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Study protocol

Keywords: ultrasound guidance, cricopharyngeal dystocia, acupuncture, swallowing disorder, stroke, rehabilitation

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Effect of ultrasound-guided targeted needling of the cricopharyngeal muscle on post-stroke cricopharyngeal dysphagia: a prospective, multicenter, randomized controlled trial

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ABSTRACT

BACKGROUND: Swallowing disorders are a common complication after stroke.

OBJECTIVE: The aim of this study was to evaluate the effectiveness of acupuncture of the cricopharyngeal muscle in the treatment of cricopharyngeal disorders and to explore a new method that is safe, intuitive, precise, and effective.

METHODS: This was a multicenter randomized controlled trial. One hundred and forty-eight patients with post-stroke cricopharyngeal muscle relaxation dysphagia who met the criteria at three hospitals were randomly divided into a control group (n=74) and a test group (n=74). The control group received conventional swallowing training with basic medication (including basic training and feeding training), and the test group received ultrasound-guided targeted acupuncture treatment of the cricopharyngeal muscle in addition to the treatment of the control group for 4 weeks. Patients in both groups used VFSS, WST, SSA, SWAL-QOL and EAT-10, PAS and NRS 2002 before and after treatment.

DISCUSSION: This trial used ultrasound-guided acupuncture to treat cricopharyngeal muscle loss relaxation, not only to explore a new method that is safe, intuitive, precise and effective, but also to provide more high-quality experimental evidence for the clinical application of the combination of Chinese and Western medicine.

Trial registration: China Clinical Trials Registry ChiCTR2200063337. registered on September 5, 2022.

Keywords: ultrasound guidance, cricopharyngeal dystocia, acupuncture, swallowing disorder, stroke, rehabilitation

Strengths and limitations of this study

Strengths: This study used a combination of Chinese and Western medicine techniques to promote the maximum therapeutic effect of the acupuncture technique, aiming to explore a new method for the safe, visual, precise and effective treatment of patients with cricopharyngeal muscle dystonia; at the same time, this study conducted the trial at three clinical research centers at the same time, which could ensure that the collected materials were more symbolic and enhance the richness and credibility of the trial basis.Weaknesses: This study was unable to conduct the experiment by double-blind method due to the limitation of experimental operation, which is the weakness of this study.

INTRODUCTION

Stroke is a common disease that seriously endangers human health and life safety, and studies [1] have shown an annual increase in its incidence of 8.3%. Swallowing disorders are a common complication in stroke patients, with a prevalence of 45% to 65%, and are a contributing factor to death in post-stroke patients [2-3]. Cricopharyngeal failure (CPD) is caused by the inability of the cricopharyngeal muscles to move in a coordinated manner during swallowing, making it difficult for the patient to deliver food smoothly into the esophagus, resulting in choking and coughing during feeding and making swallowing difficult[4]. Swallowing disorders caused by cricopharyngeal muscle relaxation are most common after stroke, especially brainstem stroke, accounting for about 80% of cases[5]. Swallowing disorders caused by misaspiration, pulmonary infection, dehydration, and malnutrition not only reduce the quality of life of patients and increase medical costs, but also seriously affect the prognosis and psychological status of patients and increase the morbidity and mortality rate and recurrence rate, and swallowing disorders have become an independent risk factor affecting the prognosis of stroke patients[6]. Therefore, it is of wide clinical significance to explore technical methods for effective treatment of post-stroke swallowing disorders.

The comprehensive treatment of swallowing disorders due to cricopharyngeal muscle dystocia after stroke is a relatively new discipline in our medical system, and currently, there is no specific and systematic treatment for swallowing disorders in Western medicine.

Both its treatment mechanism, treatment methods, indicators for pre- and post-treatment evaluation, and auxiliary instruments used are in the process of continuous improvement, and it

mainly involves swallowing training, balloon dilation, botulinum toxin injection, and cricopharyngeal myotomy[7-9], but there are no special methods, short clinical duration, poor long-term effects, and many uncertainties and shortcomings. Balloon dilation is currently used as a first-line clinical intervention[10], but protocols have not been standardized and balloon diameters, pressures, and durations vary depending on the experience and preference of the operator[11]. The duration of botulinum toxin injection effect is relatively short and patient selection and optimal injection dose are not clearly defined, which may cause serious consequences if improperly performed infiltrating other tissues around the pharynx, and related studies[12-13]have shown that patients with prolonged swallowing delay do not respond well to botulinum toxin injection. Cricopharyngeal myotomy treatment is more invasive and has a high incidence of postoperative complications, including pharyngoesophageal fistula, laryngeal recurrent nerve injury, mediastinitis and pneumonia [14]. The complication rate of endoscopic cricopharyngeal myotomy ranges from 0 to 6%, while the complication rate of transcervical surgery ranges from 0 to 39% [15]. Traditional Chinese medicine treatment focused on acupuncture, self-prescribed tonics, and Chinese rehabilitation care, which achieved good results [16-19]. Currently, many studies have shown [20] that acupuncture therapy has better efficacy in the treatment of post-stroke swallowing dysfunction, and through acupuncture, it achieves the effects of regulating the internal organs, unblocking the meridians, running the qi and blood, and opening the orifices and awakening the mind, which in turn improves the local qi and blood flow, stimulates the lingual nerve and sublingual nerve, enhances the muscle strength and coordination of the tongue muscle; enhances the excitability of the central nerve, reconstructs the nerve circuit, and accelerates the recovery of swallowing and speech function [21]. Due to its unique advantages such as significant efficacy, low price, and few side effects, it is favored by more and more clinicians and patients, which continuously promotes the application of acupuncture therapy in the treatment of swallowing disorders.

