shedding criteria: Patients who drop out on their own.

Recruitment

This trial will recruit patients online and offline to help them better understand the research information. The hospital's official website and WeChat advertising are two types of online recruitment strategies. Posters, pictures, and videos are types of offline recruitment strategies. Recruitment information for these strategies will include the research's objective, methodologies, benefits and drawbacks. Each patient will undergo a preliminary assessment and screening by the researchers, strictly according to the abovementioned inclusion and exclusion criteria. Patients who meet the inclusion criteria will be asked to sign an informed consent form.

Randomization

We will adopt a completely random method. All patients will be randomly divided into two groups in a 1:1 ratio: Speech training plus KYXF group and speech training group. Randomization software will be commissioned to generate random number sequences by a professional statistician who is not involved in treatment and outcome assessment. Patients' information will be put into 60 numbered sealed and opaque envelopes, which could be opened after informed consent is obtained. Researchers must select patients according to the inclusion and exclusion criteria, then use random numbers to assign until the total number of patients (60).

Blinding

We cannot conduct a double-blind trial due to the nature of acupressure manipulation, and only the therapists are informed of the groupings and interventions of the study participants. One of the two efficient therapies will be given to patients randomly and they will not be informed of the other. To avoid communication between patients, they must be treated in a separate personal space and wear an eye patch. Furthermore, to prevent the influence of subjective factors on the therapists, we will select individuals with no conflicts of interest to participate in the trial. We will invite professional statisticians not involved in the research to assist with data management and statistical analysis.

Table 2
Treatment types and treatment time

Type of rehabilitation	Method of treatment	Duration of treatment	Outcomes	Index
KYXF	PNF and acupressure	Once a day, 5 times a w, for 8 w	At baseline, 4 w, 8 w, 12 w, and 24 w after treatment	Frenchay
Speech training	Relaxation training, breathing training, vocal organ exercise training, articulatory training, rhythm training	Once a day, 5 times a w, for 8 w	At baseline, 4 w, 8 w, 12 w, and 24 w after treatment	Frenchay

Interventions

The trial is divided into 2 groups: the experimental group (speech training plus KYXF) and the control group (speech training). At the same time, both groups of patients will receive conventional medical

treatment and rehabilitation training 5 times a week for 8 weeks. Frenchay's functional score will be assessed at baseline, mid-treatment, end of treatment, and follow-up. All physicians and therapists must have at least 3 years of clinical experience. The treatment types and treatment time are shown in Table 2, and the two groups of interventions are as follows:

Basic treatment

According to the condition of the two groups of patients, they will receive medical treatment, rehabilitation training, and routine speech training. Medical treatment mainly includes improving cerebral circulation, nourishing cerebral nerves, regulating blood pressure, blood sugar, blood lipids, etc. Rehabilitation training mainly includes exercise therapy, occupational therapy, physical therapy, and so on, helping patients enhance muscle strength, expand the joint range of motion, reduce muscle tone, and improve motor function. Routine speech training mainly includes:

1. Relaxation training: Instruct the patient to take a deep breath and relax the muscles of all parts of the body, including the throat muscles, head, shoulders, neck, chest, abdomen, back, buttocks, legs, feet, etc.
2. Breathing training: The patient takes a sitting position, inhales slowly through the nose, and then slowly exhales through the mouth. The therapist pays attention to the direction of movement of the diaphragm and ribs to improve respiratory control and lay the foundation for vocalization, pronunciation, and rhythm.
3. Vocal organ exercise training: Including jaw training, lip training, tongue training, and soft palate training.

1) Jaw training: Instruct the patient to open and close the mouth as much as possible, repeat 5 times slowly, and then gradually increase the speed, but pay attention to keeping the range of motion between the upper and lower jaws as large as possible;

2) Lip training: Instruct the patient to move the upper and lower lips forward as far as possible, make a "u" sound, and then retract it as far back as possible, make an "i" sound, and repeat 5 times slowly. Then increase the frequency of alternating movements, trying to maintain a large range of motion of the lips;

3) Tongue training: Instruct the patient to extend the tongue as far as possible, retract it, and then roll it up, back, left, and right, repeating 5 times;

4) Soft palate training: Instruct the patient to sigh hard to promote the elevation of the soft palate or use cotton swabs to stimulate the soft palate directly. If the paralysis of the soft palate is mild, ice cubes can be used to stimulate the soft palate quickly for 1 to 3 s. This method can improve the muscle tension of the soft palate.

