EFFECTIVENESS OF AN ARTIFICIAL INTELLIGENCE-EMPOWERED VIDEO-GAME SYSTEM ON STROKE PATIENTS WITH DYSPHAGIA: A RANDOMIZED CONTROLLED TRIAL

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Effectiveness of an artificial intelligence-empowered video-game system on stroke patients with dysphagia: a randomized controlled trial

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CERTIFICATE OF ORIGINALITY

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Abstract

Background

Post-stroke dysphagia (PSD) affects 50-70% of stroke survivors, significantly increasing risks of aspiration pneumonia, malnutrition, and reduced quality of life. Traditional dysphagia rehabilitation requires frequent hospital visits, and the repetitive nature of traditional exercises often results in low compliance and engagement, leading to ineffective dysphagia management and limited improvement in swallowing function. Applying game thinking to rehabilitation training can increase participant involvement, making the rehabilitation process enjoyable. Although artificial intelligence (AI) combined with gaming has the potential to increase patient engagement, it has not been systematically explored or implemented in dysphagia rehabilitation.

Objectives

This aim of this randomized controlled trial (RCT) was to develop and assess the efficacy of a novel artificial intelligence-empowered video game system (AI-VG) in enhancing swallowing function among PSD patients. Additionally, it examined whether AI-VG system offers superior benefits in enhancing daily feeding function and training compliance compared to conventional methods.

Methods

This study employed a comprehensive approach: (1) A systematic review and network meta-analysis was conducted to evaluate and rank various therapeutic interventions for enhancing swallowing function, and feeding and daily function in PSD patients. (2) An AI-VG system was designed and developed for swallowing function training based on evidence-based nursing research methods. (3) The technology acceptance model was employed as the theoretical foundation, while in-depth interviews facilitated exploration of AI-VG system adoption among

healthcare professionals and individuals with dysphagia. (4) A pilot RCT with a 4-week intervention was conducted at a Beijing rehabilitation center to assess the feasibility and acceptance of AI-VG system. (5) A RCT was conducted at the rehabilitation center between October 2023 to July 2024. Participants were allocated to either an AI-VG system intervention or conventional therapy group, completing 30-minute daily sessions (5 days/week) for four weeks. The primary outcome measured swallowing function improvement across three timepoints (baseline [T0], post-intervention [T1], and one-month follow-up [T2]). Secondary outcomes included laryngeal function, dietary intake level, swallowing safety, nutritional status, and swallowing-related quality of life. Treatment adherence, satisfaction and acceptance were assessed, analyzing temporal outcome variations through generalized estimating equation modeling.

Results

The systematic review and network meta-analysis identified acupuncture as the most effective interventions for enhancing swallowing function, followed by the chin tuck against resistance exercise. The AI-VG system was successfully developed with three game components targeting lip, tongue, and neck exercises. The qualitative research revealed favorable perceptions regarding AI-VG system utility and usability, despite implementation challenges. In the pilot RCT, the AI-VG system group showed greater improvement in adherence, swallowing function, oral-intake function, and nutrition status than the control group after treatment. The comprehensive RCT encompassed 84 participants (experimental group: n=42, mean age=64.98±9.66 years; control group: n=42, mean age=66.43±13.12 years). The AI-VG system intervention yielded significantly enhanced swallowing function compared to conventional therapy, with mean group differences of 4.02 (95% CI=-6.16 to -1.89, P<0.001) at T1 and 4.14 (95% CI=-6.16 to -2.12, P<0.001) at T2. Oral consumption capabilities, nutritional status indicators, and swallowing-related quality of life metrics showed significant improvement (P<0.001 for

overall group × time interaction). Treatment adherence was markedly superior in the experimental cohort versus controls. The intervention group demonstrated strong acceptance and satisfaction toward the AI-VG system, while intergroup comparisons revealed no significant differences in laryngeal function or swallowing safety parameters.

Conclusion

An AI-VG system for swallowing rehabilitation was developed and its effectiveness and acceptability were assessed in individuals with PSD. AI-VG system intervention can be an effective way to strengthen swallowing, feeding, and daily living functions in patients with PSD. These findings provided valuable insights for clinical implementation of technology-enhanced rehabilitation interventions that could improve dysphagia management in stroke survivors.

Significance

By addressing key shortcomings of conventional swallowing therapies, this study presents the first empirical support for the AI-VG system as a viable rehabilitation tool for PSD. The integration of qualitative and quantitative data yielded important perspectives on its acceptance and efficacy. This study demonstrated the potential of AI technology to improve treatment adherence and patient participation in rehabilitation, while establishing a scalable framework for extending specialized dysphagia care to settings with limited access to speech-language pathologists.

Research Output

Journal Publications Arising from the Study

1. **Zhang, B.**, Wong, K. P., Liu, M., Hui, V., Guo, C., Liu, Z., Liu, Y., Xiao, Q., & Qin, J. (2025). Effect of artificial intelligence-based video-game system on dysphagia in patients with stroke: A randomized controlled trial. *Clinical nutrition (Edinburgh, Scotland)*, *45*, 81–90. https://doi.org/10.1016/j.clnu.2024.12.022
2. **Zhang, B.**, Wong, K. P., Liu, M., Hui, V., Guo, C., Liu, Y., Liu, Z., Liu, Y., Xiao, Q., & Qin, J. (2025). Face Recognition-Driven Video Game for Dysphagia Rehabilitation in Stroke Patients: A Pilot Randomized Controlled Trial. *Archives of physical medicine and rehabilitation*, *106*(3), 342–350. https://doi.org/10.1016/j.apmr.2024.10.005
3. **Zhang, B**., Wong, K. P., Guo, C., Chen, S. C., Fu, S., Kang, R., Xiao, Q., & Qin, J. (2025). Effects of Non-Pharmacological Interventions on the Swallowing Function of Patients With Post-Stroke Dysphagia: A Systematic Review and Network Meta-Analysis. *Journal of oral rehabilitation*, 52(1), 109–120. https://doi.org/10.1111/joor.13901
4. **Zhang, B.**, Ding, P., Hui, V., Wong, K. P., Liu, Y., Liu, Z., Xiao, Q., & Qin, J. (2024). Technology acceptance of the video game-based swallowing function training system among healthcare providers and dysphagia patients: A qualitative study. *Digital health*, *10*, 20552076241284830. https://doi.org/10.1177/20552076241284830
5. **Zhang, B.**, Guo, C., Hui, V., Wong, K. P., Liu, Y., Liu, Z., Xu, Y., Xiao, Q., Chen, S. C., & Qin, J. (2023). Evaluating the effectiveness of video-game based swallowing function training in patients with dysphagia: study protocol for a randomized controlled trial. *Trials*, *24*(1), 735. https://doi.org/10.1186/s13063-023-07738-7

6. **Zhang, B.**, Wong, K. P., & Qin, J. (2023). Effects of Virtual Reality on the Limb Motor Function, Balance, Gait, and Daily Function of Patients with Stroke: Systematic Review. *Medicina (Kaunas, Lithuania)*, *59*(4), 813. https://doi.org/10.3390/medicina59040813
7. **Zhang, B.**, Wong, K. P., Kang, R., Fu, S., Qin, J., & Xiao, Q. (2023). Efficacy of Robot-Assisted and Virtual Reality Interventions on Balance, Gait, and Daily Function in Patients With Stroke: A Systematic Review and Network Meta-analysis. *Archives of physical medicine and rehabilitation*, *104*(10), 1711–1719. https://doi.org/10.1016/j.apmr.2023.04.005

Journal Publications during the PhD Study period

1. Wong, K. P., Wu, S., Lin, H., Poon, K., **Zhang, B.**, & Qin, J. (2025). Finding Peace in Pixels: Exploring the Therapeutic Mechanisms of Virtual Nature for Young Adults' Mental Well-Being. In *Healthcare*, 13(8), 895
2. Liu, Y., **Zhang, B.**, Montayre, J., Koduah, A. O., & Leung, A. Y. M. (2025). Non-Pharmacological Interventions Targeting Sense of Coherence Among Older Adults and Adults With Chronic Conditions: A Meta-Analysis With Trial Sequential Analysis. *Journal of advanced nursing*, *81*(4), 2165–2198. https://doi.org/10.1111/jan.16558
3. **Zhang, B.**, Wong, A., Constantino, R. E., & Hui, V. (2024). The association between psychological distress, abusive experiences, and help-seeking among people with intimate partner violence. *BMC public health*, *24*(1), 1060. https://doi.org/10.1186/s12889-024-18350-y
4. Liu, M., Liu, M., **Zhang, B.**, Fang, M., Chen, K., Zhang, Y., Wang, Q., Tian, C., Wu, L., & Li, Z. (2024). Research hotspots and frontiers of vagus nerve stimulation in stroke: a bibliometric analysis. *Frontiers in neuroscience*, *18*, 1510658. https://doi.org/10.3389/fnins.2024.1510658
5. Wong, K. P., **Zhang, B.**, Lai, C. Y. Y., Xie, Y. J., Li, Y., Li, C., & Qin, J. (2024). Empowering Social Growth Through Virtual Reality-Based

Intervention for Children With Attention-Deficit/Hyperactivity Disorder: 3-Arm Randomized Controlled Trial. *JMIR serious games*, *12*, e58963. https://doi.org/10.2196/58963

6. Wong, K. P., **Zhang, B.**, Xie, Y. J., Wong, F. K. Y., Lai, C. K. Y., Chen, S. C., & Qin, J. (2024). Impacts of Job Demands on Turnover Intention Among Registered Nurses in Hong Kong Public Hospitals: Exploring the Mediating Role of Burnout and Moderating Effect of Pay Level Satisfaction. *Journal of nursing management*, *2024*, 3534750. https://doi.org/10.1155/2024/3534750

7. Hui, V., **Zhang, B.**, Jeon, B., Wong, K. C. A., Klem, M. L., & Lee, Y. J. (2024). Harnessing Health Information Technology in Domestic Violence in the United States: A Scoping Review. *Public health reviews*, *45*, 1606654. https://doi.org/10.3389/phrs.2024.1606654

8. Chen, S. C., Ruan, J. Y., **Zhang, B.**, Pang, L. Y., Zhong, L., Lin, S. L., Wong, K. P., Ouyang, H. X., Yeung, W. F., Fu, Q. W., & Chen, B. Q. (2024). Traditional Chinese medicine interventions based on meridian theory for pain relief in patients with primary dysmenorrhea: a systematic review and network meta-analysis. *Frontiers in medicine*, *11*, 1453609. https://doi.org/10.3389/fmed.2024.1453609

9. Wong, K. P., **Zhang, B.**, & Qin, J. (2023). Unlocking Potential: The Development and User-Friendly Evaluation of a Virtual Reality Intervention for Attention-Deficit/Hyperactivity Disorder. *Applied System Innovation*, *6*(6), 110.

10. Wong, K. P., Qin, J., Xie, Y. J., & **Zhang, B.** (2023). Effectiveness of technology-based interventions for school-age children with attention-deficit/hyperactivity disorder: systematic review and meta-analysis of randomized controlled trials. *JMIR mental health*, *10*, e51459.

Conference Presentations

1. **Zhang B**, Liu Y, Hui V, et al. (2024, November) Effectiveness of Video-game Based Swallowing Function Training in Patients with Dysphagia: A Pilot Randomized Controlled Trial. American Medical Informatics Association 2024 Annual Symposium. San Francisco, US. Oral Presentation
2. **Zhang B**, Guo C, Hui V, et al. (2024, July) Technology Acceptance of the Video-game Based Swallowing Function Training System: A Qualitative Study. Nursing Imformatics. Manchester, UK. Poster Presentation
3. **Zhang B**, Yao W, Ren Z, et al. (2024, July) Development of a prediction model for prognosis of patients with acute kidney injury in intensive care unit. Summer Institute in Nursing Informatics (SINI). Online. Oral presentation
4. **Zhang B**, Wong KP, Guo C, et al. (2023, November) Efficacy of robot-assisted and virtual reality interventions on balance, gait, and daily function in patients with stroke: A systematic review and network meta-analysis. 2023 Yonsei International Nursing Conference. Seoul, South Korea. Poster Presentation
5. **Zhang B**, Wong KP, Qin J. (2023, March) Effects of virtual reality on physical outcomes for people with stroke: A systematic review of systematic reviews. 26th East Asian Forum of Nursing Scholars 2023. Tokyo, Japan. Poster Presentation

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List of Abbreviations

AI-VG	Artificial intelligence-empowered video game
CTAR	Chin tuck against resistance
CI	Confidence intervals
EMST	Expiratory muscle strength training
FOIS	The Functional Oral Intake Scale
GEE	Generalized estimating equation
GUSS	The Gugging Swallowing Screen
IQR	Interquartile range
iTBS	Intermittent theta burst stimulation
ITT	Intention-to-treat
MMSE	Mini-Mental State Examination
MNA-SF	The Mini Nutritional Assessment Short Form
NMES	Neuromuscular electrical stimulation
PES	Pharyngeal electric stimulation
PP	Per-Protocol
PSD	Post-stroke dysphagia
RCT	Randomized controlled trail
SMD	Standardized mean differences
SSA	Standard Swallowing Assessment
SUCRA	Surface under the cumulative ranking curve
SWAL-QOL	The swallowing quality of life
TAM	Technology acceptance model
tDCS	Transcranial direct current stimulation
rTMS	Repetitive transcranial magnetic stimulation
VVST	The Volume-Viscosity Swallowing Test

Chapter 1 Introduction

1.1 Introduction

The present chapter introduces the doctoral dissertation, with Section 1.2 covering the contextual background and methodological rationale. Section 1.3 will outline the organization of this thesis, providing readers with a roadmap of the subsequent chapters and their contributions to the overall research narrative.

1.2 Background

1.2.1 Definition and Prevalence of Post-Stroke Dysphagia

Swallowing begins in the mouth, passes through the esophagus, and reaches the stomach, progressing through three sequential phases: oral, pharyngeal, and esophageal (Alfonsi, Todisco, Fresia, Tassorelli, & Cosentino, 2021). Swallowing represents an intricate physiological phenomenon characterized by remarkable speed and frequency, with healthy adults performing this action roughly 600 times per day. The entire sequence, from oral cavity to esophageal entry, typically completes within 1–2 seconds, engaging a sophisticated neuromuscular network that includes numerous cranial and spinal nerves as well as more than 30 paired muscles. Due to this highly coordinated and delicate mechanism, even slight disturbances in sensory feedback or motor execution can result in clinically meaningful dysphagia (Wilmskoetter, Daniels, & Miller, 2020). The neural circuitry responsible for swallowing is located in the rostral medulla, with extensive cortical and subcortical activation supporting motor preparation and sensory processing (Daniels et al., 2017). Consequently, stroke-related lesions in the cortical hemispheres, subcortical circuits, or brainstem can lead to dysphagia.

Dysphagia occurs when physical or functional abnormalities in the chewing-swallowing apparatus hinder proper food movement into the stomach (Tulunay-Ugur & Eibling, 2018). Individuals recovering from stroke experience serious illness combined with neurological reflex delays, placing them at elevated risk for

swallowing difficulties. This vulnerability stems from brain nerve damage that can lead to multiple impairments: delayed initiation of the pharyngeal swallow, poor coordination during the oral phase, reduced propulsive force in pharyngeal muscles, incomplete closure of the larynx, dysfunction of cricopharyngeal muscles, diminished clearance during the pharyngeal phase, and inadequate relaxation of the esophageal sphincter (Jones, Colletti, & Ding, 2020). Right hemisphere strokes are often associated with pharyngeal phase dysfunction, more severe dysphagia, and aspiration, while left hemisphere strokes typically lead to oral phase dysfunction and milder dysphagia (Daniels et al., 2017).

Globally, stroke remains the second most fatal condition and third highest contributor to disability-adjusted life years, even with significant advances in preventive care and therapeutic interventions (Collaborators, 2020). Approximately 800,000 Americans experience stroke annually, with projections indicating that the affected population will increase from 10 million to nearly 20 million by 2050, ultimately affecting more than 184 million individuals globally (Joynt Maddox et al., 2024). A 2% increase in stroke cases was observed in the European Union's 53 member countries between 2010 and 2019, with the total number reaching 1,802,560 in 2019. Notably, ischemic stroke represented 70% of this figure (Prendes et al., 2024). From 2015 onwards, stroke has emerged as China's primary cause of mortality and disability. As a significant chronic non-communicable condition, it represents a substantial threat to the wellbeing of the Chinese population (Y. Wang et al., 2017). From 1990 to 2019, the annual stroke incidence rate increases by 86% to 276.7 per 100,000 Chinese population, with an estimated 3.94 million new strokes (Ma et al., 2021).

With the improvement of medical conditions, the death rate of stroke has decreased, while the disability rate is increasing. Dysphagia, a common complication after stroke, has a high prevalence. Post-stroke dysphagia (PSD) is present in 29-81% of patients with acute stroke, based on diagnostic criteria, time

and method of evaluation, and stroke characteristics. Although many stroke patients regain swallowing function spontaneously in the early recovery period, persistent dysphagia affects 11% to 50% of individuals even six months post-stroke (Dziewas et al., 2021). The occurrence rate of swallowing difficulties reached 43.6% among patients with ischemic stroke, while individuals with hemorrhagic stroke exhibited a higher frequency at 58.8% (Song, Wu, Wang, Pang, & Zhu, 2024). It was prevalent in 42% of males and 46.2% of females. Longitudinal assessment revealed a dynamic pattern of dysphagia prevalence following stroke, with initial rates of 32.1% at 24 hours, climbing to 45.6% within 48 hours. While a modest decline to 43.4% was observed at 72 hours, the condition peaked at 53.8% one week post-onset before subsiding to 48.0% at two weeks (Song et al., 2024). Among PSD patients, 37.5% had severe dysphagia, 31.25% had moderate dysphagia, and 31.25% had mild dysphagia. Aging, obesity, comorbidities, hypertension, stroke location, low Glasgow Coma Scale scores, and the use of thrombectomy or thrombolytic therapy were contributing factors and were found to be associated with PSD (Al-Mamari, Lazarus, Al-Harrasi, Al-Noumani, & Al Zaabi, 2024).

1.2.2 Burden and Consequence of Post-Stroke Dysphagia

Individuals recovering from stroke face additional complications resulting from dysphagia, including aspiration events, aspiration-related pneumonia, nutritional deficiencies, and disturbances in psychological and social functioning. These complications contribute to compromised immune responses, extended hospital stays, higher mortality rates, and increased healthcare expenses (Nieto, Ang, & Liu, 2022). Patients experiencing stroke with accompanying swallowing difficulties show an 11-fold rise in aspiration likelihood (E. Boaden et al., 2021), which corresponds to a 12.9-fold elevation in aspiration pneumonia risk (Mandell & Niederman, 2019). The frequency of pneumonia following stroke among patients in intensive care settings varied between 22% and 47%, with variations

reflecting differences in study methodology and chest infection diagnostic criteria (Walter et al., 2007). According to study findings, 6.5% of patients with PSD suffered from aspiration pneumonia, 6.7% suffered from dehydration, 10.1% suffered from urinary tract infections, and 4.4% suffered from constipation (Bond, Doeltgen, Kleinig, & Murray, 2023). The research demonstrated markedly elevated complication frequencies in dysphagic stroke patients relative to their non-dysphagic counterparts. When accounting for potential confounding variables through statistical adjustment, impaired swallowing function independently predicted several negative consequences including respiratory infections from aspiration, hydration deficits, genitourinary infections, and intestinal stasis (Bond et al., 2023).

Research showed that PSD may increase healthcare costs. Affected patients receive chest X-rays and antibiotics more frequently, stay longer in the stroke unit, and are transferred to rehabilitation clinics more often. The cost of 1 year of treatment for PSD was estimated at $4,510 due to increased hospitalization and medical equipment costs(Bonilha et al., 2014). According to a study conducted in France, Switzerland, Argentina, Brazil, Taiwan, and the United States, the cost of the acute phase of PSD was as high as $16,900, and the cost of pneumonia in patients with PSD was as high as $27,600 (Marin, Serra-Prat, Ortega, & Clavé, 2020). Post-stroke dysphagia significantly impairs recovery and is associated with increased mortality, reaching 22.9% at 30 days and rising to 65.8% within one year (Cabre et al., 2010; Carrión et al., 2015; Labeit et al., 2023).

Beyond medical complications, dysphagia presents substantial psychosocial challenges. Dysphagia significantly reduces meal enjoyment and social interactions, leading to social withdrawal that strains relationships and diminishes psychological well-being and daily functioning for both affected individuals and their household members (Wu et al., 2022). Dysphagia not only have a high

prevalence but also a high probability of complications, so rehabilitation of post-stroke patients with dysphagia is very essential.

1.2.3 Current Approached to the rehabilitation of Post-Stroke Dysphagia

Evaluating swallowing function and implementing timely personalized training for dysphagia patients can enhance coordination of swallowing-related musculature, activate neural pathways, broaden cortical sensory regions, and facilitate restoration of the swallowing reflex arc, thereby effectively elevating patients' swallowing capabilities (Zimmerman, Carnaby, Lazarus, & Malandraki, 2020). Research by Meng et al. (Meng et al., 2018) demonstrated through a randomized controlled trial (RCT) that participants receiving surface neuromuscular electrical stimulation exhibited markedly greater improvement in swallowing function compared to those receiving conventional dysphagia therapy after a two-week intervention period, with notable increases in dysphagia severity scores.. Park et al. (J. S. Park et al., 2020) administered resistive jaw opening exercises to stroke dysphagia patients over four weeks, observing strengthened hyoid bone movement, increased oral intake capacity, and decreased aspiration incidents. These findings suggest that targeted swallowing therapy can effectively decrease patient burden, reduce hospitalization duration, lower complication rates and mortality, while enhancing overall quality of life (Bai et al., 2021).

A study by Yu-Lei et al. (Yu-Lei et al., 2022) employed dual neurostimulation techniques, intermittent theta burst stimulation (iTBS) and repetitive transcranial magnetic stimulation (rTMS), for treating dysphagia following stroke, documenting substantial enhancements in swallowing capabilities. Their work highlighted the importance of distinguishing between iTBS and rTMS parameter configurations, as previous investigations indicated that insufficient stimulation intensity might explain the reduced effectiveness observed in some rTMS clinical trials (Cheng, Sasegbon, & Hamdy, 2021). Both iTBS and rTMS techniques require specialized professional personnel and dedicated rehabilitation equipment.

Current swallowing rehabilitation devices are typically developed by technical specialists, with therapy sessions conducted during inpatient stays or at specialized rehabilitation facilities.

Recent research shows that swallowing muscle mass independently contributes to early PSD in ischemic stroke patients undergoing mechanical thrombectomy (Pinho et al., 2024). Because the neural control and muscle contractions required for swallowing are complex and are easily impaired in stroke patients, targeted exercises to improve swallowing efficiency and safety are likely to be the most widely used treatment for PSD patients (Dziewas et al., 2021). Various intervention approaches exist for dysphagia rehabilitation, spanning a spectrum from targeted to comprehensive, singular to multifaceted, and encompassing exercises that address both deglutition-specific and auxiliary motor functions. Swallowing rehabilitative therapies form a critical component of dysphagia management, including jaw mobility drills, tongue muscle conditioning, chin tuck against resistance (CTAR) (J. S. Park & Hwang, 2021), Shaker exercises (Kagaya & Inamoto, 2022), effortful swallow training (EST) (H. S. Park, D. H. Oh, T. Yoon, & J. S. Park, 2019), and respiratory muscle training (RMT) (Claus et al., 2021). Specific techniques target different physiological mechanisms, the Shaker head lift exercise corrects deficient upper esophageal sphincter opening kinematics, while expiratory muscle strength training (EMST) produces dual benefits by increasing expiratory drive and submental muscle recruitment during swallowing. These interventions aim to recalibrate oropharyngeal mechanics through alterations in muscular strength, movement velocity, and temporal coordination to generate sustainable clinical benefits (Claus et al., 2021). These rehabilitation approaches have been employed for decades to improve functional outcomes and daily living satisfaction among individuals with PSD and now constitute the cornerstone of clinical management for neurologically-based dysphagia. They function not only to improve oropharyngeal muscle strength but

also to modulate neuronal control of those strengthened muscles (J. S. Park, Lee, Jung, Choi, & Jung, 2019). Swallowing rehabilitation represents a cost-effective conservative treatment approach that simultaneously reduces dysphagia-associated morbidity and enhances overall well-being in affected adults. Nursing professionals provide essential facilitation and oversight during the implementation of oropharyngeal rehabilitation protocols (Wirth et al., 2016). Therefore, determining the most effective swallowing rehabilitation methods allows for customized and focused strategies in addressing dysphagia-related complications in adult patient populations.

Current swallowing rehabilitation approaches face several constraints including spatial limitations, a "one-to-one" training model requiring direct therapist-patient interaction, and monotonous exercise routines. Park et al. (H. S. Park et al., 2019) implemented effortful swallowing exercises targeting oropharyngeal muscle groups in PSD patients. The protocol required participants to press their tongue firmly against the palate while contracting neck muscles and performing forceful swallowing actions. Each training session consisted of 10 repetitions, conducted three times daily, five days weekly over a four-week period. Throughout these sessions, therapists verified successful completion of each effortful swallow through visual assessment and tactile confirmation (H. S. Park et al., 2019). While such therapist-dependent approaches can be effective, their scalability is limited, especially given the growing population of dysphagia patients.

Poor adherence to traditional swallowing rehabilitation is a well-documented challenge, primarily due to the monotonous and repetitive nature of the exercises, limited and delayed feedback, and the lack of engaging elements to sustain patient interest. Many post-stroke patients also experience fatigue, depression, or cognitive impairment, which further reduces motivation to maintain consistent training over several weeks. After reviewing the literature, we found that these

adherence issues have been reported not only in Korea but also in Japan and the United States, where similar therapist-led protocols have encountered high dropout rates and reduced compliance over time (Y. H. Choi & Paik, 2018; Nicholson et al., 2013; Oyake, Suzuki, Otaka, & Tanaka, 2020). In addition, the inability of traditional programs to provide remote supervision and intelligent, real-time adaptations for swallowing function rehabilitation often results in delayed intervention and suboptimal recovery outcomes (Bai et al., 2021).

1.2.4 Artificial Intelligence Approach for the Rehabilitation of Post-Stroke Dysphagia

As information technology advances, an increasing number of researchers are employing video games to facilitate rehabilitation therapy. Studies have incorporated gaming principles into rehabilitation settings, carefully selecting appropriate gamification elements for therapeutic purposes, developing patient-centered virtual environments, providing contextually relevant scenarios, and providing instantaneous multimodal feedback encompassing sight, sound, and touch, the technology allows patients to participate in instinctive therapeutic activities that make the rehabilitation process more dynamic and appealing (Cassani, Novak, Falk, & Oliveira, 2020; Laver et al., 2017). Building upon this foundation, Artificial Intelligence (AI) has become a promising tool for treating post-stroke sequelae, such as physical impairments and cognitive impairments. While AI and visual gaming elements have shown potential to enhance patient engagement and provide quantifiable metrics for rehabilitation progress (Burdea et al., 2021), the intersection of AI technologies with traditional dysphagia rehabilitation remains underexplored.

Studies predominantly demonstrate that video game applications in physical and cognitive rehabilitation contexts have established therapeutic value and clinical efficacy (R. C. Lin et al., 2020; Mekbib et al., 2021). Current approaches have yet to fully leverage AI's capabilities to objectively assess muscle movement

and exercise execution in dysphagia treatment (Ayodele Sasegbon, Cheng, & Hamdy, 2024). A study by Park et al. (2019) created a game-based version of CTAR exercise for PSD rehabilitation. Their findings revealed that patients using this approach demonstrated notably higher compliance and motivation ratings, while experiencing reduced exercise endurance and muscle fatigue compared to traditional training methods (J. S. Park, Lee, & Jung, 2019). However, their intervention focused exclusively on chin tuck resistance exercises, omitting other essential components of comprehensive swallowing rehabilitation. A research (2016) (Dondorf, Fabus, & Ghassemi, 2016) developed a biofeedback game system requiring subjects to perform forceful swallowing while wearing neck accelerometers that detected swallowing thresholds to enable interactive features. This approach, however, relied on acceleration curve analysis for outcome measurement and required extensive training for healthcare providers to operate effectively. Battel et al. (Battel & Walshe, 2022) used a combination of surface electrical signal biofeedback and games to promote swallowing training in patients. Since three electrodes had to be worn for the study, this may have prevented participants from completing the rehabilitation training remotely, requiring them to attend sessions at the hospital instead, which likely contributed to low adherence. To the best of our knowledge, no fully developed AI-empowered video games currently exist that are specifically designed for patients with PSD patients. Additionally, the field lacks high-quality clinical trials with sufficient sample sizes to conclusively validate the effectiveness of video game applications in rehabilitation for these patients.

1.2.5 Summary

PSD, affecting 50-70% of stroke survivors, significantly elevates the risks of pulmonary infections from food aspiration, nutritional deficiencies, and diminished daily functioning and well-being. Traditional dysphagia management relies heavily on therapists' subjective experience, lacking objective methods to

assess muscle movement quality. Current rehabilitation exercises require frequent hospital visits, which burden stroke patients with mobility limitations, and the repetitive nature of traditional approaches results in low patient compliance and engagement, leading to suboptimal dysphagia management and limited improvement in swallowing function. While AI and video game-based interventions show promise in patient care, the intersection of AI technologies with dysphagia rehabilitation remains underexplored. Despite AI's potential to increase patient engagement, provide telecare, and objectively monitor swallowing function, systematic implementation in dysphagia management is still lacking. Therefore, this study aims to develop a swallowing training system incorporating AI-driven video games (AI-VG) and assess its therapeutic efficacy in PSD patients through a RCT.

1.3 Organization of the Thesis

The thesis is organized into seven comprehensive chapters. **Chapter One** illustrated the background of the present study and the rationale for conducting AI-VG system intervention for PSD. In **Chapter Two**, a comprehensive systematic review and network meta-analysis is presented, Exploring the most suitable rehabilitation methods, intervention intensity and frequency for PSD and providing a basis for the development of AI-VG swallowing function training system at a later stage. **Chapter Three** describes the study's hypothetical model, aim, objective and hypothesis, and details the development of the AI-VG system. **Chapter Four** details a qualitative investigation employing semi-structured in-depth interviews to examine how potential users perceive and accept the AI-VG swallowing function training system. This approach was used to gather insights for system improvements based directly on user perspectives and experiences. **Chapter Five** illustrates a pilot study performed with RCT, to investigate the feasibility of recruitment procedure and data collection process and assess the acceptability and preliminary efficacy of the AI-VG system for PSD. **Chapter Six**

presents a RCT designed to systematically investigate the therapeutic effectiveness of the AI-VG intervention, with primary outcomes focusing on patients' swallowing function, nutrition status, swallowing related to quality of life, satisfaction. And it also discusses the results of the effects of the AI-VG system on PSD, and addresses the study's strengths, limitations, and implications for nursing practice and research. **Chapter Seven** describes the study conclusion.

Chapter 2. Effects of different interventions on swallowing function in dysphagia patients with stroke: A systematic review and network meta-analysis

2.1 Introduction

This chapter presents the literature review that forms the theoretical foundation for the AI-VG (AI-empowered video game) system developed in this study. Section 2.2 provides a comprehensive overview of the research significance and identifies key gaps in the existing literature. Section 2.3 details the methodologies employed, including systematic review and network meta-analysis. The findings derived from these analyses are presented in Section 2.4, while Section 2.5 provides a critical evaluation of these results, examining both their substantive contributions and methodological limitations. Section 2.6 concludes by summarizing the chapter's key theoretical and practical insights.

The content of this chapter was published (B. Zhang, Wong, Guo, et al., 2025): **Zhang, B.,** Wong, K. P., Guo, C., Chen, S. C., Fu, S., Kang, R., Xiao, Q., & Qin, J. (2025). Effects of Non-Pharmacological Interventions on the Swallowing Function of Patients With Post-Stroke Dysphagia: A Systematic Review and Network Meta-Analysis. Journal of oral rehabilitation, 52(1), 109–120. https://doi.org/10.1111/joor.13901.

2.2 Background

Dysphagia presents as a clinical disorder involving structural and/or functional deficiencies affecting oral and digestive organs including the oral preparatory (lips, jaw, tongue), pharyngeal (soft palate, pharynx), and esophageal phases of swallowing, leading to compromised alimentary transit safety and efficiency (Tulunay-Ugur & Eibling, 2018). A 2022 meta-analysis revealed that up to two-thirds of stroke survivors globally experience swallowing difficulties. Of those

developing early dysphagia following stroke, a minimum of 75% manifest moderate to severe symptoms (Rommel & Hamdy, 2016). The impaired swallowing function associated with post-stroke dysphagia compromises nutritional intake capabilities and potentially weakens immune defenses, ultimately impacting patients' daily activities (Horn, Simpson, Simpson, Bonilha, & Bonilha, 2022). This condition contributes to diminished immune response, extended hospital stays, higher death rates, and increased healthcare expenses (Nieto et al., 2022). Significantly, stroke patients with swallowing difficulties face an 8.5-fold greater mortality risk compared to those without dysphagia, with 30-day mortality figures ranging between 13.8% and 40% (Ouyang et al., 2020).

Research indicates that swallowing rehabilitation can effectively enhance swallowing capability, reduce hospitalization duration, and lower pneumonia incidence rates (Alamer, Melese, & Nigussie, 2020; Bath, Lee, & Everton, 2018). However, the swallowing process involves complex neurological and muscular coordination including dual hemispheric cortical activation, brainstem control centers, multiple cranial nerve pathways, and numerous oropharyngeal muscle groups working in synchronized patterns (Alfonsi et al., 2021). Despite receiving standard treatment protocols, studies show that merely 17.6% of patients manage to resume their pre-stroke dietary patterns (Carnaby, LaGorio, Silliman, & Crary, 2020). This underscores the necessity for developing more effective swallowing rehabilitation approaches to improve both swallowing function and overall daily functioning in stroke survivors.

Contemporary investigations have studied various methods for treating post-stroke swallowing difficulties, broadly classified into three categories (Bath et al., 2018): (1) neuromodulation techniques, (2) oropharyngeal muscle training regimens, and (3) traditional Chinese medical approaches. The first category includes neuromuscular transcranial direct current stimulation (tDCS), electrical stimulation (NMES), repetitive transcranial magnetic stimulation (rTMS),

intermittent theta burst stimulation (iTBS), and pharyngeal electric stimulation (PES). The second category features multiple exercise protocols such as chin tuck against resistance exercise (CTAR), tongue-pressure resistance training, shaker exercise, and expiratory muscle strength training (EMST). Traditional Chinese Medicine protocols commonly incorporate acupuncture as a therapeutic modality for dysphagia management. However, existing treatment approaches for PSD exhibit notable constraints. Both muscle strengthening exercises and traditional Chinese medicine typically require extended treatment periods spanning several weeks before demonstrating clinical benefits. Meanwhile, electrical stimulation approaches demand considerable professional support and specialized rehabilitation devices (Cheng et al., 2021). These limitations potentially reduce patient treatment adherence and may negatively impact overall therapeutic effectiveness (Bai et al., 2021).

Multiple research projects have examined various rehabilitation interventions for improving swallowing abilities in stroke survivors; however, their findings show inconsistencies, and precise therapeutic effects remain ambiguous. In a comparative study, Lim et al. (Lim, Lee, Yoo, & Kwon, 2014) evaluated traditional rehabilitation protocols against rTMS and NMES, determining that both rTMS and NMES demonstrated greater efficacy for enhancing swallowing function, though not feeding capabilities, compared to standard rehabilitation protocols. Furthermore, a RCT conducted by Xie et al. (Yu-Lei et al., 2022) identified no meaningful distinction between rTMS and iTBS regarding their impact on post-stroke swallowing recovery. Research by Huang et al. (Huang et al., 2010) established that both traditional acupuncture and electroacupuncture outperformed standard interventions for enhancing deglutitive capabilities, with equivalent results between these alternative approaches. Conversely, a systematic review (Wen, Liu, Liu, Peng, & Liu, 2022) determined that respiratory strengthening exercises and acupuncture techniques demonstrated beneficial effects for

dysphagia management and functional improvement in post-stroke rehabilitation. This review, however, found limited evidence supporting electrical stimulation's therapeutic benefit for dysphagia. Determining the most effective rehabilitation protocols will enhance clinical reasoning for physicians, inform nursing care planning, and strengthen therapeutic support systems (D'Netto, Rumbach, Dunn, & Finch, 2022). Therefore, comprehensive evaluation across therapeutic modalities remains crucial for establishing clinically-informed rehabilitation strategies targeting deglutition enhancement following cerebrovascular events.

Traditional paired meta-analysis methodology permits only direct evaluation between two specific interventions, lacking the capacity to simultaneously assess relative effectiveness across all available treatment options (Shih et al., 2022). While published meta-analyses have documented positive outcomes from interventions including tDCS (Marchina et al., 2021), rTMS (Y. Zhu & Gu, 2022), and exercise therapy (Greco et al., 2018) for improving deglutition, nutritional intake, and functional outcomes. However, no study has performed an integrated quantitative evaluation comparing the three major treatment classes (neuromodulation techniques, oropharyngeal muscle training, and traditional Chinese medical therapies) for stroke-related swallowing disorders. Network meta-analysis methods offer unique advantages by permitting simultaneous evaluation of both direct treatment comparisons and indirect inferences across intervention networks (Shim, Yoon, Shin, & Bae, 2017). This approach allows for comprehensive efficacy ranking of all available therapies. Accordingly, we employed this advanced analytic technique to determine the relative effectiveness and establish evidence-based hierarchies among all swallowing rehabilitation modalities for enhancing swallowing physiology, eating capacity, and activities of daily living in stroke survivors.

2.3 Methods

2.3.1 Registration

We conducted a network meta-analysis integrating both direct and indirect evidence, following the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-analysis network statement for reporting of systematic reviews incorporating network meta-analysis (Hutton et al., 2015). Our research protocol received registration on PROSPERO (registration number is CRD42023391951).

2.3.2 Search strategy

We systematically searched seven major academic databases (Pubmed, Embase, Cochrane Library, PEDro, CINAHL, Web of Science, and ProQuest Theses) for all available records up to September 2022. The search framework centered on two principal concepts: stroke and dysphagia. To ensure thorough coverage, we supplemented electronic searches with manual screening of reference sections from pertinent articles. The comprehensive Pubmed search strategy appears in **Appendix 1**.

2.3.3 Inclusion and exclusion criteria

Patients were included in this analysis based on the following criteria:

(1) Participants: adult patients (≥18 years) with confirmed post-stroke swallowing difficulties;

(2) Interventions: All swallowing rehabilitation methods were considered, with particular focus on three principal classifications:

- Peripheral and central stimulation techniques: neuromuscular electrical stimulation (NMES), intermittent theta burst stimulation (iTBS), transcranial direct current stimulation (tDCS), repetitive transcranial magnetic stimulation (rTMS), and pharyngeal electric stimulation (PES);
- Muscle strengthening exercises: tongue-pressure resistance training (TPRT), chin tuck against resistance exercise (CTAR), shaker exercise, and expiratory muscle strength training (EMST);
- Traditional Chinese medicine approach: acupuncture;

(3) Comparison groups: sham stimulation, no intervention, or conventional dysphagia therapy (CDT);

(4) Outcomes:

- Primary: pre- and post-intervention assessment of swallowing function using any validated quantitative clinical or radiological measurement tools;
- Secondary: pre- and post-intervention evaluation of feeding ability and daily functioning; and

(5) Study design: RCTs.

Patients were excluded in this analysis based on the following criteria:

(1) Duplicate publications;

(2) Materials with insufficient data for analysis, such as literature reviews, conference abstracts, or registered research protocols;

(3) Non-English language publications.

After deduplication, we performed initial screening based on titles and abstracts. Potentially relevant publications underwent full-text evaluation, with final inclusion determined by strict adherence to our predefined criteria. Two researchers independently conducted the selection process, with any discrepancies settled through consensus or arbitration by a senior investigator.

2.3.4 Data extraction

Two independent investigators systematically extracted all study data using a standardized extraction form. The extracted information encompassed author identification, publication year, participant numbers, onset timing, gender distribution, age demographics, intervention type, treatment intensity and frequency, evaluation instruments, outcome measurements, and reported adverse events. Any extraction discrepancies were addressed through collaborative discussion until consensus was achieved.

2.3.5 Risk of bias

Two independent assessors evaluated methodological quality in all included studies using the Cochrane Risk of Bias Tool 2.0 (RoB2) (Sterne et al., 2019). This assessment examined multiple domains: randomization processes, intervention allocation, protocol adherence, outcome data completeness, measurement methodology, selective outcome reporting, and overall bias potential. Studies received classifications of “high risk”, “low risk”, or “some concern” regarding overall bias. When evaluation differences arose between assessors, a third researcher facilitated resolution through discussion until reaching mutual agreement.

2.3.6 Data analysis

Due to scale result variations, standardized mean differences (SMD) were employed to compare intervention outcomes (Murad, Wang, Chu, & Lin, 2019). Since SMD cannot adjust for scale direction differences, we modified data from four studies (Farpour, Asadi-Shekaari, Borhani Haghighi, & Farpour, 2022; J. H. Moon, Hahm, Won, & Cho, 2018; W. Xia, C. Zheng, S. Zhu, & Z. Tang, 2016; Young Hyun et al., 2017) that used decreasing severity scores by subtracting their means from maximum scale values, ensuring consistent directional interpretation before standardization (JPT, T, & (editors), 2022). The network meta-analysis implementation employed specialized statistical techniques including frequency methodologies and complex multivariate random effects meta-regression modeling frameworks executed through the Network Command Suite within the Stata 17.0 statistical environment.

Random effects models facilitated paired meta-analysis for direct comparisons between intervention pairs. Between-study heterogeneity assessment employed the Cochrane Q test (P<0.1) and I^2 statistic (>50%) (Julian PT Higgins et al., 2019).

Network geometry plots visualized evidence relationships for swallowing function and daily feeding abilities. Node size corresponded proportionally to

participant numbers for each intervention, while connecting line thickness represented participant numbers in trials directly comparing two interventions (Salanti, Ades, & Ioannidis, 2011). Intervention effectiveness ranking utilized the surface under cumulative ranking curve (SUCRA), with values ranging from 0-1. Higher SUCRA scores indicated greater likelihood of intervention superiority (Rücker & Schwarzer, 2015).