For the assessment of swallowing function, VFSS can store the dynamic swallowing process of patients on video, and observe the compliance and coordination of various organs during the process of contrast food mass and liquid of different viscosities from the oral cavity to the esophagus from anterior-posterior and lateral positions, whether there is mis-swallowing, retention and leakage, and the opening of cricopharyngeal muscles, etc. It is helpful to analyze and

understand the lip closure, tongue strength and movement, and the pushing of food mass during the swallowing process of patients. It is considered as the "gold standard" for the diagnosis of swallowing disorders [22], and is also a good method to examine cricopharyngeal muscle relaxation [23]; the Wada drinking test (WST) is the most classic screening test for swallowing function, which classifies swallowing function into The WST is the most classic screening test for swallowing function and is divided into 5 levels, which is simple to perform and clearly graded to detect certain abnormalities in swallowing, thus screening patients with post-stroke swallowing disorders and grading the severity of swallowing disorders; Ellul et al [24] reported in 1996 that the Standard Swallowing Assessment Scale (SSA) The SSA has good reliability and validity, high sensitivity and specificity, easy to use, and is suitable for clinical use to assess swallowing function in patients with brain injury [25-26] ; the Swallowing Disorder Specific Quality of Life Scale (SWAL-QOL) can assess the swallowing-related quality of life from emotional, psychological, social interaction and physical aspects. which has been used in the assessment of swallowing disorders due to disease [27]; the Eating Assessment Questionnaire Tool-10 (EAT-10) is a validated, symptom-specific screening tool for swallowing dysfunction, and previous studies have reported high specificity of the EAT-10 for screening patients with post-stroke swallowing dysfunction [28]; the Leakage/Absorption Scale (PAS) was developed by Rosenbek, which is used to assess the extent of food aspiration into the airway and the magnitude of the ability to voluntarily remove the aspirate, is a more objective method of analysis by video-recording the imaging process in real time and analyzing the images captured by the camera and the imaging machine [29]; a commonly used nutritional screening tool is the Nutritional Risk Screen 2002 (NRS 2002), which was developed by the Danish Society for Enteral and Parenteral The NRS 2002 is the only nutritional risk screening tool that has been developed by the Danish Society of Parenteral Nutrition [30] and recommended by the European Society of Parenteral Enteral Nutrition and the Chinese Society of Parenteral Enteral Nutrition[31],The NRS 2002 has a strong evidence-based medical foundation and is the only nutritional risk screening tool to date that targets whether clinical outcomes are improved [32].

In recent years, clinical experiments and basic studies have continued to demonstrate the significant therapeutic effect of acupuncture on post-stroke swallowing disorders, and the World Health Organization (WHO) considers acupuncture as an alternative and complementary strategy

for the treatment and improvement of stroke [33]. The group found that acupuncture can effectively improve post-stroke swallowing dysfunction by reviewing the literature and combining it with clinical practice experience, but the degree of efficacy of acupuncture on cricopharyngeal muscle opening is uncertain, and it is difficult to locate it accurately because of its deep location in the neck, thin muscles, and the distribution of more important nerves, blood vessels, thyroid gland and other tissues around it. Therefore, this study directly and precisely needled the target muscle under ultrasound guidance, visualizing the operation process and effectively avoiding various complications caused by blind operation, to demonstrate the effectiveness of needling the cricopharyngeal muscle for the treatment of cricopharyngeal muscle failure flaccid dysphagia, and then explore a new method that is safe, visualized, precise and effective to achieve a joint multidisciplinary optimal combination and ultimately achieve the best therapeutic effect.

METHODS AND ANAL YSIS

Trial Design and Setting

This was a prospective, multicenter, randomized controlled trial. Subjects were from the inpatient and outpatient clinics of Henan Provincial Hospital of Traditional Chinese Medicine, the Third Affiliated Hospital of Henan University of Traditional Chinese Medicine, and the Affiliated Hospital of Henan Provincial Institute of Traditional Chinese Medicine. 148 patients who met the predefined criteria were selected and randomly divided into two groups of 74 patients each: the experimental group and the control group. All patients received treatment for a period of 4 weeks, and swallowing function was assessed before and after treatment. After data collection, the efficacy of the experimental and control groups was analyzed. Example templates for the admission plan, intervention and assessment components are shown in Table 1. Our protocol demonstrates compliance with the criteria.

TABLE 1 Eligibility screening and informed consent will be completed prior to assignment.

Timepoint	Enrollment Allocation		Treatment perod				Follow-up	
	-1 week	0 week	1 week	2 week	3 week	4 week	8 week	12 week
Enrolment								

Eligibility screen	×							
Baseline	×							
Informed consent	×							
Medical history	×							
Merger disease	×							
Allocation		×						
Interventions								
Experiment group			×	×	×	×	×	×
Control group			×	×	×	×	×	×
Assessments								
VFSS		×				×	×	×
WST		×				×	×	×
SSA		×				×	×	×
SWAL-QOL		×				×	×	×
EAT-10		×				×	×	×
PAS		×				×	×	×
NRS 2002		×				×	×	×
Safety evaluation								
Needle sensation			×	×	×	×		
Adverse events			×	×	×	×	×	×

After assignment, each patient will receive treatment over a 4-week period. Evaluations will

be performed at baseline and at weeks 4, 8 and 12 after randomization. Adverse events will be recorded in the case report form at any time. The protocol is based on the 2013 Recommendations for Interventional Trials (SPIRIT 2013) guidelines [34] and the study flow chart is shown in Table 1.