1. Articulatory training: Instruct patients to keep their lips tightly closed, puff their cheeks as much as possible, continue to pronounce "ah", and try to pronounce vowels. Then the volume is controlled from small to large, then from large to small, and the volume is changed alternately.

2. Rhythm training: Instruct the patient to read poetry, newspapers, or everyday conversations aloud as much as possible and pay attention to rhythm control, and the therapist helps the patient better control the rhythm by reminding the rhythm points.

Experimental group (speech training plus KYXF)

In addition to routine medical treatment, rehabilitation training, and speech training, patients in this group will receive KYXF for 20 minutes, 1 time/day, 5 days/week, and treatment for 8 weeks. KYXF will be divided into 5 operations:

1. The operator places one hand thumb and index finger at the bilateral Fengchi (GB20) of the patient, the other hand on the patient's forehead, with both hands gently making the patient's head do a spiral diagonal movement (pendulum clock movement).
2. The operator places one hand thumb and index finger at the bilateral Renying (ST9) of the patient, the other hand on the patient's posterior occipital, with both hands slightly against force, and ask the patient to try to lower the head, so that the mandible do a spiral diagonal movement.
3. The operator places one hand thumb on the patient's Lianquan (CV23), the other hand thumb on the patient's Shuitu (ST10), two thumbs at the same time to do rotation kneading, and places one hand thumb and four fingers on the throat of the patient to do a rapid neck pendulum clock movement.
4. The operator presses the bilateral Tiyan (In the posterior border of the mandible and lower border of the mastoid process) with both thumbs and presses the bilateral Tunyan (Between the hyoid and Adam’s apple, 0.5 cun lateral to the midline) with both forefingers, the patient is instructed to open the mouth with force and make sounds of ha, ga, ka to train the soft palate function.

5. Strengthen respiratory function through resistance breathing training. The operator places one palm on the patient's lower abdomen and applies pressure, and the other places on the patient's back neck, both hands slightly resistant to force, and asks the patient to breathe through the abdomen. First resist inhaling, then resist exhaling, and quickly press the abdomen twice at the end of exhalation to increase abdominal pressure and empty residual gas as much as possible. During exhalation, the patient can cooperate with reading words or counting and ask to pronounce "ah" twice as loudly as possible when pressurizing at the end of exhalation. This method not only trains the respiratory function but also promotes soft palate lift and trains the ability to control speech volume. For the abovementioned five KYXF operations, each operation will be carried out independently and continuously 10 times, once all operations are completed, repeat the KYXF manipulation 1 time completely. The anatomical chart of acupoints is shown in Fig. 2. The locations are presented in Table 3.

Table 3
Location of acupoints for treating dysarthria after stroke

Acupoints location	
Fengchi (GB20)	In the posterior region of the neck, below the occipital bone, in the depression between the sternocleidomastoid and the upper end of the trapezius.
Renying (ST9)	In the neck, next to the laryngeal node, the leading edge of the sternocleidomastoid muscle, and the pulsation of the common carotid artery.
Lianquan (CV23)	In the neck, on the anterior midline, above the larynx, and in the depression of the upper edge of the hyoid bone.
Shuitu (ST10)	In the neck, the anterior edge of the sternocleidomastoid muscle, flat annular cartilage.
Tiyan (New point)	In the posterior border of the mandible and lower border of the mastoid process.
Tunyan (New point)	Between the hyoid and Adam's apple, 0.5 cun lateral to the midline.

Control group (Speech training)

Patients in this group will receive routine medical treatment, rehabilitation training, speech training, 1 time/day, 5 days/week, and therapy for 8 weeks.