Both paired and network meta-analyses compared intervention effects against controls. The analysis expressed findings through SMD, each presented with 95% confidence intervals (CI), with statistical significance determined by whether CIs excluded zero. A league table organized these comparative findings.

Direct and indirect effect consistency was evaluated through loop-specific inconsistency assessment and side-splitting models (J. P. Higgins et al., 2012). Publication bias detection employed Egger's test (Egger, Davey Smith, Schneider, & Minder, 1997). Sensitivity analyses tested result robustness and identified potential studies contributing disproportionately to heterogeneity.

2.4 Results

2.4.1 Literature screening process and results

Following our comprehensive database search, we identified 15,645 articles initially. After eliminating 8,109 duplicate records, we conducted title and abstract screening on the remaining publications. This process excluded 7,462 articles that failed to satisfy our predetermined inclusion criteria. We then performed detailed full-text evaluation of 74 articles, which resulted in the exclusion of 43 papers due to non-RCT design, studies examining different intervention locations or intensities, or research on dysphagia not resulting from stroke. Through additional reference list examination of included studies, we ultimately incorporated 33 RCTs in our network meta-analysis. (**Figure 2.1**).

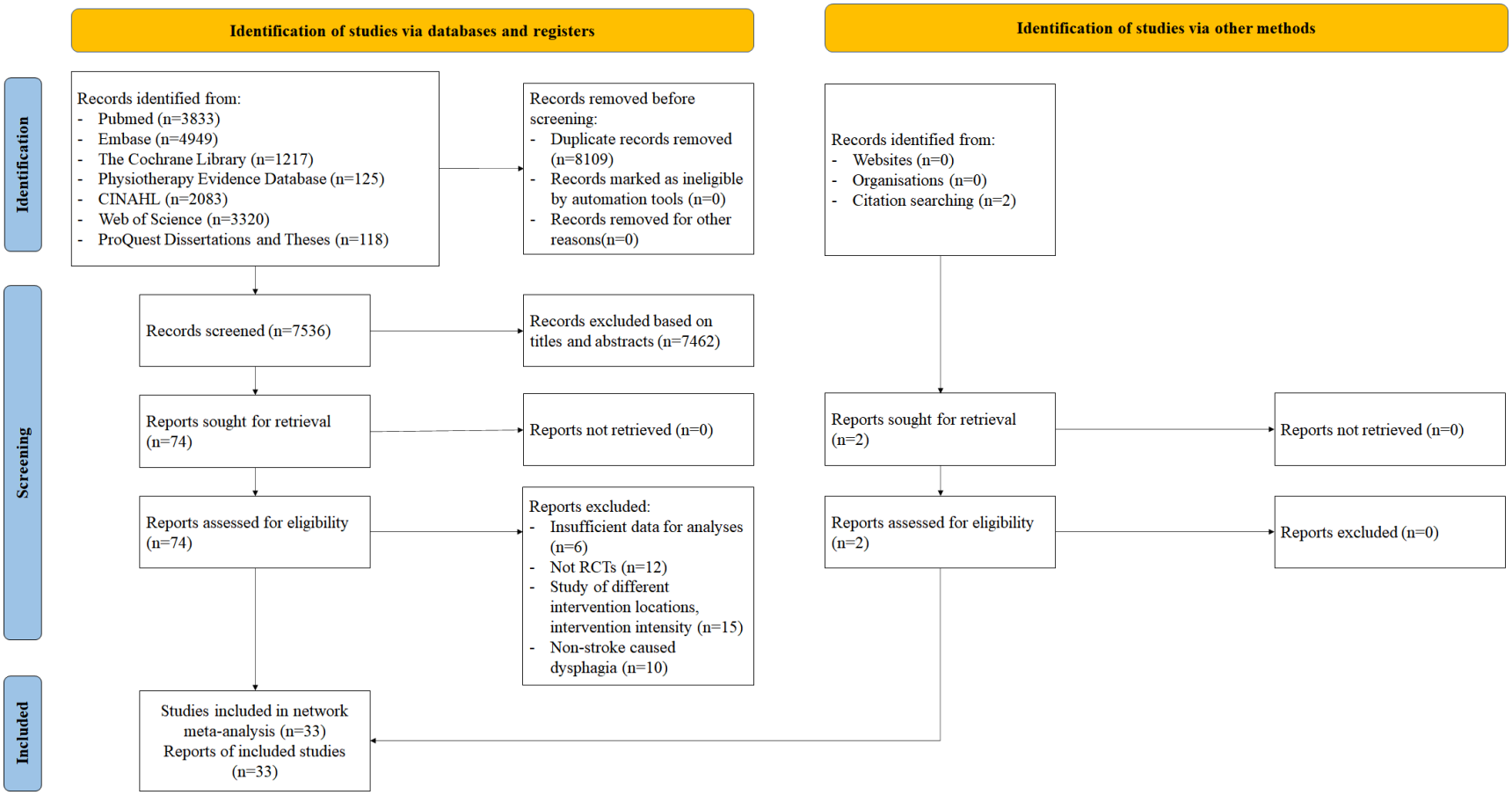


Figure 2.1 Literature screening process and results

2.4.2 Description of included studies

The systematic review analyzed 33 randomized controlled trials conducted from 2013 to 2022, involving a total of 1,341 stroke survivors (male: 795; female: 558) aged 55.3 to 79 years. The cohort comprised 630 ischemic stroke and 266 hemorrhagic stroke cases, with post-stroke durations varying from 4.1 days to 17.3 months. Geographically, the studies originated from nine nations, with South Korea contributing the majority (n=16), followed by China (n=7), while Turkey, the UK, and Iran each produced 2 studies, and the USA, Spain, Italy, and Germany contributed 1 study each. Participant numbers in individual trials ranged from 87 to 98.

The included trials examined 12 distinct intervention types. These interventions encompassed both peripheral and central stimulation techniques, including NMES (n=7), iTBS (n=2), tDCS (n=4), rTMS (n=4), and PES (n=1). Muscle-strengthening strategies involved TPRT (n=4), CTAR (n=6), shaker exercises (n=4), and EMST (n=4). Acupuncture (n=1) was the sole traditional Chinese medicine intervention. Control groups were assigned either sham treatments (n=12) or CDT (n=18). Intervention periods varied between 3 days and 8 weeks. While most studies employed two arms, one study included three intervention groups (Gao & Zhang, 2017). Complete characteristic details of all included studies appear in Table 2.1 and Table 2.2.

Table 2.1 The study characteristics of the included studies (n=33)

Study Authors, year	Country	Intervention	Sample	Sex M/F	Age, years (mean±SD)	Stroke Type ischemic/ hemorrhagic	Stroke onset (mean±SD)
Ayse Güleç 2021 (Güleç, Albayrak, Erdur, Öztürk, & Levendoglu, 2021)	Turkey	NMES	12	7/5	67.0±4.6	11/1	7.0±8.5m
		CDT	13	12/1	63.3±6.3	13/0	4±10.5m
Elif Tarihci Cakmak 2022 (Tarihci Cakmak et al., 2022)	Turkey	NMES	17	11/6	62.9±9.8	16/1	48.3±92.6w
		CDT	17	9/8	63.6±10.0	15/2	52.2±92.2w
Hee-Su Park 2019 (H. S. Park et al., 2019)	Korea	TPRT	12	6/6	66.5±9.5	NR	24.4±8.7w
		CDT	12	5/7	64.8±11.2		25.7±6.3w
H. D. KIM 2017 (H. D. Kim et al., 2017)	Korea	TPRT	18	11/7	62.2±11.0	11/7	4.9±5.5m
		CDT	17	8/9	59.3±10.2	10/7	5.3±5.6m
Huiyu Liu 2022 (H. Liu et al., 2022)	China	rTMS	23	17/6	67.6±11.7	19/4	74.2±88.2d
		sham rTMS	26	20/6	67.7±10.0	21/5	63.4±59.5
Hwan‐Hee Kim 2019 (H. H. Kim & Park, 2019)	Korea	CTAR	12	6/6	63.5±5.5	7/5	NR
		CDT	13	6/7	65.2±6.2	6/7	

Jinzhu Rao 2022 (Rao et al., 2022)	China	iTBS	33	22/11	63.4±10.4	15/18	22.0±11.1d
		sham iTBS	31	24/7	65.9±11.4	19/12	26.0±11.9d
Ji-Su Park 2020 (J. S. Park et al., 2020)	Korea	CTAR	15	9/6	62.1±10.1	7/8	NR
		sham CTAR	14	8/6	61.8±12.1	8/6	
Ji-Su Park 2019 (Ji-Su, Gihyoun, &	Korea	CTAR	19	12/7	61.0±11.2	8/11	3.6±1.2m
Young-Jin, 2019)		Shaker	18	9/9	59.5±9.3	5/13	3.9±1.2
Ji-Su Park 2018 (J. S. Park, An, Oh, &	Korea	CTAR	11	6/5	62.2±17.3	7/4	27.2±8.5w
Chang, 2018)		CDT	11	4/7	58.4±12.5	6/5	32.1±14.4w
Jing Gao 2017 (Gao & Zhang, 2017)	China	CTAR	30	13/17	70.9±6.6	NR	NR
		Shaker	30	15/15	71.1±7.1		
		CDT	30	14/16	71.1±6.4		
Jong-Bae Choi 2017 (Jong-Bae et al.,	Korea	Shaker	16	10/6	60.8±10.9	9/7	3.4±11.2
2017)		CDT	15	9/6	60.4±10.5	12/3	4.13±1.0
Jong-Hoon Moona 2018 (J. H. Moon et	Korea	TPRT	8	3/5	62.0±4.2	6/2	56.0±17.4d
al., 2018)		CDT	8	4/4	63.5±6.1	6/2	59.9±20.0d

Jong Hoon Moon 2017 (J. H. Moon, Jung, Won, Cho, & Cho, 2017)	Korea	EMST	9	6/3	63.0±5.8	6/3	21.4±5.1d
		CDT	9	6/3	63.1±5.2	7/2	21.1±4.0d
J.-S. Park 2016 (J. S. Park, Oh, Hwang, & Lee, 2016)	Korea	NMES	25	12/13	54.0±11.9	NR	35.4±5.6w
		sham NMES	25	14/11	55.8±12.2		36.0±6.1w
J.-S. Park 2016 (J. S. Park, Oh, Chang, & Kim, 2016)	Korea	EMST	14	6/8	64.3±10.7	NR	27.4±6.3w
		sham EMST	13	6/7	65.8±11.3		26.6±6.8w
J.-W. Park 2013 (J. W. Park, Oh, Lee, Yeo, & Ryu, 2013)	Korea	rTMS	9	5/4	73.7±3.8	7/2	59.9±16.3d
		sham rTMS	9	5/4	68.9±9.3	8/1	63.9±26.8d
Kyoung Don Kim 2015 (Don Kim, Lee, Lee, & Ryu, 2015)	Korea	CTAR	13	8/5	63.2±10.2	NR	15.6±2.9m
		Shaker	13	7/8	63.6±8.1		16.2±3.1m
Kyeong Woo Lee 2014 (Lee et al., 2014)	Korea	NMES	31	22/9	63.4±11.4	NR	5.0±1.4d
		CDT	26	20/6	66.7±9.5		5.5±1.1d
Lise Sproson 2018 (Sproson, Pownall, Enderby, & Freeman, 2018)	UK	NMES	13	8/5	76.0±11.4	NR	17.3±25.0m
		CDT	14	8/6	79.0±11.4		9.1±20.5m

Mi-Ja Eom 2017 (Mi-Ja et al., 2017)	Korea	EMST	13	5/8	69.2±4.1	NR	NR
		sham EMST	13	6/7	70.2±3.6		
Marilia Simonelli 2019 (Simonelli et al., 2019)	Italy	NMES	17	11/6	67.2±16.2	NR	45.2±22.3d
		CDT	16	6/10	72.4±12.3		32.6±18.1d
Maryam Tarameshlu 2019 (Tarameshlu, Ansari, Ghelichi, & Jalaei, 2019)	Iran	rTMS	6	4/2	55.3±19.6	NR	3.2±2.1m
		CDT	6	1/5	74.7±5.9		5.3±3.4m
Mei-Yun Liaw 2020 (Liaw et al., 2020)	China	EMST	10	3/7	61.2±10.7	6/4	3.0±2.0m
		CDT	11	9/2	66.8±11.5	3/8	2.4±0.7m
Philip M. Bath 2016 (Bath et al., 2016)	UK	PES	70	48/22	74.0±9.9	61/9	12.6±9.5d
		sham PES	56	46/20	74.9±12.6	48/8	14.4±10.0d
Sandeep Kumar 2022 (Kumar et al., 2022)	USA	tDCS	14	3/11	68.0±12.6	NR	NR
		sham tDCS	15	6/9	73.0±14.1		
Sima Farpour 2022 (Farpour et al., 2022)	Iran	tDCS	22	13/9	65.3±16.3	NR	4.1±4.0d
		sham tDCS	22	10/12	70.7±16.3		4.5±4.0d

Sonja Suntrup-Krueger 2018 (Suntrup-Krueger et al., 2018)	Germany	tDCS	29	17/12	68.9±11.5	29/0	116.3±98.9h
		sham tDCS	30	17/13	67.2±14.5	30/0	116.8±64.9h
Tingwei Wang 2022 (T. Wang et al., 2022)	China	TPRT	18	10/8	60.2±8.8	10/8	4.9±1.9m
		CDT	18	11/7	60.7±8.6	9/9	4.7±1.8m
Viridiana Arreola 2021 (Arreola et al., 2021)	Spain	NMES	29	19/10	70.7±12.9	28/1	466.3±903.5d
		CDT	29	19/10	73.5±11.6	28/1	630.4±1247.8d
Wenguang Xia 2016 (W. Xia et al., 2016)	China	Acupuncture	60	34/26	65.3±14.2	43/17	9.3±2.3d
		CDT	60	35/25	66.1±14.3	41/19	8.7±2.5d
Xie Yu-Lei 2022 (Yu-Lei et al., 2022)	China	iTBS	24	16/8	67.5±10.6	6/18	25.1±11.74d
		rTMS	23	18/5	64.8±11.3	7/16	29.9±17.11d
Young Hyun Ahn 2017 (Young Hyun et al., 2017)	Korea	tDCS	13	9/4	61.6±10.3	5/8	12.3±4.9m
		sham tDCS	13	6/7	66.4±10.7	11/2	11.62±4.6m

Abbreviations: rTMS: Repetitive transcranial magnetic stimulation; iTBS: Intermittent theta burst stimulation; RMT: Resting motor threshold; WST: Water-swallowing test; NR: Not report; TPRT: Tongue-pressure resistance training; CDT: Conventional dysphagia training; PAS: Penetration Aspiration Scale; NMES: Neuromuscular electrical stimulation; tDCS: Transcranial direct current stimulation; SWAL-QOL: The swallowing quality of life questionnaire; FOIS: The Functional Oral Intake Scale; MASA: The Mann Assessment of Swallowing Ability; EAT-10: The eating assessment tool; CTAR: Chin Tuck against resistance exercise; MRS: Modified Rankin Scale; BI: Barthel index; VDS: The Videofluoroscopic Dysphagia Scale; DOSS: Dysphagia Outcome and Severity Scale; VFSS: Video fluoroscopic swallowing study; FEDSS: Fiberoptic Endoscopic Dysphagia Severity Scale; EMST: Expiratory muscle strength training; DSRS: the clinical Dysphagia Severity Rating Scale; PES: Pharyngeal electric stimulation

Table 2.2 The intervention results of the included studies (n=33)

Study Authors, year	Intervention	Implementation details (process, dosage or duration)	Adverse reported	Outcome
Ayse Güleç 2021 (Güleç et al., 2021)	NMES CDT	NMES: The protocol administered electrical current with specific parameters (80 Hz fixed pulse frequency, 700 μs duration) CDT: The program combined multiple approaches including oral motor activities, sensory stimulation via temperature, positional adaptations, and therapeutic swallowing techniques Implementation schedule: Sessions occurred three times weekly for 35 days, with 30-minute daily duration	NR	PAS, FOIS
Elif Tarihci Cakmak 2022 (Tarihci Cakmak et al., 2022)	NMES CDT	NMES: Treatment delivered biphasic electrical impulses (80 Hz frequency, 700 μs duration) with maximum 25 mA intensity CDT: Individualized protocol including nutrition consistency adjustments, oral care instruction, adaptive techniques, and therapeutic exercises Implementation: 45-minute daily sessions administered five times weekly across a three-week treatment course	NR	EAT-10, SWAL-QOL
Hee-Su Park 2019 (H. S. Park et al., 2019)	TPRT CDT	TPRT: The protocol required forceful lingual pressure against the palatal surface while simultaneously engaging cervical musculature during maximum-effort swallowing maneuvers CDT: Participants performed natural deglutition without deliberate tongue or neck muscle activation Implementation: Training occurred on weekdays throughout a four-week intervention period	NR	VDS

H. D. KIM 2017 (H. D. Kim et al., 2017)	TPRT CDT	TPRT: forceful tongue pressing against the palate CDT: The comprehensive approach combined temperature-based sensory stimulation, manual facial tissue manipulation, and specialized therapeutic maneuvers Implementation: Sessions conducted weekdays throughout a four-week intervention duration	NR	PAS
Huiyu Liu 2022 (H. Liu et al., 2022)	rTMS sham rTMS	rTMS: Targeted at the affected bony layer of the mylohyoid region; Frequency: 5 Hz; Intensity: 80% of RMT; Stimulation time: 2 seconds; Interval between stimulations: 10 seconds Sham rTMS: Coil positioned at 90° to the scalp Each session lasted 20 minutes, performed 5 days weekly, with the full course spanning 2 weeks	Two participants in the rTMS treatment group reported experiencing dizziness following repeated stimulation sessions	PAS
Hwan‐Hee Kim 2019 (H. H. Kim & Park, 2019)	CTAR CDT	CTAR: Protocol incorporated both isotonic (dynamic) and isometric (static) resistance exercise components CDT: Treatment combined multiple approaches including oral-facial massage techniques, thermal-tactile sensory stimulation, and various compensatory strategy training Implementation: Sessions conducted five days weekly throughout a six-week intervention period	NR	PAS

Jinzhu Rao 2022 (Rao et al., 2022)	iTBS sham iTBS	iTBS: The protocol utilized a specialized pulse sequence delivered in 2-second trains with 10-second intervals over 190 seconds total duration (600 pulses) at 100% resting motor threshold intensity Sham iTBS: Probe positioned perpendicular to skull to prevent brain signal transmission Treatment frequency: 5 days per week for 2 weeks	Three participants in the iTBS group experienced mild, tolerable dizziness that did not impede the continuation of the experimental protocol.	PAS
Ji-Su Park 2020 (J. S. Park et al., 2020)	CTAR sham CTAR	CTAR: Isometric and isotonic exercises targeting suprahyoid muscles Sham CTAR: Utilizing a device less than 1 mm thick with minimal muscle resistance Implementation: Half-hour sessions conducted five days weekly throughout a four-week treatment period	No adverse events occurred	FOIS
Ji-Su Park 2019 (Ji-Su et al., 2019)	CTAR Shaker	CTAR: LES 100 device utilization, combined with isometric and isotonic exercises integrated with gaming elements Shaker: Focusing on isometric and isotonic exercises Intervention frequency: five days weekly throughout a four-week treatment period	Four patients reported experiencing temporary pain, fatigue, and discomfort in the neck region during the intervention.	PAS, FOIS

Ji-Su Park 2018 (J. S. Park et al., 2018)	CTAR CDT	CTAR: The protocol featured dual training phases: an isometric component requiring sustained chin tuck against resistance device maintained three times for 60-second intervals without repetitive movement, followed by an isotonic component comprising 30 consecutive cycles of forceful compression against device resistance with subsequent release CDT: The intervention integrated multiple therapeutic elements including targeted orofacial neuromuscular exercises, sensory enhancement through temperature contrast application, and specialized rehabilitative or compensatory swallowing techniques Implementation: Both approaches followed identical scheduling with 30-minute therapeutic sessions administered five days weekly across a four-week intervention period	NR	PAS
Jing Gao 2017 (Gao & Zhang, 2017)	CTAR Shaker CDT	CTAR: In a seated posture, subjects actively executed chin flexion motions to exert peak pressure on a rubber balloon placed submental Shaker: This required participants to assume supine positioning while executing isolated head and cervical elevation movements oriented toward viewing their feet CDT: Consisting of tongue and mouth exercises Intervention frequency: 7 days per week over a 6-week period	NR	VFSS
Jong-Bae Choi 2017 (Jong-Bae et al., 2017)	Shaker CDT	Shaker: Participants perform 3 head lifts in supine position; Each lift held for 60 seconds without movement; 60-second rest interval between lifts CDT: The therapeutic approach combined multiple modalities including focused orofacial muscular activations, temperature-based sensory facilitation, and specialized therapeutic or adaptive swallowing strategies Implementation: Thirty-minute therapeutic sessions delivered five days weekly throughout a four-week intervention period	Five patients reported experiencing temporary fatigue and pain during the intervention	PAS

Jong-Hoon Moona 2018 (J. H. Moon et al., 2018)	TPRT CDT	TPRT: The protocol incorporated dual tongue exercise categories: anterior and posterior isometric strength activities paired with precision-focused isometric lingual positioning tasks CDT: The intervention combined thermal sensory stimulation, targeted Mendelsohn maneuver training, and individualized dietary consistency modifications Implementation: Half-hour therapy sessions conducted five days weekly over an eight-week treatment course	NR	MASA, SWAL-QOL
Jong Hoon Moon 2017 (J. H. Moon et al., 2017)	EMST CDT	EMST: Involving deep breath and mouthpiece biting; Patients instructed to blow faster and stronger CDT: The therapeutic regimen combined targeted orofacial movement patterns, temperature-contrast sensory application, and specialized laryngeal elevation techniques through Mendelson maneuver training Implementation: Thirty-minute intervention sessions delivered on weekdays throughout a four-week treatment period	NR	PAS
J.-S. Park 2016 (J. S. Park, Oh, Hwang, et al., 2016)	NMES sham NMES	NMES: Electrical stimulation intensity progressively increased at 0.5 mA intervals Sham NMES: Minimal stimulation applied to produce a slight tingling sensation Treatment duration: Thirty minutes per day, six days a week, total six weeks	NR	VDS
J.-S. Park 2016 (J. S. Park, Oh, Chang, et al., 2016)	EMST sham EMST	EMST: Following maximum inspiration, participants positioned the specialized device mouthpiece between their lips, established oral seal, then executed forceful, rapid exhalation until achieving sufficient pressure to activate the release valve mechanism Sham EMST: Utilizing a device without spring loading Treatment frequency: five days weekly over a four-week treatment course	NR	FOIS

J.-W. Park 2013 (J. W. Park et al., 2013)	rTMS sham rTMS	rTMS: The protocol delivered ten discrete stimulation sequences at 5 Hz frequency, each sequence maintaining 10-second duration with one-minute intervals between trains. A specialized 70 mm figure-of-eight electromagnetic coil targeted the pharyngeal motor representation within the unaffected hemisphere Sham rTMS: Control condition maintained identical parameters with coil orientation modified to 90° angle, producing equivalent acoustic feedback without inducing cortical stimulation Implementation: Ten-minute therapeutic sessions administered five days weekly across a two-week intervention period	NR	VDS
Kyoung Don Kim 2015 (Don Kim et al., 2015)	CTAR Shaker	CTAR: The intervention consisted of targeted cervical flexion movements of limited range Shaker exercise: The protocol incorporated two distinct phases—an isometric component requiring supine participants to elevate the head without shoulder involvement, maintaining visual focus on feet for 60 seconds followed by equivalent rest periods, and an isotonic component involving 30 successive head-raising movements with identical visual targeting Implementation: Thirty-minute therapeutic sessions administered three days weekly throughout a six-week intervention period	NR	VFSS
Kyeong Woo Lee 2014 (Lee et al., 2014)	NMES CDT	NMES: The protocol employed 120% of mean threshold intensity with standardized electrical parameters (80 Hz frequency, 700 μs impulse length) CDT: Treatment incorporated temperature-based sensory stimulation alongside tongue strengthening activities and exercises targeting laryngeal movement patterns Implementation: Half-hour sessions conducted weekdays throughout a three-week period	No adverse events occurred	FOIS

Lise Sproson 2018 (Sproson et al., 2018)	NMES CDT	NMES: The regimen utilized 30 Hz pulse frequency with synchronized exercise performance during each 5-second stimulation interval throughout 10-minute treatment segments CDT: Intervention focused on positional adjustments and nutritional consistency modifications Implementation: Daily 30-minute sessions administered five times weekly for a four-week duration	NR	SWAL-QOL, DSRS
Mi-Ja Eom 2017 (Mi-Ja et al., 2017)	EMST sham EMST	EMST: Participants maintained an Expiratory Muscle Trainer device orally following maximum inspiration, then performed forceful, rapid exhalation maneuvers Sham EMST: Control condition utilized an identical-appearing device lacking resistance components Implementation: Sessions conducted five days weekly throughout a four-week intervention period	NR	PAS
Marilia Simonelli 2019 (Simonelli et al., 2019)	NMES CDT	NMES: Electrical parameters included 80 Hz frequency with 300 microsecond pulse width, intensity ranging 7.8-12.5 mA (average 9.3 mA) CDT: Protocol incorporated motor exercises targeting oral-facial structures, tongue, and laryngeal mechanism Implementation: Twice-daily 30-minute sessions conducted weekdays over an 8-week treatment course	No adverse events occurred	PAS, FOIS
Maryam Tarameshlu 2019 (Tarameshlu et al., 2019)	rTMS CDT	rTMS: Treatment targeted the unaffected hemisphere using 1200 pulses delivered at 1 Hz frequency with intensity set 20% above resting motor threshold during 20-minute sessions across five consecutive days	NR	FOIS

		CDT: Intervention incorporated positioning modifications, volume and pace adjustments during feeding, texture and viscosity alterations, and techniques to enhance oral sensory perception		
Mei-Yun Liaw 2020 (Liaw et al., 2020)	EMST CDT	EMST: Protocol employed the Dofin Breathing Trainer device with instructions for controlled, gentle exhalation through the mouthpiece CDT: Comprehensive approach incorporating postural education, respiratory regulation, cough enhancement techniques, thoracic mobility assessment, energy conservation strategies, and orofacial muscle exercises Implementation: Sessions conducted five days weekly throughout a six-week intervention period	NR	MRS, BI
Philip M. Bath 2016 (Bath et al., 2016)	PES sham PES	PES: The procedure connected the specialized catheter to a computerized control unit, gradually elevating 5 Hz electrical stimulation from minimal 1 mA baseline until identifying both sensory threshold and maximum comfortable intensity parameters for individual patients Sham PES: Protocol mimicked the active treatment setup without delivering actual stimulation following determination of threshold and tolerance parameters Implementation: Treatment administered over a three-day intervention period	No adverse events occurred	PAS, DSRS
Sandeep Kumar 2022 (Kumar et al., 2022)	tDCS sham tDCS	tDCS: The treatment delivered 2 milliampere direct current stimulation in twice-daily sessions, each lasting 20 minutes Sham tDCS: Control condition provided identical setup without active current delivery Implementation: Dual daily sessions conducted over a five-day intervention period	No adverse events occurred	PAS

Sima Farpour 2022 (Farpour et al., 2022)	tDCS sham tDCS	tDCS: Protocol delivered 2 milliampere stimulation for 20-minute sessions daily across five days, utilizing an anodal pad with 0.125 mA/cm² current density Sham tDCS: Control condition activated current only briefly (30 seconds) at session beginning and conclusion Implementation: Twenty-minute daily sessions administered over a five-day treatment period	Transient, tolerable itching sensations were documented in three participants receiving tDCS intervention	MASA, FOIS
Sonja Suntrup-Krueger 2018 (Suntrup-Krueger et al., 2018)	tDCS sham tDCS	tDCS: The protocol administered 1 milliampere current during 20-minute daily sessions across four consecutive treatment days Sham tDCS: Control condition delivered brief 30-second stimulation followed by 20-minute electrode placement without active current	NR	FEDSS
Tingwei Wang 2022 (T. Wang et al., 2022)	TPRT CDT	TPRT: Protocol required forceful upward lingual pressure against a specialized measurement device CDT: Treatment incorporated both motor control activities for oral-facial musculature and sensory stimulation techniques targeting the same structures Implementation: Twenty-minute sessions conducted weekdays throughout a four-week intervention period	No adverse events occurred	PAS
Viridiana Arreola 2021 (Arreola et al., 2021)	NMES CDT	NMES: The intervention delivered electrical stimulation at precisely 100% of the established motor threshold intensity CDT: Comprehensive approach incorporating fluid consistency modifications using thickening agents, textural dietary adaptations, oral care protocols, positional adjustments as needed, and nutritional counseling Implementation: Treatment frequency varied from twice-daily one-hour sessions during week one to once-daily one-hour sessions during week two, totaling 15 treatment sessions	A single participant experienced localized skin irritation at the electrode application site	PAS

Wenguang Xia 2016 (W. Xia et al., 2016)	Acupuncture CDT	Acupuncture: The treatment involved needle application at specific points across nape, scalp, and tongue regions CDT: Therapy focused on functional exercises targeting the anatomical structures involved in feeding and swallowing processes Implementation: Half-hour sessions conducted six days weekly throughout a four-week intervention period	Mild discomfort (twelve participants), localized hematoma formation (two participants), and significant pain sensation (one participant)	DOSS
Xie Yu-Lei 2022 (Yu-Lei et al., 2022)	iTBS rTMS	iTBS: The protocol delivered 50 Hz triple-pulse bursts repeated at 5 Hz frequency (2-second active, 8-second rest) for 192 seconds total duration (600 pulses) targeting the affected hemisphere "hot spot" at 100% resting motor threshold rTMS: Treatment administered 10 Hz stimulation at 100% resting motor threshold using 2-second pulse trains with 18-second intervals over 20-minute sessions (1200 pulses) at identical cortical target location Implementation: Both interventions conducted over a ten-day treatment course	No adverse events occurred	WST
Young Hyun Ahn 2017 (Young Hyun et al., 2017)	tDCS sham tDCS	tDCS: Total of 10 sessions; Duration: 20 minutes per session; Stimulation intensity: 1 mA Sham tDCS: The control condition delivered brief 1 mA stimulation lasting only 30 seconds through dual anodal electrodes, producing initial sensory perception without inducing meaningful neurophysiological alterations in cortical excitability Implementation: Sessions conducted five times weekly throughout a two-week intervention period	NR	DOSS

Abbreviations: rTMS: Repetitive transcranial magnetic stimulation; iTBS: Intermittent theta burst stimulation; RMT: Resting motor threshold; WST: Water-swallowing test; NR: Not report; TPRT: Tongue-pressure resistance training; CDT: Conventional dysphagia training; PAS: Penetration Aspiration Scale; NMES: Neuromuscular electrical stimulation; tDCS: Transcranial direct current stimulation; SWAL-QOL: The swallowing quality of life questionnaire; FOIS: The Functional Oral Intake Scale; MASA: The Mann Assessment of Swallowing Ability; EAT-10: The eating assessment tool; CTAR: Chin Tuck against resistance exercise; MRS: Modified Rankin Scale; BI: Barthel index; VDS: The Videofluoroscopic Dysphagia Scale; DOSS: Dysphagia Outcome and Severity Scale; VFSS: Video fluoroscopic swallowing study; FEDSS: Fiberoptic Endoscopic Dysphagia Severity Scale; EMST: Expiratory muscle strength training; DSRS: the clinical Dysphagia Severity Rating Scale; PES: Pharyngeal electric stimulation

2.4.3 Risk of bias

Of the 33 studies evaluated for bias, 9.1% (n=3) were low risk, 57.6% (n=19) high risk, and 33.3% (n=11) showed some concerns (**Figure 2.2**). While all included studies employed randomized controlled designs, eight publications (24.2%) failed to specify their randomization methodology. Proper allocation concealment was documented in only 13 studies (39.4%). Our analysis of blinding protocols showed that while the majority of studies (63.6%, n=21) maintained outcome assessor blinding, only one-third (33.3%, n=11) implemented participant blinding. Three studies (9.1%) reported single blinding but omitted critical details about which study components were blinded. Comprehensive blinding of participants, intervention providers, and outcome assessors was achieved in only one study. Despite these limitations, all studies utilized appropriate outcome assessment measures, maintained comparable baselines between groups, reported complete data, and avoided selective outcome reporting.

Figure 2.2 The risk of bias

2.4.4 Network diagram

Our network meta-analysis of the 33 eligible studies (illustrated in **Figure 2.3**) evaluated treatment effectiveness on swallowing function, functional oral intake capacity, and daily functional outcomes. The swallowing function network (**Figure 2.3A**) incorporated data from 28 trials (n=1,189) comparing 12 different interventions, demonstrating a star-shaped network geometry. CDT represented the largest treatment node (n=279), followed by sham control (n=240), with the remaining interventions ordered by sample size as follows: NMES (n=100), CTAR (n=85), tDCS (n=78), Shaker exercise (n=77), PES (n=70), acupuncture (n=60), iTBS (n=57), TPRT (n=56), rTMS (n=55), and EMST (n=32). The network topology contained two closed loops requiring formal inconsistency assessment. For feeding and daily function outcomes (**Figure 2.3B**), we analyzed 18 trials (n=791) evaluating 12 therapeutic approaches, with all interventions directly linked to either CDT or sham control arms, creating a characteristic star configuration that enabled both direct and indirect treatment effect estimations.

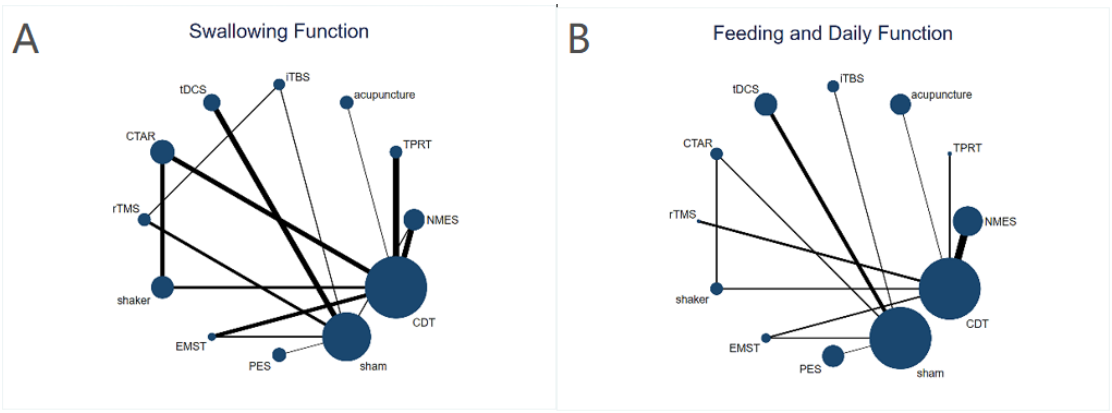


Figure 2.3 Network plots of the comparison of all interventions

A. Swallowing Function; B. Feeding and Daily Function

2.4.5 Inconsistency test

To assess potential inconsistencies in our network meta-analysis, we employed two complementary approaches: loop-specific heterogeneity evaluation and side-splitting methodology. Both analytical methods consistently

demonstrated nonsignificant inconsistency across all comparisons ($P > 0.05$ for all tests), confirming the reliability of our network estimates.

2.4.6 Paired meta-analysis

2.4.6.1 Paired meta-analysis for swallowing function outcomes

The paired meta-analysis investigating swallowing function demonstrated significant improvements across multiple interventions. When comparing iTBS, NMES, and EMST against sham control, all three interventions significantly enhanced swallowing capabilities in stroke patients. Specifically, iTBS showed SMD of 0.87 (95%CI: 0.35 to 1.38), NMES revealed SMD of 1.07 (95%CI: 0.47 to 1.67), and EMST displayed SMD of 0.96 (95%CI: 0.14 to 1.78). Notably, all these interventions exhibited zero heterogeneity. Furthermore, when comparing CTAR, shaker, and acupuncture against CDT, the analysis revealed significantly superior outcomes for all three interventions. CTAR demonstrated SMD of 1.02 (95%CI: 0.43 to 1.62), shaker showed the SMD of 1.01 (95%CI: 0.29 to 1.74), and acupuncture exhibited the most pronounced improvement with SMD of 1.73 (95%CI: 1.31 to 2.15).

Intervention parameter subgroup analysis examining duration and frequency demonstrated that 30-minute daily sessions (SMD = 0.78, 95%CI: 0.40 to 1.16), administered 5 days weekly (SMD = 0.75, 95%CI: 0.50 to 1.01), over a 4-week period (SMD = 0.88, 95%CI: 0.43 to 1.33), with 600 minutes total intervention duration (SMD = 1.01, 95%CI: 0.45 to 1.56) produced significant improvements in patient swallowing function (**Figure 2.4**).

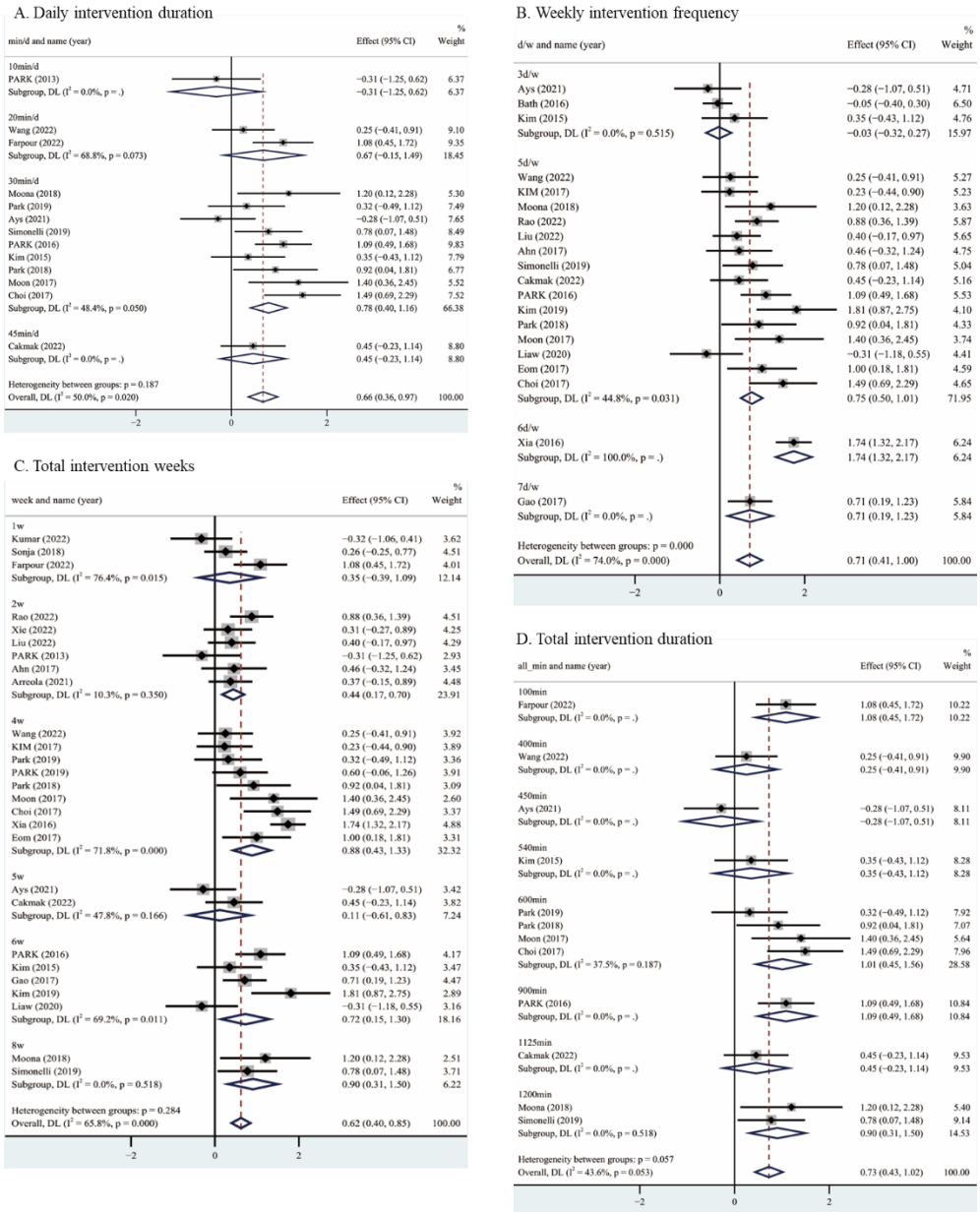


Figure 2.4 Subgroup analysis of the effect of duration and frequency on swallowing function

A. Daily intervention duration; B. Weekly intervention frequency; C. Total intervention weeks; D. Total intervention duration

2.4.6.2 Paired meta-analysis of the effects of feeding and daily function

The paired meta-analysis revealed promising results for interventions targeting feeding and daily function in PSD patients. When compared to sham control, iTBS and tDCS showed potential benefits, with iTBS demonstrating a SMD of 1.21 (95%CI: 0.67 to 1.74) and tDCS showing the SMD of 0.59 (95%CI:

-0.06 to 1.23). In comparison with conventional dysphagia therapy (CDT), both acupuncture and shaker exercise exhibited more substantial improvements in feeding and daily functioning. Acupuncture revealed a notably high SMD of 1.62 (95%CI: 1.21 to 2.04), while shaker exercise demonstrated SMD of 0.87 (95%CI: 0.13 to 1.61). Importantly, most interventions showed zero heterogeneity, indicating consistent results across studies.

Our intervention parameter subgroup analysis examining frequency and duration revealed that protocols administered 5 days weekly (SMD = 0.53, 95%CI: 0.28 to 0.78) over a 4-week period (SMD = 0.70, 95%CI: 0.12 to 1.28) produced significant enhancements in patients' feeding abilities and daily function (**Figure 2.5**).