Randomization

After signing the informed consent and completing the baseline assessment, eligible patients were randomly assigned to the trial or control group in a 1:1 ratio, following the principle of randomization, and the random number sequence was generated by SPSS, and the allocation results were processed by an allocator not involved in treatment and outcome assessment and stored in opaque sealed envelopes. Group assignment was done by professional statisticians not involved in the trial, and group assignment was done by independent researchers from the three study centers after information collection.

Blinding

The distribution of patient groups was not clear to data managers and statisticians. Experts, data managers, and statisticians were not allowed to communicate with others about patient treatment to improve the accuracy of the test metrics and to ensure the validity of the intervention and the objectivity and reliability of the assessment. Blinding was published after the statistical analysis was completed. The randomized assignor is responsible for processing the assignment results, the acupuncturist and the statistician will all be independent; the randomized assignor and acupuncturist will be aware of the assignment information and will remain blinded to the assessor and outcome statistician: this information will be available throughout the study. No blinded information may be disclosed until the data analysis is complete, and after the data analysis is complete, we will blind the results of the study for interpretation to minimize misleading data.

Inclusion and Exclusion Criteria

Inclusion Criteria. The Eligible Participants Should Meet all of the Following Criteria:

(1) Meet the above diagnostic criteria and have a first onset of disease within six months.

(2) 35 years ≤ age ≤ 75 years.

(3) Kubota's drinking water test assessment of III, IV, V.

(4) No oral or laryngeal occupational lesions.

(5) Clear consciousness, stable vital signs and ability to cooperate with rehabilitation

treatment.

(6) Able to understand and carry out simple instructions from the treatment staff, with a score of >17 in the illiterate group, >20 in the elementary school group, and >24 in the junior high school and above group on the Simple Mental State Examination Form (MMSE).

(7) Those who passed the hospital ethics committee review and signed the informed consent form.

Exclusion Criteria. Criteria for Exclusion Are the Following:

(1) Progressive deterioration of the disease, unable to adhere to treatment.

(2) Severe impairment of heart, lung, liver and kidney function.

(3) Patients with persistent status epilepticus or with impaired consciousness.

(4) Patients with severe aphasia, cognitive dysfunction or psychiatric symptoms who cannot cooperate with treatment

(5) Patients with blood pressure higher than 180/110mmHg.

Elimination Criteria

(1) Poor compliance and inability to cooperate with treatment; (2) Inability to complete follow-up or incomplete case data; (3) Serious adverse reactions; (4) Had to terminate the trial.

Sample Size

The purpose of this study was to evaluate the difference in efficacy between ultrasound-guided acupuncture cricopharyngeal muscle treatment and conventional swallowing function training for dysphagia. Based on previous studies and clinical experience, the efficiency of conventional swallowing function training is approximately 80%, and the efficiency of ultrasound-guided needling of the cricopharyngeal muscle may reach 92%[35]. According to the general requirements of medical statistics, sample size estimation using two independent sample rate comparisons was performed with the following formula.

$$N = \frac{8pq}{(P1 - P2)^2}$$

Where N is the sample size required for each treatment group, each group has an equal sample size, P1=0.8 and P2=0.92.P1=(P1+P2)/2 was calculated to be 0.86 and q=1-p was calculated to be 0.14. By substituting the above parameters and values into the formula, 67 cases per group will be required. Considering a 10% exclusion rate, the final estimated sample size would be 74 cases per

group (148 cases in total)

Experimental flow chart

This was a multicenter, randomized controlled trial. From case screening to randomization, to group intervention, pre- and post-treatment scores, and follow-up all followed the trial plan protocol strictly, as detailed in Figure 1.