Sample Size Estimation

The purpose of this clinical trial is to evaluate the safety and efficacy of KYXF in the treatment of DAS. Our early clinical study with a small sample (10 cases in each group) found that 2 weeks of the experimental group and the control group could improve scores on the Frenchay scale by 3.65 ± 1.38 and 2.44 ± 1.26 points, respectively. The significance test level is set to 0.05, and the test power is set to 0.9. The sample size is calculated as follows:

$N = 2\times [(Z_{\alpha/2} + Z_{\beta}) \times \sigma/\delta]^2$ (1)

N is the sample size required for each group. When α is 0.05 and β is 0.1, the normal distribution quantile table shows the following:

$$Z_{\alpha/2} = 1.96$$
$$Z_{\beta} = 1.282$$

σ and δ represent the larger standard deviation and allowable error between the two groups, which are 1.38 and 1.21, respectively. The result is 27 by substituting these data into the formula, so the number of samples in each group is about 27. Therefore, there are 30 cases in the experimental group and 30 cases in the control group. (Including 10% shedding rate).

Quality Control

All researchers will be required to receive standard training before the study begins to guarantee the quality of this study. In addition, we will invite qualified clinical trial experts from the First Affiliated Hospital of Henan University of Chinese Medicine to monitor the data of this study and make detailed regulations on intervention, statistical analysis, and evaluation. If problems are discovered during the study, the trial plan can only be changed with the ethics committee's approval. A quality control team will regularly check whether the test procedures and data management meet the standards.

Outcome Assessments

Frenchay score is dysarthria's most widely used function assessment scale[8]. Originally, its contents include respiration, reflexes, palate, larynx, jaw, lips, tongue, and intelligibility, 8 major items, 29 minor items, each 29 minor items has 5 scoring criteria from “a” (normal) to “e” (severely abnormal)[18]. We adapted the FDA by replacing alphabetic coding with numeric scoring and rated 29 items on a 4-point scale. They are normal (4 points), mild abnormal (3 points), moderate abnormal (2 points), obvious abnormal (1 point), and severely abnormal (0 points)[21]. Evaluate the severity of dysarthria according to the proportion of normal items in the total items. In other words, the a-point items are totaled, and the rating score of the FDA ranges from 0 to 29 points. Grade: very severe:0–6/29; Severe:7–13/29; Moderate:14–17/29; Mild:18–26/29; Normal:27–29/29[21].

Safety Evaluation and Adverse Events

Blood routine, urine routine, pulse, electrocardiogram, and liver and kidney function will be measured before and after treatment to evaluate the safety of the study. During treatment, researchers will pay close attention to the patient's health. If someone has nausea, vomiting, and other adverse events, researchers will immediately deal with them and record them in detail on the Case Report Form (CRF). After treatment, researchers will analyze the incidence of adverse events, and patients involved in adverse events will be compensated.

Data Collection and Management

All patient information will be truthfully, completely, and accurately recorded in CRFs, including the treatment time, outcome assessment, adverse event, safety assessment, etc. The relevant data will be managed by data researchers, and the personal data of each patient will be kept strictly confidential. Without the written permission of the research group leader, data will not be shared with anyone other

than data researchers. Researchers must submit the CRF on time at the end of this study, and the quality control team will evaluate its validity and completeness.

Statistical analysis

Statistical analysis will be performed using SPSS19.0 software for statistical analysis after all experimental data are verified correctly. The mean ± standard deviation (± S) will be used to indicate the centralized and discrete trends when the measurement data satisfies the normal distribution, paired T-test will be used for intra-group comparison and independent sample T-test will be used for inter-group comparison; If the normal distribution is not satisfied, the median and interquartile range (M, Q) will be used to represent the centralized and discrete trends, and the Wilcoxon rank-sum test will be used to analyze the difference; The count data will be analyzed by chi-square test; The test level will be set at 0.05, and $P<0.05$ is considered statistically significant.