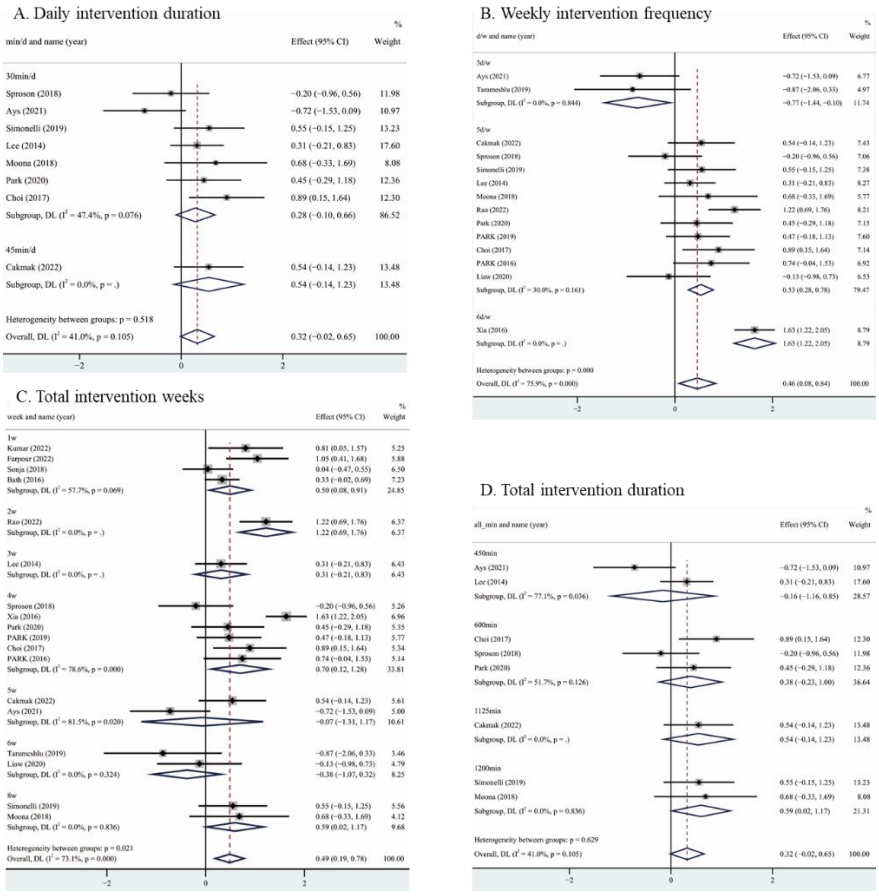


Figure 2.5 Subgroup analysis of the effect of duration and frequency on feeding and daily life

A. Daily intervention duration; B. Weekly intervention frequency; C. Total intervention weeks; D. Total intervention duration

2.4.7 Network meta-analysis and probability ranking for swallowing function outcomes

The network meta-analysis revealed a comprehensive ranking of interventions for improving swallowing function in PSD patients. Acupuncture emerged as the most effective intervention, with the highest SUCRA of 99.0% and a SMD of -2.40 (95%CI: -3.38 to -1.43). CTAR intervention showed the second strongest treatment effect, achieving 89.9% on the SUCRA scale with SMD of -1.83 (95% CI -2.69 to -0.97). Shaker exercises ranked third in therapeutic efficacy, attaining a SUCRA score of 80.5% and SMD of -1.57 (95% CI -2.45 to -0.70) when compared to sham control. Among the remaining interventions, TPRT demonstrated moderate efficacy with a SUCRA value of 60.4% (SMD: -1.06, 95% CI: -1.90 to -0.20). NMES showed comparable effectiveness, attaining 60.3% SUCRA (SMD: -1.03, 95% CI: -1.07 to -0.36). EMST yielded a SUCRA score of 59.2% (SMD: -1.02, 95% CI: -1.77 to -0.28), while iTBS presented more modest results with 46.3% SUCRA (SMD: -0.72, 95% CI: -1.32 to -0.11), as detailed in **Table 2.2 lower left triangle and Figure 2.6A**.

When compared with CDT, the treatment efficacy analysis revealed significant differences in swallowing improvement. Acupuncture demonstrated the most pronounced therapeutic effect, followed by CTAR which showed a SMD of -1.16 (95% confidence interval: -1.63 to -0.68). Shaker exercises also exhibited considerable efficacy with SMD of -0.90 (95% CI: -1.40 to -0.40). These comparative effectiveness results are presented in **the lower left quadrant of Table 2.3**.

Table 2.3 Network analysis of swallowing function, and feeding and daily function

NMES	0.96 (-0.78, 2.70)	**1.94 (0.47, 3.42)**	1.41 (-0.80, 3.62)	1.11 (-0.80, 3.03)	0.98 (-0.73, 2.70)	-0.46 (-2.32, 1.39)	0.85 (-0.61, 2.30)	0.57 (-0.92, 2.06)	-0.22 (-2.39, 1.95)	0.21 (-1.53, 1.94)	0.32 (-0.33 ,0.97)
0.03 (-0.59, 0.64)	TPRT	0.98 (-1.10, 3.07)	0.45 (-2.21, 3.11)	0.15 (-2.27, 2.58)	0.02 (-2.24, 2.29)	-1.42 (-3.79, 0.95)	-0.11 (-2.19, 1.96)	-0.39 (-2.49, 1.71)	-1.18 (-3.81, 1.45)	-0.75 (-3.04, 1.53)	-0.64 (-2.25, 0.98)
1.37 (0.60, 2.15)	**1.35 (0.54, 2.15)**	Acupuncture	-0.53 (-3.02, 1.96)	-0.83 (-3.07, 1.41)	-0.96 (-3.03, 1.11)	**-2.41 (-4.59, -0.22)**	-1.10 (-2.95, 0.76)	-1.37 (-3.26, 0.52)	-2.16 (-4.62, 0.30)	-1.74 (-3.82, 0.35)	**-1.62 (-2.94, -0.30)**
-0.31 (-1.22, 0.59)	-0.34 (-1.39, 0.71)	**-1.69 (-2.84, -0.54)**	iTBS	-0.30 (-1.89, 1.29)	-0.43 (-2.32, 1.46)	-1.88 (-4.61, 0.86)	-0.57 (-2.66, 1.53)	-0.84 (-2.74, 1.06)	-1.63 (-3.52, 0.25)	-1.21 (-2.57, 0.16)	-1.09 (-3.21, 1.02)
-0.65 (-1.44, 0.14)	-0.68 (-1.63, 0.27)	**-2.02 (-3.08, -0.97)**	-0.34 (-1.07, 0.40)	tDCS	-0.13 (-1.67, 1.41)	-1.58 (-4.08, 0.93)	-0.27 (-2.06, 1.52)	-0.54 (-2.09, 1.01)	-1.34 (-2.87, 0.20)	**-0.91 (-1.72, -0.09)**	-0.79 (-2.60, 1.02)
0.80 (0.17, 1.42)	**0.77 (0.11, 1.43)**	-0.58 (-1.39, 0.24)	**1.11 (0.06, 2.16)**	**1.45 (0.49, 2.40)**	CTAR	-1.45 (-3.80, 0.91)	-0.14 (-1.41, 1.14)	-0.41 (-2.02, 1.20)	-1.20 (-3.05, 0.64)	-0.78 (-2.08, 0.53)	-0.66 (-2.26, 0.93)
-0.77 (-1.63, 0.09)	-0.80 (-1.81, 0.22)	**-2.15 (-3.26, -1.03)**	-0.46 (-1.06, 0.15)	-0.12 (-0.80, 0.56)	**-1.57 (-2.59, -0.55)**	rTMS	1.31 (-0.86, 3.48)	1.03 (-1.16, 3.23)	0.24 (-2.47, 2.95)	0.67 (-1.70, 3.04)	0.78 (-0.95, 2.52)
0.54 (-0.10, 1.18)	0.52 (-0.16, 1.19)	**-0.83 (-1.66, -0.00)**	0.86 (-0.21, 1.92)	**1.19 (0.23, 2.16)**	-0.25 (-0.69, 0.18)	**1.31 (0.29, 2.34)**	Shaker	-0.27 (-1.89, 1.34)	-1.07 (-3.13, 0.99)	-0.64 (-2.23, 0.95)	-0.52 (-1.83, 0.78)
-0.01 (-0.72, 0.71)	-0.03 (-0.84, 0.77)	**-1.38 (-2.31, -0.45)**	0.31 (-0.65, 1.27)	0.64 (-0.21, 1.50)	**-0.80 (-1.61, 0.00)**	0.76 (-0.16, 1.69)	-0.55 (-1.37, 0.27)	EMST	-0.79 (-2.65, 1.06)	-0.37 (-1.68, 0.95)	-0.25 (-1.60, 1.10)
-1.08 (-1.99, -0.17)	**-1.11 (-2.16, -0.05)**	**-2.45 (-3.61, -1.30)**	-0.77 (-1.63, 0.10)	-0.43 (-1.17, 0.31)	**-1.88 (-2.94, -0.82)**	-0.31 (-1.13, 0.51)	**-1.62 (-2.69, -0.55)**	**-1.07 (-2.04, -0.11)**	PES	0.43 (-0.88, 1.73)	0.54 (-1.53, 2.62)
-1.03 (-1.70, -0.36)	**-1.06 (-1.91, -0.20)**	**-2.40 (-3.38, -1.43)**	-0.72 (-1.32, -0.11)	-0.38 (-0.79, 0.04)	**-1.83 (-2.69, -0.97)**	-0.26 (-0.80, 0.28)	**-1.57 (-2.45, -0.70)**	**-1.02 (-1.77, -0.28)**	0.05 (-0.57, 0.67)	Sham	0.11 (-1.50, 1.73)
-0.36 (-0.76, 0.04)	-0.38 (-0.85, 0.08)	**-1.73 (-2.39, -1.07)**	-0.04 (-0.98, 0.89)	0.29 (-0.54, 1.12)	**-1.16 (-1.63, -0.68)**	0.41 (-0.48, 1.31)	**-0.90 (-1.40, -0.40)**	-0.35 (-1.01, 0.31)	0.72 (-0.23, 1.67)	0.67 (-0.05, 1.39)	CDT

The lower left triangle presents swallowing function network meta-analysis results, while the upper right triangle displays findings from the feeding and daily function network meta-analysis.

Abbreviations: NMES: Neuromuscular electrical stimulation; TPRT: Tongue-pressure resistance training; iTBS: Intermittent theta burst stimulation; tDCS: Transcranial direct current stimulation; CTAR: Chin Tuck against resistance exercise; rTMS: Repetitive transcranial magnetic stimulation; EMST: Expiratory muscle strength training; PES: Pharyngeal electric stimulation; CDT: Conventional dysphagia training.

2.4.8 Network meta-analysis and probability ranking for feeding and daily function outcomes

The network meta-analysis revealed that acupuncture demonstrated the most significant improvement in feeding and daily function, with a SMD of -1.62 (95%CI: -2.94 to -0.30) compared to CDT. Acupuncture achieved the highest SUCRA of 88.4%, followed by iTBS with a SUCRA of 76.0% and CTAR with a SUCRA of 69.1%. However, comparative analysis revealed no statistically significant differences among the remaining interventions when evaluated against either sham control or standard therapy. Complete results are presented in the **upper right quadrant of Table 2.2** and graphically represented in **Figure 2.6B**.

The comprehensive evaluation of combined treatment effects (**Figure 2.6C**) revealed a clear efficacy hierarchy among interventions. Acupuncture consistently demonstrated optimal therapeutic outcomes across both swallowing function and feeding and daily activity measures. Subsequent analysis identified CTAR and shaker exercises as the secondary-tier interventions, while PES showed relatively limited clinical effectiveness compared to other modalities.

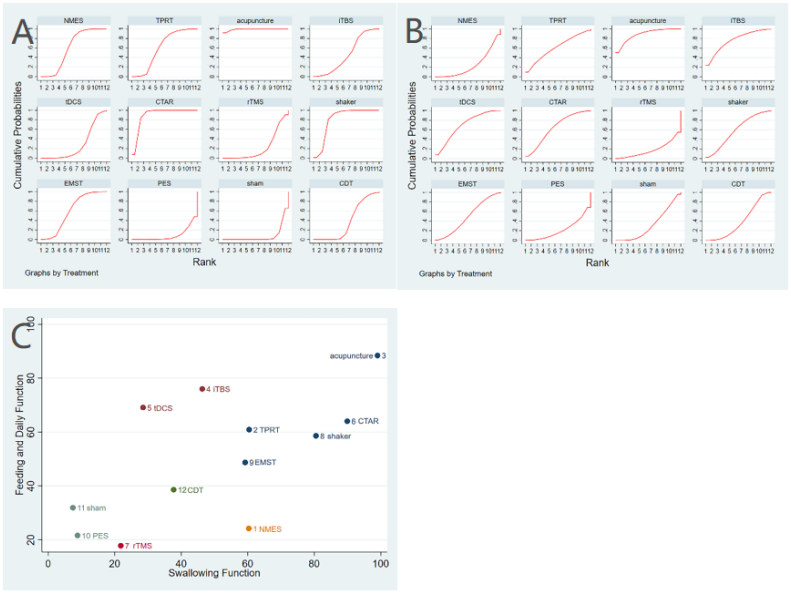


Figure 2.6 The probability ranking of the effects of all interventions

A. SUCRA of swallowing function; B. SUCRA of feeding and daily function; C. Ranking results for the combination of swallowing function, and feeding and daily function

2.4.9 Safety

We assessed the safety profile of the interventions based on adverse events documented across clinical trials. In seven studies, no notable adverse reactions were observed. Another seven studies identified specific intervention-related side effects: iTBS and rTMS induced manageable dizziness; tDCS was associated with slight itching; NMES caused localized skin irritation at electrode sites; CTAR and shaker exercises resulted in temporary discomfort; and acupuncture produced localized issues including hematoma and pain. The remaining studies lacked detailed reporting on adverse events.

2.4.10 Publication bias and sensitivity analysis

The assessment of publication bias using Egger's test demonstrated no significant evidence of small-study effects for either swallowing function (*P*=0.241) or feeding and daily functioning outcomes (*P*=0.961).

We conducted sensitivity analysis separately for swallowing function and feeding and daily function results. These analyses demonstrated no substantial changes in outcomes, confirming the robustness and stability of our study findings (**Figure 2.7**).

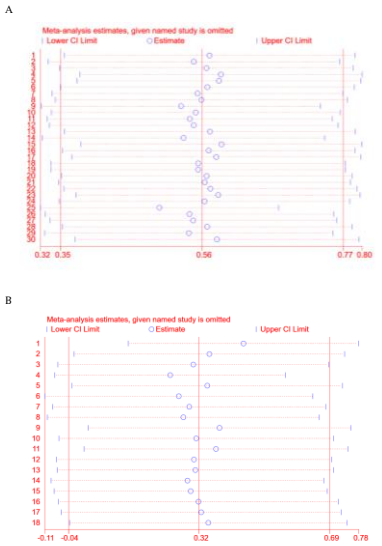


Figure 2.7 Sensitivity analysis of swallowing function, and feeding and daily function

A: swallowing function; B: feeding and daily function

2.5 Discussion

Based on the evidence presented, this represents the first network meta-analysis to comprehensively evaluate multiple therapeutic modalities for PSD rehabilitation. This comprehensive systematic review and network meta-analysis synthesized evidence from 33 RCTs (total N=1,341). The results revealed a clear hierarchy of treatment efficacy, with acupuncture demonstrating superior effectiveness for improving both swallowing function and feeding/daily living performance. Among the various rehabilitation approaches evaluated, CTAR exercises consistently ranked as the second most beneficial intervention across outcome measures. The findings contribute valuable evidence to support evidence-based clinical practices in PSD rehabilitation.

Previous paired meta-analyses had confirmed the effectiveness of all three intervention categories, neuromodulation techniques (both peripheral and central), muscle strengthening exercises, and traditional Chinese medicine approaches, in improving deglutition function in PSD patients, which corroborates our present findings (Jiang et al., 2022; J. S. Park & Hwang, 2021). Our network meta-analysis contributes valuable additional evidence to the field of swallowing rehabilitation by offering a more comprehensive clinical perspective. Specifically, our findings identify which interventions demonstrate superior effectiveness for PSD rehabilitation, addressing not only improvements in swallowing capacity but also enhancements in feeding ability and daily functional performance.

Swallowing represents a precisely orchestrated sensorimotor process that progresses through four distinct yet seamlessly integrated phases: oral preparatory, oral transit, pharyngeal, and esophageal. This complex physiological sequence initiates with labial seal formation and culminates in cricopharyngeal relaxation, involving precisely timed activation of over 25 muscle pairs and coordinated

neural control across multiple cranial nerves (Dziewas et al., 2021). The successful execution of swallowing depends on intact connectivity within a multi-level neural network comprising cortical initiation areas, subcortical modulation centers, and brainstem pattern generators (Wilmskoetter et al., 2020). Among neurological conditions, stroke stands as the most prevalent disorder disrupting this sophisticated swallowing network, consequently producing PSD (Dziewas et al., 2021).

2.5.1 Traditional Chinese medicine

When comparing all three intervention categories, acupuncture demonstrates superior effectiveness. The therapeutic effects of acupuncture in dysphagia management appear to be mediated through multiple neurophysiological mechanisms. Current evidence suggests that acupoint stimulation may facilitate functional recovery by improving local and cerebral microcirculation through vasodilation effects, directly activating α motor neurons to enhance neuromuscular transmission, repairing impaired brainstem reflex pathways damaged by ischemic events, promoting cortical reorganization via neuroplasticity mechanisms (J. Zhang, Lu, Wu, Nie, & Yu, 2021). . These combined actions on both central and peripheral components of the swallowing network contribute to the observed clinical improvements in deglutition function post-stroke. This finding aligns with clinical guidelines, as both the European Stroke Organization and European Society for Swallowing Disorders recommend acupuncture for treating PSD (Dziewas et al., 2021).

However, acupuncture is a traditional Chinese medicine treatment in which acupuncture needles are placed into the human body, which is an invasive and invasive operation. Therefore, acupuncture operations require a high level of aseptic awareness among physicians and hospital management systems. At this stage, many acupuncture doctors do not standardize the operation of acupuncture, and there is a lack of awareness about the prevention of hospital-acquired

infections (T.-H. Kim, Kang, & Park, 2015; S.-y. Moon, Park, Lee, & Son, 2018). It may lead to the risk of syncope, local pain from needling, infection, bleeding, haematoma or organ damage to the patient (W. Xia et al., 2016; J. Zhang, Shang, Gao, & Ernst, 2010). A one-year survey in the acupuncture department of a Chinese hospital found that 7.6% of patients developed hospital-acquired infections after acupuncture (P. Zhou et al., 2019). In a prospective survey of adverse events with acupuncture, 72.9% of adverse events were found to be directly related to acupuncture treatment, including bleeding, pain at the needle site, bruising or blistering, delayed or forgotten removal of needles, or defective needles used (Won, Lee, Bang, & Lee, 2022). Due to the patient's excessive stress or fear of acupuncture, there is a high risk of vagal excitation and resulting syncope (Xu et al., 2023). To avoid adverse events such as infection and bleeding due to acupuncture or improper operation of the acupuncturist, strict control of needle quality is needed, and the acupuncturist should receive strict standardized training and pre-testing to know the physical condition of the patient before acupuncture, which will greatly result in higher patient treatment costs and lower economic benefits. Some patients who have received acupuncture reported that "it hurts to hold a position for a long-time during acupuncture" "I feel like I'm being treated like a lab rat because of the different levels of skill of the acupuncturists" "Many patients are still working and it's hard to come to the hospital three times a week to complete the treatment" (Cao et al., 2020). Because acupuncture must be completed in the hospital, it may result in a greater burden of travel for the patients.

2.5.2 Swallowing exercises focusing on muscle strength

Our analysis identified CTAR and Shaker exercises as the second and third most effective interventions, respectively, for improving swallowing function in PSD. Notably, CTAR demonstrated additional clinical value by ranking third for enhancing feeding and daily functional outcomes. The therapeutic efficacy of CTAR stems from its unique biomechanical action: during administration, patients

perform controlled chin tuck motions against the resistance of an elastic rubber ball positioned submentally. This dual-modality approach simultaneously engages the suprahyoid muscle group through both dynamic (isotonic) and static (isometric) contraction paradigms. The resulting mechanical loading induces muscular adaptations including hypertrophy and improved neuromuscular activation patterns, ultimately enhancing the force-generating capacity of these crucial swallowing muscles (Yoon, Khoo, & Rickard Liow, 2014). This mechanism explains CTAR's superior performance compared to conventional non-resistive exercises in our network meta-analysis. The shaker exercise requires patients in supine position to lift their head while viewing their toes, producing isometric and isotonic contractions of swallowing-related musculature (Jong-Bae et al., 2017). The shaker exercise requires patients in supine position to lift their head while viewing their toes, producing isometric and isotonic contractions of swallowing-related musculature.

Research by Park et al. (J. S. Park & Hwang, 2021) demonstrated that CTAR not only generates greater suprahyoid muscle activation compared to shaker exercise but also more selectively engages the sternocleidomastoid muscle, thereby enhancing patient exercise adherence. Recent research by Su et al. (2019) (Ji-Su et al., 2019) demonstrated the benefits of gamifying CTAR training, reporting both enhanced swallowing function outcomes and significantly greater patient engagement compared to conventional approaches. This pioneering work highlights the potential of incorporating game design elements into dysphagia rehabilitation. As serious gaming platforms, virtual reality systems, and AI-driven technologies continue to evolve, there exists substantial opportunity to integrate these cutting-edge digital solutions with evidence-based muscle strengthening protocols. Such innovative combinations could yield more sophisticated, interactive rehabilitation tools that simultaneously optimize therapeutic efficacy

while maximizing patient motivation and adherence through immersive, personalized training experiences.

2.5.3 Peripheral and central stimulation methods

Our network analysis findings regarding peripheral and central stimulation align partially with previous research. Similar to Chiang et al. (Chiang et al., 2019), our analysis revealed comparable improvements in swallowing function between PES and sham interventions, with no statistically significant differences observed. While PES theoretically offers neurophysiological benefits by modulating pharyngeal cortical excitability through targeted pulse stimulation, several factors may explain these neutral findings: First, the stimulation parameters employed across studies may have been subtherapeutic for optimal neural modulation. Second, the inclusion criteria of several trials incorporated patients with mild dysphagia severity who demonstrate higher rates of spontaneous neurological recovery, potentially obscuring treatment-specific effects. Third, variations in electrode placement and stimulation protocols across studies may have contributed to inconsistent treatment delivery. These methodological considerations highlight the need for more standardized protocols and careful patient stratification in future PES research to better evaluate its true therapeutic potential (Bath et al., 2016). Additionally, PES implementation requires endoluminal catheter insertion via nasal or oral routes, potentially causing patient discomfort (A. Sasegbon, Cheng, Zhang, & Hamdy, 2020).

However, our results diverged from Chiang's study (Chiang et al., 2019) regarding other neurostimulation therapies. Our analysis identified rTMS as the most effective neurostimulation approach, followed by NMES. This effectiveness hierarchy likely stems from their different mechanisms, NMES exerts its therapeutic effects peripherally by directly stimulating weakened oropharyngeal muscles, whereas rTMS operates centrally by facilitating cortical reorganization and neuroplasticity in stroke-affected pharyngeal motor representations (Y. W.

Chen et al., 2016). NMES also offers practical advantages as the most cost-effective and easily applicable electrical stimulation method (Y. W. Chen et al., 2016). The observed discrepancies between our results and Chiang's study (Chiang et al., 2019) may primarily reflect differences in study design and analytical approach. Chiang's investigation exclusively NMES when administered alongside conventional rehabilitation therapies, thereby constraining their ability to isolate and quantify NMES-specific treatment effects. In contrast, our systematic methodology incorporated placebo-controlled trials that evaluated NMES as a monotherapy, providing more robust evidence regarding its independent therapeutic efficacy. This fundamental distinction in trial selection criteria and comparison frameworks likely accounts for the variation in conclusions between studies. Our inclusion of direct NMES-versus-placebo comparisons enabled more precise estimation of the intervention's intrinsic value, unconfounded by concurrent conventional treatments.

2.5.4 Safety

Our analysis identified transient adverse effects, particularly pain, across all three intervention categories. Importantly, these effects were temporary in nature, and no participants withdrew from training due to these adverse reactions (Farpour et al., 2022; W. Xia et al., 2016). This suggests that all three intervention approaches are generally safe and effective for clinical application. Nevertheless, a critical limitation warrants emphasis: the majority (57.6%) of included studies failed to document adverse event reporting, revealing a substantial evidence gap in treatment safety profiles. Future research should prioritize comprehensive documentation and reporting of safety outcomes to more thoroughly establish the risk profiles of these interventions.

2.5.5 Practice implications

PSD frequently leads to severe complications including aspiration pneumonia, nutritional deficiencies, and dehydration, often necessitating specialized

respiratory support and enteral feeding management (Matos, Oliveira, Oliveira, & Braga Neto, 2022). This underscores the critical importance for healthcare providers to acquire evidence-based knowledge and practical skills related to dysphagia rehabilitation following stroke. Research has demonstrated that prompt interventions addressing medication management for dysphagia, nutritional support, complication prevention, comprehensive patient assessment, and treatment education can effectively reduce aspiration incidents (Martin-Borret et al., 2014). This comprehensive network meta-analysis bridges the research-practice gap by identifying the most effective dysphagia interventions, providing clinicians with empirically validated treatment recommendations for stroke rehabilitation.

2.5.6 Strengths and limitations

Our investigation offers substantial methodological strengths in providing evidence-based guidance for clinical practitioners by evaluating established swallowing rehabilitation approaches. The research adhered rigorously to PRISMA guidelines and exclusively incorporated RCTs, enhancing the robustness and reliability of our findings. Nevertheless, several limitations warrant acknowledgment.

First, intervention duration varied considerably across studies, with stimulation methods typically implemented over shorter periods compared to muscle strengthening exercises. We did not conduct additional analyses to assess how these variations in treatment length influenced outcomes or their sustainability over time. Second, the included trials employed diverse assessment methods for swallowing function, necessitating the use of SMD for analytical purposes. Consequently, result interpretation requires appropriate caution. Finally, quality assessment classified three included studies as having low methodological rigor. Although our assessment revealed no concerns regarding publication bias or inconsistency, subsequent research ought to prioritize strict adherence to blinding

protocols and allocation concealment methods to minimize selection bias and strengthen outcome reliability.

2.6 Conclusions

This network meta-analysis highlights acupuncture, CTAR, and shaker exercises as the most effective interventions for improving swallowing function in patients with PSD. Additionally, our findings indicate that acupuncture, iTBS, and CTAR exercise likely provide optimal outcomes for improving feeding capabilities and daily functioning. Given its cost-effectiveness and ease of implementation, CTAR emerges as a recommended rehabilitation strategy for PSD patients. Healthcare providers can readily adopt this intervention to improve swallowing function, reduce aspiration pneumonia risks, and ultimately enhance quality of life. Moving forward, well-designed randomized controlled trials are needed. These should include robust methodological elements, such as proper allocation concealment and participant blinding, to further validate these findings. Healthcare practitioners' understanding of these various interventions remains essential for proper implementation of care protocols and optimization of patient satisfaction and participation.

Chapter 3. Design the artificial intelligence-empowered video game swallowing rehabilitation system for post-stroke dysphagia patients

3.1 Introduction

This chapter delineates the conceptual framework and development process of the artificial intelligence-empowered video game (AI-VG) system for swallowing rehabilitation. Commencing with an overview in Section 3.1, subsequent sections describe the study's research aims (3.2), theoretical foundations (3.3), and systematic exposition of the AI-VG system's design rationale (3.4) and developmental chronology (3.5).

3.2 Aims and Objectives

3.2.1 Research aims

The primary purpose of this investigation was to create a swallowing rehabilitation platform integrating artificial intelligence with video game elements. Additionally, this RCT sought to evaluate the AI-VG system's practical application and user acceptance, while simultaneously investigating its clinical effectiveness across critical metrics for post-stroke dysphagia (PSD) patients. Specifically, the research focused on assessing impacts on swallowing function, swallowing-related quality of life, and nutritional status.

3.2.2 Research objectives

The objectives of this study comprised three distinct components:

(1) To design and develop an evidence-informed AI-VG system specifically targeting swallowing function improvement in PSD patients.

(2) To evaluate the feasibility and user acceptance of the AI-VG system among individuals experiencing post-stroke swallowing difficulties.

(3) To investigate the comparative effectiveness of the AI-VG system against conventional rehabilitation approaches on critical outcomes including swallowing

function, quality of life related to dysphagia, and nutritional status in the post-stroke dysphagia population.

3.2.3 Research questions

The study addressed two primary research questions:

(1) What are the feasibility and patient acceptance of the AI-VG system for PSD patients?

(2) To what extent does the AI-VG system improve swallowing function, swallowing-related quality of life, and nutritional status?

3.2.4 Hypothesis

We hypothesize that after a 4-week of AI-VG system rehabilitation training for dysphagia, participants in the intervention group would demonstrate superior improvements compared to the control group at both immediate post-intervention (T1) and 1-month follow-up (T2) periods across multiple clinical parameters:

(1) AI-VG system is feasible and acceptable among PSD patients.

(2) PSD patients in the intervention group will have significantly greater improvement in swallowing function (primary outcome) at T1 and T2 when compared with those in the control group.

(3) PSD patients in the intervention group are expected to exhibit significantly more substantial improvements in swallowing-related quality of life and nutritional status at both T1 and T2 compared to those in the control group.

3.3 Theoretical framework

Based on the immersion theoretical model established by Yang et al. (X. Yang, 2015) and the technology acceptance model (TAM) (Strudwick, 2015) widely used at domestic and overseas, we designed the theoretical framework for this study. TAM, first proposed by Davis in 1989, has emerged as a foundational framework in information systems research, providing a systematic approach to understanding and predicting technology adoption behaviors (Strudwick, 2015). TAM is a predominant theoretical framework for examining user adoption of new

technologies. According to TAM, external variables (e.g., system design, social influence) indirectly affect technology adoption by shaping two key perceptual constructs: perceived usefulness and perceived ease of use. These cognitive evaluations collectively shape users' technological attitudes, which sequentially determine adoption intentions and ultimate utilization patterns. Within the TAM framework, perceived usefulness denotes the subjective assessment of performance enhancement expected from technology adoption, while perceived ease of use reflects the anticipated cognitive/physical effort required for system interaction (Strudwick, 2015). TAM has gained significant traction in healthcare research, emerging as a pivotal theoretical framework for investigating user acceptance of health information technologies. Its dual focus on perceived usefulness and ease of use provides critical insights into adoption barriers and facilitators across clinical settings (Holden & Karsh, 2010).

The following theoretical framework model was formed in this study: effectiveness assessment in this study includes effectiveness, acceptance and adherence. Effectiveness comes from the evaluation of patients' dysphagia rehabilitation index, which mainly assesses patients' swallowing function, swallowing-related quality of life, and nutrition status. This study evaluated acceptance through patients' assessment of seven key dimensions related to the AI-VG system: perceived usefulness, perceived ease of learning, perceived ease of use, perceived safety, perceived applicability, perceived satisfaction, and intention to use. Adherence was mainly derived from the increase in patient compliance. **Figure 3.1** illustrates the theoretical framework developed for applying the intervention to post-stroke dysphagia patients.

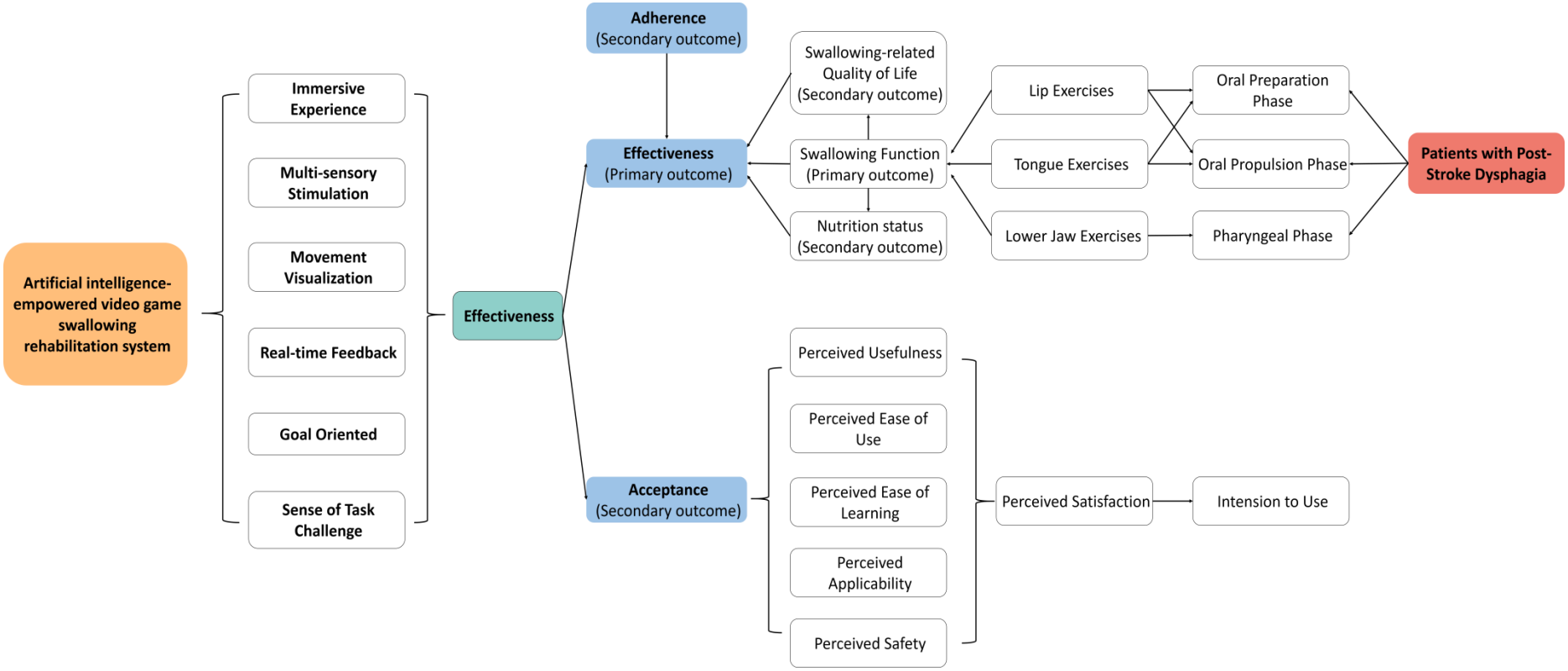


Figure 3.1 Application of the theoretical framework constructed in this study in patients with dysphagia

3.4 The rationale of the artificial intelligence-empowered video game swallowing rehabilitation system

Based on the comprehensive findings from the systematic review and network meta-analysis presented in Chapter Two, combined with an extensive literature review, we established the theoretical foundation for developing the AI-VG system. The systematic review revealed the most effective intervention approaches and key factors contributing to successful swallowing rehabilitation, which directly informed our system design decisions.

The content and objectives of the game were carefully crafted based on two key principles identified through our research synthesis. First, the intervention and the game must align with users' knowledge, experience, and Information and Communication Technology (ICT) competencies (Johnsen, Fossum, Vivekananda-Schmidt, Fruhling, & Slettebø, 2018). Second, the training protocol should incorporate evidence-based practices in dysphagia rehabilitation that emerged from our network meta-analysis results. The target users for this study were patients with dysphagia, and our systematic review of swallowing function training approaches provided crucial insights into current best practices, expected competency levels, and optimal intervention methods. These findings from Chapter Two's comprehensive analysis formed the cornerstone of our AI-VG system's theoretical framework and guided its development to ensure maximum therapeutic effectiveness.

Swallowing serves dual functions, facilitating nutritional intake while protecting airways. In normal physiology, food consumed orally travels through the esophagus into the stomach (Wilkinson, Codipilly, & Wilfahrt, 2021). This process consists of four sequential coordinated phases: oral preparation, oral propulsion, pharyngeal, and esophageal phases. Multiple peripheral muscle groups facilitate these swallowing movements, including masticatory, facial, suprahyoid, soft palate, pharyngeal, infrahyoid, and intrinsic lingual muscles (van der Bilt,

Engelen, Pereira, van der Glas, & Abbink, 2006). When neurological disorders affect the central nervous system, they typically cause dysfunction and poor coordination of oropharyngeal musculature, frequently resulting in dysphagia (Alfonsi, Todisco, Fresia, Tassorelli, & Cosentino, 2023). Additional factors such as advanced age or weakness in facial, palatal and pharyngeal muscles may also contribute to swallowing difficulties. Consequently, targeted muscle rehabilitation represents a common and effective approach for improving swallowing function in affected patients.

The esophageal phase of swallowing primarily operates under somatic and autonomic nervous system control, characterized by peristaltic contraction waves moving through both striated and smooth esophageal muscles. This phase presents significant challenges for improvement through rehabilitation exercises (I. M. Lang, 2009). Therefore, dysphagia rehabilitation interventions typically focus on the earlier stages of the swallowing process: the oral preparation phase, oral propulsion phase, and pharyngeal phase, where therapeutic exercises can produce more meaningful functional improvements.

(1) Lip Exercise: After food enters the mouth, it is manipulated and chewed through the contraction of lips, cheek muscles, orbicularis oris muscle and buccinator muscle (Panebianco, Marchese-Ragona, Masiero, & Restivo, 2020). Therefore, exercises that stretch, strengthen, or otherwise improve the basic motor properties of the muscle are very common in swallowing training (Schimmel, Ono, Lam, & Müller, 2017). Hagg et al. (Hägg & Anniko, 2008) demonstrated that lip training was effective in improving lip strength and swallowing ability of patients. Mul et al. (Mul et al., 2019) discovered that patients demonstrating greater cheek pressure and endurance exhibited less severe dysphagia symptoms. Their research indicated that targeted exercises involving cheek or lip movements could effectively enhance swallowing function in affected individuals. By improving the strength and coordination of the muscle tissues of the mouth and face, which will

help patients to improve their chewing efficiency, and improving swallowing ability.

(2) Tongue Exercises: In patients with neurological conditions, dysphagia typically results from diminished oral sensation, leading to weakened swallowing reflexes and muscle function, with particular impact on the tongue musculature. Therefore, tongue movement exercises are the most common method used by dysphagia clinicians, and a survey of 60 clinicians found that they recommended tongue movement exercises for all patients (Carnaby & Harenberg, 2013). Tongue-focused exercises can enhance patients' swallowing pressure and tongue strength, effectively improving both muscle power and coordination. These interventions, particularly those involving tongue elevation and lateral movements, optimize oral transit function and consequently enhance overall swallowing capability (Michael A. Crary, 2016; Robbins et al., 2007). Tongue extension exercises increase the patient's tongue strength, elevate the hyoid bone to lower the upper esophageal sphincter pressure, and increase the opening of the upper esophageal sphincter, which helps the food bolus enter to the esophagus (Robbins et al., 2007).

(3) Chin tuck against resistance: Chin tuck against resistance (CTAR) emerged as one of the most effective training methods for improving swallowing function, according to our network meta-analysis results presented in Chapter Two. This evidence-based approach specifically targets the strengthening of suprahyoid muscles through controlled resistance exercises. The mechanism involves the patient performing jaw contraction movements against a measured resistance, typically using a rubber ball positioned between the chin and sternum (B. Zhang, Wong, Guo, et al., 2025). When the patient contracts their chin to compress the ball, this action creates targeted resistance that effectively exercises the suprahyoid muscle group. Based on these findings from our network meta-analysis, we incorporated the core principles of CTAR into our AI-VG system design to maximize therapeutic effectiveness. The game mechanics were specifically

developed to simulate and gamify the key movements and resistance patterns that make CTAR successful in clinical practice.

3.5 Design and development of the artificial intelligence-empowered video game swallowing rehabilitation system

To create a patient-centered AI-VG system, we implemented the "Task, User, Performance, and Function"(TURF) usability framework (J. Zhang & Walji, 2011). Within healthcare environments, the TURF framework conceptualizes usability as the effectiveness, efficiency, and satisfaction experienced by target users when accomplishing work-related objectives through specific task sequences. This framework guided the design of various game elements, including rules, challenges, interactions, and goals.

A multidisciplinary research and development team was assembled to ensure successful AI-VG system development. The team consisted of a nursing PhD student with a medical master's degree who led the research and designed game content and scenarios, an IT specialist who handled technical development, two PhD supervisors who provided quality control oversight, and two dysphagia nursing experts who ensured alignment between rehabilitation training and clinical practice. Additionally, the nursing PhD student and two postgraduate students who received training certificates in dysphagia rehabilitation conducted iterative testing and provided feedback throughout the development process. The team held regular meetings during key development phases including early design, mid-design, early development, mid-development, and testing to achieve consensus on design decisions and address development challenges.

The AI-VG system was developed based on our network meta-analysis findings, incorporating CTAR and muscle training methods. The system comprises two main components: a computer display screen and a camera, which is a precision facial recognition module that detects changes in participants' facial

muscles and expressions. The system provides real-time biofeedback through computational game control based on the detected facial movements.

Game One – Lip Exercise: the game "Collecting carrots": In this game displayed on the computer screen, participants control the game character through specific cheek movements: bilateral cheek drumming, left cheek drumming, and right cheek drumming. The character navigates left and right across the screen to reach designated positions where carrots automatically fall into the character's basket. Participants must complete each of the three cheek movements (bilateral, left, and right) 15 times to successfully complete the exercise.

Game Two – Tongue Exercises: the "Maze Challenge": This game presents participants with a maze-solving challenge on the computer screen. Participants use various tongue movements to control the game character's navigation. The specific tongue movements comprise extension, upward, downward, leftward, and rightward movements. These tongue positions correspond directly to character movements within the maze (forward, up, down, left, and right). The maze pathways are specifically designed to follow therapeutic tongue movement patterns, with successful maze completion occurring when patients complete their prescribed tongue exercises. Each tongue movement must be performed 15 times.

Game Three – Neck Exercise: the "Little bird flying": In this game, participants see a flying bird on the computer screen. They control the bird's flight path by performing neck flexion exercises. Participants perform the exercise by pressing their chin against a rubber ball, maintaining the position for 2-3 seconds, then releasing upward to make a virtual bird fly downward and navigate around obstacles. The protocol requires guiding the bird around obstacles 15 times in total. (**Figure 3.2**).