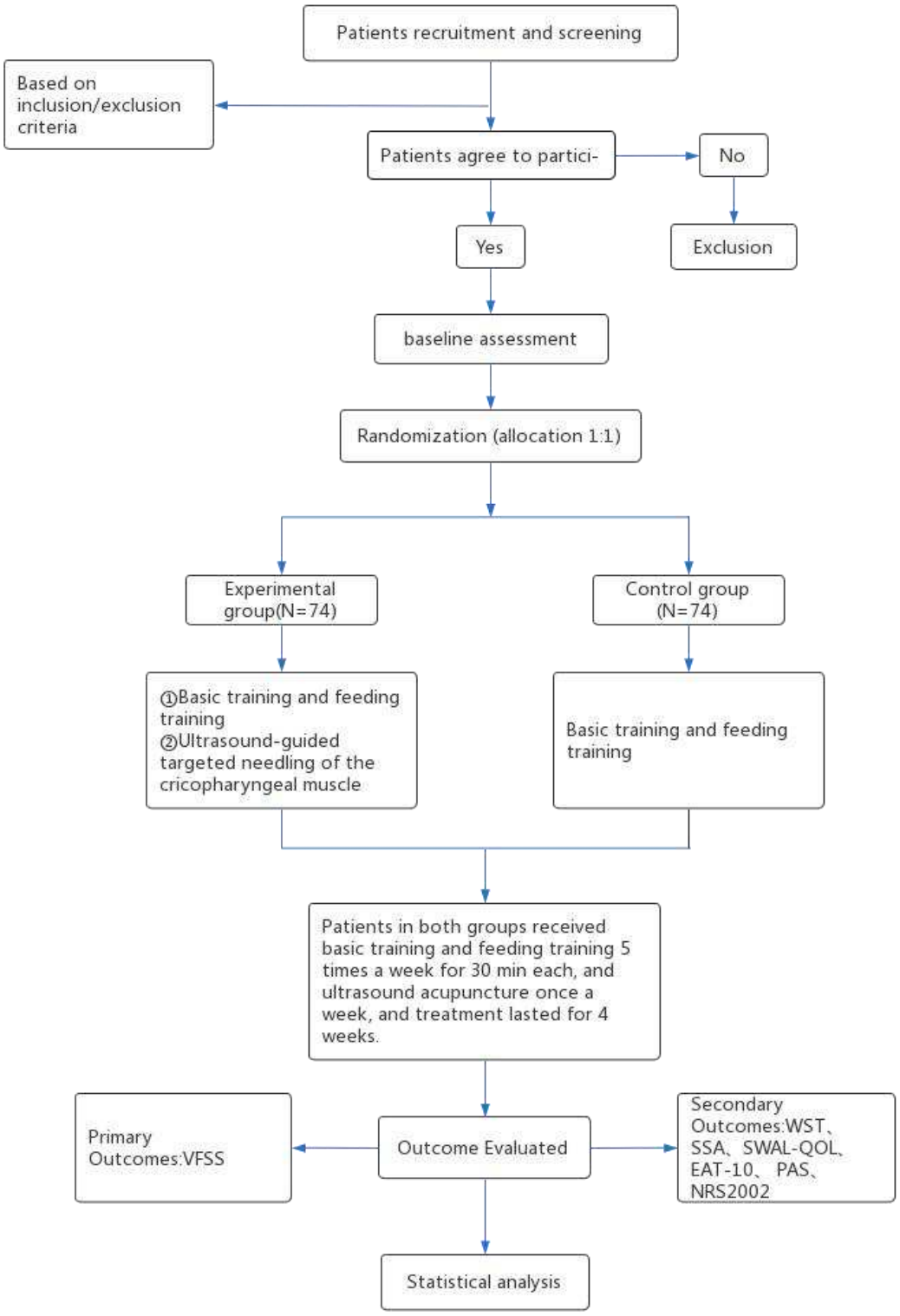


FIGURE 1: VFSS, swallowing X-ray televisual examination; WST, Wakita drinking test; SSA, Standardized Swallowing Function Assessment Scale; SWAL-QOL, Swallowing Disorder Specific Quality of Life Scale; EAT-10, Eating Assessment Questionnaire Survey Tool-10; PAS,

leakage/misaspiration scale; NRS 2002, Nutrition Risk Screening 2002.

Recruitment

Research plans and methods regarding subjects are developed in advance, such as preparing informed consent forms, data collection methods (videos, pictures), explaining the advantages and disadvantages of treatment methods, safety and security during treatment, etc., to help subjects understand the purpose and procedures of the trial as much as possible.

In addition, we put up recruitment posters on hospital and community billboards and used the Internet for promotion and recruitment. Each participant was initially judged and screened by the study team based on the above inclusion and exclusion criteria, and a final review was conducted after signing the informed consent form, and participants who passed the review were included in the test.

Interventions

The study was divided into two groups: a trial group and a control group. The control group received basic medication and regular swallowing training (including basic training and feeding training), while the experimental group received ultrasound-guided targeted needling of the cricopharyngeal muscle in addition to the control group. both groups received basic training and feeding training 5 times per week for 30 min each time, and ultrasound needling three times per week for 4 weeks.

Experimental Group

The control group was treated with ultrasound-guided and balloon-positioned targeted needling of the cricopharyngeal muscle. METHODS: The patient was placed in supine position, and the silicone catheter (Changyuan Shunhang Medical Equipment Co., Ltd.) was gently inserted into the patient's esophagus from the oral cavity and completely passed through the cricopharyngeal muscle. If the patient did not cough and was able to vocalize, 4 mL of saline was injected into the balloon to expand the balloon and hold the needle plug to avoid the backflow of saline back to the syringe, and the catheter was slowly lifted upward from the bottom upward until it stopped when there was resistance, suggesting that this is equivalent to the cricopharyngeal The lower edge of the cricopharyngeal muscle was marked with a marker at this position; the high-frequency line array probe of Navi series color ultrasound diagnostic system V2.0.0 (China Guangdong food and drug supervision machinery production license 20122302) was placed on the

right side of the anterior neck to determine the position of the balloon, and the probe was placed laterally at the level of the 6th cervical vertebra to precisely locate the position of the cricopharyngeal muscle, and after marking the position on the skin, saline was withdrawn and the catheter was pulled out. The skin was routinely disinfected, the cricopharyngeal muscle was carefully identified at the positioning mark, and the cricopharyngeal muscle was used as the target muscle. Treatment was continued three times a week for 4 weeks, with the end point of treatment being the resumption of transoral feeding.

Control Group

Basic training and feeding training were used. The basic training is: ① pharyngeal cold stimulation and empty swallowing. ②Vocal atresia training. ③Mendelsohn method. ④Lingual muscle training. The feeding training is: sitting position for those who can sit up, with the neck slightly flexed forward, 30° semi-recumbent position for those who cannot sit up, with the helper on the patient's healthy side. The form of food should be selected according to the degree and location of swallowing disorder, based on the principle of easy first and then difficult. The food should be made into jelly or paste, with uniform density, appropriate viscosity and not easily loosened, easily deformed when passing through the pharynx and esophagus, and not left on the mucosa. You can also use medical thickeners for feeding training. Try a small amount (3-4ml) at first, and then increase the amount at your discretion. At the same time, mouth swallowing, reciprocal swallowing, lateral swallowing, nod-like swallowing and other auxiliary swallowing movements can be used. Swallowing function training is performed in a one-to-one manner, once a day for 30 min, for 20 days as a course of treatment.