Discussion

In this study, we combine PNF with the theory of TCM and conduct an innovative method of KYXF manipulation, aiming to explore the safety and rehabilitation efficacy of DAS and to further standardize and expand the clinical application of integrated traditional Chinese and western medicine in the treatment of DAS. Speech is a unique and crucial high-level neural activity of human beings. However, in the early stage of stroke, most patients only pay attention to the recovery of limb function and neglect the rehabilitation of speech, missing the best rehabilitation period and leaving pronunciation defects, which has a significant negative impact on the patients' quality of life and also harms their mental health. DAS is a problem that has been largely neglected in the past, even if it is a very disabling condition[8]. Although the number of clinical trials on rehabilitation has increased substantially, there are still many gaps and shortcomings in the evidence base for interventions to improve the recovery of speech function after stroke[17]. A proper rehabilitation protocol plays an important role in improving speech impairment after stroke, not only achieving more adequate speech therapy but also easing collaboration between multidisciplinary treatment teams[8]. Therefore, we designed this prospective, large sample randomized controlled trial protocol to explore the effect of KYXF on DAS. In addition, we hope to develop guidelines for rehabilitation protocols that combine more treatments and individualized rehabilitation interventions and include aftercare for speech impairments as a clearer focus of future research[22, 23].

Acupoint selection

Modern medicine believes that DAS is caused by bilateral cortical medulla tract damage, which causes the ambiguous nucleus which innervates the larynx muscle group activity, and the hypoglossal motor nucleus which innervates the glossal muscle damage, further causing glossopharyngeal nerve, vagus nerve and hypoglossal nerve paralysis[24]. On the point selection, Lianquan is close to the throat, while Fengchi is close to the medulla oblongata. Both are innervated by the sensory fibers of the vagus nerve

and the glossopharyngeal nerve. They are surrounded by the occipital artery, occipital vein, vertebral artery, and lingual artery, among other blood vessels[25]. Due to the nature of acupoints containing many high-density nerve endings, we speculate that stimulating the above two acupoints can directly affect the glossopharyngeal area. On the one hand, it can excite the glossopharyngeal nerve, vagus nerve, hypoglossal nerve, and other fibers, directly mobilizing the physiological functions of the soft palate and tongue, as well as other vocal organs; on the other hand, it can increase the circulation of qi, relieve qi-blockage, make the human body relax and balance through invigorating the flow of qi, and promote the recovery of human function[26]. However, the specific mechanism of action still needs to be confirmed. Renying and Shuitu are acupuncture points on the foot Yangming meridian that connect to the kidney, spleen, liver, heart, bile, small intestine, Chong meridian, Conception meridian, and other organs and systems. They are key points of the throat. In the anatomical position, both are located on the anterior edge of the sternocleidomastoid muscle, surrounded by the cervical cutaneous nerve, cervical branch of the facial nerve, deep carotid bulb, sympathetic nerve trunk, and laterally with descending branch of the hypoglossal nerve and vagus nerve. It may activate the laryngeal nerves and muscles, enhance their activity, regulate the regularity of vocal cord movement, and enhance pronunciation clarity by stimulating the laryngeal acupoints. Tiyan point is located at the anterior and inferior margins of the mastoid process, as well as the posterior margin of the mandible. It is associated with the styloid pharyngeal muscle, which can lift the throat and pharynx, allowing the tongue root to be pressed back and improving pronunciation[27]. The Tunyan point is located between the hyoid bone and Adam's apple. Its deep layer has the pharyngeal constrictor muscle controlled by the vagus nerve and the styloid pharyngeal muscle controlled by the glossopharyngeal nerve, which can improve throat movement and restore normal pronunciation. These points are innervated by the glossopharyngeal nerve and vagus nerve. Acupressure, when stimulated, can not only upload the excitation to the central nervous system, promoting the reconstruction of damaged neuron transmission function and reflex arc; it can also improve the local blood circulation of the vocal organs, release the adhesive tissues, and increase cerebral blood flow, but the specific mechanism of action still needs to be confirmed. What is exciting is that research has shown that acupressure can play a positive role in treating neurological disorders[28]. Furthermore, because of the special anatomical structure of the acupoints mentioned above, we use acupressure to treat, which not only has an obvious therapeutic effect without side effects but is also simple and safe, and the patient suffers less pain, as the acupressure technique, strength, and depth can be adapted to the individual.