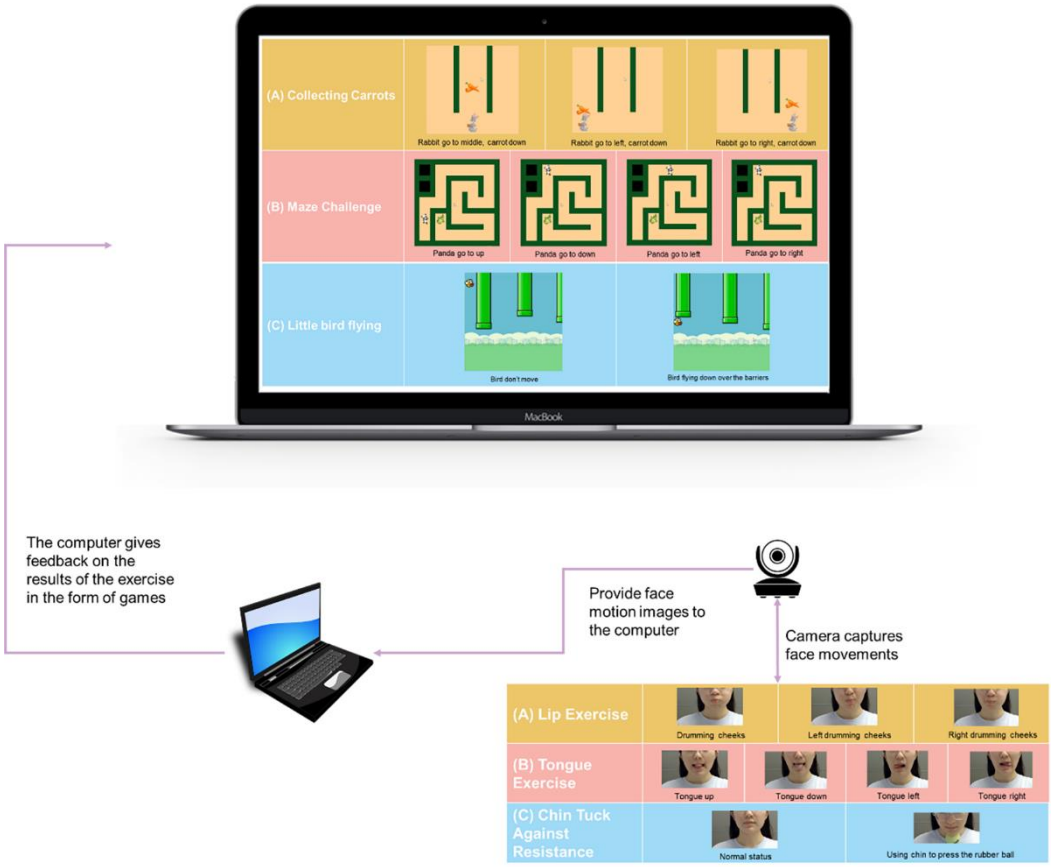


Figure 3.2 Game contents and applications of the artificial intelligence-empowered video-game swallowing function training

Chapter 4. Acceptance of the artificial intelligence-empowered video game swallowing function training system among healthcare providers and patients: a qualitative study

4.1 Introduction

This Chapter will present a qualitative study to investigate the acceptance of the artificial intelligence-empowered video game (AI-VG) system by potential users, patients and healthcare providers, of the AI-VG system. Section 4.2 will condense the background. Section 4.3 will introduce the methods of the qualitative study. The results will be presented in Section 4.4, The discussion of the results and the strength, limitations will be reported in Section 4.5. Section 4.6 will report the part of the AI-VG system that has been modified based on the results of the qualitative study.

The content of this chapter was published (B. Zhang et al., 2024): **Zhang, B**., Ding, P., Hui, V., Wong, K. P., Liu, Y., Liu, Z., Xiao, Q., & Qin, J. (2024). Technology acceptance of the video game-based swallowing function training system among healthcare providers and dysphagia patients: A qualitative study. *Digital health*, *10*, 20552076241284830. https://doi.org/10.1177/20552076241284830

4.2 Background

Understanding user acceptance prior to clinical implementation is essential for the AI-VG swallowing training system. This study employed the Technology Acceptance Model (TAM) to examine factors influencing acceptance among potential users. Researchers conducted structured interviews with healthcare professionals and patients experiencing dysphagia to investigate the various factors influencing system adoption and implementation.

4.3 Methods

A qualitative descriptive methodology guided this investigation. We employed semi-structured individual interviews, which provided flexibility during data collection while generating detailed narratives that enabled researchers to analyze participants' understanding of the research topic (McCaughan, Sheard, Cullum, Dumville, & Chetter, 2018). Both qualitative data collection and analytical procedures were documented according to the Consolidated criteria for reporting qualitative research (COREQ) (Tong, Sainsbury, & Craig, 2007).

4.3.1 Participants and settings

Purposive sampling was used in this study to recruit both healthcare providers and dysphagia patients as research participants. Healthcare providers were included as they represent potential system users who can identify potential limitations between game tasks, difficulty levels, and established therapeutic practices.

Here were healthcare providers' criteria:

The inclusion criteria: (1) minimum 3 months employment at the rehabilitation center; (2) at least 3 months experience in dysphagia treatment or care; (3) one week experience using the AI-VG dysphagia training system in this trial; and (4) proficiency in Chinese communication.

The exclusion criteria: (1) temporary staff, visiting practitioners, or interns.

Here were patients' criteria:

The inclusion criteria: (1) hospitalization during the study period; (2) physician-confirmed dysphagia via Gugging Swallowing Screen (all severity levels included); (3) aged 18 or older; (4) one week experience using the AI-VG dysphagia training system in this study; and (5) Chinese-language proficiency.

The exclusion criteria: (1) structural etiology of dysphagia (e.g., post-radiotherapy, post-head/neck surgery including laryngectomy/cordectomy); (2) cognitive status was evaluated via the Mini-Mental State Examination (MMSE),

with a threshold score of less than 24 indicating impairment (Rjoob & Rjoob, 2022).

4.3.2 Sample size

Sample size determination in this qualitative investigation was guided by the principle of data saturation. This methodological approach involved continuing participant recruitment and interviews until the information provided by new participants became repetitive and redundant with previously collected data (Vasileiou, Barnett, Thorpe, & Young, 2018). The research team systematically assessed the emergence of themes during ongoing data analysis, and when consecutive interviews failed to generate new conceptual insights or thematic elements, this indicated that theoretical saturation had been achieved, signaling that the sample size was sufficient for comprehensive understanding of the phenomenon under study.

4.3.3 Ethical considerations

The interview scheduling and location were established through direct in-person arrangements with participants. Before commencing the interviews, the research team thoroughly explained the study objectives and its scientific importance to all participants. Each individual provided formal written consent after receiving this information, and participant identities were protected through a coding system using English letters and numerical identifiers, patients were designated with the code “P” while healthcare providers received the code “M”. This investigation received ethical approval from two institutional review boards: the Research Ethics Committee of Beijing Xiaotangshan Hospital (LS20230720-1) and the Hong Kong Polytechnic University (HSEARS20230502007).

4.3.4 Data collection

The interview methodology adhered to strict audio recording protocols, with assurances to participants that recordings would be used exclusively for transcription purposes. For participants declining audio recording, researchers

performed live transcription. Each interview lasted approximately 25-45 minutes. All transcribed information was returned to participants for verification, ensuring accuracy. Throughout the research process, memo-writing was flexibly utilized to document researcher impressions, reflections on research questions, and analytical insights that emerged during interviews.

The interview protocol was designed through an extensive review of existing literature and grounded in the theoretical foundations of the TAM, with expert review and refinement from specialists in both dysphagia management and informatics (Davis, 1985; Nguyen et al., 2020). The interview protocol evolved dynamically during the study, with certain questions being modified (such as simplifying terminology) or supplemented to explore important elements that emerged from earlier interviews (Malterud, 2017). The structured interview protocol included eight core thematic questions designed to evaluate user perceptions and acceptance of the AI-VG system:

(1) “What do you think of this AI-VG system?”;

(2) “What outcomes do you think can be achieved through the use of this system?”;

(3) “Do you like it? What do you like most about the system?”;

(4) “Do you dislike it? What do you dislike most about the system?”;

(5) “Are you interested in using the system?”;

(6) “Why would you want to use it? Or why would you prefer to NOT use it?”;

(7) “Would you recommend this to others? Can you suggest any changes to improve this system?”;

(8) “Any other comments?”.

4.3.5 Analysis

Within 24 hours following each interview, the researcher performed verbatim transcription from recordings into Microsoft Word documents. Original data was systematically numbered and marked throughout the research process to facilitate

retrieval. Coding was conducted using Nvivo 14 software to enable both within-case and between-case comparative analysis (McCaughan et al., 2018).

This study employed a thematic analysis guided by theoretical principles, aligning with the TAM framework and the study's core research objectives (Nguyen et al., 2020). The analysis focused on three key aspects: the perceived usefulness of the AI-VG system, its ease of use for both dysphagia patients and healthcare providers, and their willingness to adopt the system. The data collection and analysis process were a collaborative effort between a PhD student and an experienced clinical nurse, with two supervisors overseeing and verifying the findings. Initially, researchers conducted an in-depth review of the original Chinese interview transcripts to extract significant insights. A systematic coding process followed, beginning with preliminary code assignment, then categorizing similar codes into groups, and ultimately synthesizing broader themes. The coding framework underwent continuous iterative refinement during analysis to maintain consistency with both the underlying theoretical foundations and study objectives (Brooks, McCluskey, Turley, & King, 2015). To enhance the rigor of the analysis, two researchers independently conducted thematic coding, and any discrepancies in theme organization or hierarchy were resolved through structured discussions until consensus was reached. Additionally, to maintain the fidelity of translated interview excerpts, a back-translation technique was employed (H. Y. Chen & Boore, 2010). One researcher first translated the selected quotes into English, after which a second researcher retranslated them back into Chinese. The original and back-translated Chinese versions were then compared to identify and correct any inconsistencies, ensuring that the intended meaning was preserved accurately.

While healthcare providers and dysphagia patients represent distinct groups with different roles in the rehabilitation process, we analyzed their data together because both groups are essential stakeholders in the implementation and use of the AI-VG system. The healthcare providers offer critical insights into the clinical

appropriateness and therapeutic potential of the system, while patients provide direct user experience feedback as the intended end-users. This combined analysis allowed us to develop a comprehensive understanding of the AI-VG system's usability and effectiveness from both clinical and user perspectives. Additionally, analyzing these groups together enabled us to identify areas where healthcare providers and dysphagia patients perspectives aligned or differed, which was crucial for making informed decisions about system refinements. This approach follows established practices in health technology assessment where multiple stakeholder perspectives are integrated to ensure both clinical validity and user acceptability of new interventions.

The study employed two specific approaches to establish trustworthiness of the research findings: (1) Retention of Original Data: All audio recordings, field notes, and analytical memos gathered throughout the study were carefully documented and systematically stored. During both data collection and analysis, two researchers actively engaged in the analytical process, continuously cross-referencing emerging insights with the original data to ensure accuracy and consistency. (2) Feedback methodology: The thematic analysis was conducted independently by two researchers, who then compared their results to identify common themes and sub-themes. In cases where discrepancies arose, a third researcher was consulted to provide an external perspective and facilitate consensus, thereby reinforcing the rigor of the analytical process.

4.4 Result

4.4.1 Characteristic of participants

Between July and October 2023, the study successfully recruited a total of 19 participants, comprising 8 healthcare professionals and 11 dysphagia patients. The healthcare professionals group included 4 nurses, 3 rehabilitation therapists, and 1 physician, with participants averaging 9.38 years of experience in dysphagia rehabilitation. The patient group consisted of 4 males and 7 females, with an

average age of 58.2 years. Detailed socio-demographic information for healthcare providers was presented in **Table 4.1**, while patient demographic characteristics were documented in **Table 4.2**.

Table 4.1 Demographic characteristics of healthcare providers (n=8)

Caregiver	Age	Gender	Educational status	Professional title	Duty	Work experience of dysphagia, years
M1	26	Male	Bachelor	Junior	Nurse	5
M2	33	Female	Bachelor	Junior	Nurse	2
M3	31	Female	Bachelor	Intermediate	Nurse	7
M4	36	Female	Bachelor	Intermediate	Rehabilitation therapist	12
M5	38	Female	Bachelor	Senior	Head of nurse	8
M6	51	Female	Associate degree	Intermediate	Rehabilitation therapist	31
M7	34	Female	Master's degree or above	Intermediate	Doctor	9
M8	25	Female	Master's degree or above	Junior	Rehabilitation therapist	1

Table 4.2 Demographic characteristics of dysphagia patients (n=11)

Patient	Age	Gender	Educational status	Residence	Diagnose	Co-morbidities (self-reported)
P1	64	Female	High school	Urban	Stroke	Hypertension, hyperlipemia
P2	59	Female	Junior school	Urban	Meningioma	Hyperlipemia; anemia
P3	30	Female	Bachelor	Urban	Acoustic neuroma	NA
P4	76	Female	Bachelor	Urban	Stroke	NA
P5	43	Male	High school	Urban	Stoke	Hypertension, diabetes
P6	59	Female	High school	Suburb	Stoke	Hypertension, diabetes
P7	75	Female	High school	Urban	Alzheimer disease	NA
P8	78	Female	High school	Urban	Stoke	Hypertension, diabetes
P9	71	Male	Junior school	Urban	Guillain-barre syndrome	NA
P10	36	Male	Bachelor	Urban	Schwannoma	NA
P11	49	Male	High school	Urban	Stoke	Hypertension, diabetes

4.4.2 Theme results

Analysis of user responses revealed three core thematic categories with seven subordinate themes concerning the AI-VG swallowing therapy platform (Figure 4.1). These thematic sections corresponded to the key factors affecting system acceptance according to the TAM: perceived usefulness, perceived ease of use, and intention to use.

Four sub-themes emerged within the perceived usefulness category:

(1) “Sufficient training content to support the needs of patients with dysphagia”

(2) “AI-VG system increase patient interest and initiative by adding interactive to rehabilitation”

(3) “Game pages allow visualization and intuitive show of training results”

(4) “Training can be completed efficiently”

The perceived ease of use theme contained one sub-theme:

(1) “Learning how to use it is easy through user-friendly and simple interface”

The intention to use theme encompassed two contrasting sub-themes:

(1) “High flexibility for patients without geographical and time limitations”

(2) “Practical use in the real world is still challenging”

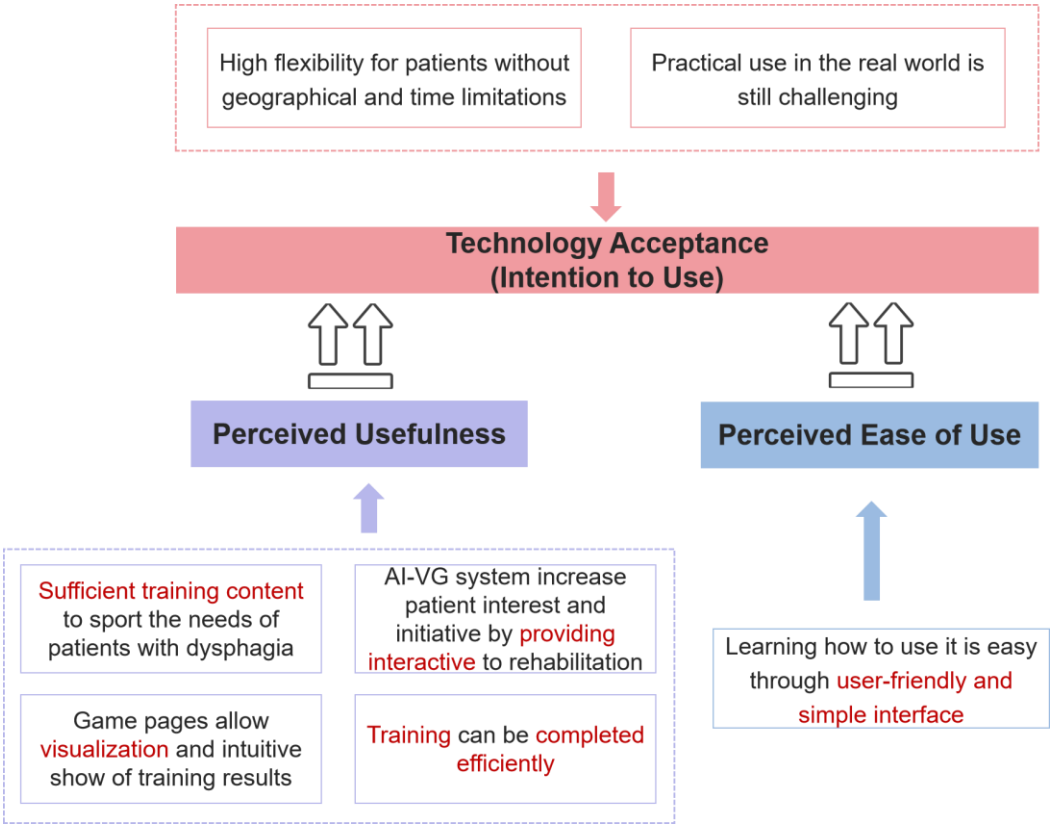


Figure 4.1 Summary of identified themes and subthemes

4.4.2.1 Perceived usefulness

(1) ***Sufficient training content to support the needs of patients with dysphagia***

The majority of participants reported that the three games comprising the AI-VG system provided comprehensive coverage of their rehabilitation needs and were sufficient for their daily therapeutic requirements.

"I don't think they (patients) are up to the physical quality required to do too many programs...they don't have the ability to do training for a long time ..... I think that's enough (three games). Because the more programs they do, the more they may forget or not understand…We need to consider the patients' capacity for learning and their attention span." (M1)

"The current games can improve swallowing... Because the rehabilitation therapist provides exercises also like 'pointing here' or 'pointing there' (fingers to the face), as well... I think for now, I think it's good." (P6)

(2) ***AI-VG system increase patient interest and initiative by providing interactive to rehabilitation***

Participants indicated that the game-based rehabilitation format significantly enhanced their interest in therapy. They found this approach novel, as they had not previously experienced game-based rehabilitation. The interactive gaming elements actively stimulated their motivation and engagement with the therapeutic process.

"It's okay, I think it's more interesting for the patient, it's not just that we're doing some training exercises or electrical stimulation and everyone is the same in every case. Because rehabilitation is a pretty boring process, it's more fun to have something new to add to the training. I think it's a good method." (M7)

"The game is pretty interesting and fun. Might be more fun if there were set challenges or difficulty levels." (P3)

"I quite like this one (game)... Because this is really quite simple. For older people, I think it works and has fun." (P4)

(3) ***Game pages allow visualization and intuitive show of training results***

The AI-VG system offers immediate visual and auditory feedback to participants regarding their completion of therapeutic activities. Study participants expressed that this visual representation of training outcomes served as a motivational factor encouraging continued engagement with their rehabilitation program.

"And there is feedback to them (the patient). It's more visualized. 'Eh, I made it. Eh, I didn't make it', that motion picture of the game, I think it's pretty good." (M4)

"It feels good to be confronted with direct evaluation... Unlike traditional therapy where progress can sometimes feel abstract, this game provides immediate feedback on my performance… It's definitely good for functional exercise as well, I'm not just completing the swallowing training, I have to understand how to play the game, and I think it's good for my cognition as well." (P7)

(4) ***Training can be completed efficiently***

The AI-VG swallowing training system enables patients to perform their rehabilitation exercises at home, eliminating travel requirements. Additionally, this

technology transforms the rehabilitation model from an individual "one-to-one" approach to a more efficient "one-to-many" framework, conserving therapists' clinical time and allowing them to complete their work more productively.

"Now this kind of rehabilitation, it's a whole day's work... You have to keep talking and keep reminding him (the patient) to do it... ... (Using video games) I can train several patients at the same time. At least, I can do one on two, and I can look over here and I can look over there, because I can listen to the sound. Well, I can listen to it, and if you "ding", that means you did it, and I can focus on the patient who didn't ding over here... I don't have to focus on one patient all the time." (M4)

"When there's nothing else to do, like when I get home, I can do it whenever I want. It's a game. It's just a game." (P5)

4.4.2.2 Perceived ease of use

(1) ***Learning how to use it is easy through user-friendly and simple interface***

Participants reported that the AI-VG swallowing system featured intuitive operation that could be quickly mastered without requiring extensive computer skills. They appreciated the simplistic game interface design, noting that patients could use the system without experiencing dizziness or eye strain when viewing the computer screen. The straightforward page layout facilitated easy comprehension for patients.

"I think the ease of use is pretty high. Because there are not too many keys, if there are more keys it may be more complicated to use, but I see that (video game) does not seem to have too many keys." (M1)

"I can do this myself. It doesn't hurt my eyes to look at it, and I don't get dizzy when I use it." (P3)

"It's easy to use… even someone with less intelligence than me can use this." (P9)

"There's nothing inconvenient about using it. I already know how to use it." (P11)

"It's not complicated, it's not complicated, and it's easy to understand, easy, I understand it all anyway." (P4)

4.4.2.3 Intention to use

(1) ***High flexibility for patients without geographical and time limitations***

The AI-VG system based rehabilitation approach offers dysphagia patients multiple options for completing their therapeutic exercises with greater ease and efficiency. This flexibility allows patients to engage with the gaming platform across various settings, at home, in community centers, or during hospital stays, thereby eliminating travel time constraints. Patients gain autonomy in selecting both the timing and environment most conducive to their comfort when performing their rehabilitation activities.

> *"After all, not all patients have a rehabilitation hospital in the neighborhood where they live. They may be traveling a long distance or they may be outpatients who have to run to the hospital every day. So, it's hard for patients to keep training. So, I think this (video game) would be better." (M3)*

> *"It's pretty convenient if you do it at home. This is convenient for us because we usually have things to do and we forget to exercise…I took a look at this and thought it was fun and would like to use this." (P6)*

> *"Patients like me, I just can't swallow and now I can't do it (rehabilitation) on an outpatient clinic...I have to be hospitalized...it's easier for me to do it myself at home like this one...there are more options." (P10)*

(2) ***Practical use in the real world is still challenging***

Despite considerable positive feedback regarding the AI-VG system, participants identified several practical implementation challenges. These included elderly patients requiring family assistance with computer operation, the need for improved accuracy in facial recognition technology, refinement of background supervision capabilities, and the importance of implementing graduated difficulty levels within games to maintain user interest and engagement.

"As long as the patient's cognition is good, they can basically cooperate, but some may have to have someone to supervise or push them. But if it's one of these cognitively problematic ones, then someone definitely has to supervise them, that is, push them to train." (M7)

"I'm old and may need my daughter's help to train with this, I'm not very good at using the computer. You see, I didn't grow up with all this technology…The screen, the camera, it all makes me nervous." (P2)

"The game is pretty interesting and fun. Might be more fun if there were set challenges or difficulty levels." (P3)

4.5 Discussion

This investigation employed qualitative research methods and incorporated feedback from diverse stakeholders including patients, physicians, nurses, and rehabilitation specialists who represent potential users of the AI-VG swallowing function training system. The findings revealed that despite certain practical implementation challenges, users expressed confidence in the future application of AI-VG system technology for dysphagia rehabilitation and generally perceived the system as both useful and user-friendly.

The adoption of new technologies poses a considerable challenge for innovators, particularly in the realm of healthcare. As mobile health technologies continue to expand, the integration of advanced but potentially invasive features, such as sensors, facial recognition, and deep learning, may amplify user concerns and hinder adoption rates (Nadal, Sas, & Doherty, 2020). Furthermore, healthcare providers' perceptions of technology play a crucial role in determining the successful implementation of new treatment devices. The TAM, which emphasizes perceived usefulness and ease of use as primary influencing factors, has been widely recognized as an effective framework for analyzing users' acceptance and attitudes toward emerging technologies (Nguyen et al., 2020).

Video games are an evolving technological innovation that creates immersive, interactive experiences by utilizing computer-generated environments to provide

real-time feedback on users' decisions, movements, and facial expressions (R. Y. Zhang et al., 2021). Existing research has primarily focused on the cognitive and physical advantages of video games, highlighting their positive impact on memory enhancement (Yu & Chan, 2021), attention (Peñuelas-Calvo et al., 2022), perception (Bediou et al., 2018), psychological wellbeing (reducing depression and anxiety) (Ruiz et al., 2022), and pain management (Sajeev et al., 2021). However, fewer studies have specifically examined user acceptance of video game technologies in rehabilitation contexts.

Perceived usefulness was conceptualized as users' subjective assessment of swallowing function improvement following AI-VG system utilization for dysphagia rehabilitation (H. C. Lin et al., 2017). Our findings indicated that participants viewed the system as beneficial. The comprehensive design incorporated three exercise types targeting facial, tongue, chin, and neck muscles, providing sufficient training content for dysphagia patients. The interactive elements and visual result presentation enhanced patient interest and initiative during rehabilitation, enabling efficient training completion. When engaging with the AI-VG system, patient-computer interaction generated positive perceptions toward new learning approaches, fostering active engagement and improved content absorption (Sun, Tsai, Finger, Chen, & Yeh, 2008). Our findings indicated that participants viewed the system as beneficial. The comprehensive design incorporated three exercise types targeting facial, tongue, chin, and neck muscles, providing sufficient training content for dysphagia patients. The interactive elements and visual result presentation enhanced patient interest and initiative during rehabilitation, enabling efficient training completion. When engaging with the AI-VG system, patient-computer interaction generated positive perceptions toward new learning approaches, fostering active engagement and improved content absorption (Padilla-Meléndez, del Aguila-Obra, & Garrido-Moreno, 2013).

Perceived ease of use referred to users' estimation of how readily they could operate the AI-VG system for swallowing rehabilitation (H. C. Lin et al., 2017). Most participants reported that learning the system was straightforward due to its user-friendly interface. User adoption intention is significantly affected by required operational effort (Nguyen et al., 2020). Consistent with previous research, participants emphasized the importance of user-friendly design elements including clean graphics and accessible information (Dünnebeil, Sunyaev, Blohm, Leimeister, & Krcmar, 2012). Prior studies identified that repeated hands-on experience combined with reference materials foster comfort, particularly among initially hesitant patients (Chock & Perna, 2014). Healthcare provider demonstrations and simplified user guides can enhance usability. Additional research is needed to adapt technology for individuals with severe cognitive or mobility limitations.

Participants demonstrated high intention to use the AI-VG system in future clinical practice, primarily due to its flexibility allowing rehabilitation without temporal or geographical constraints. This corresponds with Portz et al. (2019) (Portz et al., 2019), who noted increasing patient interest in health management technologies, with particular benefits for those distant from healthcare providers through improved care access. Once exposed to technology, older patients typically become consistent users (Wildenbos, Peute, & Jaspers, 2017). Healthcare providers also showed strong adoption intention, believing proper system implementation would enhance productivity and service quality while reducing patient travel time. Clinicians' medical knowledge and digital familiarity enhanced both perceived utility and usability, strongly affecting adoption intent (Rouidi, Elouadi, & Hamdoune, 2022).

Nevertheless, real-world implementation challenges exist, including elderly patients' computer proficiency limitations requiring family assistance and the need for background monitoring of training processes. These results align with the work

of Scott et al. (2018) (Scott Kruse et al., 2018), who identified obstacles like technical skill requirements, support availability, and other barriers hindering technology adoption in clinical settings. Advancements in background monitoring, system accuracy, patient education, and policy formulation have the potential to overcome these challenges and drive the broader adoption of information technology in healthcare (Schwarz, Ward, & Willcock, 2014).

Given conventional exercises' widespread clinical adoption for dysphagia management, understanding gamification's role in enhancing patient engagement is crucial. Future research should better define clinical benefits across various dysphagic populations when comparing traditional approaches with gamified alternatives. In addition to therapeutic effectiveness, assessing user experience offers valuable perspectives that, when integrated with clinical outcomes, can enhance system usability and adoption rates.

Our qualitative research, combined with thematic analysis, provided valuable insights into the acceptance of the AI-VG system from a diverse range of stakeholders. By engaging participants early in the development process, we gathered user-driven feedback that directly contributed to refining the system's functionality, ultimately shaping future rehabilitation models. Through this analysis, we identified several practical challenges that could hinder real-world implementation, including restricted access to necessary computer equipment and the need for adequate supervision during system use. Overcoming these barriers is essential to unlocking the full potential of the AI-VG system, ensuring its effectiveness in rehabilitation settings, and facilitating broader adoption among both patients and healthcare providers.

However, several limitations warrant consideration when interpreting our findings. First, acceptance data represented participants with only one week of experience, excluding long-term user perspectives. Since target training intensity wasn't reached, swallowing function data weren't obtained and all dysphagia

causes were included. Future randomized controlled trials should explore the system's efficacy. Second, our sample was limited to one rehabilitation hospital, potentially missing diverse perspectives from other organizations. Third, while aiming for age diversity, we did not maintain balanced representation across age groups. Fourth, although grounded in TAM theory and comprehensive literature review, the interview guide was not pilot tested for structural validation prior to use. This lack of preliminary testing may have limited our ability to identify potential weaknesses or ambiguities in the questions. Additionally, to ensure the AI-VG system remained broadly applicable, we did not assess participants' prior technological experience. However, this factor could have systematically affected users' subjective assessments of the system's usability and perceived clinical utility. Future research should incorporate an evaluation of participants' technological backgrounds while still preserving the system's generalizability. This approach would enable a deeper understanding of how prior experience impacts technology acceptance and user engagement.

4.6 Refinement of the artificial intelligence-empowered video game system based on the qualitative study results

Based on the findings from our qualitative study exploring the acceptance, experiences and feedback of both dysphagia patients and healthcare providers who tested the AI-VG system, our research team conducted several meetings to discuss and implement system improvements.

First, the interface was enhanced by enlarging the game display and webcam feed, allowing users to more clearly view both their facial movements and the game elements simultaneously. Second, we introduced multiple difficulty levels for each game, enabling progressive challenges as patients improve their swallowing function. Third, the system's feedback mechanism was refined to provide more detailed real-time performance metrics, including exercise duration, movement accuracy, and completion rates. Additionally, we incorporated audio

cues and clearer visual instructions to guide users through each exercise, making the system more intuitive and user-friendly for dysphagia patients. These refinements were implemented to optimize the therapeutic effectiveness and user experience of the AI-VG system, addressing the key concerns and suggestions identified in our qualitative research.

Chapter 5. Effectiveness of an artificial intelligence-empowered video game swallowing function training on post-stroke patients with dysphagia: a pilot study

5.1 Introduction

This chapter presents a feasibility study employing a pilot randomized controlled trial (RCT) design to evaluate an artificial intelligence-empowered video game (AI-VG) system for PSD dysphagia rehabilitation. The chapter is organized as follows: 5.1 introduces the research context and objectives; 5.2 describes the experimental design and procedures, compliant with the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist. Section 5.3 presents the findings of the pilot study, followed by an in-depth discussion in Section 5.4.

The content of this chapter was published (B. Zhang et al., 2024): **Zhang, B.,** Wong, K. P., Liu, M., Hui, V., Guo, C., Liu, Y., Liu, Z., Liu, Y., Xiao, Q., & Qin, J. (2024). Face Recognition-Driven Video Game for Dysphagia Rehabilitation in Stroke Patients: A Pilot Randomized Controlled Trial. *Archives of physical medicine and rehabilitation*, S0003-9993(24)01309-1. Advance online publication. https://doi.org/10.1016/j.apmr.2024.10.005

5.2 Methods

5.2.1 Study design

This pilot study employed a single-blinded, RCT design with a 4-week intervention period. The study protocol received approval from two ethics committees: Hong Kong Polytechnic University (HSEARS20230502007) and Beijing Xiaotangshan Hospital (LS20230720-1), with additional registration at ClinicalTrials.gov (NCT05978700).

All research phases adhered to SPIRT reporting guidelines (Chan et al., 2013). Treatment allocation utilized 1:1 randomization generated through R software. A nurse not involved in assessment or intervention procedures performed the

randomization and secured assignment details in opaque sealed envelopes to maintain allocation concealment.

5.2.2 Participants

5.2.2.1 Study setting and participants

This phase of the investigation utilized a convenience sampling approach to recruit patients from a rehabilitation center in Beijing, China.

The following inclusion criteria were applied: (1) stroke diagnosis confirmed by CT, MRI, or other diagnostic examinations; (2) dysphagia diagnosis established using the Gugging Swallowing Screen; (3) first stroke with disease duration less than one year; (4) age 18 years or older; and (5) no clinically meaningful cognitive deficits (Mini-Mental State Examination score ≥ 24) and ability to correctly follow instructions.

Patients were excluded from the study based on these criteria: (1) significant systemic health conditions, including severe cardiac, pulmonary, hepatic, renal diseases, or hematological disorders that could potentially compromise the research intervention's safety or effectiveness; (2) physical limitations such as an inability to maintain a seated position, bilateral blindness, or profound visual impairments that would substantially impede participation; (3) underlying neurological conditions like motion sickness, vestibular dysfunction, or balance disorders that could interfere with the study's protocol; and (4) pre-existing medical histories involving epilepsy, active malignancy, or other complex neurological diseases that might introduce confounding variables or pose additional health risks during the research intervention. Several exclusion criteria were specifically related to AI-VG system requirements or represented safety precautions to prevent potential harm to participants from AI-VG system technology use.

5.2.2.2 Sample size

Utilizing a one-sided confidence interval of 80% to balance reasonable certainty in trial decisions with practical study constraints and budget considerations, the estimated pilot trial sample size was calculated at 9% of the planned main study sample (Cocks & Torgerson, 2013). A total of 20 patients will be included, of which 10 will be include in the video-game group and 10 will be include in the conventional rehabilitation group. All participants in the usability assessment received complete study information and provided signed informed consent prior to enrollment.

5.2.2.3 Assignment of interventions: allocation

To ensure unbiased group allocation, an independent biostatistician conducted randomization via R software (version 4.2.1), employing the sample () function to distribute participants equally between Group 1 (intervention) and Group 2 (control) through computer-generated random numbers (1-20 range)

A research assistant (nurse) who remained uninvolved in all study components secured the randomization assignments in sequentially numbered opaque envelopes. Following completion of informed consent and baseline assessments, each eligible participant received an envelope according to their enrollment sequence and was assigned to their respective group based on the number contained inside.

5.2.3 Interventions

This study aimed to assess video game effects on swallowing rehabilitation. Both control and intervention groups received rehabilitation programs with identical components and duration, differing only in the video game element.

5.2.3.1 Instrumentation

As described in Chapter 3, the AI-VG swallowing rehabilitation system comprised a computer screen and camera. During sessions, participants faced the computer while the facial recognition device detected changes in facial muscles

and expressions. The system provided real-time biofeedback through computer-controlled game interactions.

5.2.3.2 Intervention

The intervention protocol consisted of daily 30-minute sessions, conducted 5 times weekly over a 4-week period (B. Zhang, Wong, Guo, et al., 2025). The AI-VG system was implemented in the experimental group, while the control group adhered to traditional swallowing rehabilitation. Additionally, all participants received consistent baseline care, including dietary guidance, optimal positioning instruction, breath control methods, cough facilitation strategies, and sensory stimulation.

Participants in the experimental group performed swallowing function training using the AI-VG system. They sat facing the computer screen and completed the AI-VG training protocol.

The control group engaged in conventional swallowing function training comprising: (1) Lip exercises: opening/closing mouth, bilateral cheek drumming, left cheek drumming, and right cheek drumming; (2) Tongue exercises: tongue extension, upward, downward, leftward, and rightward movements; (3) Neck exercises: maximal head lowering while squeezing a rubber ball placed on the neck. Each specific movement lasted 2-3 seconds and was repeated 15 times before progressing to the next movement.

5.2.3.3 Criteria for discontinuing

All participants maintained unconditional withdrawal rights throughout the study period without penalty. Investigators reserved the right to discontinue participation for non-compliance (e.g., repeated missed sessions or uncooperative behavior). Data collected prior to withdrawal remained eligible for analysis, though excessive attrition would trigger replacement protocols. The study incorporated predefined termination criteria for safety concerns (e.g., aspiration events or severe vomiting). The trial involved no foreseeable risks or financial

compensation, as assessments were non-invasive and the gaming interface excluded violent content.

To control routine care influences, all participants received the same standardized baseline treatment in terms of duration and intensity. Weekly monitoring of treatment progress and status ensured consistent implementation of usual care across groups.

5.2.4 Assignment of interventions: Blinding

The evaluation process maintained methodological rigor through evaluator blinding to participant group assignment. This evaluator was excluded from both treatment administration and statistical analysis procedures. However, due to the distinctive nature of AI-VG system, it was not feasible to implement blinding for either participants or therapists.

5.2.5 Outcome measures

An independent evaluator, masked to participant grouping, administered all outcome measures at baseline and study completion. The assessment schedule included baseline measurements prior to intervention initiation (pre-training) and follow-up evaluation after completing the 4-week treatment protocol (post-training).

Prospective subjects were fully briefed on study protocols and involvement criteria during enrollment. The researcher meticulously explained the study's benefits and implications while emphasizing the significance of completing the entire research protocol. All participants were explicitly informed of their unconditional right to withdraw from the study at any point during the research process without penalty or compromise to their standard care. Throughout the follow-up period, the researcher maintained continuous monitoring of participant status and proactively communicated to support study completion. For participants who withdrew, outcome data were collected up to the point of withdrawal, provided informed consent was obtained.

A standardized baseline questionnaire was administered to collect detailed demographic and clinical characteristics from all participants, systematically documenting age, gender, specific neurological diagnosis, time since onset, occupational category, marital status, history of tobacco use and alcohol consumption, along with relevant comorbid conditions including hypertension, diabetes mellitus, and hyperlipidemia.

5.2.5.1 Primary outcomes

The primary outcomes are aimed at evaluating the acceptability and feasibility of AI-VG system by patients.

Drawing upon established theoretical frameworks and empirical studies, the acceptance questionnaire was systematically developed and subsequently refined through iterative expert review. Based on the Technology Acceptance Model (TAM) (Strudwick, 2015), the instrument assessed seven dimensions. Each domain included five items evaluated using a 5-point Likert scale (1 – 5, strongly disagree – strongly agree). This paper-based, anonymously completed questionnaire was reviewed by four content experts and demonstrated strong content validity with an index of 0.967.

Adherence measurement was based on objective documentation of patients' actual swallowing function training completion. The researcher systematically recorded training metrics including number of completed sessions and training duration. Patients were considered adherent when they completed a minimum of 10 training sessions (Essery, Geraghty, Kirby, & Yardley, 2017).

5.2.5.2 Secondary outcomes

The secondary outcomes focus on the evaluation of the effectiveness of the AI-VG system.

The Gugging Swallowing Screen (GUSS) was used to evaluate participants' swallowing function through water and substances of varying consistencies. water and substances of varying consistencies. GUSS comprises two sections: a

preliminary indirect swallowing test (Part 1) and three direct swallowing subtests (Part 2). These four sequential subtests each have a maximum score of 5 points, requiring full marks to advance. Failing to achieve 5 points in any subtest stops the examination, requiring specialized diet and/or further imaging assessment. The maximum total score is 20, indicating normal swallowing without aspiration risk. Among assessment tools for PSD, the GUSS has proven particularly effective, demonstrating a sensitivity of 0.97 and specificity of 0.67 (E. Boaden et al., 2021).

The Functional Oral Intake Scale (FOIS) utilizes a 7-level hierarchical classification to evaluate swallowing-related dietary capacity, with scoring criteria spanning from Level 1 (complete inability for oral nutrition) to Level 7 (unrestricted oral intake across all food textures and consistencies) (M. A. Crary, Mann, & Groher, 2005).

Standard Swallowing Assessment (SSA) was utilized to measure dysphagia severity through a three-part evaluation: clinical assessment, 5 ml water swallow test, and 60 ml water swallow test. Higher scores on the SSA (range 18-46) indicate more severe swallowing difficulties. This assessment demonstrates strong diagnostic properties with 0.90 specificity, 0.97 sensitivity (Lin Perry, 2001).

The Volume-Viscosity Swallowing Test (VVST) was a validated screening tool with high sensitivity and specificity for detecting dysphagia. The VVST employs three viscosities (nectar, liquid, and pudding) in progressively increasing bolus volumes, with immediate progression to higher viscosity if safety issues occur (coughing, wet voice, or ≥3% oxygen desaturation). A positive VVST result indicates failure to reach maximum bolus volume in any viscosity category(Rofes, Arreola, Mukherjee, & Clavé, 2014).

The Swallowing Quality of Life (SWAL-QOL) instrument is a multidimensional tool featuring 10 specialized subdomains complemented by a 14-item symptom severity scale. Utilizing a 0-100 metric scale, the measure inversely correlates numerical values with dysphagia impact, whereby diminished

scores indicate greater swallowing-related quality of life deterioration (D. Y. Kim, Park, Park, & Kim, 2020).

5.2.6 Statistical analysis

Data collection and analysis utilized Microsoft 2019 and SPSS version 29.0. A *P*-value of less than 0.05 was considered statistically significant across all analyses. For baseline variable assessment, categorical variables (e.g., gender and residence area) were analyzed using χ^2 tests, while continuous data underwent normality testing. Non-parametric statistical tests were utilized for datasets exhibiting non-normal distribution. Findings were summarized using the most suitable descriptive statistics for each dataset: frequencies (%), means ± standard deviation (SD), or medians with IQR

For normally distributed data, between-group comparisons employed Student's t-tests, while within-group comparisons (pre- and post-intervention) utilized paired t-tests (Mishra, Pandey, Singh, Keshri, & Sabaretnam, 2019). When normality assumptions were violated, non-parametric alternatives were implemented: Mann-Whitney U tests analyzed between-group differences, while Wilcoxon Signed-Rank tests evaluated within-subject changes across time points (Lachin, 2020). Effect size calculations utilized the absolute value of Cohen's *d* or Hedges' *g* coefficients.

To address potential participant attrition during the intervention period, all data underwent intention-to-treat analysis (including all randomized participants). When participants discontinued the intervention, immediate contact was initiated to investigate withdrawal reasons and encourage continued participation in measurement sessions to minimize follow-up data loss. Missing data from participants who discontinued treatment or were lost to follow-up were handled using the last observation carried forward approach within the intention-to-treat analysis framework.

5.3 Results

5.3.1 Clinical Characteristics

Among the 26 recruited patients, 14 received experimental intervention while 12 served as controls. Evaluations occurred at two timepoints: pre-intervention (T0, 0Wks) and post-intervention (T1, 4Wks). All enrolled participants completed the full study protocol (**Figure 5.1**).

In the AI-VG system group, participants averaged 66.5 years of age (SD = 8.25), with 8 participants (57.1%) being male and 11 participants (78.6%) presenting an ischemic stroke diagnosis. The conventional care group participants' mean age was 66.2 ± 14.99 years, with 10 participants (83.3%) being male and 10 participants (83.3%) diagnosed with ischemic stroke. Initial group characteristics showed comparable distributions across all measured demographic and clinical variables ($P > 0.05$, **Table 5.1**).