Equipment

This study will be conducted using the Navi series color ultrasound diagnostic system V2.0.0. In the main interface, settings are made for patient information, probe model, sound output power & sound output index, examination mode, etc. With the wiGuide magnetic navigation system, you can see the position of the needle to be fed more clearly in the portable ultrasound system, and enhance the visualization of the needle feeding process for better During the process, adjust the needle position; enter the wiGuide calibration interface. Hold the probe up in the air and press the [Start] button to begin calibration. Wait a few seconds until the system indicates that the process is complete. When calibration is complete, exit this interface and return to the main image

interface and observe the signal indicator; the signal should return to the top of green. This medical device has been approved to meet the relevant standards for radio wave interference resistance and can be used in hospitals, clinics and other environmentally qualified institutions. Therefore necessary precautions will be taken to keep the console at a distance of not less than 15 feet from motors, typewriters, elevators and other sources of strong electromagnetic radiation; operate the equipment in an enclosed environment (walls, floors or ceilings made of wood, plastic or concrete materials) to ensure that the console is protected from electromagnetic interference.The functional description of the wiGuide magnetic navigation system is described in detail in Table 2.

TABLE 2 Functional description of the wiGuide magnetic navigation system

Serial number	Description of the part name of the wiGuide magnetic navigation system	Function Description
1	wiGuide magnetic navigation system shows: active area	This refers to an area surrounding the probe. In this area, the system system may be able to detect the presence of a needle.
2	wiGuide Magnetic navigation system display: Needle	Planar injection: When the needle tip is in the plane of the ultrasound image, the needle is green. Planar injection: When the needle tip is not in the plane of the ultrasound image, the needle is red.
3	wiGuide Magnetic Navigation System display: Probes	Plan view of the probe, with the central white line representing the ultrasound plane. Note that the position of the notch on the probe coincides with the position in the upper left corner of the image.
4	In the image display: Position	The colored solid lines at both ends indicate the estimated projection of the needle position on the ultrasound plane. With optimal operating conditions, there is a high probability that the needle will be located between the two colored solid lines relative to the ultrasound image.

5	In the image display: Needle Path	The dotted line in the middle indicates the trajectory of the needle when the operator advances the needle from that position.
6	In the image display: Target Point	The box indicates the position in which the needle tip is located. Under optimal operating conditions and expert use, it is highly likely that the needle tip is within the box. In-plane injection: The box is green when the needle tip is in the plane of the ultrasound image. Out-of-plane injection: When the tip of the needle is not in the ultrasound image plane, the box is red.

FIGURE 2 Ultrasound visualization of the cricopharyngeal muscle

The cricopharyngeal muscle is located at the entrance of the esophagus, i.e., at the junction of the esophagus and hypopharynx. The cricopharyngeal muscle is visualized on ultrasound at the site indicated by the arrow in Figure 2, as shown in Figure 2 below.



Outcome Assessments

All data collectors underwent rigorous professional training to assess patients' swallowing function before treatment, 4 weeks after treatment, by swallowing X-ray televisual examination (VFSS), Puddlefield drinking test, Standard Swallowing Assessment Scale (SSA), Swallowing Disorder Specific Quality of Life Scale (SWAL-QOL), Eating Assessment Questionnaire Tool-10 (EAT-10), Leakage The Standard Swallowing Assessment Scale (SSA), Swallowing Disorder Specific Quality of Life Scale (SWAL-QOL), Eating Assessment Questionnaire-10 (EAT-10), Leakage/Absorption Scale (PAS), and Nutritional Risk Screening Form 2002 (NRS 2002) were assessed at the week 8 and 12 follow-up visits, and the Standard Swallowing Assessment Scale (SSA), Swallowing Disorder Specific Quality of Life Scale (SWAL-QOL), Eating Assessment Questionnaire-10 (EAT-10), Leakage/Absorption Scale (PAS), and Nutritional Risk Screening Form 2002 (NRS 2002) were completed at the week 8 and 12 follow-up visits. Screening Scale 2002 (NRS 2002) to assess swallowing function.

Primary Outcomes

The primary outcome was a swallowing X-ray fluoroscopy (VFSS), which is the "gold standard" for the diagnosis of swallowing disorders and provides a dynamic understanding of the lip closure, tongue strength and movement, and the pushing of the food mass during swallowing, and identifies the period and specific site of swallowing disorders. According to the patient's oral and pharyngeal phases in the swallowing situation and the degree of misopharyngeal swallowing, 10 is normal, 9-7 is mildly abnormal, 6-2 is moderately abnormal, and 2-0 is severely abnormal,

and the specific scoring criteria are shown in Table 3.