PNF

PNF was founded in the 1940 s, it is characterized by stimulating proprioceptive receptors such as position sense and kinematic sense through the helical diagonal assisted movement, active and resistance movement of the trunk and limbs, and supplemented by visual and auditory stimulation to transmit a large amount of skin sensory and motor information to the nervous system. Not only does it activate cortical patterns useful for various rehabilitation programs, but it may also have a positive effect on functional outcomes and enhance neuroplasticity[29, 30]. In this study, while performing acupressure

stimulation, we cooperate with the spiral diagonal movement of the head, jaw, and neck to stimulate the proprioceptors in the skin, muscles, tendons, ligaments, etc. The sensory impulses generated by these stimuli are transmitted to the spinal cord through peripheral nerves and then sent to the sensory centers of the cerebral cortex through the medial lemniscus, promoting brain function reorganization. PNF can stimulate the patient's skin sensation during implementation while providing visual and auditory stimulation that can effectively guide patients to exercise and stimulate active movement, improve activation and coordination of movements, and strengthen the doctor-patient relationship[31]. In addition, using PNF therapy while performing acupressure can accelerate the blood flow of the whole body and the venous qi and blood so that the essence can quickly reach the lesion.

Outcome Measurements Selection

The Frenchay scale has been widely used in dysarthria assessment[8, 32, 33]. It is mainly used to assess the severity of dysarthria, which is divided into two aspects: articulation (reflex, breathing, and speech) and structure (lips, tongue, jaw, soft palate, and throat), including 8 major items and 29 minor items. Therefore, the Frenchay scale will be used as an outcome indicator to reduce the interference of subjective factors and simplify dysarthria assessment. Before the trial begins, we will conduct unified training for all therapists, strictly standardize the manipulation, and minimize the deviation caused by the inconsistency of therapists. Furthermore, because this is a single-blind experiment, all our results will be measured and recorded by professional statisticians who are not involved in the study. We hope this study will provide strong evidence for treating DAS, incorporate or update rehabilitation guidelines for dysarthria, and further standardize and expand the rehabilitation treatment of Traditional Chinese and Western medicine.

Limitations

There are limitations to this study. (1) We cannot conduct a double-blind trial because the KYXF manipulation involves acupressure treatment. However, we will select individuals with no conflicts of interest to participate in the trial, and all therapists will receive unified training to regulate the operation and time strictly. Furthermore, patients will be treated individually without being informed of the other groups, minimizing subjective and objective bias. (2) KYXF combines TCM acupressure and PNF techniques. Although studies have shown that they can effectively improve neurological diseases such as stroke, there are still few studies in the field of dysarthria, and more basic research is needed to enrich the theoretical system. This study protocol's objective is to evaluate KYXF's effectiveness and safety. (3) This is a single-center study and cannot recruit patients from different regions. Based on this study, we will subsequently consider recruiting patients from different areas to conduct a multi-center study.

Conclusion

Multidisciplinary rehabilitation is an integral part of improving and maintaining function throughout the life of a patient with neurological disease[34]. A common protocol for the multidisciplinary team would improve the rehabilitation outcomes. In the field of neurological rehabilitation, treating neurological

disorders with integrated traditional Chinese and Western medicine is the future development trend. Our study protocol combines acupressure and PNF techniques and will highlight the efficacy and safety of KYXF in treating DAS. It will also lay the groundwork for future larger clinical trials to evaluate whether the new treatment for DAS is suitable for all types of patients.

Abbreviations

DAS: Dysarthria after stroke

Frenchay: Assessment of dysarthria

CRF: Case report form

SOP: Standard operating procedure

SPSS: Statistical Package for the Social Sciences

MRI: Magnetic resonance imaging

PNF: Proprioceptive neuromuscular facilitation

CT: Computed tomography

TCM: Traditional Chinese medicine

Declarations

Ethical Approval

This study has been approved by the Ethics Committee of the First Affiliated Hospital of Henan University of Chinese Medicine (reference no. 2020HL-115-01).