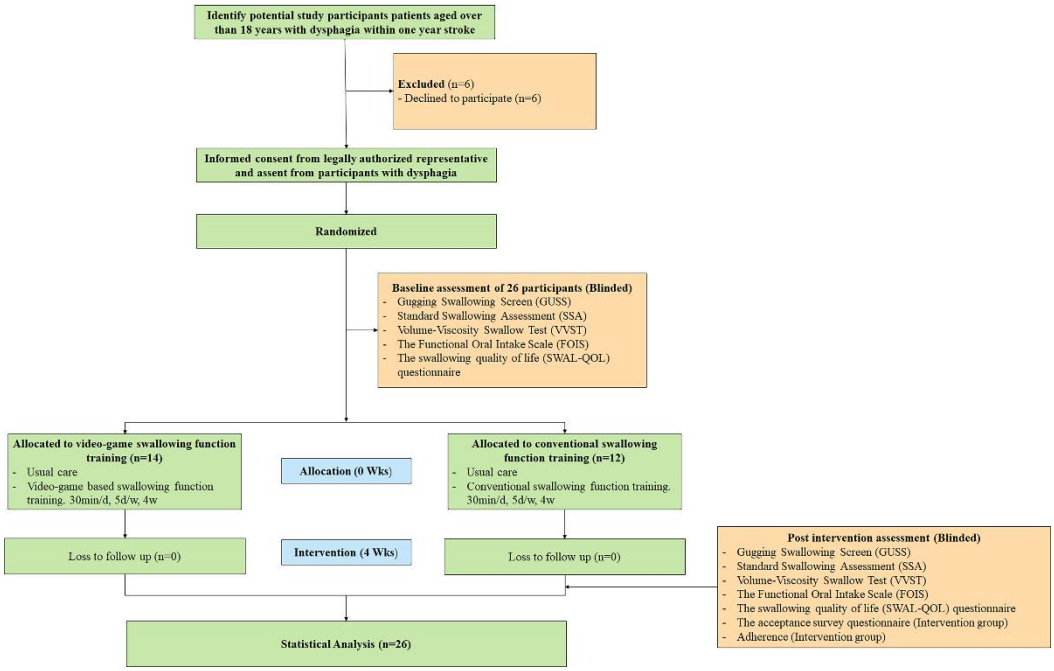


Figure 5.1 The flow chart of the trial

Table 5.1 Baseline characteristics of participants

Variables	Coding	Video-game group (n=14, %)	Conventional group (n=12, %)	t/ χ^2	*P*-Value
Diagnosis	Ischemic Stroke	11 (78.6%)	10 (83.3%)	0.094*	0.759
	Hemorrhagic Stroke	3 (21.4%)	2 (16.7%)		
Disease duration (moths)	Mean ± SD	1.91±0.85	2.19±2.21	-0.349†	0.730
Gender	Male	8 (57.1%)	10 (83.3%)	1.033*	0.216
	Female	6 (42.9%)	2 (16.7%)		
Age (years)	Mean ± SD	66.5±8.25	66.2±14.99	0.054†	0.958
Occupation type	Mainly mental work	1 (7.1%)	1 (8.3%)	0.791*	0.997
	Mainly physical work	0 (0.0%)	0 (0.0%)		
	Part mental, part physical	1 (7.1%)	1 (8.3%)		
	Unemployed	1 (7.1%)	1 (8.3%)		
	Retirement	11 (78.6%)	9 (75.0%)		
Marital status	Married	14 (100.0%)	11 (91.7%)	0.006*	0.937
	Divorced	0 (0.0%)	1 (8.3%)		
Smoking history		4 (28.6%)	3 (25.0%)	0.042*	0.838
Alcohol consumption history		2 (14.3%)	2 (16.7%)	0.028*	0.867
Hypertension		10 (71.4%)	8 (66.7%)	0.069*	0.793
Diabetes		8 (57.1%)	3 (25.0%)	2.735*	0.098
Coronary heart disease		1 (7.1%)	1 (8.3%)	0.013*	0.910

Hyperlipidemia		2 (14.3%)	2 (16.7%)	0.028*	0.867
Gastroesophageal reflux disease		0 (0.0%)	2 (16.7%)	0.725*	0.394
Swallowing function	GUSS	8.43±6.71	8.58±7.18	-0.057†	0.955
	SSA score	30.79±5.63	31.50±5.20	-0.334†	0.741
	VVST	2.14±0.54	2.33±0.65	-0.819†	0.421
	FOIS	3.79±1.53	3.92±1.83	-0.199†	0.844
Swallowing-related quality of life	SWAL-QOL	130.57±37.78	120.75 ± 26.98	0.750†	0.460

* Chi-square test; † *t*-test.

5.3.2 Results of Acceptability and Adherence

The AI-VG dysphagia rehabilitation system exhibited high patient acceptability within the intervention group, with individual scores spanning from 95 to 105 points and achieving a mean score of 101.93 points, as comprehensively outlined in **Table 5.2**. Regarding treatment adherence, the intervention group achieved a mean score of 17.64±2.98 compared to 15.17±2.48 in the control group. Statistical analysis revealed significantly higher adherence among intervention group patients compared to control group patients ($t = 2.28$, $P = 0.032$), as shown in **Table 5.2** and illustrated in **Figure 5.2C**.

5.3.3 Results of Swallowing Function

Pretreatment assessment established comparable baseline swallowing function across groups. Following the intervention period, intervention and control groups demonstrated significant improvements in swallowing function ($P < 0.05$). Comparative analysis showed that intervention group patients achieved superior improvements in both GUSS ($Z = -2.434$, $P = 0.015$) and FOIS ($Z = -2.886$, $P = 0.004$) scores relative to control group patients, as illustrated in **Table 5.2**, **Figure 5.2 A and B.**

5.3.4 Results of Swallowing-related quality of life

After completing the 4-week therapeutic program, both participant cohorts exhibited measurable improvements in swallowing-related quality of life relative to their pretreatment status. However, the intervention group demonstrated greater improvement (57.79±34.46) versus controls (41.08±34.03), though this difference was not statistically significant (t = -1.24, P = 0.227), as detailed in **Table 5.2** and **Table 5.3**.

Table 5.2 The comparisons between pre- and post-treatment evaluations in the intervention group and the control group.

Function	Variables	Pre-treatment vs Post treatment								Intervention group vs Control group			
		Intervention group (n=14)				Control group (n=12)				Intervention group Changes	Control group Changes	Effect Size	*P*-Value
		T0	T1	Effect Size	*P*-Value	T0	T1	Effect Size	*P*-Value				
Swallowing function	GUSS	3.50 (3.00, 15.25)	19.00 (16.25, 19.25)	1.39*	**0.001**	4.00 (3.00, 16.00)	16.00 (4.50, 18.00)	0.59*	**0.003**	5.50 (3.00, 15.25)	4.25 (1.00, 8.00)	0.75*	**0.015**
	SSA score	30.79 ±5.63	23.21 ±4.53	1.48†	**<0.001**	31.50 ±5.20	25.58 ±4.48	1.22†	**<0.001**	-7.57±4.35	-5.92 ± 2.07	0.47†	0.22
	VVST	2.00 (2.00, 2,25)	1.00 (1.00, 1.25)	1.87*	**0.001**	2.00 (2.00, 3.00)	2.00 (1.00, 2.00)	1.23*	**0.003**	-1.00 (-1.00, -1.00)	-1.00 (-1.00, -0.25)	0.38*	0.334

	FOIS	4.00 (2.00, 5.00)	7.00 (5.50, 7.00)	1.59*	**0.001**	4.00 (2.25, 5.00)	6.00 (4.00, 6.00)	0.70*	**0.002**	2.00 (2.00, 3.00)	1.00 (1.00, 1.00)	1.06*	**0.004**
Swallowing-related quality of life	SWAL-QOL	130.57 ± 37.78	72.79 ± 21.06	1.88†	**<0.001**	120.75 ± 26.98	79.67 ± 20.17	1.72†	**0.002**	-57.79 ± 34.46	-41.08 ± 34.03	0.49†	0.227
Acceptability			101.93 ±3.15										
Adherence			17.64 ±2.98			15.17 ±2.48		0.89†	**0.032**				

* Hedges' *g*; † Cohen's *d*

Table 5.3 Changes in swallowing function and swallowing-related quality of life, and sub-domain of swallowing function and swallowing-related quality of life of the two groups between pre-treatment and post-treatment

Function	Variables	Sub-domain	Test	AI-VG group	Conventional care group	*P* -Value
Swallowing function	GUSS	Total score	Pre	3.50 (3.00, 15.25)	4.00 (3.00, 16.00)	0.955
			Post	19.00 (16.25, 19.25)	16.00 (4.50, 18.00)	**0.015**
			P -Value	**0.001**	**0.003**	
		Preliminary assessment	Pre	3.50 (3.00, 5.00)	4.00 (3.00, 5.00)	0.956
			Post	5.00 (5.00, 5.00)	5.00 (3.50, 5.00)	0.217
			P -Value	**0.007**	**0.026**	
		Semisolid	Pre	0.00 (0.00, 5.00)	0.00 (0.00, 5.00)	0.952
			Post	5.00 (5.00, 5.00)	5.00 (1.00, 5.00)	0.235
			P -Value	**0.011**	**0.059**	
		Liquid	Pre	0.00 (0.00, 5.00)	0.00 (0.00, 5.00)	0.952

		Post	5.00 (5.00, 5.00)	5.00 (0.00, 5.00)	0.240
		P -Value	**0.020**	0.102	
	Solid	Pre	0.00 (0.00, 0.25)	0.00 (0.00, 5.00)	0.509
		Post	4.00 (1.50, 4.25)	1.00 (0.00, 3.00)	**0.038**
		P -Value	**0.003**	**0.026**	
SSA	Total score	Pre	30.79 ±5.63	31.50±5.20	0.741
		Post	23.21±4.53	25.58±4.48	0.22
		P -Value	**<0.001**	**<0.001**	
	Preliminary assessment	Pre	10.00 (9.00, 12.25)	10.50 (8.00, 12.75)	0.697
		Post	8.00 (8.00, 8.50)	8.00 (8.00, 10.00)	0.378
		P -Value	**0.002**	**0.018**	
	A scoop of water (5ml)	Pre	11.00 (6.50, 11.00)	9.50 (7.00, 11.00)	0.933
		Post	5.00 (5.00, 6.00)	6.00 (6.00, 8.00)	**0.012**
		P -Value	**0.003**	**0.005**	

		A bottle of water (60ml)	Pre	12.00 (11.50, 12.00)	12.00 (12.00, 12.00)	0.346
			Post	8.50 (6.50, 11.25)	10.00 (10.00, 12.00)	0.240
			P -Value	**0.005**	**0.011**	
Swallowing-related quality of life	SWAL-QOL	Total score	Pre	130.57±37.78	120.75±26.98	0.460
			Post	72.79±21.06	79.67±20.17	0.227
			P -Value	**<0.001**	**0.002**	
		Eating Desire	Pre	9.00 (6.25, 12.00)	12.00 (9.50, 13.00)	0.140
			Post	5.50 (3.75, 8.50)	6.50 (5.25, 9.00)	0.349
			P -Value	**0.030**	**0.008**	
		Food Selection	Pre	8.00 (4.75, 10.00)	6.50 (6.00, 8.75)	0.694
			Post	4.00 (2.00, 6.00)	4.00 (4.00, 7.50)	0.651
			P -Value	**0.008**	**0.013**	

Eating Duration	Pre	4.00 (3.75, 7.00)	4.00 (4.00, 6.75)	0.767
	Post	2.00 (2.00, 2.25)	2.00 (2.00, 2.00)	0.389
	P -Value	**0.003**	**0.003**	
Symptom Frequency	Pre	45.50 (34.75, 56.25)	41.50 (35.00, 47.25)	0.368
	Post	22.00 (19.75, 27.50)	26.00 (20.50, 38.25)	0.315
	P -Value	**0.001**	**0.003**	
Burden	Pre	6.50 (5.00, 8.00)	5.00 (2.50, 6.75)	0.100
	Post	2.00 (2.00, 4.00)	3.50 (2.00, 4.75)	0.240
	P -Value	**0.001**	**0.015**	
Mental Health	Pre	10.00 (5.75, 17.75)	10.00 (7.00, 16.75)	0.958
	Post	5.50 (5.00, 7.25)	6.50 (5.00, 10.00)	0.315
	P -Value	**0.007**	**0.025**	

Social	Pre	15.57 (10.00, 23.50)	10.00 (5.00, 20.00)	0.176
	Post	5.00 (5.00, 10.00)	5.00 (5.00, 9.50)	0.636
	P -Value	**0.001**	**0.012**	
Sleep	Pre	6.50 (2.00, 9.25)	4.50 (2.00, 7.50)	0.283
	Post	4.00 (2.00, 6.00)	4.50 (2.25, 7.50)	0.427
	P -Value	**0.016**	0.726	
Fatigue	Pre	12.00 (3.00, 15.00)	6.00 (3.00, 8.25)	0.196
	Post	7.50 (3.00, 9.00)	6.00 (3.00, 6.00)	0.425
	P -Value	0.132	1.000	
Communication	Pre	2.00 (2.00, 6.25)	4.00 (2.00, 7.50)	0.491
	Post	2.00 (2.00, 3.00)	2.50 (2.00, 4.00))	0.248
	P -Value	**0.042**	0.071	

Fear	Pre	9.50 (7.75, 13.50)	11.00 (9.25, 14.75)	0.278
	Post	4.50 (4.00, 6.25)	6.00 (4.25, 7.00)	0.220
	P-Value	**0.002**	**0.002**	

* GUSS, the Gugging Swallowing Screen; SSA, Standardized Swallowing Assessment; SWAL-QOL, the swallowing quality of life questionnaire.

** Since Volume-Viscosity Swallow Test (VVST), and Functional Oral Intake Scale (FOIS) have no sub-domain, these two scales were not analyzed.

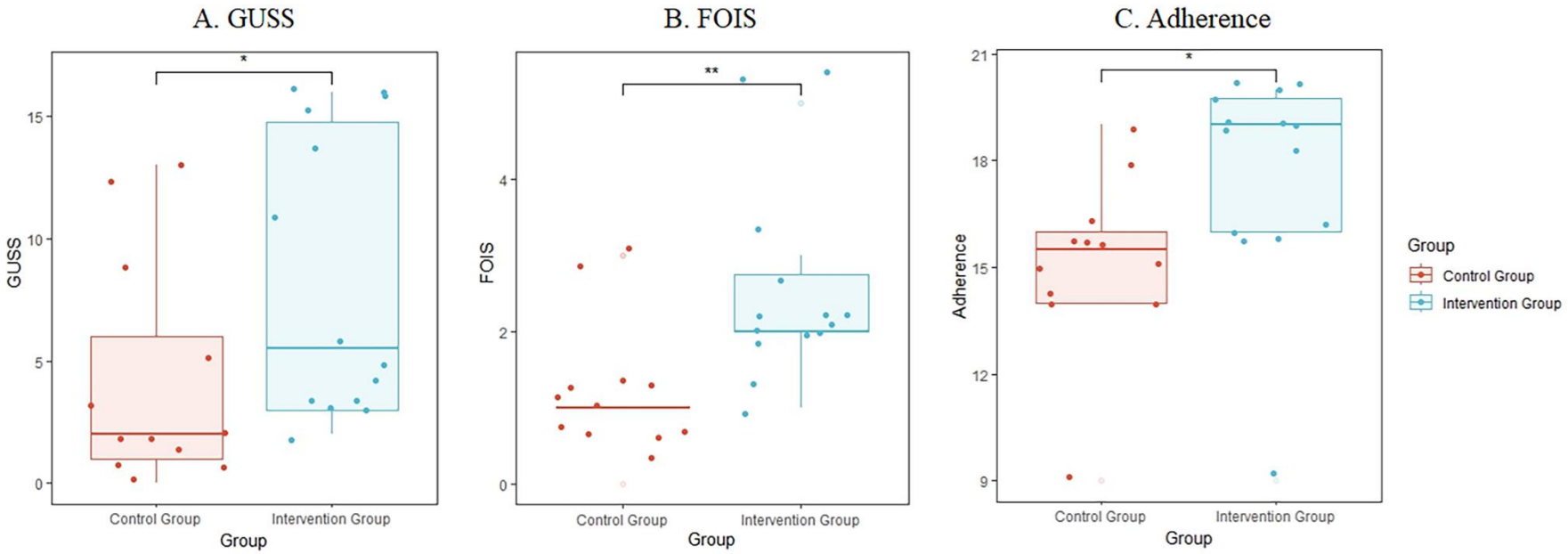


Figure 5.2 Changes in swallowing function and adherence in (A) Gugging Swallowing Screen (GUSS), (B) Functional Oral Intake Scale (FOIS), and (C) Adherence.

5.4 Discussion

The 4-week AI-VG system training intervention yielded substantial enhancements in both swallowing capacity and swallowing-related quality of life among PSD participants. Between-group comparisons showed significantly greater therapeutic gains in the AI-VG system group versus conventional care therapy, indicating the potential effectiveness of this technological approach to dysphagia rehabilitation. The AI-VG system received high acceptance ratings, and patients in this group exhibited greater adherence than those in the conventional group, indicating high feasibility for swallowing rehabilitation.

The AI-VG system training utilizes visual and auditory positive feedback, stimulating patient interest while enhancing confidence through game task completion, contributing to swallowing function recovery (Constantinescu, Rieger, Mummery, & Hodgetts, 2017). Our findings revealed higher acceptance and adherence in the AI-VG system group compared to controls, consistent with Park et al. (J. S. Park, G. Lee, et al., 2019), who reported significantly higher motivation and interest scores in their gaming group. The game-based training's design, which provides patients with a tangible sense of achievement upon successfully completing challenges, appears to be a key factor driving increased system acceptance and participant adherence. Moreover, the incorporation of face-recognition technology eliminated the requirement for additional specialized equipment, relying solely on a standard computer, which significantly enhanced patient comfort and training convenience.

Our results differed from Park et al., (J. S. Park, G. Lee, et al., 2019), who found that while video games improved swallowing function, they were not superior to conventional training. This discrepancy may stem from differences in intervention design, their system included only chin tuck against resistance exercise, whereas our AI-VG system addresses multiple phases of the swallowing process. Swallowing consists of oral preparatory, oral transport, pharyngeal, and esophageal phases (Shaw & Martino, 2013). Our system targets muscle rehabilitation across the first three phases

through facial, tongue, and chin movements. As the esophageal phase (phase IV) deglutition is primarily reflexive, our protocol intentionally excluded motor training for this autonomic process. This explained why our findings diverged from those reported by Park et al., (J. S. Park, G. Lee, et al., 2019).

The AI-VG swallowing rehabilitation system produced clinically meaningful improvements in post-stroke dysphagia recovery, evidenced by significantly greater gains in both GUSS and FOIS scores compared to conventional therapy. Although SSA and VVST results showed comparable between-group performance, qualitative analysis revealed the AI-VG system group developed superior functional eating capacities - particularly in managing solid food textures and demonstrating improved safety with reduced liquid volumes. These advancements are clinically significant as they indicate potential for transitioning toward normalized diets, potentially reducing aspiration pneumonia risk and improving nutritional intake. These results demonstrate consistency with recent evidence from Hou et al. (Hou et al., 2024) and Battel et al. (Battel & Walshe, 2023). The GUSS demonstrates strong diagnostic accuracy, with validated sensitivity and specificity for detecting dysphagia through a standardized two-phase assessment protocol comprising, this hierarchical testing structure enables precise identification of both the presence and severity of swallowing impairment while minimizing aspiration risk during evaluation (Michaela Trapl et al., 2007). A Cochrane review recognized it as the most effective multi-consistency assessment for PSD (Elizabeth Boaden et al., 2021). The FOIS records not only functional levels of oral intake but also considers enteral nutrition use (W. Zhang, Pan, Zong, Wang, & Xie, 2022). The observed FOIS score enhancement may primarily stem from the enrollment of severely dysphagic patients receiving enteral feeding who demonstrated marked functional recovery. The simpler SSA screening uses only water volumes for evaluation, while the VVST's minimal functional gradations (no safety and effectiveness impairment/ Impaired efficacy but no impaired safety/ Impaired safety (with/without

associated efficacy issues)), potentially explain the lack of significant differences in these measures.

The SWAL-QOL results indicated that the AI-VG system intervention produced clinically meaningful improvements in swallowing-specific quality of life for post-stroke patients, suggesting its potential as a complementary approach to conventional rehabilitation. The SWAL-QOL instrument evaluates 11 distinct QOL domains affected by dysphagia, encompassing eating motivation, psychological well-being, social interactions, sleep quality, and communication abilities (Colleen A McHorney et al., 2002). Post-treatment evaluation demonstrated significant gains for AI-VG system participants in multiple QOL aspects including food motivation, nutrition selection, consumption time, dysphagia symptoms, distress levels, emotional state, community participation, sleep quality, communicative ability, and swallowing-related apprehension. The comprehensive improvements observed across multiple domains reveal a holistic enhancement in swallowing-related quality of life. More than just restoring swallow function, the AI-VG system meaningfully enhanced patients' psychological well-being and social participation. By targeting both the physical and emotional aspects of swallowing difficulties, the intervention demonstrates a sophisticated approach to patient care that recognizes the interconnected nature of physical function and overall well-being. Research indicates dietary improvements can enhance patients' experience of pleasure, development and maintenance of meaningful social relationships, and strengthened sense of belonging (Namasivayam-MacDonald, Ayub, Najeeb, & Shune, 2022). SWAL-QOL assessment demonstrates robust associations with swallowing function while simultaneously capturing broader clinical and psychosocial influences, including baseline stroke severity, cognitive status, coexisting medical conditions, and contextual social determinants. A comprehensive approach to patient quality of life should extend beyond dysphagia to encompass functional limitations, activity participation, and environmental factors associated with swallowing difficulties. While the current study did not demonstrate statistically

significant between-group differences in swallowing-related quality of life outcomes, further investigation with expanded sample sizes remains necessary to definitively establish the therapeutic efficacy of the AI-VG system for this important patient-reported measure. Future research should adopt a more comprehensive and multidimensional approach to evaluating dysphagia rehabilitation interventions. Proposed assessments would include precise quantitative measurements encompassing multiple physiological domains: detailed oral intake capacity assessments, comprehensive tracking of coughing episodes including frequency and severity, systematic longitudinal monitoring of weight fluctuations, and in-depth nutritional status analyses. By integrating these nuanced parameters, researchers can develop a more holistic understanding of the intricate relationships between biomechanical swallowing gains and their psychosocial sequelae in daily functioning. Such a methodological approach would not only provide deeper insights into intervention efficacy but also potentially uncover subtle interconnections between physiological rehabilitation and patient well-being, ultimately advancing the scientific understanding of dysphagia management strategies.

Future AI-VG system development for swallowing rehabilitation could incorporate additional game levels and enhanced graphics to create more immersive, age-appropriate gaming experiences for diverse patient populations. Implementing adaptive difficulty adjustment based on individual swallowing function capabilities would likely increase patient engagement and motivation (Cler, Mittelman, Braden, Woodnorth, & Stepp, 2017). Video game-based rehabilitation may also promote neuroplasticity in stroke patients by enabling higher intensity practice and increased therapeutic dosage compared to conventional approaches (Bao, Chan, & Merzenich, 2001).

5.4.1 Study limitations

Although this investigation offers important preliminary evidence regarding AI-VG system's applicability for PSD rehabilitation, several critical limitations warrant careful consideration. The research was constrained by site-specific restrictions,

preventing the utilization of the gold standard assessment method, the videofluoroscopic swallow study. Instead, the team relied on well-established assessment scales with demonstrated high sensitivity and specificity in previous research.

The pilot study's limited sample size represents a significant methodological constraint, underscoring the necessity for future large-scale RCTs to comprehensively validate the AI-VG system intervention's effectiveness. Moreover, the research's design focused exclusively on immediate post-intervention outcomes, subsequent investigations should implement planned follow-ups at 3-, 6-, and 12-month intervals to establish the temporal trajectory of therapeutic effects.

The game-based intervention's design itself presented notable limitations. While ingeniously integrating swallowing exercises into an interactive format, the current system incompletely addressed certain critical muscular movements, such as lip rounding and closure. This partial approach potentially compromises the intervention's comprehensive rehabilitation potential.

Moving forward, researchers should prioritize developing a more holistic and sophisticated game system. This enhanced approach would incorporate a broader spectrum of targeted exercises, addressing a wider range of physiological movements and potentially maximizing the intervention's effectiveness in improving swallowing function. Future iterations must strive for a more nuanced, comprehensive rehabilitation strategy that captures the full complexity of dysphagia management. These methodological considerations not only highlight the current study's limitations but also provide a robust roadmap for subsequent research, emphasizing the iterative nature of technological innovation in medical rehabilitation.

5.4.2 Conclusion

This groundbreaking research illuminates the transformative potential of AI-VG system in swallowing function rehabilitation for PSD patients. Beyond merely demonstrating feasibility and efficacy, the study unveils a paradigm shift in therapeutic

approaches to neurological rehabilitation. The AI-VG system methodology emerges not just as an alternative, but as a sophisticated, patient-centered intervention that transcends traditional rehabilitation strategies.

By leveraging advanced technological solutions, this approach addresses critical challenges in dysphagia management. The interactive, gamified rehabilitation platform offers more than conventional methods, providing patients with an engaging, motivational experience that potentially enhances neuroplasticity and motor learning. The system's personalized nature allows for real-time feedback, adaptive difficulty levels, and continuous performance tracking, which are fundamental to effective neurological rehabilitation.

The research suggests that AI-VG system could fundamentally restructure clinical dysphagia management. By transforming monotonous therapeutic exercises into interactive, goal-oriented experiences, the technology simultaneously addresses physical rehabilitation and psychological engagement. Improved patient motivation and compliance emerge as significant ancillary benefits, potentially accelerating recovery trajectories. Moreover, the approach represents a nuanced integration of technological innovation with clinical expertise. It doesn't seek to replace traditional rehabilitation methods but to complement and enhance existing protocols. The potential for more precise, data-driven interventions opens exciting possibilities for personalized medical treatment, where rehabilitation strategies can be continuously refined based on individual patient responses.

As healthcare increasingly embraces digital transformation, AI-VG system stands as a compelling example of how technology can revolutionize patient care, offering hope and improved outcomes for individuals navigating the complex challenges of post-stroke dysphagia rehabilitation.

Chapter 6. Effectiveness of an artificial intelligence-empowered video game system on stroke patients with dysphagia: a randomized controlled trial

6.1 Introduction

This chapter presents a randomized controlled trial (RCT) designed to evaluate the therapeutic efficacy of an artificial intelligence-empowered video game (AI-VG) system for post-stroke dysphagia (PSD) rehabilitation. The chapter is organized as follows: Section 6.1 provides an overview of introduction, while Section 6.2 details the research methodology in accordance with CONSORT 2010 guidelines. Section 6.3 will report the pilot study's findings, and discussion will be presented at Section 6.4.

The content of this chapter was published (B. Zhang, Wong, Liu, et al., 2025): **Zhang, B.**, Wong, K. P., Liu, M., Hui, V., Guo, C., Liu, Z., Liu, Y., Xiao, Q., & Qin, J. (2025). Effect of artificial intelligence-based video-game system on dysphagia in patients with stroke: A randomized controlled trial. *Clinical nutrition (Edinburgh, Scotland)*, *45*, 81–90. https://doi.org/10.1016/j.clnu.2024.12.022

6.2 Methods

6.2.1 Study aim and objectives

This RCT study had two primary objectives: (1) To evaluate the therapeutic effects of the AI-VG system on swallowing recovery in PSD patients relative to conventional rehabilitation approaches; (2) To evaluate the acceptability and satisfaction of patients using the AI-VG system.

The primary research objectives centered on evaluating the program's efficacy by comparing participant outcomes between the AI-VG system and conventional care approaches after a four-week implementation period. The study methodology involved a comprehensive assessment of multiple outcome measures to thoroughly analyze the intervention's effectiveness:

(1) Swallowing function (primary outcome),

(2) Laryngeal function (secondary outcome),

(3) Oral intake function (secondary outcome),

(4) Nutritional status (secondary outcome), and

(5) Swallowing-related quality of life (secondary outcome).

The research team formulated a primary hypothesis predicting that participants utilizing the AI-VG system would demonstrate significantly greater improvements in swallowing function relative to the control therapy following the 4-week intervention period. More specifically, the study anticipated more pronounced enhancements in several critical domains among the intervention group, including laryngeal functional capacity; oral intake capabilities; nutritional parameters, and swallowing-related quality of life

The secondary research objective focused on comprehensively assessing patient perspectives, specifically examining the acceptability and overall satisfaction with the innovative AI-VG system intervention. To achieve this aim, a set of targeted evaluation objectives were established:

(1) To assess the adherence to AI-VG system and conventional care.

(2) To assess the acceptance to individuals who participate in AI-VG system group.

(3) To assess the satisfaction of participants who participate in AI-VG system group.

6.2.2 Study design

This study was a two-arm, assessor-blinded RCT. This research consisted of an initial 4-week intervention period followed by an additional 4-week follow-up phase. Methodological rigor was ensured through strict adherence to the SPIRT reporting guidelines (Chan et al., 2013). Treatment allocation was computer-generated using R statistical software with a 1:1 allocation ratio. An independent nurse, blinded to baseline assessments and uninvolved in trial delivery, implemented the randomization sequence via sealed opaque envelopes. Participants in the experimental arm completed the AI-VG system rehabilitation, while controls received conventional dysphagia therapy. The

RCT approach was used because it is considered the gold standard among efficacy assessment methods and is capable of generating the highest level of evidence and making well-justified causal inferences (Cartwright, 2007).

The evidence-based parameters for dysphagia rehabilitation dosage established in prior investigations (Chapter 2, Section 2.4.6) informed the determination of optimal intervention duration in the current exercise protocol. The forest plots revealed that interventions lasting 30min per day, 5 days a week, 4 weeks can significantly improve PSD swallowing function, and feeding and daily function.

6.2.3 Sampling

6.2.3.1 Study settings

This study was conducted in a rehabilitation center in Beijing (China). This rehabilitation center is a specialized medical facility equipped with comprehensive rehabilitation equipment and staffed by a professional healthcare team. Patients admitted to this center receive daily care and typically stay for more than two months, which ensures the smooth implementation of the research study. The extended hospitalization period, which can range from two to six months, provides an adequate time window for the complete implementation of the research protocol and follow-up assessments. This long-term inpatient model also helps minimize participant dropout and ensures consistent treatment delivery throughout the study period.

All clinical staff at the rehabilitation center have been properly informed about the study and received appropriate training regarding the research protocols, ensuring standardized care delivery while maintaining the integrity of the RCT design.

6.2.3.2 Participant eligibility criteria

Participants were considered eligible for the study if they met the following comprehensive inclusion criteria: (1) stroke diagnosis was confirmed based on clinical presentation and neuroimaging findings, following the criteria of the AHA/ASA. Neurological confirmation was established through CT or MRI scans (Sacco et al., 2013); (2) dysphagia verified through the Gugging Swallowing Screen (GUSS)

assessment; (3) initial cerebral hemispheric stroke event with a disease progression of less than twelve months; (4) age over than 18; and (5) cognitive functioning assessed as intact, demonstrated by a MMSE score of 24 or higher, with sufficient cognitive capacity to comprehend and execute study instructions accurately.

We deliberately limited enrollment to patients within 12 months of first-ever stroke to minimize heterogeneity from cumulative cerebrovascular injury, and target the neuroplasticity-sensitive recovery period when rehabilitation yields optimal functional gains. The one-year timeframe captures patients beyond the acute phase while still within the period where significant neuroplasticity and recovery potential exist (Dromerick et al., 2021). Our intervention required participants to understand and follow therapeutic instructions. Cognitive impairment could significantly impact a patient's ability to engage in the rehabilitation process, potentially confounding our results.

The exclusion criteria encompassed the following conditions: (1) diagnosed mental disorders or significant cognitive impairments that would compromise study participation; (2) presence of warning indicators suggesting potential cancer or other serious medical conditions necessitating immediate medical intervention. This criterion was developed as a safety measure. Patients requiring urgent medical attention for potentially life-threatening conditions would not be appropriate candidates for a research study and should receive immediate standard medical care; or (3) diagnosed epilepsy or visual limitations that would substantially interfere with the ability to effectively engage with computer-based systems.

Patients with significant cognitive impairments were excluded as they might have difficulty understanding instructions, providing reliable feedback, or engaging consistently with the AI-VG rehabilitation system. This criterion helps ensure that observed outcomes are attributable to the intervention rather than to variations in cognitive ability or comprehension. Given that our intervention utilized AI-VG technology, patients with conditions that could be triggered by screen exposure

(epilepsy) or those unable to adequately perceive the visual components of the intervention (visual impairment) were excluded. This criterion both ensures participant safety and maintains the fidelity of intervention delivery across participants. The exclusion criteria were carefully designed to complement our AI-VG rehabilitation system and incorporated precautionary measures to protect participants from any potential adverse effects associated with AI-VG technology, such as eye strain, motion sickness, or triggering of photosensitive conditions.

Following the comprehensive screening process, eligible patients diagnosed with dysphagia will be formally invited to consultation with the primary investigator. During this meeting, the remaining study details will be thoroughly explained, addressing any outstanding questions, and participants will be requested to provide their written informed consent for study participation.

6.2.3.3 Sampling method

Participants were recruited through convenience sampling, a non-probability selection method. Following ethics approval, the research team organized meetings with the rehabilitation department director, rehabilitation therapists, head nurses, doctor and nursing staff at the rehabilitation center to explain the importance of the study, its procedures, detailed research content, and recruitment process. The collaborative approach ensured all clinical staff understood their roles in identifying potential participants.

Research posters were displayed in strategic locations including outpatient departments, ward lobbies, and rehabilitation therapy rooms to increase awareness of the study. After potential participants were admitted to the hospital, trained nurses conducted cognitive assessments, while rehabilitation therapists performed swallowing function evaluations using the GUSS.

Eligible patients were contacted by research personnel who provided comprehensive study information. Participants submitted written informed consent and

were subsequently randomized into intervention or control groups after baseline data collection.

6.2.3.4 Sample size

Sample size was calculated using the formula for comparing two independent means ($N=2\left[\frac{(t_\alpha+t_\beta)S}{\delta}\right]^2$). A rigorous approach to sample size calculation was essential to ensure adequate statistical power while maintaining feasibility within the clinical setting. The calculation was based on results from our pilot RCT, which provided preliminary data on the effectiveness of the intervention (Karim et al., 2019).

The sample size calculation was based on our pilot RCT data demonstrating a 3.96-point between-group difference in GUSS scores (intervention: 16.79±4.73 vs control: 12.83±6.65), yielding a Cohen's d=0.75 (B. Zhang et al., 2024). This effect size was considered clinically meaningful for patients with post-stroke dysphagia, as it represented substantial improvement in swallowing function. While acknowledging that pilot-based estimates may have wider variability and lower precision, this approach ensured that the calculation was based on data closely aligned with our specific intervention, target population, and study context, thereby supporting methodological relevance while preserving the rigor of randomization in the definitive trial.

Our sample size calculation incorporated both Type I (α) and Type II (β) error rate (Freiman, Chalmers, Smith, & Kuebler, 2019; Schulz & Grimes, 2005). We set α at 0.05, meaning there is a 5% probability of detecting a treatment effect when one does not actually exist. This significance level of 0.05 is widely accepted in clinical research as it provides a reasonable balance between the risks of false positive findings and the ability to detect true treatment effects. We set β at 0.15, corresponding to a statistical power (1-β) of 85%. This means our study has an 85% probability of detecting a true treatment effect of the magnitude specified (Cohen's d = 0.75) if it exists. This power level exceeds the conventional minimum of 80% often used in clinical trials (Tam, Lo, & Woo, 2020), offering greater assurance in detecting clinically meaningful group differences.

Based on a two-sided significance level of 0.05 and a desired power of 85%, the required sample size was calculated to be 32 participants per group. To compensate for potential dropouts, the per-group sample size was augmented by 20% (A. Cook & Sheikh, 2001), yielding a final sample size of 38 per group (76 in total). Calculations were performed using G*Power 3.1 (Faul, Erdfelder, Lang, & Buchner, 2007), a widely accepted tool for statistical power analysis in clinical research.

6.2.4 Randomization and allocation concealment

Participants underwent randomization into two distinct intervention groups (AI-VG system and conventional therapy group). To effectively mitigate selection bias and ensure allocation concealment, a comprehensive randomization procedure was implemented.

To prevent potential selection bias, the randomization procedure was conducted by an independent biostatistician uninvolved in trial recruitment or evaluation. Using R statistical software, the specialist generated a randomized numerical sequence (range: 1-90) which was automatically allocated to either Group 1 (intervention) or Group 2 (control) through the “sample ()” function, ensuring balanced group sizes. Allocation concealment was rigorously maintained using sequentially numbered, opaque, tamper-evident sealed envelopes prepared by an independent research nurse uninvolved in recruitment, assessment, or intervention delivery. These envelopes were numbered sequentially and used to randomly assign participants. Following the acquisition of informed consent and completion of baseline assessments, eligible participants received the subsequent available sequentially numbered envelope, which determined their group assignment based on the enclosed group designation. Critically, the envelope was opened only after the participant had been fully enrolled in the study and completed all preliminary baseline assessments.

6.2.5 Blinding

Given the nature of the intervention, we employed a single-blind study design. Multiple measures were taken to minimize potential bias while acknowledging the practical limitations of blinding in rehabilitation research.

Outcome assessments were conducted by a blinded evaluator with no involvement in treatment administration or statistical analysis. To maintain blinding, several precautions were implemented: (1) all subjects were thoroughly briefed to maintain blinding by withholding treatment group information from outcome evaluators; (2) assessment sessions were scheduled at times when intervention sessions were not occurring to prevent the evaluator from inadvertently observing treatment delivery; and (3) all treatment-related materials were removed from assessment areas prior to evaluation.

Given the technologically distinctive nature of the AI-VG system, neither participants nor treating clinicians could be blinded to group assignment. Participants were inevitably aware of whether they were receiving the AI-VG system therapy or conventional swallowing therapy. Similarly, therapists needed to be aware of which intervention they were delivering to ensure protocol adherence.

6.2.6 Treatment conditions

Participants received the intervention in 30-minute daily sessions, administered 5 times weekly over 4 weeks (a total of 20 sessions per participant). Both the experimental and control groups received their respective interventions according to this standardized schedule. In addition to the group-specific interventions, all participants in both groups received usual care for dysphagia, which included nutritional guidance, posture adjustment training, breathing pattern exercises, cough technique refinement, and thermal-tactile intervention. These usual care components were delivered by the regular rehabilitation staff at the center following standardized protocols to ensure consistency across all participants.

6.2.6.1 Instrumentation

In the pre-study period, an AI-VG system based swallowing exercise system was developed (Chapter 3). The system comprised a computer with a high-definition display screen and a built-in facial recognition camera. This technology was specifically designed to provide an interactive and engaging rehabilitation experience for PSD patients.

The AI-VG system utilized advanced computer vision algorithms to detect and track facial muscle movements. Participants were positioned facing the computer screen and camera at an optimal distance of 50-70 cm to ensure accurate facial recognition. The integrated camera captured real-time video of the participant's face, which was then processed by the AI software.

The facial recognition technology functioned by identifying and tracking key facial landmarks. The system tracked the displacement of these key points to infer the direction of muscle movements. When participants performed prescribed swallowing exercises, the AI algorithm analyzed the displacement vectors of these facial landmarks in real-time, converting these movements into game controls. This created an intuitive biofeedback mechanism where appropriate muscle activation and movement patterns directly controlled game elements on the screen.

6.2.6.2 Intervention group

Swallowing function training was delivered to the intervention group via the AI-VG system. Each session began with a setup phase where participants were seated in a comfortable, upright position in a chair positioned 50-70 cm from the computer screen. The system was calibrated to recognize the participant's facial features and establish baseline parameters for muscle movement detection. During the main training phase, participants engaged with the video game interface, which presented three games requiring specific swallowing-related muscle movements, including lip exercises, tongue exercise, and chin tuck against resistance. Real-time facial muscle changes were captured by the system and translated into game commands. the AI-VG system inferred

muscle movement directions by tracking the displacement of key facial landmark points, providing immediate visual feedback through the game interface.

6.2.6.3 Control group

Control group participants underwent traditional swallowing function training comprising three primary intervention components. The lip training tasks consisted of mouth opening, mouth closing, and cheek drumming on both sides and individually. The tongue exercises incorporated targeted movements including tongue extension, upward tongue positioning, downward tongue positioning, leftward tongue movement, and rightward tongue movement. Each specific movement was performed for a duration of 2-3 seconds and repeated 15 times before transitioning to the subsequent movement. The chin tuck resistance technique required participants to maintain their head in the lowest possible position while compressing a neck-placed rubber ball for 2-3 seconds, with this action repeated 15 times. These conventional exercises targeted the same muscle groups as the AI-VG system intervention but utilized traditional therapeutic approaches rather than technological assistance.

Both interventions were designed to improve swallowing function by targeting the same underlying musculature. The key difference was the method of delivery: technology-assisted game-based approach for the intervention group versus conventional exercise-based approach for the control group. In the intervention group, participants were instructed by a therapist during the first week on how to use the AI-VG system. For the following three weeks, they performed the training independently using the system, accompanied by a nurse whose role was limited to answering questions related to system operation. In the control group, participants were taught the swallowing rehabilitation exercises by a therapist during the first week, after which they completed the exercises independently for three weeks, with a nurse reminding them daily to perform their training.

Table 6.1 provides a detailed comparative overview of the therapeutic protocols implemented in both the experimental and control arms, highlighting key procedural

commonalities and distinctions. **Table 6.2** provides a detailed description of the treatment schedules for the experimental and control groups.