TABLE 3 Swallowing X-ray televisual fluoroscopy (VFSS) scoring criteria [22]

Swallowing Stages	Score	Scoring Criteria
Oral Period	0	Cannot deliver food from the mouth to the throat, but flows out of the mouth and lips, or only by gravity into the throat
	1	Cannot form chunks of food into the throat, only fragments of food into the throat
	2	Cannot deliver food completely into the throat in one swallow, and some food remains in the mouth after one swallowing action
	3	Food can be delivered to the throat in one swallow
Pharyngeal phase	0	Inability to cause pharyngeal supination, atresia of the epiglottis and closure of the soft palate arch, inadequate swallowing reflex
	1	There is a large amount of residual food in the pharyngeal recess and pear-shaped fossa
	2	A small amount of residual food is retained, and all the residual food can be swallowed into the lower pharynx with several swallows
	3	One swallow is sufficient to deliver food into the esophagus
Degree of misopharyngeal	0	Mostly swallowed by mistake, but no choking
	1	Mostly swallowed, but with coughing
	2	A little swallowing without coughing
	3	A few swallowing errors with choking and coughing
	4	No accidental aspiration

Secondary Outcomes

Secondary indicators included the Kubota Drinking Test (WST), Standard Swallowing Assessment Scale (SSA), Swallowing Disorder Specific Quality of Life Scale (SWAL-QOL), Eating Assessment Questionnaire Tool-10 (EAT-10), Leakage/Absorption Scale (PAS), and Nutritional Risk Screening 2002 (NRS 2002)

(1) Kubota drinking test (WST) [36]

patients were asked to sit upright and drink 30 mL of warm boiled water. Normal swallowing function:grade 1, within 5 seconds; suspected swallowing dysfunction:grade 1, more than 5 seconds or grade 2; abnormal swallowing function:grade 3~5. The specific evaluation criteria are shown in Table 4.

TABLE 4 Watering test in puddle field (WST) scoring criteria

Grading	Performance
Grade1 (Excellent)	Able to swallow water smoothly without choking and coughing
Grade 2(good)	Able to swallow water smoothly in 2 or more times without choking and coughing
Grade 3(moderate)	Able to swallow water smoothly in one sitting, but choking occurs
Grade 4(OK)	Can swallow water in 2 or more times, but choking occurs
Grade 5(poor)	Frequent coughing and inability to swallow all the water

(2) Standard swallowing function assessment scale (SSA) Standard swallowing function assessment scale [37]

The SSA was divided into three parts: (1) clinical examination, including basic conditions such as consciousness, head and trunk control, breathing, lip closure, soft palate movement, laryngeal function, pharyngeal reflex and spontaneous coughing; (2) observation of patients swallowing 5 ml of water; and (3) observation of patients swallowing 60 ml of water. The total score of the scale was 18-46. The lower the score, the better the patient's swallowing function was suggested.

(3) Swallowing disorder-specific quality of life scale (SWAL-QOL) [38]

The assessment of swallowing-related quality of life was collected using the SWAL-QOL, which contains 11 dimensions and 44 entries, of which 10 dimensions assess patients' quality of life and 1 dimension assesses patients' swallowing symptoms. The dimension assessing quality of life contained 30 entries, of which 8 were related to swallowing, for a total of 25 entries. These included: "psychological burden", "eating time", "appetite", "food choice", "verbal communication", "fear of eating", "mental health", and "social interaction", all entries were A 5-point scale was used, with a maximum score of 150 on the Quality of Life Scale and a

maximum score of 70 on the Swallowing Symptom Dimension. The higher the score, the better the quality of life of the patient.

(4) Eating Assessment Questionnaire Tool-10 (EAT-10) [39]

The EAT-10 scale can be a specific screening scale for early identification of malabsorption, occult malabsorption and swallowing abnormalities. The scale has a specificity of 94.92% and a sensitivity of 82.09% [40]. It consists of 10 questions, each divided into 5 levels, with a score of 0 for no impairment, 4 for severe impairment, and a total score of ≥3 indicating possible problems with swallowing ability and safety.

(5) Leakage/misaspiration scale (PAS) [41]

The scale is scored according to the degree of food misaspiration into the airway and the size of the ability to remove the misaspiration voluntarily, with a score range of 1 to 8. The higher the score, the more severe the misaspiration. The specific scoring criteria are shown in Table 5.

TABLE 5 Leakage/misaspiration scale (PAS) scoring criteria

Level	Rating	Endoscopy Description
Normal	1	Reference material (food mass) does not enter the airway
Infiltration	2	The reference entered the airway and remained above the vocal cords without residue
	3	The reference material stays above the vocal folds, with visible residue
	4	The reference material touches the vocal folds, no residue
	5	The reference touches the vocal folds and residue is visible
Misaspiration	6	The reference material passes through the vocal folds without residue under the vocal folds
	7	The reference material passes through the vocal folds, residue is visible under the vocal folds, and the patient responds
Resting aspiration	8	The reference material passes through the vocal folds, residue is visible under the vocal folds, and the patient does not respond

(6) Nutritional risk screening assessment [42]

The Nutritional Risk Screening Method (NRS) was used to assess the patient's upper arm circumference (midway between the shoulder dislocation and the elbow joint) and calf circumference (about 10 cm below the lower edge of the patella), which were measured and recorded by a soft ruler. The scoring system included the severity of the primary disease (0 to 3 points), the status of nutritional impairment at admission (0 to 3 points), and age ≥70 years plus 1 point, for a total score of 0 to 7 points. A total score of ≥3 points means there is a nutritional risk; a total score of <3 points means no nutritional risk.

Safety Evaluation and Adverse Events

Any adverse events and their treatment will be recorded throughout the treatment. Adverse events associated with acupuncture treatment include severe pain, syncope, bleeding, or any other discomfort. During the intervention, the researcher will closely monitor the patient's condition.