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Author Contribution

Hongxia Feng proposed the concept for this trial and designed the study. Xiaolei Song and Yuhan Zhang contributed to the conception, design, and manuscript writing, they are co-first authors. Kaiqi Su revised

this manuscript and conducted the preliminary experiment. Wei Zhao and Hao Liu assisted in the recruitment of patients. All authors approved the submitted version of the manuscript.

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Figures

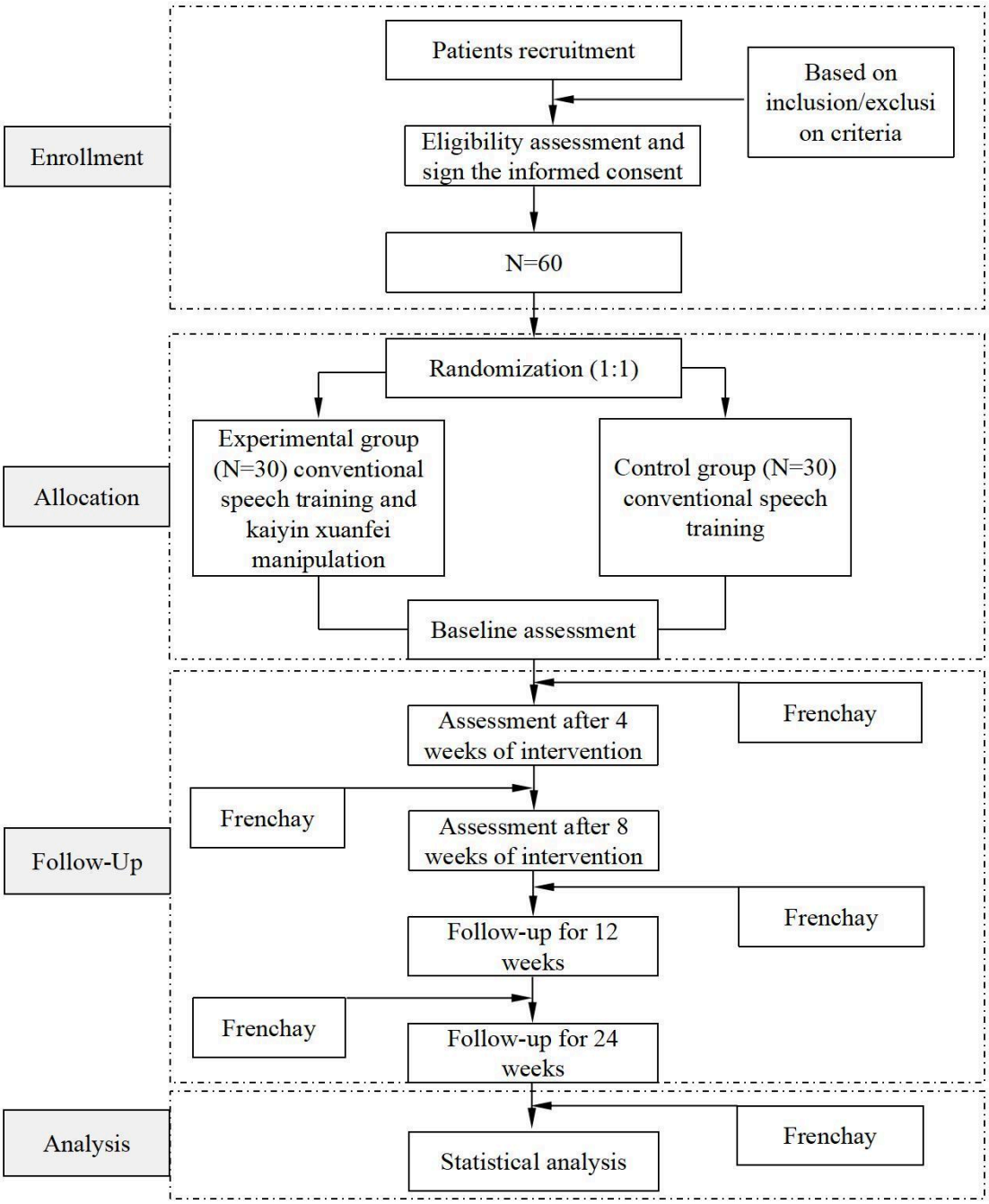

Figure 1

Flowchart of the trial

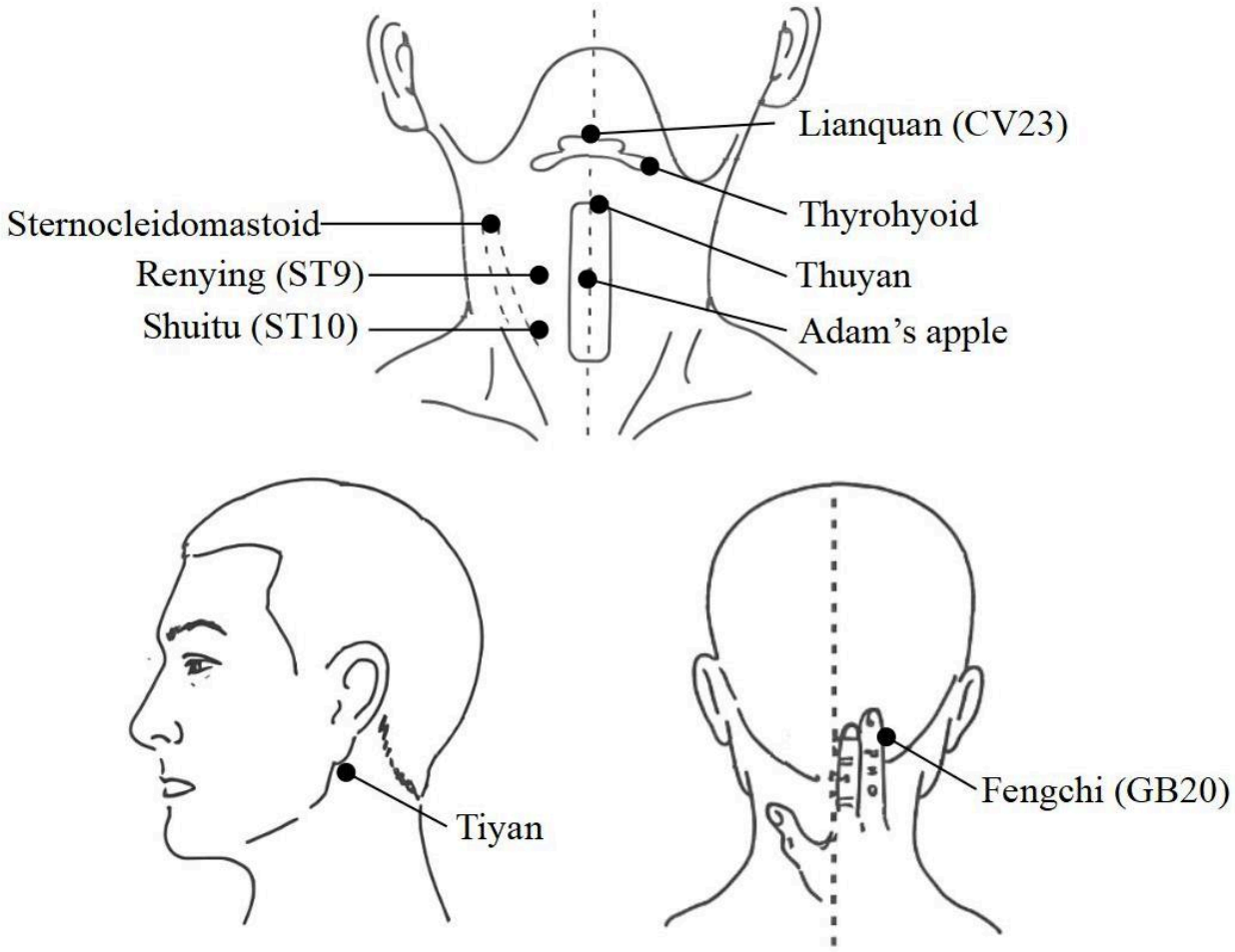

Figure 2

The anatomical chart of acupoints