Table 6.1 Comparison of intervention and control groups

	Intervention group	Control group	Difference	Similar
Content	Lip exercise, tongue exercise, chin tuck against resistance	Lip exercise, tongue exercise, chin tuck against resistance		√
Interventionist	Research investigator	Nurse	√	
Method of delivery	Artificial intelligence-empowered video game system	Face to face mentoring	√	
Training length	30min	30min		√
Frequency	30min/d, 5d/w, 4 weeks	30min/d, 5d/w, 4 weeks		√
Venue	Rehabilitation center patient's own ward	Rehabilitation center patient's own ward		√
Concomitant care	Daily feeding education, position training, breathing control exercises, cough technique improvement, and thermal tactile stimulation	Daily feeding education, position training, breathing control exercises, cough technique improvement, and thermal tactile stimulation		√

Table 6.2 The treatment schedules for experimental and control groups

Week	Intervention group	Control group
Week 1	Therapist-guided familiarization with the AI-VG system	Therapist-guided practice of lip, tongue, and jaw (chin tuck) movements
Week 2	Independent training using the AI-VG system, focusing on accuracy and correct movement patterns	Independent practice, focusing on accurate repetition of each movement
Week 3	Independent training with increased game challenge and feedback to enhance coordination and endurance	Independent practice with emphasis on endurance and smooth movement transitions
Week 4	Independent integrated practice	Independent integrated practice
Week 8	Post-intervention follow-up assessments	Post-intervention follow-up assessments

6.2.7 Data collection methods and procedures

Data was collected at three points: baseline (T0), week 4 (T1), and week 8 (T2). The research investigator initially briefed potential participants on study details and assessed their eligibility. Following the acquisition of written informed consent and verification of inclusion criteria, a blinded evaluator collected participants' baseline data (T0) before intervention commencement. The same outcome measures were administered again at T1 and T2 following the intervention. **Table 6.2** outlines the data collection procedures at each time point in detail.

Table 6.3 Data collection process

Outcome	Baseline (T0)	Week 4 (T1)	Week 8 (T2)
Participant information sheet (Appendix 2, 4)	√		
Informed consent (Appendix 3,5)	√		
Cognitive assessment (Appendix 7)	√		
Gugging Swallowing Screen (Appendix 7,8)	√	√	√
The volume-viscosity swallow test (Appendix 7,8)	√	√	√
Standardized swallowing assessment (Appendix 7,8)	√	√	√
The Functional Oral Intake Scale (Appendix 7,8)	√	√	√
The Swallowing Quality of Life (Appendix 7,8)	√	√	√
Mini Nutritional Assessment Short Form (Appendix 7,8	√	√	√
Acceptance questionnaire (Appendix 7,8)		√	
Satisfied questionnaire (Appendix 7,8)		√	
Adherence (Appendix 7,8)		√	

During baseline data collection (T0), the researcher provided a comprehensive overview of the study protocols to potential participants. After obtaining written informed consent from those willing to join, the research team conducted eligibility screening based on predetermined criteria. Qualified individuals then completed

baseline measurement data, including sociodemographic characteristics, swallowing function, nutritional status, and swallowing-related quality of life. These baseline data were an important reference point for subsequent comparative analyses throughout the intervention period.

For week 4 data collection (T1), post-intervention outcomes will be assessed within three days of completing the training. Additionally, intervention group patients will evaluate the AI-VG system's acceptance and satisfaction.

For Week 8 data collection (T2), participants who remain hospitalized were assessed for short-term efficacy within 3 days of arriving at Week 8, and those discharged from the hospital were notified by phone to return to the rehabilitation center for assessment two days prior to the data collection date.

Paper-based scales were exclusively utilized throughout the assessment process to ensure standardization and accessibility for all participants. A speech therapist, who remained blinded to the participant allocation, conducted comprehensive evaluations of all patients and completed the scales accordingly. This blinding procedure was crucial to minimizing potential assessment bias that might influence the reliability of our findings. The speech therapist had extensive clinical experience and received specialized training in administering the specific assessment tools employed in this study to ensure consistency in evaluation methods.

To maintain data integrity, a nurse who independent from recruitment, intervention, and assessment procedures performed the data entry tasks, transferring all information from paper scales into Excel sheet. Additionally, a second independent nurse conducted thorough verification of all entered data to ensure accuracy and reliability, comparing each digital entry against the original paper records. This double-checking protocol helped identify and rectify any potential discrepancies before final analysis.

6.2.8 Outcome measures

6.2.8.1 Primary outcomes

This study evaluated swallowing function using the Gugging Swallowing Screen (GUSS).

The GUSS systematically evaluates the patient's swallowing function through a series of structured tests involving water and substances of varying consistencies, where higher scores correlate with enhanced swallowing abilities and improved functional outcomes (M. Trapl et al., 2007). The assessment is organized into two distinct sections: a preliminary indirect swallowing test (Part 1) that evaluates vigilance, voluntary coughing, and saliva swallowing; and three direct swallowing subtests (Part 2) that progressively challenge the patient with semisolid food, liquid, and solid food. These four sequential subtests each have a maximum score of 5 points, requiring full marks to advance to more challenging consistencies. This stepwise approach prioritizes patient safety while providing detailed functional information. Failing to achieve 5 points in any subtest stops the examination immediately.

The maximum total score achievable on the GUSS is 20, indicating normal swallowing function without aspiration risk, while lower scores reflect varying degrees of dysphagia severity with corresponding dietary recommendations. Scores ranging from 0 to 9 indicate severe dysphagia with a high risk of aspiration, 10 to 14 reflect moderate dysphagia with moderate risk, 15 to 19 correspond to mild dysphagia with low risk, and a score of 20 indicates normal swallowing function. Among the various assessment tools available for post-stroke dysphagia (PSD), the GUSS has proven particularly effective in clinical settings, showing high sensitivity (0.97) and moderate specificity (0.67) in identifying swallowing impairments (E. Boaden et al., 2021), making it highly reliable for detecting patients at risk of aspiration while minimizing false negatives.

6.2.8.2 Secondary outcomes

(1) The Standard Swallowing Assessment (SSA)

The Standard Swallowing Assessment (SSA) is a comprehensive clinical tool to evaluate both laryngeal and pharyngeal function in patients with suspected dysphagia

(Liang et al., 2021). The SSA incorporates both observational components and direct swallowing trials to thoroughly assess swallowing capabilities. During evaluation, speech therapist observes factors such as alertness, postural control, respiratory patterns, oral motor function, and voluntary cough strength. This is followed by controlled swallowing trials with water to detect any signs of impaired swallowing such as coughing, choking, voice changes, or delayed swallow initiation (L. Perry, 2001).

The SSA scale generates scores ranging from 18 to 46 points, with the scoring system designed to reflect the severity of swallowing dysfunction. Higher scores on this assessment indicate more serious subjective dysphagia symptoms and greater functional impairment (Liang et al., 2021). The comprehensive nature of this assessment allows clinicians to develop targeted intervention strategies based on specific areas of deficit identified during evaluation.

(2) The Functional Oral Intake Scale (FOIS)

The Functional Oral Intake Scale (FOIS) assessed the degree of oral intake for both solids and liquids. This validated clinical measure consists of a seven-level hierarchical scale that systematically categorizes patients based on their ability to consume various consistencies and quantities orally (M. A. Crary et al., 2005).

The FOIS classification system ranges from level 1, indicating complete dependence on non-oral feeding with no oral intake, to level 7, representing total oral intake with no restrictions (H. Zhou, Zhu, & Zhang, 2017). Higher scores on the FOIS correspond directly to better oral intake functionality and greater dietary independence. The scale's systematic approach provides clinicians with objective data to guide nutritional management decisions and helps document meaningful functional improvements in swallowing capabilities that directly impact patients' quality of life and nutritional status (Aoyagi et al., 2021).

(3) The Volume-Viscosity Swallowing Test (VVST)

The Volume-Viscosity Swallowing Test (VVST) represents a significant advancement in dysphagia screening methodology, distinguished by its systematic

approach to evaluating swallowing function across precisely controlled food parameters. Unlike other assessment tools, VVST uniquely focuses on testing swallowing safety and efficiency across different bolus volumes and viscosities, offering a more refined and specific evaluation protocol.

The VVST is a well-validated dysphagia screening instrument demonstrating robust diagnostic accuracy across multiple studies. Research by Guillén-Solà et al. (2013) (Guillén-Solà et al., 2013) demonstrated its exhibits good diagnostic accuracy, with sensitivity ranging from 84.2% to 88.2% and specificity between 64.7% and 81.0% in detecting swallowing safety impairments. Subsequent investigations revealed even higher sensitivity (88.2-100%) for aspiration detection, though with more variable specificity (28-71.4%), while penetration identification showed moderate sensitivity (34.3-83.7%) and consistent specificity (64.7-70.6%) (Rofes et al., 2014). For swallowing efficacy assessment, recent data indicates balanced sensitivity (79%) and specificity (75%) metrics (Riera et al., 2021).

VVST's methodological involves a systematic progression through three distinct viscosities (liquid, nectar, and pudding) combined with incremental bolus volume administration (5, 10, and 20 mL), with immediate progression to higher viscosity if safety issues occur (coughing, wet voice, or ≥3% oxygen desaturation) (Rofes et al., 2014). A positive VVST result indicates failure to reach maximum bolus volume in any viscosity category.

(4) The swallowing quality of life (SWAL-QOL)

The Swallowing Quality of Life (SWAL-QOL) instrument represents a psychometrically validated, multidimensional assessment tool comprising 10 subdomains that evaluate dysphagia-related quality of life impacts across physical, psychological, and social functioning parameters. These clinically relevant dimensions include food selection, burden, mental health, social functioning, fear, eating duration, eating desire, communication, sleep, and fatigue. Additionally, it includes a separate symptom scale comprising 14 items that evaluate the frequency and severity of specific

dysphagia symptoms. The SWAL-QOL instrument utilizes a five-point Likert scale for all items, where numerically lower responses correspond to more severe dysphagia-related quality of life limitations (D. Y. Kim et al., 2020). The questionnaire takes approximately 15-20 minutes to complete, making it practical for clinical settings while still capturing comprehensive data.

The SWAL-QOL offers unique value as a patient-centered instrument that captures dysphagia's subjective burden, complementing physiological measures by revealing functional and psychosocial impacts often undetected by clinical assessments alone (D. Y. Kim et al., 2020). The instrument exhibits robust psychometric characteristics, with subscale Cronbach's α coefficients of 0.79-0.95 indicating high internal consistency, established test-retest reliability, and demonstrated responsiveness to clinical improvement (C. A. McHorney et al., 2002).

(5) Mini Nutritional Assessment Short Form (MNA-SF)

The Mini Nutritional Assessment Short Form (MNA-SF) was employed to evaluate the nutritional status of dysphagia patients. This validated screening instrument is routinely employed in clinical settings for efficient detection of existing or impending malnutrition. The MNA-SF has demonstrated high sensitivity of 85.2%-89.3% and specificity of 81.8%-94.3% in detecting nutritional deficiencies across various patient populations (Dent, Hoogendijk, Visvanathan, & Wright, 2019).

The MNA-SF evaluates six essential nutritional domains: (1) recent dietary intake reduction, (2) body weight changes, (3) physical mobility status, (4) acute disease or psychological distress, (5) cognitive or neurological impairments, and (6) anthropometric measurements (BMI or calf circumference). Each component is scored, with a cumulative score ranging from 0 to 14 points. Patients scoring 12-14 points are classified as having normal nutritional status, 8-11 suggests malnutrition risk, and 0-7 signifies malnutrition. (Lera, Sánchez, Ángel, & Albala, 2016).

Research has demonstrated that combining MNA-SF with BMI measurements significantly enhances the assessment's accuracy in detecting malnutrition (Martín et

al., 2016). This combined approach provides a more comprehensive nutritional evaluation by incorporating both screening results and anthropometric measurements, allowing for more precise identification of patients requiring nutritional intervention. The integration of these complementary metrics offers clinicians valuable information for developing targeted nutritional support strategies for dysphagia patients.

(6) The acceptance survey questionnaire

The acceptance survey questionnaire was developed through a comprehensive process of literature review and expert consultation, undergoing multiple iterations. The instrument comprised two primary sections: ① **Basic information** encompassing demographic and health-related data such as age, gender, occupation, and medical condition; ② **Acceptance of AI-VG system**: the widely used Technology Acceptance Model (TAM) as a theoretical model (Strudwick, 2015), seven dimensions of perceived usefulness, perceived ease of use, perceived ease of learning, perceived applicability, perceived safety, perceived satisfaction, and intension to use. The seven dimensions of technology acceptance were systematically evaluated through the questionnaire. Perceived usefulness assessed participants' beliefs about the AI-VG system's effectiveness in improving swallowing function, while perceived ease of use measured how intuitive and effortless they found the system to operate. Perceived ease of learning examined how readily participants could acquire the necessary skills to use the system effectively. Perceived applicability gauged participants' assessment of the AI-VG system's relevance to their specific condition and rehabilitation needs. Perceived safety investigated participants' confidence in the AI-VG system's safety during implementation. Perceived satisfaction evaluated overall contentment with the experience of using the AI-VG system. Finally, intention to use measured participants' willingness to adopt the technology for ongoing rehabilitation.

Five questionnaire items assess each dimension using a standardized Likert scale with extreme anchors (1=strongly disagree; 5=strongly agree), the Cronbach's α for the acceptability component was 0.983. The self-administered questionnaire used in

this section was reviewed by four experts, and the overall questionnaire had a content validity index of 0.967. The questionnaires were all paper-based and were filled in anonymously.

(7) The satisfaction questionnaire

The satisfaction assessment tool was systematically designed based on an extensive review of existing literature, incorporating 15 items organized into three specific domains: (1) training content characteristics, (2) training format features, and (3) personal user experience. Responses were quantified using a 5-point Likert scale (ranging from 1 = “strongly disagree” to 5 = “strongly agree”), where elevated scores corresponded to greater user satisfaction with the AI-VG rehabilitation system. The self-administered questionnaire used in this section was reviewed by four experts, and the overall questionnaire had a content validity index of 0.973.

(8) Adherence

Adherence was measured by tracking patients’ completion of swallowing function training. The researcher documented the number of sessions completed. Adherence was categorized as follows: good adherence was defined as completing more than 80% of prescribed training sessions; average adherence represented 50% to 80% session completion; and poor adherence was characterized by less than 50% session completion. Training was considered complete when patients successfully participated in more than 10 training sessions (Essery et al., 2017).

In the control group, participants were instructed in conventional swallowing exercises by a therapist during the first week. For the subsequent three weeks, they practiced independently in their ward and documented each session in a paper diary, which was later collected by the research team. In the intervention group, the same training schedule was applied. However, after receiving instruction on how to use the AI-VG system in the first week, participants completed the remaining three weeks of exercises with the system. Session frequency and duration were automatically recorded

via the system's backend, providing objective adherence data without reliance on self-report.

(9) Demographic information

Baseline demographic characteristics (age, gender, occupation, marital status, residence, and comorbidities) were systematically collected prior to randomization, enabling intergroup comparability analysis and evaluation of population generalizability. The details are presented in Appendix 6.

6.2.9 Assessment of the study process

Beyond outcome assessment, it is crucial to examine how methodological aspects potentially shaped the study results (Begun, Berger, & Otto-Salaj, 2018). Key process indicators worthy of evaluation include enrollment strategies, intervention delivery methods, and follow-up completion rates. Analyzing recruitment patterns and participant retention insights regarding selection criteria appropriateness and engagement enhancement techniques (S. C. Cook, Godiwalla, Brooks, Powers, & John, 2015). Implementation consistency assessments help clarify actual intervention exposure across participants. Follow-up completion rates can illuminate participant engagement patterns, identify potential barriers to continued participation, and help researchers determine whether study findings represent the entire enrolled population or a potentially biased subset (Bhide, Shah, & Acharya, 2018). These metrics provide critical context for interpreting treatment effects, especially when differential attrition occurs between intervention groups.

6.2.9.1 Recruitment and retention rate

Enrollment efficiency is reflected through recruitment rates, which demonstrate a study's capacity to attract an adequate participant pool. Retention rates serve as indicators of a study's ability to maintain participant involvement throughout its duration (Lamberti et al., 2021). Recruitment rate was calculated by dividing the number of enrolled participants by the total number of eligible individuals identified. Retention rate referred to the proportion of initially enrolled participants who completed

each follow-up assessment (Bremer & Sarker, 2023). When participants declined to participate, we attempted to document their reasons for refusal to better understand potential barriers to enrollment.

6.2.9.2 Implementation of fidelity

Implementation of fidelity refers to whether interventions are conducted according to the planned protocol. Implementation fidelity encompasses protocol adherence, interventionist competence, and intervention context (Hasson, 2010). Carroll et al. (2007) (Carroll et al., 2007) defined protocol adherence as compliance with prescribed content, coverage, frequency, and duration. In the present study, content refers to the information delivered to participants through the AI-VG system and rehabilitation nurses. Coverage refers to the various communication modalities available for information dissemination to participants: the AI-VG system and rehabilitation nurses. Frequency refers to the rhythm of rehabilitation, while duration indicates the time spent on rehabilitation. Swallowing rehabilitation training in the intervention group was documented through screenshots recorded in the AI-VG system backend. An independent rehabilitation nurse conducted fidelity assessments using standardized evaluation forms to verify protocol adherence during training sessions, while also documenting mean health education duration.

6.2.10 Ethical considerations

The study received ethical approval from the Institutional Review Board of The Hong Kong Polytechnic University (Approval No. HSEARS20230502007) and the Ethics Review Committee of Beijing Xiaotangshan Hospital (Approval No. LS20230720-1). The research was registered on ClinicalTrials.gov under the identifier NCT05978700. Prior to participation, all patients provided written informed consent. Consistent with ethical standards for human subject research, the study was conducted in accordance with the World Medical Association's Declaration of Helsinki (2025) (Association, 2025). The Declaration emphasizes that participant health must take

precedence over all other considerations, and researchers bear responsibility for protecting participants' health, rights, and safety.

6.2.10.1 Autonomy

Individuals meeting the selection criteria maintained their right to choose whether to participate in the study. All potential participants were given adequate time to consider participation and were free to withdraw at any time. To ensure informed decision-making, cognitive function was screened using the MMSE (Cockrell & Folstein, 2002). This screening procedure protected vulnerable populations by preventing individuals with potential cognitive limitations from unknowingly participating in the research.

6.2.10.2 Beneficence

Eligible participants received a comprehensive information sheet (**Appendices 2 and 4**) outlining the study objectives and methodological procedures. The trained nurse verbally explained the study details to each potential participant. All participants provided written informed consent prior to enrollment (**Appendix 3** and **Appendix 5**) in duplicate, with one copy retained by the participant and the other by the research team. Participants were encouraged to ask any health-related questions throughout their involvement in the study, including during the exercise sessions, at the week 4 (T1) and week 8 (T2) data collection points, or at any other time during the intervention period.

6.2.10.3 Non-maleficence

Grounded in evidence-based nursing, the intervention was reviewed by dysphagia nursing experts to ensure the relevance and suitability of its training content. Both the intervention and assessment procedures were non-invasive, eliminating the possibility of causing harm to participants. The interventions were delivered by qualified nurses who adhered to professional nursing ethical standards. Research investigators continuously monitored the study progress to ensure participant safety. After each intervention session, participants were specifically asked about their condition and

whether they experienced any discomfort, allowing for immediate identification and addressing of any potential adverse effects.

The occurrence, severity, outcome and relevance to the intervention of the adverse event will be recorded. If GUSS or FOIS assessments indicate a decline in swallowing function or intake ability at any assessment point, our protocol includes immediate safety measures. Research investigator will promptly alert the participant's managing healthcare team through a standardized notification procedure. Specifically, a decline of ≥5 points on GUSS (M. Trapl et al., 2007) or ≥1 level on FOIS (M. A. Crary et al., 2005) from the previous assessment will trigger clinical review. The managing speech-language pathologist and/or medical team will be notified within 24 hours to evaluate the participant and implement appropriate clinical interventions as needed. This safety monitoring procedure ensures timely clinical response to any deterioration in swallowing function and maintains participant safety throughout the study period.

6.2.10.4 Justice

To maintain methodological rigor, the intervention protocol was carefully designed. Participants in both groups received equivalent intervention dosages, ensuring comparable treatment exposure across study groups, the control group received the same intervention except AI-VG system. To compensate for their time, each participant received a vapor eye mask at T2.

6.2.10.5 Confidentiality

Participant information was collected in acoustically isolated private spaces to ensure data protection, with signed consent materials kept in access-controlled filing. To protect participant identities, questionnaires-maintained anonymity by using the first initials of participants' names as identification codes, with no personal identification information collected on the questionnaires themselves. Following group assignment disclosure, the principal investigator recorded participants' identifying information in a password-protected, encrypted Excel database accessible only to the research team.

6.2.11 Data management

Data collection utilized paper-based questionnaires with protocols ensuring all questions were answered, thereby eliminating missing values. Following the assessment of participant outcome measures by a blinded speech therapist, two nurses not involved in the research study transcribed all paper questionnaires into Excel spreadsheets. This data was subsequently imported into the SPSS for coding and statistical analysis. This systematic approach to data management-maintained data integrity while preserving the blinding protocols established for outcome assessment.

6.2.12 Statistical analyses

All analyses were performed using IBM SPSS Statistics 29.0, employing a threshold of $P<0.05$ for statistical significance evaluation.

6.2.12.1 Intention-to-treat principle

Statistical analyses adhered to the intention-to-treat (ITT) approach to preserve the benefits of randomization and reduce bias. All participants initially randomized were analyzed in their assigned groups, irrespective of any protocol deviations, non-compliance, or dropout. Missing data due to participant withdrawal or loss to follow-up were imputed using the last observation carried forward method (Hollis & Campbell, 1999).

The ITT approach was employed as it represents the gold standard for RCT analysis, preserving the randomization scheme and providing conservative effect estimates (Elkins & Moseley, 2015). First, ITT analysis preserves the prognostic balance between treatment groups achieved through randomization, thereby maintaining internal validity. Second, this approach yields clinically meaningful effect estimates that reflect real-world therapeutic utility, accounting for typical adherence patterns observed in routine practice settings. Third, it protects against potential selection bias that could occur if only completers or adherents were analyzed, as these participants might differ systematically from those who dropped out or had poor adherence (Flecha, de Oliveira, Marques, & Gonçalves, 2016).

6.2.12.2 Statistical analysis of the baseline demographics and outcomes

Baseline characteristics and outcome measures were analyzed using descriptive statistics. Normality testing was conducted on all continuous data, with nonparametric tests employed for non-normally distributed datasets. Normally distributed data were expressed as mean ± SD, while nonparametric variables were summarized as median (IQR). Nominal data, such as patient gender and marital status, were described using absolute numbers and percentages, as illustrated in **Table 6.3**.

6.2.12.2 Statistical analysis for baseline characteristic homogeneity test

Group differences in demographic variables and outcome measures were compared at baseline to validate randomization effectiveness. The Shapiro-Wilk test assessed normality for ordinal and ratio variables. Between-group comparisons of continuous variables employed independent samples t-tests for normally distributed data and Mann-Whitney U tests for nonparametric distributions. Nominal variables were examined through chi-square (χ^2) tests to assess proportional group differences (Hess & Hess, 2017). **Table 6.4** presents a comprehensive overview of the specific statistical analysis methods applied to each study variable.

6.2.12.3 Statistical analysis for the feasibility outcomes

Recruitment efficiency, participant retention, and attrition patterns were analyzed through descriptive statistical methods, reporting raw participant counts alongside their percentage equivalents. Median and interquartile range were used to indicate adherence in both groups, and acceptance and satisfaction in the intervention group.

6.2.12.4 Statistical analysis of the intervention efficacy outcomes

Longitudinal changes in outcomes were analyzed using generalized estimating equations (GEE) to assess: (1) between-group differences at follow-up timepoints (T1, T2) versus baseline (T0), and (2) temporal trends across measurement intervals (da Silva, Colosimo, & Demarqui, 2019).

The selection of GEE as our primary analytical approach was based on several methodological strengths particularly relevant to our study design. GEE provides a robust framework for analyzing longitudinal data with repeated measurements,

allowing us to account for within-subject correlation across multiple time points (M. Wang, 2014). Unlike traditional repeated-measures ANOVA, GEE does not require the strict assumption of normality for dependent variables or sphericity for the covariance matrix, providing greater flexibility for analyzing clinical outcome measures that frequently deviate from normal distributions (de Melo, Daldegan‐Bueno, Menezes Oliveira, & de Souza, 2022).

A key advantage of GEE for our study was its ability to model time as a factor while simultaneously examining group-by-time interactions, enabling us to determine both whether outcomes changed significantly over time and whether these changes differed between intervention and control groups (Wilson, Lorenz, Wilson, & Lorenz, 2015). Furthermore, GEE is relatively robust to misspecification of the correlation structure, providing valid inference even when the working correlation matrix is incorrectly specified, which enhances the reliability of our findings. Finally, GEE yields population-averaged estimates that directly address our research question regarding the average effect of the intervention across the study population, rather than subject-specific effects, thereby providing clinically relevant interpretations of treatment efficacy (Preisser, Young, Zaccaro, & Wolfson, 2003).

6.2.12.4 Sensitivity Analysis

To evaluate the robustness of the research findings, this study employed Per-Protocol (PP) analysis as a key component of the sensitivity analysis approach. Unlike the primary ITT analysis which includes all randomized participants regardless of protocol adherence, PP analysis exclusively focuses on participants who fully complied with the study protocol, thereby excluding those who withdrew prematurely or significantly deviated from the prescribed interventions (Molero-Calafell, Burón, Castells, & Porta, 2024).

PP analysis allows for the assessment of treatment efficacy under ideal conditions of compliance, providing valuable insights into the biological or mechanistic effects of the intervention when administered as intended (Le-Rademacher, Gunn, Yao, & Schaid,

2023). This “explanatory” perspective complements the more pragmatic view offered by the ITT analysis, which reflects the real-world effectiveness of the intervention policy. Comparing the results from both analytical approaches enables a comprehensive examination of the consistency and reliability of the study results under different analytic assumptions. The concordance or discrepancy between ITT and PP results can reveal important information about the impact of protocol non-adherence on treatment outcomes (Tripepi, Chesnaye, Dekker, Zoccali, & Jager, 2020). If the two analytic approaches yield similar conclusions, this would enhance the credibility of our findings; otherwise, meaningful differences between the two analytic approaches could highlight key factors related to implementation challenges, participant engagement, or differential effects between adherence subgroups. This dual-analytic framework strengthens methodological robustness by combining parametric and nonparametric approaches, thereby increasing confidence in the intervention effect estimates.

Table 6.4 Statistical analysis methods of different outcomes

Outcomes	Data Analysis Approaches	Details of Outcomes
Baseline characteristics of demographics and outcomes of interest	Descriptive statistics	Outcomes in this study
Ordinal data or ratio (continuous) data, normal distribution	Mean, standard deviation	- Post-stroke dysphagia patients: Disease duration, age - Outcome of interest: Swallowing Quality-of-Life Questionnaire (SWAL-QOL)
Ordinal data or ratio (continuous) data, non-normal distribution	Median, interquartile range	- Outcome of interest: Gugging Swallowing Screen (GUSS), Standard Swallowing Assessment (SSA), Functional Oral Intake Scale (FOIS), The Volume-Viscosity Swallowing Test (VVST), Mini-Nutritional Assessment Short Form (MNA-SF)
Nominal data	Absolute number and percentage	- Post-stroke dysphagia patients: Diagnosis, gender, occupation, marital, residence, smoking history, drinking history, hypertension, diabetes, coronary

		heart disease, hyperlipidemia, gastroesophageal reflux disease
Homogeneity test of baseline characteristics	Statistical inference	Outcomes in this study
Ordinal data or ratio (continuous) data, normal distribution	Independents t-test	- Post-stroke dysphagia patients: Disease duration, age - Outcome of interest: SWAL-QOL
Ordinal data or ratio (continuous) data, non-normal distribution	Mann Whitney U test	- Outcome of interest: GUSS, SSA, FOIS, VVST, MNA-SF
Nominal (categorical) data	Chi-square	- Post-stroke dysphagia patients: Diagnosis, gender, occupation type, marital status, residence, smoking history, drinking history, hypertension, diabetes, coronary heart disease, hyperlipidemia, gastroesophageal reflux disease
Feasibility outcomes	Descriptive statistics	Outcomes in this study
Numeric variable	Absolute number and percentage	- The recruitment rate, retention rate and attrition rate

Ordinal data or ratio (continuous) data, non-normal distribution	Median, interquartile range, Mann-Whitney U test	- Adherence - Acceptability - Satisfaction
Efficacy outcomes	Statistical inference	Outcome in this study
Ordinal data or ratio (continuous) data	Standard Generalized Estimating Equation	- Outcome of interest: GUSS, SSA, FOIS, VVST, MNA-SF, SWAL-QOL

6.3 Results

6.3.1 Subject Recruitment and Dropouts

From October 2023 to July 2024, potential participants were recruited from a Beijing rehabilitation center through dual channels: clinician referrals and self-enrollment via study posters (featuring QR codes) displayed in wards and outpatient clinics. Screening against predefined eligibility criteria identified 102 PSD patients (89 referred by healthcare providers, 13 self-enrolled), of whom 95 met inclusion criteria. Eleven eligible candidates (11.6%) declined participation due to disinterest.

Following informed consent and baseline assessments, the remaining 84 participants were randomized equally (n=42 per group) using a computer-generated allocation sequence. There were 42 participants in each group. One participant (2.3%) of the intervention group lost contact at the post-intervention investigation (Discharged from the hospital and not answering the phone, resulting unavailable). Two participants (4.8%) of the conventional group dropped out at week 2 (one of them discharged from the hospital; on was too tired to complete the exercise). Following the CONSORT guideline, **Figure 6.1** shows the recruitment and drop-out of the participants in this study.

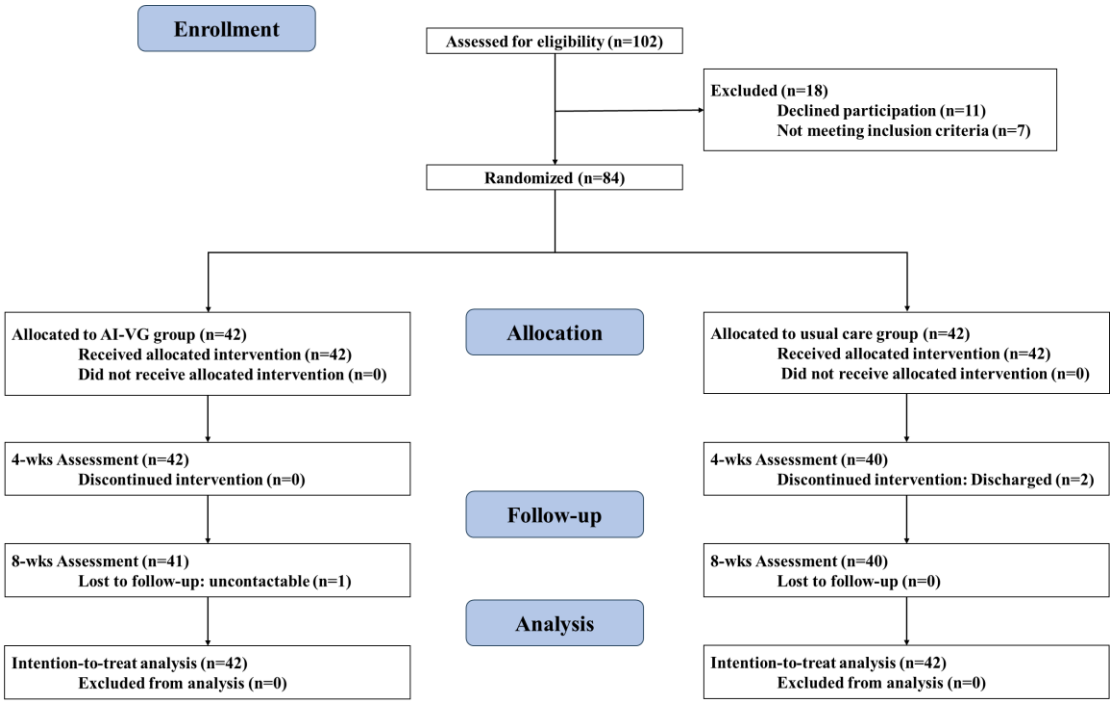


Figure 6.1 CONSORT Flowchart

6.3.2 Baseline Characteristics

6.3.2.1 Demographics of participants at baseline

Tabel 6.5 shows the demographic of the PSD participants involved in this study. Most patients with PSD were diagnosed with ischemic stroke (69/84, 82.1%). The study participants had a mean age of 65.70 years, with a SD of 11.48. Participants were randomly divided into two groups: the AI-VG system group, consisting of 42 patients with a male representation of 57.1% and a mean age of 64.98±9.66 years, and the conventional group, comprising 42 patients with 69.0% male participants and a mean age of 66.43±13.12 years. The mean disease duration is 1.72 (SD=1.50) months. Most participants were retired (56/84, 66.7%), while 27.4% of them were still working (23/84). 89.3% PSD patients were married (75/84), and 61.9% participants were living in rural/suburban areas (52/84). 33.3% (28/84), and 28.6% (24/84) of the participants had a history of smoking and alcohol consumption, respectively. Hypertension was the most prevalent condition, affecting 81.0% (68/84) of the participants, followed by diabetes with 50.0% (42/84). Hyperlipidemia was observed in 35.7% (30/84) of participants, while coronary heart disease and gastroesophageal reflux disease each affected 19.0% (16/84) of the cohort.

Tabel 6.5 Demographic data of the participants by group assignment (n=84)

Variables		Total (n=84, %)	AI-VG group (n=42, %)	Conventional group (n=42, %)	t/Z/χ^2	P-Value
Diagnosis	Ischemic Stroke	69 (82.1)	35 (83.3)	34 (81.0)	0.081	0.776
	Hemorrhagic Stroke	15 (17.9)	7 (16.7)	8 (19.0)		
Disease duration (months)	Mean ± SD	1.72±1.50	1.67±1.48	1.76±1.53	-0.283	0.778
Gender	Male	53 (63.1)	24 (57.1)	29 (69.0)	1.278	0.258
	Female	31 (36.9)	18 (42.9)	13 (31.0)		
Age (years)	Mean ± SD	65.70±11.48	64.98±9.66	66.43±13.12	-0.578	0.565
Occupation type	Mainly mental work	9 (10.7)	5 (11.9)	4 (9.5)	3.260	0.515
	Mainly physical work	5 (6.0)	4 (9.5)	1 (2.4)		
	Part mental, part physical	9 (10.7)	3 (7.1)	6 (14.3)		
	Unemployed	5 (6.0)	2 (4.8)	3 (7.1)		
	Retirement	56 (66.7)	28 (66.7)	28 (66.7)		
Marital status	Married	75 (89.3)	39 (92.9)	36 (85.7)	4.959	0.175
	Widowhood	3 (3.6)	0 (0.0)	3 (7.1)		
	Divorced	3 (3.6)	2 (4.8)	1 (2.4)		
	Unmarried	3 (3.6)	1 (2.4)	2 (4.8)		
Residence	Rural/suburban	52 (61.9)	28 (66.7)	24 (57.1)	0.808	0.369
	Towns/urban	32 (38.1)	14 (33.3)	18 (42.9)		
Smoking history		28 (33.3)	14 (33.3)	14 (33.3)	0.000	1.000
Drinking history		24 (28.6)	11 (26.2)	13 (31.0)	0.233	0.629
Hypertension		68 (81.0)	32 (76.2)	36 (85.7)	1.235	0.266
Diabetes		42 (50.0)	21 (50.0)	21 (50.0)	0.000	1.000
Coronary heart disease		16 (19.0)	7 (16.7)	9 (21.4)	0.309	0.578
Hyperlipidemia		30 (35.7)	15 (35.7)	15 (35.7)	0.000	1.000
Gastroesophageal reflux disease		16 (19.0)	8 (19.0)	8 (19.0)	0.000	1.000

6.3.2.2 The outcome of interest at baseline

Table 6.6 shows the scores of the primary (GUSS) and secondary outcomes (SSA, FOIS, VVST, MNA-SF, and SWAL-QOL) for all participants (n=84) and by treatment group (AI-VG system group, n=42; conventional group, n=42) at baseline. After the normality test, only SWAL-QOL conformed to normality, expressed as mean ± SD. Other outcomes were expressed using the median (IQR).

The primary outcome measured by GUSS median score was 7.00 (IQR: 3.00-11.00) for the total sample, with the AI-VG system group scoring 6.50 (IQR: 3.00-11.25) and the conventional group scoring 7.00 (IQR: 3.00-11.00). For secondary outcomes, the SSA median score was 34.00 (IQR: 29.25-36.00) overall, with the AI-VG system group scoring 34.00 (IQR: 30.00-35.25) and conventional group 33.50 (IQR: 28.75-36.00). The FOIS median score was 4.00 (IQR: 2.00-4.00) overall, with AI-VG system group at 4.00 (IQR: 2.00-4.00) and conventional group at 3.00 (IQR: 2.00-5.00). The VVST median scores were 2.00 (IQR: 2.00-3.00) overall, 2.00 (IQR: 2.00-3.00) for AI-VG system, and 3.00 (IQR: 2.00-3.00) for conventional. MNA-SF median scores were identical across both groups at 8.00 (IQR: 6.00-10.00). The mean total score of SWAL-QOL was 128.56 (SD=23.62), with the AI-VG system group scoring 133.31 (SD=27.64) and the conventional group scoring 123.81 (SD=17.87).

Table 6.6 The outcomes of interest at baseline (n=84)

Variables		Possible range	Total (n=84, %)	AI-VG group (n=42, %)	Conventional group (n=42, %)	*t*/*Z*	*P*-Value
Primary outcome	GUSS, median (IQR)	0-20	7.00 (3.00-11.00)	6.50 (3.00-11.25)	7.00 (3.00-11.00)	-0.10	0.921
Secondary outcomes	SSA score, median (IQR)	18-46	34.00 (29.25-36.00)	34.00 (30.00-35.25)	33.50 (28.75-36.00)	-0.20	0.84
	FOIS, median (IQR)	1-7	4.00(2.00-4.00)	4.00 (2.00-4.00)	3.00 (2.00-5.00)	-0.65	0.52
	VVST, median (IQR)	1-3	2.00 (2.00-3.00)	2.00 (2.00-3.00)	3.00 (2.00-3.00)	-1.05	0.30
	MNA-SF, median (IQR)	6-14	8.00 (6.00-10.00)	8.00 (6.00-10.00)	8.00 (6.00-10.00)	-0.57	0.57
	SWAL-QOL, mean ± SD	220	128.56±23.62	133.31±27.64	123.81±17.87	1.871	0.065

Abbreviation: AI-VG, artificial intelligence-based video-game; GUSS, Gugging Swallowing Screen; SSA, Standard Swallowing Assessment; FOIS, Functional Oral Intake Scale; VVST, Volume-viscosity swallow test; MNA-SF, Mini-Nutritional Assessment Short Form; SWAL-QOL, Swallowing Quality-of-Life Questionnaire.

6.3.2.3 Comparison between the intervention group and control group at baseline

Table 6.5 demonstrates balanced baseline characteristics between groups, with no significant differences observed in diagnosis (χ^2=0.081, *P*=0.776), disease duration (months) (*t*=-0.283, *P*=0.778), gender (χ^2=1.278, *P*=0.258), age (years) (*t* =-0.578, *P*=0.565), occupation type (χ^2=3.260, *P*=0.515), marital status (χ^2=4.959, *P*=0.175), residence (χ^2=0.808, *P*=0.369), smoking history (χ^2=0.000, *P*=1.000), drinking history (χ^2=0.233, *P*=0.629), hypertension (χ^2=1.235, *P*=0.266), diabetes (χ^2=0.000, *P*=1.000), coronary heart disease (χ^2=0.309, *P*=0.578), hyperlipidemia (χ^2=0.000, *P*=1.000), and gastroesophageal reflux disease (χ^2=0.000, *P*=1.000).

Table 6.6 presents a comprehensive comparison of primary and secondary outcomes between the AI-VG system group and conventional group, with no statistically significant differences observed across all measured parameters. For the primary outcome, there was no significant difference in GUSS between the AI-VG system group and the conventional group (*Z*=-0.10, *P*=0.921). Similarly, all secondary outcomes showed no significant differences between groups: SSA (*Z*=-0.20, *P*=0.84), FOIS (*Z*=-0.65, *P*=0.52), VVST (*Z*=-1.05, *P*=0.30), MNA-SF (*Z*=-0.57, *P*=0.57), and SWAL-QOL (*t*=1.871, *P*=0.065).

6.3.3 Feasibility Outcomes

Feasibility metrics included recruitment time, eligibility percentage, enrollment rate, retention percentage, and dropout rate.

Time used for participant recruitment: Participant recruitment was conducted over a 10-month period. The recruitment was held in a rehabilitation center in Beijing. Beijing Xiaotangshan Rehabilitation Center operates more than 1,600 patients' beds, and the researcher chose four departments: Tiantan Xiaotangshan Rehabilitation Center (Neurological Rehabilitation), Sports Rehabilitation (Jishuitan Xiaotangshan Rehabilitation Center), Integrative Medicine Rehabilitation, and Comprehensive Internal Medicine for patient recruitment. 60% of these departments are stroke patients, and the average hospitalization period of stroke patients is 3 months-6 months. A nurse from each of the four units, independent of the study team, was assigned to identify and refer to eligible participants. Posters were also displayed in outpatient clinics and rehabilitation therapy clinics to encourage participants to enroll on their own. Since this was a patient-directed rehabilitation study, the recruitment department had no impact

on the intervention. Therefore, no comparisons were made between participants recruited from different departments.

Eligibility rate and recruitment rate: Healthcare providers referred to 89 PSD patients, with an additional 13 patients self-enrolling by scanning the poster's QR code. Of the 102 total patients screened, 95 met the study's eligibility criteria, resulting in an eligibility rate of 93.1%. After receiving detailed study information and being invited to participate, 84 out of the 95 eligible patients agreed to join the research. This yielded a recruitment rate of 88.4% following the initial screening process.

Retention rate and attrition rate: The overall retention rate in this study was 96.4% (81/84), with an attrition rate of 3.6% (3/84). In the intervention group, the retention rate was 97.6% (41/42), and one participant (2.4%) lost to follow-up after discharge due to being discharged from the hospital and not answering the phone, resulting in unavailability. In the control group, the retention rate was 95.2% (40/42). One participant dropped out in week 2 because discharged from the hospital, and refused to conduct the exercise at home. One participant dropped out in week 2 because too tired to complete the exercise.