If the patient has any discomfort, the intervention will be stopped immediately and the patient will be treated accordingly. Details of any medical incidents will be reported in detail in the CRF. The Principal Investigator will review all adverse events on a regular basis and those that meet the criteria for serious adverse events will be reported to the local Institutional Review Board.

Statistical Analysis

After checking and verifying that all experimental data were correct, the study was statistically analyzed using SPSS 21.0 software. Data were expressed as mean±standard deviation (±s) for those that were measures and met normal distribution, and median (interquartile range) [Md(P25,P75)] for those that did not meet normal distribution. 2 groups of data met normal distribution and chi-square by t-test, and those that did not meet normal distribution by the Mann-Whitney U rank sum test. Count data were tested by chi-square test. The difference was considered statistically significant at $P<0.05$.

Quality Control

To reduce potential errors and ensure trial quality, all acupuncturists and assessors were required to receive professional training prior to the trial. The training course includes the recruitment, intervention and assessment process. Data completeness and accuracy will be monitored by clinical trial experts at the Clinical Research Center of the First Affiliated Hospital of Traditional Chinese Medicine of Henan University. All clinical trial experts are independent of the subject principles. In addition, a quality control team will be established to monitor the

experimental procedures for compliance with standard guidelines and statistical analysis will be performed when the total number of samples collected reaches 74. The Principal Investigator will obtain these interim results and decide whether to continue the trial. If, in the results of the interim data, the efficacy of the experimental group is lower than the other two groups, we will stop the trial.

DISCUSSION

1. Select ultrasound guidance

Ultrasound, a non-invasive, radiation-free examination, allows specific measurement of changes in anterior cervical structures during swallowing, avoiding the subjectivity of the patient himself. Also having a high-frequency probe, bedside ultrasound is simple and portable, allowing objective assessment of dysphagia in patients who are bedridden and have limited mobility for long periods of time. It has been shown [43] that the use of ultrasound to assess the movement of the lateral wall of the pharynx in normal subjects and stroke patients avoids the traditional manometry and electromyography that only detects changes in pharyngeal pressure but does not visualize the anatomy, and there is no statistical difference in this index between ultrasound and swallowing angiography techniques. Therefore, real-time observation of pharyngeal constriction muscle by ultrasound technique is a practical method.

In recent years, balloon catheters have been increasingly used in the treatment of swallowing dysfunction due to cricopharyngeal muscle loss of relaxation [44-45]. This technique has been studied by domestic and foreign scholars since the beginning of this century, and after more than 10 years of research and development, it has gradually become a routine means of treating dysphagia after stroke. The catheter is inserted through the nasal cavity into the esophagus, and the catheter is slowly lifted upward until it feels embedded, at which time the catheter is positioned at the lower edge of the cricopharyngeal muscle, but because each dilatation requires blind penetration, and the same balloon dilatation is performed when the balloon is lifted entirely by subjective The use of ultrasound combination can not only visually and dynamically display the entire process of the balloon passing through the cricopharyngeal muscle, but also observe the state of the cricopharyngeal muscle in real time, achieving a double positioning effect on the cricopharyngeal muscle and maximizing the accuracy of the subsequent needling of the cricopharyngeal muscle [46].

2. Cricopharyngeal muscle and swallowing

The cricopharyngeus muscle [47] (cricopharyngeus muscle, CP) belongs to the transverse muscle, which is not arbitrarily controlled, and it is located at the lower edge of the hypopharyngeal constrictor muscle, which together with the thyropharyngeal muscle and hypopharyngeal constrictor muscle constitute the upper esophageal sphincter (UES), which is the barrier at the junction of the pharynx and esophagus, because of its deep position in the neck, the It is difficult to locate it accurately because of its deep location in the neck, thin muscles, and the distribution of more important nerves, blood vessels, thyroid gland and other tissues around it. Cricopharyngeal dysfunction [48] (CPD), or cricopharyngeal muscle dyslaxation, is usually considered as a functional disorder, which is a swallowing disorder caused by incomplete or complete non-opening of the cricopharyngeal muscle during swallowing due to inability to relax or uncoordinated relaxation of the cricopharyngeal muscle spasm, which is jointly innervated by two nerves, namely vagus and sympathetic nerves. Any lesion in the neural pathway of central nerve conduction to the innervation of the cricopharyngeal muscle may lead to spasm of the cricopharyngeal muscle and inability to coordinate the swallowing process [49]. Swallowing dysfunction after stroke is a common clinical symptom, and 80% of patients with swallowing dysfunction in brainstem infarction are caused by cricopharyngeal muscle failure. Swallowing dysfunction caused by cricopharyngeal muscle failure is mainly due to insufficient laryngeal elevation and anterior displacement during the pharyngeal phase, insufficient expansion at the entrance of the esophagus, and spasm or failure of cricopharyngeal muscle relaxation, resulting in retention of the food mass in the epiglottis valley and the pear-shaped crypt, causing misaspiration and leading to swallowing[50]. Therefore, by giving a certain amount of stimulation to the cricopharyngeal muscle to retrain the opening and closing of the cricopharyngeal muscle, the symptoms of CPD can be relieved and the recovery of swallowing function can be promoted.

3. Acupuncture stimulation of the cricopharyngeal muscle

Acupuncture therapy is an important part of Chinese traditional medicine and has been widely used in many countries and regions. Acupuncture therapy has been widely used in the treatment of many clinical departments to regulate the meridian conduction of the whole body through acupuncture stimulation to adjust qi and blood and the function of the internal organs, and to stimulate the motor nucleus in the brainstem through neurons to activate the relevant areas of

the cortex on both sides of the brain and to promote the reconfiguration of the motor cortex and the central reflexes of the brainstem. thereby restoring swallowing function [51]. However, adverse events such as bleeding and bruising from acupuncture have also been reported. Kong Fanliang et al [52] conducted a statistical analysis of the relevant literature on acupuncture adverse events in China and abroad from 1985 to 2014 and concluded that the top 4 acupuncture adverse events were, in order, needle sickness, tissue and organ damage, infection, and bleeding. Some scholars have used biochemical tests, CT, MRI, and other tests to scientifically and objectively observe the presence or absence of qi, and Xu Pei et al [53] observed the distance between the milli-needle and the surrounding anatomical tissues when the milli-needle was used to obtain qi at the Neiguan acupoint under ultrasound intervention, demonstrating that the use of ultrasound can also be used to observe the presence of qi in humans during acupuncture. The use of ultrasound guidance can be used as an adjunct to acupuncture, which is relatively safe, but still subject to adverse events. The special imaging of different tissue structures under ultrasound can effectively avoid important tissue structures such as blood vessels and nerves when acupuncture is performed, reducing the incidence of adverse acupuncture events. At the same time, ultrasound-guided acupuncture can provide an imaging basis for obtaining qi or not, which is beneficial for improving the accuracy and effectiveness of acupuncture.

4. Combination of subjective and objective outcome measures

In addition to the scale assessment chosen in this study, we used the assessment method of swallowing X-ray televisual examination (VFSS) and a combination of subjective and objective methods to reduce the influence of a series of human interventions on the experimental results and to make the study more convincing. An important limitation of our study was the pinprick test, for which a double-blind trial was not possible. To reduce this bias, each group of patients will be treated in a different room at a different time and communication between each group will be prohibited. The acupuncturists involved in this study have been uniformly trained to strictly standardize acupuncture practice and to minimize errors in this study.

5.Conducting multicenter clinical trials

The study will be conducted in three clinical research centers (Henan Provincial Hospital of Traditional Chinese Medicine, the Third Affiliated Hospital of Henan University of Traditional Chinese Medicine, and the Affiliated Hospital of Henan Provincial Institute of Traditional Chinese

Medicine) according to the same trial plan, and the clinical data will be collected at the same time, and then the statistical analysis will be conducted after consistent aggregation, and finally the trial report will be made. The multi-center clinical trial will help to accelerate the rate of subject selection, collect sufficient subjects in a shorter period of time, and reduce the time of the clinical trial; the same period of time can ensure that the collected materials are more symbolic, and enhance the richness and credibility of the trial basis; in addition, because investigators from different centers will join the clinical study, it will help to learn from the strengths and complement the weaknesses, and improve the clinical trial's In addition, because investigators from different centers will join this clinical study, it will help to learn from each other and complement each other's strengths and improve the design, conduct, and presentation of clinical trials. However, because multicenter trials are more complex than single-center trials at the institutional level, the following options will be used to reduce the challenges and improve the accuracy of the study when planning and executing a multicenter trial. First, the multicenter trial will identify a principal investigator who will assume responsibility for the trial results and process and act as a coordinator among the centers; second, learn to train the investigators participating in the trial based on the same trial planning protocol; third, ensure that the investigators at each center follow the trial planning protocol, including stopping their enrollment in the trial if the clinical protocol is violated; fourth, fully utilize the duties of the monitor Fifth, after the clinical trial is completed, we will jointly draft a summary report and hold a summary meeting.

In conclusion, this report describes a prospective, multicenter, randomized controlled trial to systematically evaluate the effect of ultrasound-guided acupuncture of the cricopharyngeal muscle on swallowing rehabilitation in patients with cricopharyngeal muscle dystonia. The clinical efficacy on swallowing was observed, and it was determined whether ultrasound-guided needling of the cricopharyngeal muscle was effective in improving swallowing dysfunction caused by cricopharyngeal muscle failure. This study not only aims to explore a new method for the safe, visual, precise and effective treatment of patients with cricopharyngeal dystonia, but also to provide more high-quality experimental evidence for the clinical application of ultrasound-based external Chinese medicine treatment.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

VFSS：Video fluoroscopic Swallowing Study

WST：Water Swallow Test

SSA：Standardized Swallowing Assessment

SWAL-QOL：Swallowing Quality of Life

EAT-10：Eating Assessment Tool-10

PAS：Penetration and Aspiration Scale

NRS 2002：Nutritional Risk Screening 2002

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Trial Status

Patient recruitment for this study began on October 1, 2022, and the study is ongoing. Protocol version number and date: V2.02021 September 1, 2012. Patient recruitment is expected to be completed in October 2023.

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contributions

KR and YL developed the concept of this trial and designed the study. xH and KR contributed equally to the conception, design, and writing of the manuscript. YW helped to search the literature and assisted with patient recruitment. XJ, HQ participated in the revision and editing of this manuscript. All authors approved the final version of the manuscript.

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Ethics declarations

The study conformed to the principles of the Declaration of Helsinki and was approved by the Ethics Committee of Henan Provincial Hospital of Traditional Chinese Medicine (Second Affiliated Hospital of Henan University of Traditional Chinese Medicine) (ethics code number: 1193-01). Written informed consent from guardians will be obtained from all participants and participants under the age of 18 years prior to the start of the evaluation.

Consent for publication

Not applicable

Competing interests

The authors declare no competing interests.

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Not applicable, because it is an experimental plan type article, the manuscript does not include any experimental data for the time being and no analysis data set was generated.

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