6.3.4 Efficacy Outcomes

6.3.2.1 Efficacy of AI-VG system on primary outcome (Gugging Swallowing Screen)

The efficacy of the AI-VG system in addressing primary outcomes is demonstrated in **Tables 6.7-6.8** and **Figure 6.2**. The analysis revealed progressive improvement in mean GUSS scores across both groups from T0 to T1 and T2. Notably, the AI-VG system group demonstrated superior GUSS relative to controls, with statistically significant between-group differences at T1 (mean difference, MD -4.02 ± 1.09, 95 % CI, -6.16 – -1.89, $P < 0.001$) and T2 (MD -4.14 ± 1.03, 95 % CI, -6.16 – -2.12, $P < 0.001$). The GEE modeling confirmed significant interaction terms (group * time) at T1 ($\beta = 4.381$, 95 % CI, 3.441 – 5.321, $P < 0.001$) and T2 ($\beta = 5.048$, 95 % CI, 4.023 – 6.072, $P < 0.001$), validating the AI-VG system group's effectiveness in improving PSD patients' swallowing function.

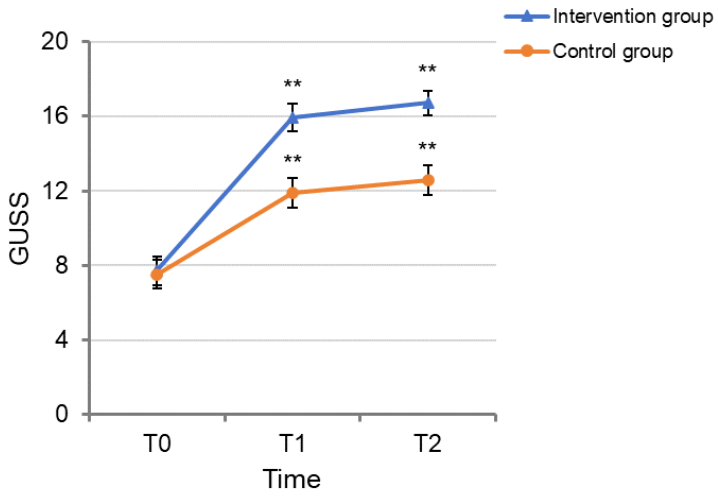
Table 6.7 Results of Gugging Swallowing Screen over different time point measurements

Outcome by group	Baseline			Post-intervention			Follow-up		
Gugging Swallowing Screen score, mean±SD	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*
Intervention group	7.71±0.78	-0.19±1.10 (-2.34, 1.96)	0.862	15.93±0.73	-4.02±1.09 (-6.16, -1.89)	<0.001	16.71±0.64	-4.14±1.03 (-6.16, -2.12)	< 0.001
Control group	7.52±0.77			11.90±0.80			12.57±0.81		

Table 6.8 Results of generalized estimating equation analysis on Gugging Swallowing Screen

Gugging Swallowing Screen	β	95%CI		*P*
		Lower limits	Upper limits	
Group (AI-VG system group vs conventional care group)	0.190	-1.957	2.338	0.862
Time				
Baseline	Reference			
4th W	4.381	3.441	5.321	< 0.001
8th W	5.048	4.023	6.072	<0.001
Group * time				
Group * T0	Reference			
Group * T1	3.833	2.200	5.467	< 0.001
Group * T2	3.952	2.299	5.606	< 0.001

Figure 6.2 The change of Gugging Swallowing Screen at week 4 (T1) and week 8 (T2)



6.3.2.2 Efficacy of AI-VG system on secondary outcome

(1) Standard Swallowing Assessment

Initial SSA score comparisons revealed no significant baseline differences between the AI-VG system group and controls. Subsequent assessments showed non-significant reductions in the intervention group at both T1 (MD 1.48±0.90, 95% CI, -0.28 – 3.24, $P = 0.10$) and T2 (MD 0.83±0.86, 95% CI, -0.84 – 2.51, $P = 0.33$) timepoints (**Table 6.9, Figure 6.3**). GEE modeling identified a significant group*time interaction at T1 (β = -1.762, 95% CI, -3.024 – -0.500, $P = 0.006$), whereas the interaction at T2 was not significant (β = -1.119, 95% CI, -2.454 – 0.216, $P = 0.100$) (**Table 6.10**).

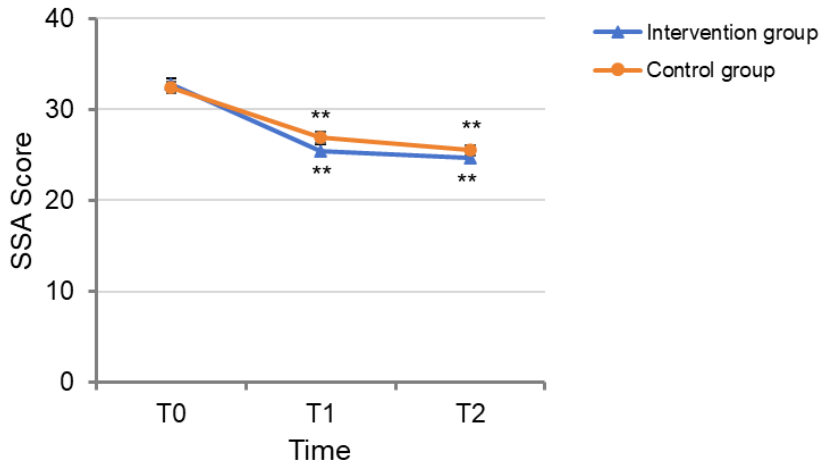
Table 6.9 Results of Standard Swallowing Assessment over different time point measurements

Outcome by group	Baseline			Post-intervention			Follow-up		
Standard Swallowing Assessment score, mean±SD	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*
Intervention group	32.71±0.58	-0.29±0.85 (-1.94, 1.37)	0.735	25.43±0.69	1.48±0.90 (-0.28, 3.24)	0.10	24.69±0.66	0.83±0.86 (-0.84, 2.51)	0.33
Control group	32.43±0.62			26.90±0.57			25.52±0.55		

Table 6.10 Results of generalized estimating equation analysis on Standard Swallowing Assessment

Standard Swallowing Assessment	β	95%CI		*P*
		Lower limits	Upper limits	
Group (AI-VG system group vs conventional care group)	0.286	-1.370	1.941	0.735
Time				
Baseline	Reference			
4th W	-5.524	-6.137	-4.911	<0.001
8th W	-6.905	-7.729	-6.081	<0.001
Group * time				
Group * T0	Reference			
Group * T1	-1.762	-3.024	-0.500	0.006
Group * T2	-1.119	-2.454	0.216	0.100

Figure 6.3 The change of Standard Swallowing Assessment at week 4 (T1) and week 8 (T2)



(2) Functional Oral Intake Scale

Significant enhancements in FOIS scores were observed over time in the intervention group when compared to the control group. At baseline, both groups had comparable FOIS scores (MD -0.17±0.31, 95% CI, -0.78 – 0.45, P = 0.593). The significant differences emerged at T1 (MD -1.07±0.31, 95% CI, -1.68 – -0.46, P = 0.001) and were maintained at T2 (MD -1.19±0.29, 95% CI, -1.76 – -0.62, P < 0.001) (**Table 6.11 and Figure 6.4**). At both week 4 (β = 0.905, 95% CI, 0.568 – 1.241, P < 0.001) and week 8 (β = 1.024, 95% CI, 0.684 – 1.363, P < 0.001), significant group-by-time interactions were detected, highlighting the sustained superiority of the intervention in improving functional oral intake capabilities (**Table 6.12**).

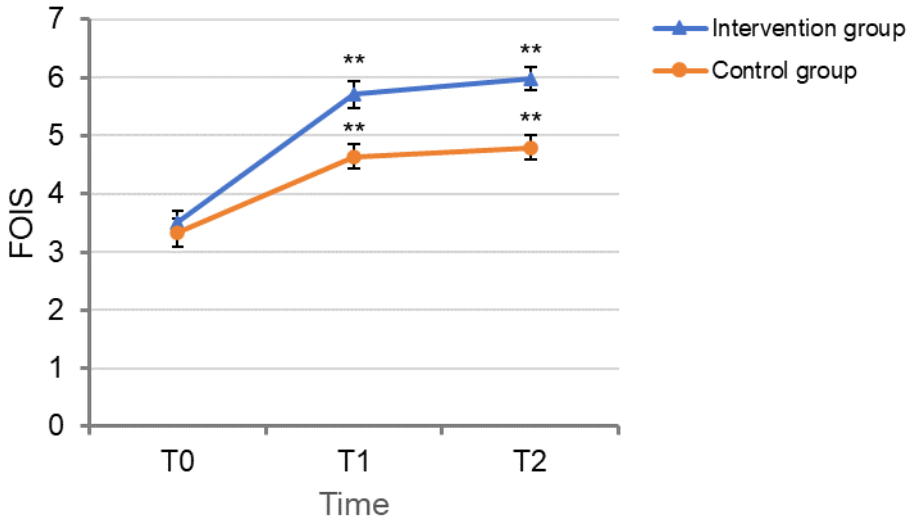
Table 6.11 Results of Functional Oral Intake Scale over different time point measurements

Outcome by group	Baseline			Post-intervention			Follow-up		
Functional Oral Intake Scale, mean±SD	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*
Intervention group	3.50±0.20	-0.17±0.31 (-0.78, 0.45)	0.593	5.71±0.23	-1.07±0.31 (-1.68, -0.46)	0.001	5.98±0.20	-1.19±0.29 (-1.76, -0.62)	<0.001
Control group	3.33±0.24			4.64±0.21			4.79±0.21		

Table 6.12 Results of generalized estimating equation analysis on Functional Oral Intake Scale

Functional Oral Intake Scale	β	95%CI		*P*
		Lower limits	Upper limits	
Group (AI-VG system group vs conventional care group)	0.167	-0.445	0.778	0.593
Time				
Baseline	Reference			
4th W	1.310	1.076	1.543	<0.001
8th W	1.452	1.231	1.673	<0.001
Group * time				
Group * T0	Reference			
Group * T1	0.905	0.568	1.241	<0.001
Group * T2	1.024	0.684	1.363	<0.001

Figure 6.4 The change of Functional Oral Intake Scale at week 4 (T1) and week 8 (T2)



(3) Volume-Viscosity Swallow Test

Although not statistically significant, the AI-VG system group exhibited greater improvements in VVST results compared to the control group. At baseline, both groups had similar VVST scores (MD 0.12±0.12, 95% CI, -0.11 – 0.35, *P* = 0.311). At post-intervention, the intervention group demonstrated lower scores, indicating better swallowing function (MD 0.24±0.13, 95% CI, -0.02 – 0.50, *P* = 0.071), a difference that approached statistical significance. This trend continued at follow-up (MD 0.21±0.13, 95% CI, -0.05 – 0.47, *P* = 0.11) (**Table 6.13 and Figure 6.5**). The group and time interactions were not statistically significant at either week 4 (β = -0.119, 95% CI, -0.348 – 0.110, *P* = 0.308) or week 8 (β = -0.095, 95% CI, -0.321 – 0.131, *P* = 0.409) (**Table 6.14**).

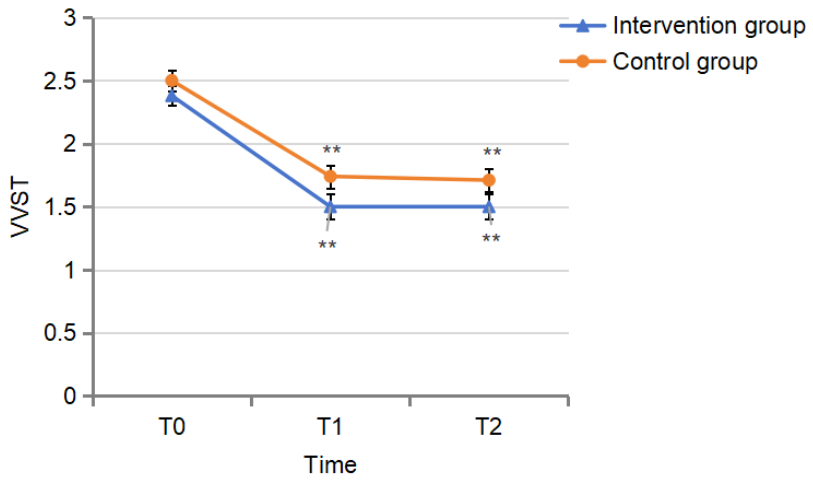
Table 6.13 Results of Volume-Viscosity Swallow Test over different time point measurements

Outcome by group	Baseline			Post-intervention			Follow-up		
Volume-Viscosity Swallow Test, mean±SD	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*
Intervention group	2.38±0.08	0.12±0.12 (-0.11, 0.35)	0.311	1.50±0.10	0.24 ± 0.13 (-0.02, 0.50)	0.071	1.50±0.10	0.21±0.13 (-0.05, 0.47)	0.11
Control group	2.50±0.08			1.74±0.09			1.71±0.09		

Table 6.14 Results of generalized estimating equation analysis on Volume-Viscosity Swallow Test

Gugging Swallowing Screen	β	95%CI		*P*
		Lower limits	Upper limits	
Group (AI-VG system group vs conventional care group)	-0.119	-0.350	0.111	0.311
Time				
Baseline	Reference			
4th W	-0.762	-0.934	-0.590	<0.001
8th W	-0.786	-0.954	-0.617	<0.001
Group * time				
Group * T0	Reference			
Group * T1	-0.119	-0.348	0.110	0.308
Group * T2	-0.095	-0.321	0.131	0.409

Figure 6.5 The change of Volume-Viscosity Swallow Test at week 4 (T1) and week 8 (T2)



(4) Mini-Nutritional Assessment Short Form

MNA-SF results demonstrated progressive improvement in nutritional status among both groups, with the intervention group showing more substantial benefits. At T1, participants in the AI-VG system group demonstrated a significantly higher MNA-SF score compared to the conventional care group (MD -1.00±0.47, 95 % CI, -1.92 – -0.08, $P = 0.034$) (**Table 6.15**, and **Figure 6**). However, no significant differences were noted at T2 (MD -0.79±0.48, 95% CI, -1.73 – 0.16, $P = 0.102$). A significant group-by-time interaction was identified at T1 ($\beta = 0.690$, 95 % CI, 0.097 – 1.284, $P = 0.023$), although this interaction effect was not sustained at week 8 ($\beta = 0.476$, 95% CI, -0.127 – 1.080, $P = 0.122$) (**Table 6.16**).

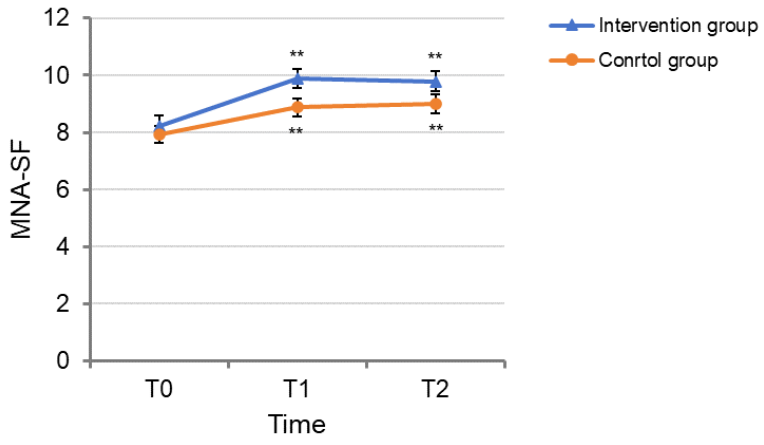
Table 6.15 Results of Mini-Nutritional Assessment Short Form over different time point measurements

Outcome by group	Baseline			Post-intervention			Follow-up		
Mini-Nutritional Assessment Short Form, mean±SD	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*
Intervention group	8.24±0.34	-0.31±0.45 (-1.20, 0.58)	0.493	9.88±0.34	-1.00±0.47 (-1.92, -0.08)	0.034	9.79±0.34	-0.79±0.48 (-1.73, 0.16)	0.102
Control group	7.93±0.30			8.88±0.32			9.00±0.34		

Table 6.16 Results of generalized estimating equation analysis on Mini-Nutritional Assessment Short Form

Mini-Nutritional Assessment Short Form	β	95%CI		*P*
		Lower limits	Upper limits	
Group (AI-VG system group vs conventional care group)	0.310	-0.576	1.195	0.493
Time				
Baseline	Reference			
4th W	0.952	0.510	1.40	<0.001
8th W	1.07	0.62	1.52	<0.001
Group * time				
Group * T0	Reference			
Group * T1	0.690	0.097	1.284	0.023
Group * T2	0.476	-0.127	1.080	0.122

Figure 6.6 The change of Mini-Nutritional Assessment Short Form at week 4 (T1) and week 8 (T2)



(5) The swallowing quality of life

The AI-VG system group exhibited greater SWAL-QOL score reductions than the conventional care group at both T1 (MD 16.43±4.05, 95% CI, 8.50 – 24.36, $P < 0.001$) and T2 (MD 21.00±3.51, 95% CI, 14.14 – 27.87, $P < 0.001$) (**Table 6.17**, and **Figure 6.7**). The GEE models further confirmed significant group-by-time interactions at T1 (β = -25.929, 95 % CI, -35.898 – -15.959, $P < 0.001$) and T2 (β = -30.500, 95 % CI, -40.261 – -20.739, $P < 0.001$) (**Table 6.18**).

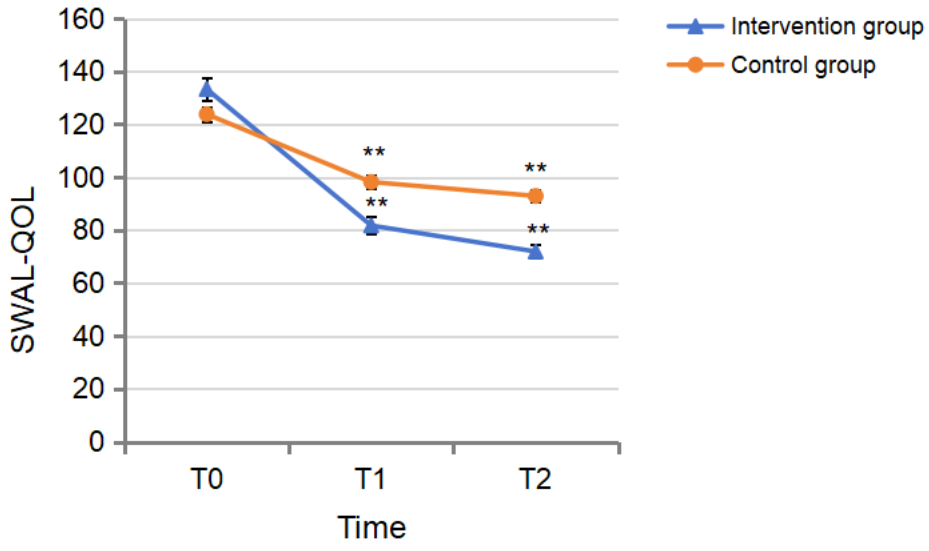
Table 6.17 Results of Swallowing quality of life over different time point measurements

Outcome by group	Baseline			Post-intervention			Follow-up		
Swallowing quality of life, mean±SD	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*	Mean±SD	Difference between groups (95% CI)	*P*
Intervention group	133.31 ± 4.21	-9.50 ± 5.02 (-19.33, 0.33)	0.058	81.74±3.22	16.43 ± 4.05 (8.50, 24.36)	<0.001	71.90±2.57	21.00 ± 3.51 (14.14, 27.87)	<0.001
Control group	123.81 ± 2.72			98.17±2.45			92.90±2.38		

Table 6.18 Results of generalized estimating equation analysis on Swallowing quality of life

Swallowing quality of life	β	95%CI		*P*
		Lower limits	Upper limits	
Group (AI-VG system group vs conventional care group)	9.500	-0.334	19.334	0.058
Time				
Baseline	Reference			
4th W	-25.643	-32.262	-19.023	<0.001
8th W	-30.905	-37.274	-24.535	<0.001
Group * time				
Group * T0	Reference			
Group * T1	-25.929	-35.898	-15.959	<0.001
Group * T2	-30.500	-40.261	-20.739	<0.001

Figure 6.7 The change of Swallowing quality of life at week 4 (T1) and week 8 (T2)



(6) Adherence, Acceptance, Satisfied, and Safety

Training adherence was significantly greater in the AI-VR group (18.00 [17.00 – 20.00]) compared to conventional care (16.00 [15.00 – 17.00]; $P < 0.001$, **Table 6.19**). Only participants in the AI-VG system completed the acceptability and satisfaction assessments, yielding median scores of 103.00 [100.50 – 104.00] and 73.00 [72.00 – 74.00], respectively (**Table 6.19**).

One participant in the AI-VG system group experienced transient dizziness during the trial, which spontaneously resolved after intervention cessation, and the participant resumed participation the following day without recurring discomfort.

Table 6.19 Results of adherence, acceptance and satisfaction

Outcome by group		Possible range	Post-intervention Mean±SD	Difference between groups (95% CI)	*p*
Acceptability	Intervention group	21-105	103.00 (100.50-104.00)	-	-
Satisfaction	Intervention group	15-75	73.00 (72.00-74.00)	-	-
Adherence	Intervention group	0-20	18.00 (17.00-20.00)	5.452	<0.001
	Control group	0-20	16.00 (15.00-17.00)		

6.3.5 Sensitivity analysis

To assess the consistency of our results, sensitivity analyses were performed utilizing both intention-to-treat (ITT) and per-protocol (PP) analytical approaches

across all outcome measures. Both analyses showed consistent treatment effect results, enhancing the validity of our main findings.

Analysis of the primary outcome (GUSS assessed swallowing function) revealed consistent treatment effects across both analytical approaches. The ITT analysis demonstrated significant between-group differences post-intervention (MD -4.02±1.09, 95% CI, -6.16 – -1.89, *P*<0.001) and at follow-up (MD -4.14±1.03, 95% CI, -6.16 – -2.12, *P*<0.001). PP analysis yielded comparable results (post-intervention: MD -4.24±1.11, 95% CI, -6.42 – -2.07, *P*<0.001; follow-up: MD -4.39±1.05, 95% CI, -6.44 – -2.33, *P*<0.001). GEE models confirmed significant group*time interactions in both ITT (T1: β=3.833, 95% CI, 2.200 – 5.467, *P*<0.001; T2: β=3.952, 95% CI, 2.299 – 5.606, *P*<0.001) and PP (T1: β=3.787, 95% CI, 2.173 – 5.402, *P*<0.001; T2: β=3.929, 95% CI, 2.303 – 5.555, *P*<0.001) analyses (**Tables 6.20-6.21**).

For secondary outcomes, both analytical approaches showed similar results. Improvement in SSA scores at T1 and T2 were not significant in either the ITT or PP analyses (**Table 6.20**). There was a significant interaction between group and time in both ITT (β=-1.762, 95% CI, -3.024 – -0.500, *P*=0.006) and PP analyses (β=-1.791, 95% CI, -3.029 – -0.554, *P*=0.005; **Table 6.21**) at week 4 for SSA scores. VVST results showed consistent trends without reaching statistical significance in both analyses (**Table 6.20 and Table 6.21**). FOIS demonstrated significant improvements in the intervention group with nearly identical same results in ITT (post-intervention: MD -1.07±0.31, *P*=0.001; follow-up: MD -1.19±0.29, *P*<0.001) and PP analyses (post-intervention: MD -1.12±0.32, *P*<0.001; follow-up: MD -1.24±0.29, *P*<0.001; **Table 6.21**). For nutritional status (MNA-SF), the PP analysis strengthened the findings by showing significance at both post-intervention (MD -1.25±0.46, *P*=0.007) and follow-up (MD -1.02±0.48, *P*=0.031), while ITT analysis reached significance only at post-intervention (MD -1.00±0.47, *P*=0.034; **Table 6.20**). The GEE model consistently confirmed significant group × time interactions across both analyses, supporting the intervention's effectiveness (**Table 6.21**). Regarding swallowing-related quality of life

(SWAL-QOL), both analyses confirmed significant benefits at post-intervention (ITT: MD 16.43±4.05, P<0.001; PP: MD 17.78±4.02, P<0.001) and follow-up (ITT: MD 21.00±3.51, P<0.001; PP: MD 22.71±3.37, P<0.001; **Table 6.20**).

The high consistency between the ITT analysis and the PP analysis for all outcomes enhanced the reliability of the results.

Table 6.20 Per-protocol analysis: outcome differences between both groups at baseline and at four and eight weeks according to the general estimating equation

Outcome by group		Baseline			Post-intervention			Follow-up		
		Mean ± SD	Difference between groups (95% CI)	*p*	Mean ± SD	Difference between groups (95% CI)	*p*	Mean ± SD	Difference between groups (95% CI)	*p*
Primary outcome	**GUSS score, mean ± SD**									
	Intervention group	7.75 ± 0.81	-0.46 ± 1.10 (-2.63, 1.71)	0.679	16.03 ± 0.76	-4.24 ± 1.11 (-6.42, -2.07)	< 0.001	16.85 ± 0.65	-4.39 ± 1.05 (-6.44, -2.33)	< 0.001
	Control group	7.29 ± 0.75			11.78 ± 0.81			12.46 ± 0.82		
Secondary outcome	**SSA score, mean ± SD**									
	Intervention group	32.73 ± 0.60		0.870	25.28 ± 0.72	1.65 ± 0.93 (-0.16, 3.47)	0.074	24.50 ± 0.67		0.249

Control group	32.59 ± 0.61		-0.14 ± 0.86 (-1.82, 1.54)		26.93 ± 0.59			25.51 ± 0.56		1.01 ± 0.8 (-0.71, 2.73)	
FOIS score, mean±SD											
Intervention group	3.48 ± 0.21		-0.21 ± 0.32 (-0.83, 0.41)	0.513	5.73±0.23	-1.12±0.32 (-1.74, -0.50)	<0.001	6.00 ± 0.20		-1.24 ± 0.29 (-1.82, -0.67)	<0.001
Control group	3.27 ± 0.23				4.61±0.22			4.76 ± 0.21			
VVST score, mean±SD											
Intervention group	2.40 ± 0.09		0.11±0.12 (-0.12, 0.35)	0.352	1.50±0.10	0.23 ± 0.14 (-0.03, 0.50)	0.087	1.50 ± 0.10		0.21±0.14 (-0.06, 0.47)	0.129
Control group	2.51 ± 0.09				1.73±0.09			1.71 ± 0.09			
MNA-SF score, mean±SD											

Intervention group	8.35 ± 0.35	±	-0.52 ± 0.45 (-1.40, 0.36)	±	0.247	10.05 ± 0.34	±	-1.25 ± 0.46 (-2.15, -0.34)		0.007	9.95 ± 0.34	±	-1.02 ± 0.48 (-1.95, -0.09)	±	0.031
Control group	7.83 ± 0.29	±				8.80 ± 0.32					8.93 ± 0.34	±			
SWAL-QOL score, mean ± SD															
Intervention group	132.55 ± 4.28	±	-7.43 ± 4.93 (-17.10, 2.24)	±	0.132	81.08 ± 3.22	±	17.78 ± 4.02 (9.90, 25.66)	±	<0.001	70.75 ± 2.40	±	22.71 ± 3.37 (16.10, 29.33)	±	<0.001
Control group	125.12 ± 2.45	±				98.85 ± 2.41	±				93.46 ± 2.37	±			

Abbreviation: GUSS, Gugging Swallowing Screen; SSA, Standard Swallowing Assessment; FOIS, Functional Oral Intake Scale; VVST, volume-Viscosity Swallow Test; SWAL-QOL, Swallowing Quality-of-Life Questionnaire; MNA-SF, Mini-Nutritional Assessment Short Form.

Table 6.21 Per-protocol analysis: changes in primary and secondary outcomes at 4-week (T1) and 8-week (T2) in control and intervention group compared to baseline (T0) based on GEE models.

	β	95%CI		*P*
		Lower limits	Upper limits	
GUSS				
Group (VG vs Control)	0.457	-1.712	2.627	0.679
Time				
Baseline	Reference			
4th W	4.488	3.548	5.427	< 0.001
8th W	5.171	4.150	6.191	<0.001
Group * time				
Group * T0	Reference			
Group * T1	3.787	2.173	5.402	< 0.001
Group * T2	3.929	2.303	5.555	< 0.001
SSA				
Group (VG vs Control)	0.140	-1.539	1.818	0.870

Time				
Baseline	Reference			
4th W	-5.659	-6.227	-5.090	<0.001
8th W	-7.073	-7.848	-6.298	<0.001
Group * time				
Group * T0	Reference			
Group * T1	-1.791	-3.029	-0.554	0.005
Group * T2	-1.152	-2.440	0.136	0.080
FOIS				
Group (VG vs Control)	0.207	-0.412	0.826	0.513
Time				
Baseline	Reference			
4th W	1.341	1.111	1.572	<0.001
8th W	1.488	1.273	1.703	<0.001
Group * time				
Group * T0	Reference			

Group * T1	0.909	0.585	1.232	<0.001
Group * T2	1.037	0.715	1.359	<0.001
VVST				
Group (VG vs Control)	-0.112	-0.348	0.124	0.352
Time				
Baseline	Reference			
4th W	-0.780	-0.953	-0.608	<0.001
8th W	-0.805	-0.973	-0.636	<0.001
Group * time				
Group * T0	Reference			
Group * T1	-0.119	-0.348	0.110	0.308
Group * T2	-0.095	-0.321	0.131	0.409
MNA-SF				
Group (VG vs Control)	0.51	-0.361	1.403	0.247
Time				
Baseline	Reference			

4th W	0.976	0.525	1.427	<0.001
8th W	1.098	0.640	1.555	<0.001
Group * time				
Group * T0	Reference			
Group * T1	0.724	0.118	1.331	0.019
Group * T2	0.502	-0.115	1.120	0.111
SWAL-QOL				
Group (VG vs Control)	7.428	-2.243	17.099	0.132
Time				
Baseline	Reference			
4th W	-26.268	-32.935	-19.602	<0.001
8th W	-31.659	-38.010	-25.307	<0.001
Group * time				
Group * T0	Reference			
Group * T1	-25.207	-34.796	-15.617	<0.001
Group * T2	-30.141	-39.447	-20.836	<0.001

Abbreviation: GUSS, Gugging Swallowing Screen; SSA, Standard Swallowing Assessment; FOIS, Functional Oral Intake Scale; VVST, volume-Viscosity Swallow Test; SWAL-QOL, Swallowing Quality-of-Life Questionnaire; MNA-SF, Mini-Nutritional Assessment Short Form.

6.4 Discussion

This RCT investigates the previously unexplored application of AI-VG system for PSD rehabilitation. Findings indicate that the intervention effectively enhances both swallowing function and related quality of life. Furthermore, the AI-VG system achieved exceptionally high patient acceptance and satisfaction rates

6.4.1 Improvement in Swallowing Function

The AI-VG system demonstrated significant therapeutic benefits for PSD, enhancing both swallowing physiology and oral intake capacity. These findings corroborate existing evidence supporting technology-assisted dysphagia rehabilitation (Hou et al., 2024; C. M. Li et al., 2016).

The integration of artificial intelligence with video game technology creates a powerful rehabilitation platform through several technical mechanisms. First, advanced computer vision and deep learning algorithms enable the AI system to track orofacial movements with precision in real time (Shu, Barradas, Qin, & Koike, 2025). Unlike traditional rehabilitation methods that rely on subjective assessments, the AI system objectively quantifies movement parameters including tongue elevation, lip seal integrity, and pharyngeal contraction timing with millisecond precision, the direction and displacement of muscle movements can be recognized within 0.02 seconds, with an accuracy of up to 97% (Grishchenko, Ablavatski, Kartynnik, Raveendran, & Grundmann, 2020; Roy & Chanda, 2022). This high-resolution temporal and spatial monitoring enable detection of subtle movement patterns that might be imperceptible through conventional observation. The integration of AI with gaming technology enhances facial movement detection precision while enabling faster feedback delivery.

Second, the video game interface transforms abstract motor patterns into concrete visual objectives through gamification elements (Tolks, Schmidt, & Kuhn, 2024). The AI-VG rehabilitation system provides real-time visual feedback of participants' movement during therapeutic exercises, fostering both motor learning

and psychological empowerment to optimize swallowing recovery (Constantinescu et al., 2017). By mapping swallowing movements to game mechanics, the system makes implicit motor patterns explicit and manipulable. This visualization creates a direct cognitive link between intention, action, and outcome that conventional therapy struggles to establish.

However, the study found no significant differences in SSA and VVST results between participants receiving the AI-VG intervention and those receiving conventional care. This variation might stem from the distinct measurement characteristics of these assessment tools. The SSA primarily concentrates on evaluating laryngeal reflex ability using water, with a specific focus on aspiration risk assessment rather than providing a comprehensive analysis of dysphagia symptoms. Similarly, while VVST offers valuable information, its scope is specifically limited to the physiological mechanics of swallowing across systematically varied food properties (Y. Lin et al., 2022). In contrast, GUSS and FOIS assessments demonstrated significant improvements in the AI-VG system group because they capture broader functional changes in swallowing ability. GUSS encompasses multiple food textures and evaluates the entire swallowing process, including preparatory, oral, and pharyngeal phases, providing a more comprehensive picture of functional improvement. FOIS, as a functional outcome measure, directly reflects patients' real-world dietary capabilities and restrictions, measuring practical improvements in daily nutritional intake patterns and dietary advancement (Y. H. Park, Bang, Han, & Chang, 2015). These tools are particularly sensitive to functional gains that translate to clinically meaningful outcomes such as diet level advancement and reduced feeding tube dependence.

The study outcomes emphasize the value of additional research exploring AI-VG system therapies in swallowing disorders. The differential responses observed across various assessment instruments provide valuable insights into how AI-VG system interventions impact swallowing function. While some metrics showed

significant improvement and others did not, this pattern suggests that the AI-VG system may preferentially enhance certain aspects of swallowing function over others. The positive changes in GUSS and FOIS scores indicate that AI-VG system therapy effectively improves functional swallowing capabilities with direct relevance to patients' dietary advancement and quality of life. Future research should aim to elucidate the specific neurophysiological and biomechanical mechanisms through which AI-VG system intervention exerts their effects, and how these therapeutic approaches can be refined to produce more comprehensive improvements across all domains of swallowing function. Additionally, investigation into the optimal dosage, timing, and specific patient populations most likely to benefit from AI-VG system intervention would further enhance clinical application of this promising therapeutic approach.

Although patient engagement is an important factor influencing the success of rehabilitation interventions, it was not designated as the primary outcome in this study. The rationale is that the primary research objective was to evaluate the direct clinical effectiveness of the AI-VG system in improving swallowing function, as measured by validated functional scales. While enhanced engagement is a key mechanism through which the intervention may exert its effects, it is an intermediate or process-related variable rather than an endpoint reflecting functional recovery. In other words, patient engagement facilitates adherence, motivation, and active participation, which in turn may lead to improvements in swallowing outcomes. Future research could incorporate engagement-related metrics as secondary outcomes or mediators to better elucidate the pathway from intervention to functional improvement, thereby clarifying the role of engagement in maximizing therapeutic benefits.

6.4.2 Impact on Nutrition and Quality of Life

Consistent with Battel et al.'s findings, participants using the AI-VG system experienced more pronounced gains in both nutritional status and swallowing-

related quality of life than those in the control group (Battel & Walshe, 2023). The AI-VG intervention's impact on swallowing function may lead to greater dietary flexibility and eating satisfaction, which in turn supports psychological well-being and improves quality of life and nutritional outcomes. Moreover, nutritional status exhibits an indirect influence on overall quality of life. By addressing nutritional deficits, patients may avoid typical sequelae like weight reduction, limited movement, and exhaustion, which subsequently promotes social interaction and life quality improvement (Zeng et al., 2024).

The relationship between the AI-VG system intervention and improved nutritional status may be due to several reasons. First, the enhanced motor control achieved through precise AI-guided exercise facilitates more efficient bolus manipulation and transport (Malandraki, 2023). This improvement directly enables patients to consume a wider variety of food with different textures and consistencies, moving beyond restricted modified diets toward more nutritionally complete options (Gupta, Gupta, & Gupta, 2022).

Second, the gamification elements of AI-VG system appear to mitigate the learned disuse phenomenon commonly observed in dysphagia patients. Research by Pizzorni (2019) (Pizzorni, 2019) demonstrated that stroke patients often develop avoidance behaviors around eating due to fear of aspiration or social embarrassment. The non-threatening, playful context of AI-VG system therapy reduces anxiety associated with swallowing attempts, encouraging more frequent practice both during therapy and in daily life. This increased willingness to engage in oral intake creates more opportunities for nutritional consumption.

Third, the real-time biofeedback provided by the AI-VG system facilitates neural reorganization specific to swallowing-related sensory processing. Functional neuroimaging studies have demonstrated that sensory feedback during swallowing exercises enhances activity in the insular cortex and sensorimotor integration areas (Qiao et al., 2022). These neural regions are critical for

developing awareness of bolus location and characteristics, allowing for safer and more efficient intake of various food consistencies that contribute to balanced nutrition.

It should be noted that the relationship between swallowing function and nutritional status appears to be bidirectional. While improved swallowing function enables better nutritional intake, emerging evidence suggests that nutritional status itself may impact rehabilitation outcomes. Borges et al. (2024) (Borges, Taveira, Eduardo, & Cavalcanti, 2024) found that a decrease in skeletal muscle quality and function as a result of muscle loss led to a decrease in the patient's chewing ability, swallowing sensation, and motor mechanisms.. This finding suggests that malnutrition may impair muscle function required for effective swallowing, potentially creating a negative feedback loop.

The AI-VG system intervention may help break this cycle by simultaneously improving swallowing mechanics and nutritional intake. The initial gains in swallowing function enable improved nutrition, which then supports muscle strength and endurance needed for continued swallowing improvement. This virtuous cycle may partially explain the accelerated early improvements observed in our study.

The enhancement in swallowing-related quality of life observed in the AI-VG system group extends beyond functional gains. Dysphagia after stroke can have a profound psychosocial impact, with many patients experiencing social isolation, embarrassment, and reduced enjoyment of meals (Leiman et al., 2023). The AI-VG system intervention not only recovers the ability to swallow, but also restores confidence in swallowing, thereby addressing both the physical and psychological aspects of dysphagia.

The gamified nature of the intervention transforms the potentially frustrating process of rehabilitation into a participatory activity with clear goals and measurable progress. This shift in perspective may contribute to a sense of self-

efficacy, and patients who believe in their ability to improve are more likely to engage in the challenging activities required for recovery (Rogus-Pulia & Hind, 2015).

In addition, improved swallowing function helps to restore normal eating patterns, which has important social implications. Meals are important socialization opportunities, and being able to participate in shared meals may reduce the isolation and depression common after stroke (Bailey & Waddoups, 2024). This ability to reintegrate into society is likely to contribute to the overall quality of life of PSD patients.

While immediate post-treatment MNA-SF results demonstrated notable group disparities, these differences normalized at subsequent follow-up. The observed temporal trajectory suggests that the AI-VG system accelerates early-phase nutritional recovery, likely mediated by enhanced patient adherence and intensive swallowing exercise engagement, which promote faster restoration of functional oral intake. However, the eventual parity in nutritional outcomes between groups at T2 suggests that while the AI-VG system approach may offer short-term advantages in rehabilitation tempo, both interventions ultimately converge toward equivalent long-term nutritional endpoints. This finding corroborates existing literature documenting comparable asymptotic patterns in dysphagia recovery trajectories across different therapeutic modalities (C. E. Lang et al., 2021; Teasell, Murie Fernandez, McIntyre, & Mehta, 2014). In the setting of post-stroke dysphagia, early improvement of swallowing function is clinically important. The first few weeks after stroke are a critical period when patients are at highest risk for complications related to aspiration pneumonia and malnutrition (S. Li, 2023). By accelerating functional recovery during this vulnerable period, AI-VG system intervention can reduce morbidity and hospitalization, leading to potential economic and clinical benefits.

6.4.3 Adherence, Satisfaction, and Acceptance

Adherence rates were significantly greater in the intervention group versus controls, with parallel elevations in satisfaction and acceptance scores specific to the AI-VG system protocol. These results align with Park et al.'s (2019) (J. S. Park, G. Lee, et al., 2019) findings demonstrating that game-based interventions enhance motivation, sustain engagement, and decrease physical fatigue. By utilizing just standard computer equipment, the AI-VG system appears to lower barriers to participation while maintaining engagement, which may underline its favorable user evaluations.

The AI-VG system addresses the psychological need for self-determined intrinsic motivation by giving patients control over their rehabilitation experience, providing immediate performance feedback that indicates progress, and creating opportunities for social interaction or comparison through game elements (Flannery, 2017). In addition, higher adherence rates may be due to gamified rehabilitation exercises reducing the threat response. Traditional dysphagia exercises can trigger anxiety and frustration, especially when patients are directly confronted with their limitations. Gaming interfaces distance themselves psychologically from the disability by reframing the exercise as a gaming challenge rather than a reminder of the impairment (Lieberoth, 2015). This cognitive reframing may reduce negative emotional responses and encourage continued patient participation.

The high level of satisfaction and acceptance of the AI-VG system highlights the importance of technical design considerations in rehabilitation technology. Minimum hardware requirements (standard computer equipment with a camera) may help to reduce the technical barriers typically associated with specialized rehabilitation equipment, thereby increasing acceptance. Such user-friendly design corroborates TAM principles, wherein system accessibility directly impacts technology acceptance rates (Venkatesh, 2000). The real-time visual feedback provided by AI components offers significant advantages over traditional

treatments. Motor learning research has consistently shown that immediate, specific feedback accelerates skill acquirement and maintains engagement (Lohse, Boyd, & Hodges, 2016). The AI system's ability to detect minor movements and instantly validate correct performance reduces the uncertainty and frustration that can build up during unsupervised practice. Additionally, the system's ability to objectively quantify progress, such as time to complete a game, can increase patient satisfaction by making "improvement visible and measurable". Traditional rehabilitation often relies on subjective assessments or infrequent clinical measurements, making patients unsure of their day-to-day progress, and the game feedback generated by the AI-VG system provides solid evidence of improvement, which has the potential to increase patients' self-efficacy and interest in continuing to practice (Dixon, Thornton, & Young, 2007).

While our current AI-VG system has shown promising results in terms of adherence and satisfaction, several potential enhancements may further improve these aspects in future iterations of the technology. Integrating social features (e.g., cooperative or competitive multiplayer options) can leverage social motivation to maintain long-term engagement (Pereira, Bermúdez i Badia, Jorge, & Cameirão, 2021). Social motivation tends to outperform individual motivation in maintaining consistent health behaviors. Exploring personalization beyond difficulty adjustment may enhance the system's attraction to different patient preferences and cultural backgrounds. Additionally, incorporating principles from habit formation research could help shift rehabilitation exercises from deliberate practice to more automated routines integrated into daily life (Yujie Zhu et al., 2024). Future research should also explore the potential of combining the AI-VG system with other engagement-enhancing strategies, such as telemedicine visits, supportive counseling, or family engagement. Multimodal approaches that address all aspects of motivation and barriers to participation may achieve higher levels of acceptance and satisfaction than technology alone.

6.4.4 Feasibility of this study

As the first RCT evaluating AI-VG system therapy for PSD, our study demonstrates promising feasibility evidenced by exceptional retention (96.4%), minimal attrition, and favorable participant evaluations.

This study demonstrated a robust recruitment process spanning 10 months across four departments within Beijing Xiaotangshan Rehabilitation Center. The eligibility rate was exceptionally high at 93.1% (95/102), demonstrating strong alignment between our selection criteria and the target PSD population characteristics. This rate exceeds the commonly accepted threshold for feasibility studies and suggests that the selection criteria effectively identified suitable candidates without being overly restrictive (Simpson, Sweetman, & Doig, 2010). The recruitment rate of 88.4% (84/95) further supports the acceptability of the study protocol to eligible patients.

The high eligibility and recruitment rates observed in this study compare similarly or favorably to dysphagia rehabilitation interventions. For instance, Yang et al. (2023) reported 94.1% recruitment efficiency in community-based dysphagia rehabilitation (C. Yang et al., 2023). Similarly, Park et al. (2019) achieved a recruitment rate of 81.1% in their swallowing therapy intervention for patients with post-stroke dysphagia (Hee‐Su Park, Dong‐Hwan Oh, Taehyung Yoon, & Ji‐Su Park, 2019). Our study's recruitment rate of 88.4% exceeds these figures, suggesting that the intervention protocol was particularly appealing to the target population of PSD patients in a rehabilitation setting. The dual recruitment approach utilizing healthcare provider referrals and self-enrollment via QR code posters likely contributed to this success by providing multiple pathways for potential participants to learn about and join the study.

The retention rate for all participants was 96.4% (81/84), which is one of the most compelling measures of intervention feasibility. This rate exceeds that reported for similar stroke rehabilitation interventions, where retention rates

typically range from 70-95% (Nordio et al., 2022; Wenguang Xia, Chanjuan Zheng, Suiqiang Zhu, & Zhouping Tang, 2016). The nearly equivalent retention rates (intervention: 97.6% vs control: 95.2%) indicate comparably high protocol adherence and tolerability across both treatment modalities. The higher retention rates achieved in our study with PSD patients highlight the acceptability and appropriateness of AI-VG system for PSD, despite the complex psychological and physical challenges associated with post-stroke dysphagia.

The recruitment setting of Beijing Xiaotangshan Rehabilitation Center, with its large capacity of over 1,600 beds and specialized rehabilitation departments, proved to be advantageous for participant recruitment. The center's patient population, with approximately 60% being stroke patients and average hospitalization periods of 3-6 months, aligned well with the intervention timeline and facilitated continuous participant engagement. However, this single-center approach may limit generalizability to smaller facilities or different healthcare systems. Future research should consider multi-center trials to enhance external validity while maintaining the successful recruitment and retention strategies employed in this study.

The recruitment period of 10 months, while effective in achieving the target sample size, may be considered lengthy for implementation in routine clinical practice. Future studies should explore strategies to streamline the recruitment process without compromising the high eligibility and recruitment rates achieved in this study. Potential approaches might include enhanced healthcare provider education about referral criteria, placement of recruitment materials in more prominent locations, and utilization of digital platforms to promote self-registration (Lacey et al., 2017). Additionally, the over-reliance on provider referrals (87% of potential participants) compared to self-enrollment (13%) suggests a potential selection bias that should be addressed in future studies.

6.4.5 Implications for research and for clinical practice

Effective dysphagia rehabilitation necessitates an interdisciplinary team approach, integrating the specialized expertise of speech-language pathologists, physical therapists, physicians, and nursing staff to address the condition's physiological, functional, and psychosocial dimensions (K. C. Chen et al., 2021; Jones et al., 2020). Successful treatment hinges on effective patient and family engagement, prioritizing individual values and needs. Game-based training has been found to significantly increase patient involvement and motivation (Vieira, Ferreira da Silva Pais-Vieira, Novais, & Perrotta, 2021). By leveraging computer and artificial intelligence technologies, real-time performance feedback becomes possible, potentially optimizing rehabilitation efficiency. This study effectively demonstrated the potential of AI-VG system to support swallowing rehabilitation for post-stroke dysphagia patients, offering an innovative approach that addresses existing gaps in intelligent rehabilitation methodologies.

The adoption of the AI-VG system has had a significant impact on the development of dysphagia nursing practice. Traditionally, nurses have played an important supportive role in dysphagia care, focusing primarily on screening, monitoring, and implementing specified interventions (Hines et al., 2011). The integration of the AI-VG system creates opportunities for nurses to take a more active role in the rehabilitation process.

The accessibility and user-friendly nature of the AI-VG system allows nurses to assist with swallowing therapy at the bedside without requiring constant presence of speech-language pathologists. This role expansion aligns with current trends in nursing practice toward greater autonomy and professional skill development in nursing practice (Mather, Gale, & Cummings, 2017). Studies have shown that nurse-led dysphagia screening and intervention programs can significantly reduce pneumonia rates and improve patient outcomes (Hines, Kynoch, & Munday, 2016; Khor et al., 2023).

The implementation of the AI-VG system requires a reconceptualization of nursing roles in the rehabilitation setting. In addition to traditional nursing functions, nurses are uniquely positioned to act as technology facilitators and patient advocates in this emerging model of care (P. P. Choi, 2015). Their ongoing presence and therapeutic relationship with the patient create opportunities for technology orientation, troubleshooting, and reinforcement of correct technology that sporadic therapy visits cannot provide (Gellert et al., 2015).

The high level of satisfaction our study achieved among both patients and healthcare providers suggests that, when introduced correctly, the AI-VG system can successfully fulfill these requirements. Extending rehabilitation beyond the scheduled therapy sessions through nurse-assisted AI-VG system training is of particular interest for optimizing the window of neuroplasticity after stroke (Liu, Yin, Lee, Peng, & Yang, 2022). By treating more frequently during this period, nurses can help maximize the potential for rehabilitation during hospitalization and during transitions when therapy services may be limited.

From a healthcare economics perspective, the AI-VG system offers potential benefits consistent with current value-based care programs. By improving the efficiency of rehabilitation and potentially accelerating functional recovery, this technology can reduce length of stay, lower complication rates, and minimize rehospitalization rates (Feng, 2023). Reducing reliance on professional therapists through nurse-assisted or patient-directed practices may address labor shortages in rehabilitation. This is especially important in underserved areas where employment opportunities for speech-language pathologists are limited. Expanding the reach of specialized knowledge through technology could lead to a more equitable distribution of rehabilitation services (Zirbel, Zhang, & Hughes, 2018).

6.4.6 Strength, innovation and significance of this study

This study possesses several methodological and practical strengths. The use of a RCT design, recognized as the most rigorous approach for evaluating intervention effectiveness, provides robust evidence for the AI-VG system. Single-blind outcome assessment minimized measurement bias, enhancing the validity and reliability of the findings. A longitudinal design with three assessment points (baseline, post-intervention, and follow-up) allowed examination of both immediate and sustained effects, addressing a limitation of many rehabilitation studies that focus only on short-term outcomes. This temporal perspective is particularly important in neurorehabilitation, where reinforcement of learning and neural reorganization may extend beyond the active intervention period. Carefully matched control groups received standard care of equal intensity, ensuring that differences observed were attributable to the AI-VG system rather than disparities in treatment dose or attention.

From a technological perspective, the AI-VG system applied artificial intelligence to remove device-dependent interaction limitations, filling a gap in technology-assisted rehabilitation for PSD. It overcame time and space constraints by supporting remote delivery, aligning with modern trends in telerehabilitation and decentralized care. Developed in collaboration with experienced dysphagia care professionals, the system incorporated gamified exercises that maintain therapeutic effectiveness while maximizing patient engagement and minimizing cognitive load, addressing common barriers to technology adoption in clinical practice. Compared with specialized systems requiring custom hardware, it operates on a standard computer with a camera, significantly lowering implementation barriers and expanding accessibility.

The system was designed using an integrated theoretical framework combining the Immersion Theoretical Model (ITM) and the Technology Acceptance Model (TAM). This dual-theory approach ensured that the intervention was both effective (ITM) and acceptable to users (TAM), enhancing

immersion, reducing technical barriers, and fostering user engagement. This framework also provides a basis for understanding the mechanisms underlying success in intervention and for guiding future technology-based rehabilitation designs.

Clinically, the AI-VG system addressed evidence gaps identified in previous systematic reviews and RCTs by determining optimal, comprehensive PSD rehabilitation strategies. It represents a shift from a therapist-dependent, one-on-one model to a patient-centered approach that offers immediate, objective biofeedback, visualizes progress, and empowers patients to take an active role in their rehabilitation. This aligns with healthcare priorities to improve patient function and quality of life, enable standardized care, reduce clinician workload, and promote multidisciplinary teamwork. The system's modular architecture allows for adaptation to other neurological or functional impairments, integration with additional biofeedback modalities, and development of adaptive algorithms for personalized rehabilitation.

The significance of this study lies in its potential to improve both individual patient outcomes and the broader rehabilitation landscape. By enhancing swallowing function and quality of life for patients while enabling healthcare providers to deliver standardized, efficient, and multidisciplinary care, the AI-VG system offers a clinically impactful solution to post-stroke dysphagia. Its low hardware requirements and remote delivery capability address the shortage of rehabilitation resources and expand access to underserved populations, thereby contributing to greater health equity. Scientifically, the study generates high-quality evidence for the integration of AI and gamification in neurorehabilitation, promotes interdisciplinary collaboration between nursing, rehabilitation sciences, and computer engineering, and establishes a replicable framework for future technology-assisted interventions. Conducted in a real-world clinical environment,

the findings demonstrate strong ecological validity and translational potential, supporting the AI-VG system's adoption in diverse healthcare settings.

6.4.7 Limitations of this study

The following limitations should be acknowledged. First, the single-center design at a rehabilitation hospital may constrain the external validity of these findings to other clinical settings. To strengthen the external validity and broaden the applicability of the results, future research should expand to multiple centers with a larger and more diverse sample. Conducting studies across various healthcare settings and geographical regions would provide a more comprehensive understanding of the AI-VG system's effectiveness and applicability in different populations.

Second, the absence of baseline assessments for participants' technological proficiency and educational background may have influenced outcomes related to adherence, acceptance, and satisfaction with the AI-VG system intervention. Individuals with greater familiarity with technology could have found the system easier to navigate, whereas differences in educational attainment might have impacted users' comfort and ability to engage effectively with the platform. To enhance inclusivity and better tailor future interventions, subsequent studies should evaluate these factors at baseline and adjust rehabilitation protocols accordingly.

Third, the inherent visibility of the AI-VG system intervention precluded participant and therapist blinding, potentially introducing performance bias through heightened expectations. The awareness of group assignments could have affected both participant engagement and implementer conduct. Although blinding poses challenges in technology-based studies, future trials may address this issue by employing active control conditions or sham interventions to help minimize expectancy effects.

Fourth, this study emphasized short-term outcomes, limiting insight into the sustained effectiveness of the AI-VG system intervention. To better understand its long-term impact and durability, future research should include extended follow-up periods, such as six months to one year, to determine whether gains in swallowing function and quality of life persist over time.

Fifth, the severity of stroke at baseline was not measured using standardized tools such as the NIH Stroke Scale/Score (NIHSS), nor were the specific brain regions affected by the stroke evaluated. These factors could significantly influence the recovery of dysphagia and should be considered in future research. Including these evaluations would improve the ability to stratify participants and determine who may respond most favorably to the AI-VG intervention.

Sixth, no follow-up qualitative study was conducted after the completion of the RCT to explore patients' experiences with the AI-VG system. Such qualitative insights could help uncover the underlying reasons for the intervention's effectiveness and guide further refinement of the AI-VG system. Future research should integrate qualitative methods alongside quantitative assessments to provide a more holistic understanding of intervention impact.

Seventh, the study did not perform subgroup analyses based on the severity of dysphagia. Future studies should consider stratifying participants according to dysphagia severity to examine potential differential effects of the AI-VG intervention across severity levels.

Chapter 7. Conclusion

This study introduces an AI-VG system as a novel intervention for PSD patients, a condition associated with severe complications such as aspiration pneumonia and malnutrition. Given the limitations of current rehabilitation methods, we developed this gamified approach to evaluate its feasibility and preliminary efficacy in enhancing swallowing function, quality of life, and nutritional outcomes in PSD patients

This research began with a comprehensive systematic review and network meta-analysis of existing rehabilitation strategies for PSD. This represented the first systematic evaluation specifically focused on identifying the most effective training methods for this patient population. Through rigorous analysis of available evidence, we identified: (1) Chin tuck against resistance was the effective and appropriate method in improving patients' swallowing function, and feeding and daily function. (2) The duration and frequency of the intervention showed that a 30-min daily intervention, 5 days per week, 4 weeks, and 600 min of total intervention time significantly improved the swallowing function, and the feeding and daily function of the PSD patients. This systematic review established a critical foundation for understanding the landscape of dysphagia rehabilitation and highlighted the substantial gap in innovative, patient-centered interventions tailored to the unique challenges of post-stroke swallowing dysfunction.

This study has filled in the research gap on the technology-enhanced approaches to dysphagia rehabilitation by developing a novel AI-VG system. As the first application of gamification principles integrated with artificial intelligence for swallowing therapy, this pioneering innovation addresses the critical need for engaging and personalized rehabilitation tools. The system's algorithms adapt to individual patient capabilities, while its real-time biofeedback mechanisms transform traditional repetitive exercises into an interactive experience with achievement-based progression, visual rewards, and adaptive difficulty levels,

significantly enhancing patient motivation and potentially improving therapy adherence and outcomes.

With the post-use acceptance interviews, this study fills a research gap regarding user perspectives and implementation considerations for technology-enhanced dysphagia rehabilitation. By collecting healthcare provider and patient perspectives, we identified key factors influencing clinical adoption and patient engagement with the AI-VG system. Findings indicate high acceptance rates among both stakeholder groups, with healthcare providers believing that AI-VG system relieves their workload, while patients report higher motivation and interest in adhering to treatment. This user-centered approach enables targeted improvements to the system's interface, difficulty levels, and movement variations, ensuring that interventions effectively meet clinical requirements and patient preferences prior to efficacy testing.

This study fills a research gap in the efficacy of AI-enhanced gamified rehabilitation for the treatment of PSD through a randomized controlled trial. We provided the first controlled evidence comparing this innovative approach to traditional therapies and showed that the AI-VG system group achieved statistically and clinically significant improvements in multiple outcome areas. PSD Patients using the AI-VG system demonstrated outstanding results in swallowing function, oral intake level, and swallowing-related quality of life. Extremely high patient satisfaction and training adherence further validate the potential of this approach to transform rehabilitation participation and outcomes in this challenging clinical population.

This study has insightful implications for clinical practice and future approaches to dysphagia rehabilitation. By determining the effectiveness of an AI-VG system intervention, we have explored a new field of dysphagia rehabilitation, combining technological innovation with patient-centered care. Our findings

provide guidance for clinicians seeking more effective and engaging rehabilitation programs for PSD patients.

Future research should focus on refining AI algorithms to further personalize treatment, expanding the variety of game-based exercises, exploring tele-rehabilitation applications to improve accessibility, and improving AI algorithms to recognize patients' facial muscle movement tracks. To further validate these promising results and develop optimal treatment programs, more research with larger and more diverse patient populations is necessary.

This innovative research provides the foundation for a new generation of rehabilitation strategies that utilize the power of AI and video gamification to facilitate rehabilitation, improve patient prognosis, and ultimately transform the rehabilitation experience for patients with post-stroke dysphagia.

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Appendix

Appendix 1. Search strategy used in PubMed

#1. [mh ^"cerebrovascular disorders"] or [mh "basal ganglia cerebrovascular disease"] or [mh "brain ischemia"] or [mh "carotid artery diseases"] or [mh "intracranial arterial diseases"] or [mh "intracranial arteriovenous malformations"] or [mh "intracranial embolism and thrombosis"] or [mh "intracranial hemorrhages"] or [mh ^stroke] or [mh "brain infarction"]

#2. [mh ^"brain injuries"] or [mh ^"brain injury, chronic"]

#3. (stroke or cva or poststroke or "post-stroke" or cerebrovasc* or cerebral next vasc*):ti,ab

#4.((cerebral* or cerebell* or brain* or vertebrobasilar) near/5 (isch*emi* or infarct* or thrombo* or emboli* or apoplexy*)):ti,ab

#5. ((brain* or cerebral* or subarachnoid) near/5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)):ti,ab

#6. [mh ^hemiplegia] or [mh paresis]

#7. (hemipleg* or hemipar* or paresis or paretic or brain next injur*):ti,ab

#8. [mh ^"neurologic"]

#9. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8

#10. [mh ^" deglutition disorders"]

#11. ("swallowing disorder" or dysphagia or "oropharyngeal dysphagia" or "esophageal dysphagia"):ti,ab

#12. (dysphag*):ti,ab

#13. #10 or #11 or #12

#14. #9 and #13

Appendix 2. Information sheet

Effect of an artificial intelligence-empowered video-game system in stroke patients with dysphagia: A randomized controlled trial

You are invited to participate in the above project supervised by Prof. Jing Qin, who is a professor at the School of Nursing, and conducted by Miss. Bohan Zhang who is a registered nurse and a Ph.D. student of the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (Reference Number: HSEARS20230502007).

Introduction

This study aims to develop an artificial intelligence-empowered video-game swallowing rehabilitation system (AI-VG) for post-stroke patients with dysphagia, and to investigate its impact on improving swallowing function, and feeding and daily function compared to traditional dysphagia training. Timely swallowing rehabilitation is important because of the high incidence of dysphagia and the potential for multiple complications and serious consequences. The results of the study will provide evidence for timely and effective rehabilitation of patients with post-stroke dysphagia.

Study Content

You are invited to complete the questionnaires, which will take you about half an hour. You will then be asked to take part in a procedure to investigate the effect of AI-VG system on swallowing function. Measurements will be taken by the AI-VG system (you will be faced with the computer and a camera, the camera will detect changes in the participant's facial

muscles and expressions, the computer through the computation of real-time game control to obtain biofeedback. The AI-VG system have three games: (1) Game One - Lip Exercise: the game “Collecting carrots” appears on the computer screen. Participants move the character in the game by drumming cheeks, left drumming cheeks and right drumming cheeks. After the character in the game moves to the left and right to reach the designated place, the carrot will automatically fall into the back basket of the character in the game, participants need to complete drumming cheeks, left drumming cheeks and right drumming cheeks 15 times, respectively. (2) Game Two - Tongue Exercises: the “Maze Challenge” game appears on the computer screen. The participant uses tongue movements to make the characters in the game move. The participant extends the tongue, tongue up, tongue down, tongue left, tongue right, and the game character in the labyrinth is activated, up, down, left, and right by the participant ‘s tongue movements. The route out of the maze was designed based on the patient’s tongue movement route, and the game character walked out of the labyrinth when the patient completed the tongue movement. Each movements repeat 15 times. (3) Game Three – Neck Exercise: the “Little bird flying” game appears on the computer screen. In this game, participants control the direction of the bird’s flight by lowering their jaw. Participants use their chin to press the rubber ball, hold it for 2-3 seconds and then lift it up and the bird will fly down and around the obstacle. Participants are required to go around the obstacle a total of 15 times.). The whole training will take about once a day for 30 min per session, 5 times a week for 4 weeks.

Risk or Discomfort

This study is a clinical trial, but does not involve any invasive operation. The swallowing exercises performed by the subjects conformed to clinical standards, and the participants were supervised by experienced health care staff throughout the training process. The risk of physical, psychological, social, and economic discomfort to the participants during the study was low. Since the use of AI-VG system as an intervention method may cause discomfort such as visual fatigue in participants, the study will be stopped and observed

immediately when participants experience any discomfort. If the discomfort is not relieved after half an hour, it will be immediately reported to the doctor in charge and relevant treatment will be given.

Privacy

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and her team and supervisor will have access to personal data and research data for the purposes of the study. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit of the research.

All information related to you will remain confidential and all study data will be stored on PolyU's OneDrive with a password and will not be stored on personal devices. The information collected will be kept until four years after project completion. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access or destruction of the information you provide.

Right

You have every right to withdraw from the study before or during the measurement without penalty of any kind.

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Miss. Bohan Zhang (tel. no.: +852 6113 / email: bohan.zhang@) of PolyU under the following situations:

a. if you have any other questions in relation to the study;

b. if, under very rare conditions, you become injured as a result of your participation in the study; or

c. if you want to get access to/or change your personal data before (the expiry date).

In the event you have any complaints about the conduct of this research study, you may contact Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

In case of a serious adverse event[1], please report to the Principal Investigator/Chief Investigator immediately and the Principal Investigator/Chief Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

Thank you for your interest in participating in this study.

[1] SAE is any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

(Reference: NIA Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

Appendix 3. Consent form

CONSENT TO PARTICIPATE IN RESEARCH

Effect of an artificial intelligence-empowered video-game system in stroke patients with dysphagia: A randomized controlled trial

This study aims to develop an artificial intelligence-empowered video-game (AI-VG) swallowing rehabilitation system for post-stroke patients with dysphagia, and to investigate its impact on improving swallowing function, and feeding and daily function compared to traditional dysphagia training. Timely swallowing rehabilitation is important because of the high incidence of dysphagia and the potential for multiple complications and serious consequences. The results of the study will provide evidence for timely and effective rehabilitation of patients with post-stroke dysphagia.

In the swallowing training based on the AI-VG system, the participant will use a computer for a training session of about 30 minutes. In traditional dysphagia training, the participant will be led by a rehabilitation instructor for about 30 minutes of training activities. The frequency of training is once a day, five times a week for four weeks.

All data collected this time will only be used for scientific research and will be analyzed anonymously, and all personal data will be kept strictly confidential.

I _____ hereby consent to participate in the captioned research conducted by Prof. Jing Qin and Miss. Bohan Zhang of School of Nursing at The Hong Kong Polytechnic University.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed. Participants in this study may experience eyestrain, and may need to be photographed and videotaped.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary. I

acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

If you have any questions, you may contact Miss Bohan Zhang (tel. no.:+852 6113 / email: bohan.zhang@).

Name of participant _____

Signature of participant _____

Name of Parent or Guardian (if applicable) _____

Signature of Parent or Guardian (if applicable) _____

Name of researcher _____

Signature of researcher _____

Date _____

Appendix 4. Information sheet (Chinese version)

THE HONG KONG POLYTECHNIC UNIVERSITY 香港理工大學

信息表

基于人工智能的视频游戏的吞咽功能训练对卒中后吞咽障碍患者的疗效：一项随机、单盲、对照试验

亲爱的参与者：

我们邀请你参加上述项目，由香港理工大学护理学院的秦璟教授指导，并由香港理工大学护理学院的注册护士和博士生张博寒小姐实施。本项目已获得理大机构审查委员会（PolyU IRB# HSEARS20230502007）和北京小汤山医院伦理委员会（LS20230720-1）的批准，实验注册号（ClinicalTrials.gov, NCT05978700. https://clinicaltrials.gov/study/NCT05978700）。

介绍

本研究旨在为吞咽障碍患者开发一种基于人工智能的视频游戏的吞咽康复设备，与传统的吞咽困难训练相比，研究其对改善吞咽功能以及进食和日常功能的影响。由于吞咽困难的发病率很高，而且有可能导致多种并发症和严重后果，因此及时进行吞咽康复非常重要。该研究的结果将为吞咽障碍患者的及时有效康复提供证据。

研究内容

我们邀请您填写 9 个量表，这将花费您大约**半小时**的时间。

实验组：您将被要求参加使用一个设备，调查视频游戏对吞咽功能的影响。研究将由视频游戏设备进行。您将面对一台电脑和一个摄像头，摄像头将检测被试者的面部肌肉和表情的变化，电脑通过计算实时控制游戏获得生物反馈。该视频游戏有三个游戏。整个训练大约需要**每天一次，每次 30 分钟，每周 5 次，持续 4 周**。

对照组：参与常规吞咽障碍康复训练。

风险或不适

本研究是一项临床试验，但**不涉及任何侵入性操作**。研究期间，参与者的身体、心理、社会和经济不适的风险很低。由于使用视频游戏作为干预方法，可能会导致研究参与者出现肌肉酸痛、视力疲劳等轻微不适。研究人员会提前告知参与者可能出现的不适，并指导参与者采取

正确的训练方法，适当休息以防范不适。如果出现明显不适将立即停止研究并观察。如果不适半小时后仍不能缓解，则立即向主管医生汇报并给予相关处理。

潜在的益处

参加本项目的研究，将有助于您进行吞咽功能的康复训练，提供吞咽功能和生活质量，帮助临床医护更好的选择适合吞咽障碍患者的训练方法，为患者的康复训练提供指导和依据。

保护措施

受试者进行的吞咽练习符合临床标准，而且在整个训练过程中，参与者都有经验丰富的医护人员进行监督。如果出现明显不适将立即停止研究并观察。如果不适半小时后仍不能缓解，则立即向主管医生汇报并给予相关处理。如果参与者在研究中受到损害，研究人员将根据损害程度，提供相应的医疗救治，并在 48 小时内上报伦理委员会，给予相应的处理或赔偿。考虑到吞咽障碍患者存在吞咽功能障碍的特点，研究人员会给予患者足够的训练指导，确保参与者能够正确安全地操作训练程序。如出现呛咳等情况，会立即停止训练并向主管医生汇报，采取必要的应急措施。

如果不参加此研究，其他备选治疗方案

您可以选择不参加本项研究，这对您获得常规治疗不会带来任何不良影响。目前针对您的健康情况，常规的治疗方法有日常进食健康教育、进食体位训练、呼吸训练、咳嗽技巧培训等。

是否一定要参加并完成本项研究？

您是否参加这个研究完全是自愿的。如果您不愿意，可以拒绝参加，这对您目前或未来的卫生医疗不会有任何负面影响。即使您同意参加之后，您也可以在任何时间改变主意，告诉研究者退出研究，您不会因退出试验而遭到歧视或报复，也不会影响您获得正常的医疗服务。当您决定不再参加本研究时，希望您及时告知您的研究医生，研究医生可就您的健康状况提供建议和指导。

研究参与者在参与研究前、研究后和研究过程中的注意事项？

研究参与者在参与研究前、研究后和研究过程中如出现**视觉疲劳、呛咳**等不适症状，请及时联系研究人员。

参加该项研究的费用

研究所涉及的视频游戏设备、调查问卷等费用均由研究者提供。

研究过程**全程免费**，不会收取任何费用。

发生研究相关伤害的处理

当您的健康状况在参加本研究期间受到伤害时，请告知研究者（张博寒 1326196 ），我们会采取必要的医疗措施。如果您在研究中受到损害，研究人员将根据损害程度，提供相应的医疗救治，并在 48 小时内上报伦理委员会，给予相应的处理或赔偿。

研究参与者的个人信息会得以保密吗？

研究参与者作为研究的一部分，仅提供研究数据。任何可以确定研究参与者身份的研究数据都被称为个人数据。个人数据不包括身份已被删除的数据（匿名数据）。我们将在研究中尽量减少对个人数据的使用。研究人员及其团队和指导老师将为研究目的而接触到个人数据和研究数据。所有数据仅作为研究使用，不会外泄和与非研究团队成员共享。

权利

你完全有权在测量前或测量过程中退出研究，而不会受到任何形式的惩罚。如果你有任何问题，你可以现在或以后询问我们的研究人员：张博寒小姐（电话：+86 1326196 ；电子邮件：bohan.zhang@ ）

感谢你对参与本研究的兴趣。

Appendix 5. Consent form (Chinese version)

THE HONG KONG POLYTECHNIC UNIVERSITY 香港理工大學

知情同意书

School of Nursing 護理學院

基于人工智能的视频游戏的吞咽功能训练对吞咽障碍患者的疗效：一项随机、单盲、对照试验

本研究旨在为吞咽障碍患者开发一种基于人工智能的视频游戏的吞咽康复设备，与传统的吞咽困难训练相比，研究其对改善吞咽功能以及进食和日常功能的影响。该研究的结果将为吞咽困难患者的及时有效康复提供证据。

参与者已被告知“基于**人工智能的**视频游戏的吞咽功能训练对吞咽障碍患者的疗效：一项随机、单盲、对照试验”项目的研究背景、目的、步骤、风险及获益情况。参与者有足够的时间和机会进行提问，问题的答复参与者很满意。参与者也被告知，当参与者有问题，或想进一步获得信息，应当与谁联系（张博寒 1326196 ）。参与者已经阅读这份知情同意书，并且同意参加本研究。参与者知道在研究期间任何时刻无需任何理由都可以退出本研究。参与者被告知参与者将得到这份知情同意书的副本，上面包含参与者和研究者的签名。

此次收集的所有数据仅用于科学研究，并将进行匿名分析，所有个人数据将被严格保密。

本人_____，同意参加由护理学院秦璟教授和张博寒小姐主持的上述研究。本人知晓此研究所得的资料可能被用作日后的研究及发表，但本人的隐私权利将得以保留，即本人的个人资料不会被公开参与。

研究人员已向本人清楚解释列在所需信息卡上的研究程序，本人知晓当中涉及的利益及风险；本人自愿参与研究项目。本人知晓本人有权就程序的任何部分提出疑问，并有权随时退出而不受任何惩处。

如有任何疑问，请联系张博寒小姐（电话：1326196 ；电子邮件：bohan.zhang@ ）。

参与者签名 _____ 联系电话_____

家长或监护人（如适用，关系_____） 签名 _____联系电话_____

研究人员签名 ____ _____

日期 _____

Appendix 6. Case Report Form (Chinese version)

基于人工智能的视频游戏的吞咽功能训练对吞咽障碍患者的疗效：一项随机、单盲、对照试验

病例报告表

版本号：1.0

版本日期：2023 年 10 月 4 日

筛 选 号：|_|_|_|_|

随 机 号：|_|_|_|_|

姓名缩写：|_|_|_|_|

试验机构： 北京小汤山医院

试验开始时间：20|__|__|年|__|__|月|__|__|日

试验结束日期：20|__|__|年|__|__|月|__|__|日

记录人签名：_____

病例报告表（CRF）填表说明

1. 病例报告表请用黑色签字笔填写，字迹应清晰，易于辨认。
2. 每项填写内容务必准确、清晰，不得随意更改，如发现内容有误，应当在原记录上划单横线，不得用任何方式掩盖，并在旁边注明正确内容及修改原因，由研究者签名并注明日期。举例：~~58.6~~ 56.8 ZQ2012-8-21。
3. CRF 每一页及其所有项目均应填写，不得留空。在“□”处填写“×”表示选择此项。如果此项“未做”则填入“ND”，“不知道”则填入“UK”，“不能提供”或“不适用”则填入“NA”。并且在每次随访末页的备注栏内说明情况。
4. 表格中日期格式为“年/月/日”，包括受试者的出生日期。如果不知道具体日期，请用“UK”表示，如“年/月/UK”。
5. CRF 中需填入数值的部位均预留了空格，如“|_|_|_|”，填写时请将个位数字填入最右方的空格，如左侧留有空格，请填入“0”，例如：患者血压为 120/80mmHg，则填入“血压：|1|2|0|/|0|8|0|mmHg”。
6. 请务必完成每页 CRF 最上部分的内容，包括：

A. 患者姓名拼音缩写四格需填满。如姓名为两个字，则填写每个汉字的前两个拼音字母大写；如姓名为三个字，则填写前两个汉字的首字母大写，及最后一个汉字的前两个拼音字母大写；如姓名为四个字或四个字以上，则只填写前四个字的首字母大写。举例：张红| Z | H | H | O |　李书明| L | S | M | I |　刘月娥| L | Y | E |—|　欧阳晓慧| O | Y | X | H |

B. 受试者筛选号，为受试者签署知情同意书的顺序号，例如第 1 个受试者为 0001，以此类推。

7. 不要改变病例报告表的格式，如发现表中没有位置填写记录者希望记录的资料时，请将有关信息记录于后面的空白附页中，并保留以上记录副本。
8. 试验期间应如实填写不良事件记录表。记录不良事件的发生时间、严重程度、持续时间、采取的措施和转归。

临床研究流程图

步骤	时期	筛选期	干预期		随访期
	研究随访	访视 0	访视 1	访视 2	访视 3
	研究日期（天）	-7 天	0	28±3 天	56±3 天
1	签署知情同意书	×			
2 临床资料	受试者基本资料	×			
	临床诊断	×			
	既往史	×			
3 试验检查	认知功能	×	×	×	×
	意识程度	×	×	×	×
	吞咽功能（GUSS）	×	×	×	×
	吞咽功能（VVST）	×	×	×	×
	吞咽功能（SSA）	×	×	×	×
	功能性经口摄食量表（FOIS）		×	×	×
	吞咽生存质量量表(SWAL-QOL)		×	×	×
	微型营养评价简表（MNA-SF)		×	×	×
	接受度调查			×	
	满意度调查			×	
4	入选与排除标准	×			
5	有效性评价			×	×
6	依从性评价			×	
7	临床安全性评价			×	×
8	不良事件监测	×	×	×	×
9	方案偏离记录	×	×	×	×
10	填写 CRF	×	×	×	×

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　访视 0（筛选期）

一、受试者病历简况

1. 签署知情同意书

签署知情同意书日期：　20|__|__|年|__|__|月|__|__|日

2.受试者基本资料

姓名缩写：|_|_|_|_|	性别：　□ 男　□ 女
出生日期：|__|__|__|__|年|__|__|月|__|__|日	受试者筛选号：|_|_|_|_|
入住日期：|__|__|__|__|年|__|__|月|__|__|日	
患病日期：|__|__|__|__|年|__|__|月|__|__|日	

卒中类型	①缺血性卒中　②出血性卒中
职业类型	①以脑力劳动为主　②以体力劳动为主 ③部分脑力劳动，部分体力劳动 ④无业
婚姻状况	①已婚 ②丧偶 ③离异 ④未婚
居住地	①农村/郊区　②城镇/市区
生活方式	①吸烟史 ②饮酒史 ③两者均有 ④两者均无
合并症	①　高血压病史 ②糖尿病史 ③冠心病史 ④其他：____

3.临床诊断（记录本次诊断）

No	临床诊断	备注
1		
2		
3		
4		
5		
6		
7		
8		
9		

4.既往病史

最近一年内是否患急性或慢性疾病？ ☐ 否 → 无需填写下列项； ☐ 是 → 请填写下列项；					
序号	**疾病名称**	**诊断日期/发生日期**	**目前存在否**		**结束日期**
			是	否	
1		____年__月__日	☐	☐	____年__月__日
2		____年__月__日	☐	☐	____年__月__日
3		____年__月__日	☐	☐	____年__月__日
4		____年__月__日	☐	☐	____年__月__日
5		____年__月__日	☐	☐	____年__月__日

注：患病情况包括过敏史

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　访视 0（筛选期）

二、受试者筛选

入选标准（任何选择为“否”，则该志愿受试者不能入选）	**是**	**否**
1、 根据临床体征和神经影像学证据确诊脑卒中，临床诊断依据美国心脏协会/美国卒中协会声明，神经影像学确诊依据计算机断层扫描（CT）或磁共振成像（MRI）图像	☐	☐
2、 经咽喉吞咽功能筛查（GUSS）诊断为吞咽困难	☐	☐
3、 首次大脑半球发病且病程小于 1 年	☐	☐
4、 年龄大于 18 岁	☐	☐
5、 无明显认知障碍，能正确执行指令，且迷你精神状态检查（Mini-Mental State Examination, MMSE）得分≥24	☐	☐
6、 提供知情书面同意	☐	☐

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

排除标准（任何选择为“是”，则该志愿受试者不能入选）	**是**	**否**
1、结构性病变（如放疗、肿瘤、头颈部广泛手术）引起的吞咽障碍	☐	☐
2、合并严重的心、肺、肝、肾和血液系统疾病	☐	☐
3、肢体缺损或瘫痪、双眼失明、严重视力障碍阻碍使用电脑	☐	☐
4、晕车或前庭功能障碍	☐	☐
5、有癫痫或恶性肿瘤	☐	☐
6、怀孕或哺乳期	☐	☐

【筛选结果】

受试者符合所有入选标准并不具备任何一项排除标准，且未撤回知情同意书。

□否，填写试验完成情况页。

□是，受试者进入试验：受试者随机号|__|__|__|：

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　访视 1（0 天）

访视1（0天）

受试者是否完成本次访视：□否，原因：_____

□是（若是，请完善后续随访表）

本次访视时间：20|__|__|年|__|__|月|__|__|日

一、　基线检查

检查项目	**诊断日期/发生日期**	**检查结果**
简易智能精神状态检查量表（MMSE）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（GUSS）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（VVST）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（SSA）	|__|__|__|__|年|__|__|月|__|__|日	
功能性经口摄食量表（FOIS）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽生存质量量表(SWAL-QOL)	|__|__|__|__|年|__|__|月|__|__|日	
微型营养评价简表（MNA-SF)	|__|__|__|__|年|__|__|月|__|__|日	

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

访视2（28±3天）

受试者是否完成本次访视：□否，原因：_____

□是（若是，请完善后续随访表）

本次访视时间：20|__|__|年|__|__|月|__|__|日

一、　有效性评价

检查项目	**诊断日期/发生日期**	**检查结果**
吞咽功能（GUSS）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（VVST）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（SSA）	|__|__|__|__|年|__|__|月|__|__|日	
功能性经口摄食量表（FOIS）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽生存质量量表(SWAL-QOL)	|__|__|__|__|年|__|__|月|__|__|日	
微型营养评价简表（MNA-SF)	|__|__|__|__|年|__|__|月|__|__|日	
接受度调查	|__|__|__|__|年|__|__|月|__|__|日	
满意度调查	|__|__|__|__|年|__|__|月|__|__|日	

二、 依从性评价

检查项目	**诊断日期/发生日期**	**检查结果**
康复日记完成情况	|__|__|__|__|年|__|__|月|__|__|日	
参与者完成训练数量	|__|__|__|__|年|__|__|月|__|__|日	

研究者签名： 填表日期：**20**|__|__|年|__|__|月|__|__|日

试验总结

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　访视 3（56±3 天）

访视3（56±3天）

受试者是否完成本次随访：□否，原因：_____

□是（若是，请完善后续随访表）

本次随访时间：20|__|__|年|__|__|月|__|__|日

一、 有效性评价

检查项目	**诊断日期/发生日期**	**检查结果**
吞咽功能（GUSS）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（VVST）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽功能（SSA）	|__|__|__|__|年|__|__|月|__|__|日	
功能性经口摄食量表（FOIS）	|__|__|__|__|年|__|__|月|__|__|日	
吞咽生存质量量表(SWAL-QOL)	|__|__|__|__|年|__|__|月|__|__|日	
微型营养评价简表（MNA-SF)	|__|__|__|__|年|__|__|月|__|__|日	

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　不良事件

不良事件　　□无 □有

如果在试验期间没有不良事件发生，请在此□中打“×”，并在此表下方签名。

请用标准医学术语记录所有观察/询问到的不良事件。每一栏记录一个不良事件。

不良事件描述			
开始发生时间			
结束时间[1]			
不良事件 特点	□阵发性 □发作次数□□ □持续性	□阵发性 □发作次数□□ □持续性	□阵发性 □发作次数□□ □持续性
不良事件记录 报告及程度[2]	□轻 □中 □重 □报告 有□ 无□	□轻 □中 □重 □报告 有□ 无□	□轻 □中 □重 □报告 有□ 无□
严重不良事件	□是 □否	□是 □否	□是 □否
与试验 的关系	□肯定有关 □很可能有关 □可能有关 □可能无关 □无关	□肯定有关 □很可能有关 □可能有关 □可能无关 □无关	□肯定有关 □很可能有关 □可能有关 □可能无关 □无关
转归	□消失 后遗症 有□ 无□ □继续 □死亡	□消失 后遗症 有□ 无□ □继续 □死亡	□消失 后遗症 有□ 无□ □继续 □死亡
纠正治疗	□是 □否	□是 □否	□是 □否
因不良事件而退出试验	□是 □否	□是 □否	□是 □否
备 注	1. 如果不良事件仍存在，请不要填写此项。 2. 程度： 症状按轻(询问出)；中(主动叙述但能忍耐)；重(有客观表现,难忍耐)填写。		

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　严重不良事件和器械缺陷记录

严重不良事件　　□无 □有　若有，请附 SAE 报告表

器械缺陷记录　　□无　　□有，详见下表：

器械缺陷详细情况及处理记录：	
1	
2	
3	
4	
5	

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

方案偏离记录表

是否发生方案偏离的情况？　　☐ 否　　☐ 有 ，请将方案偏离情况记录在下表中

序号	方案偏离描述	发生日期（年/月/日）	采取的措施	是否为显著的方案偏离
		____/___/___	☐ 警告后继续研究 ☐ 重新安排随访 ☐ 受试者剔除（脱落） ☐ 未采取措施，研究结束 ☐ 其他措施，请注明____________________	☐ 是 ☐ 否
		____/___/___	☐ 警告后继续研究 ☐ 重新安排随访 ☐ 受试者剔除（脱落） ☐ 未采取措施，研究结束 ☐ 其他措施，请注明____________________	☐ 是 ☐ 否
		____/___/___	☐ 警告后继续研究 ☐ 重新安排随访 ☐ 受试者剔除（脱落） ☐ 未采取措施，研究结束 ☐ 其他措施，请注明____________________	☐ 是 ☐ 否

研究者签名：　　　　填表日期：**20**|__|__|年|__|__|月|__|__|日

受试者筛选号：|_|_|_|_|　　受试者姓名拼音缩写：|_|_|_|_|　　试验完成情况

试验完成情况

（筛选失败/完成/终止试验）

是否完成试验：　□是

□否（若未完成，请填写后续表格）：

未完成原因：　□筛选失败(若是，请填写下表)

□终止试验(若是，请填写下表)

筛选失败	终止试验
日期： 20|__|__|年|__|__|月|__|__|日 失败原因： _____ _____ _____	终止日期： 20|__|__|年|__|__|月|__|__|日 首先提出终止试验的是： □受试者 □研究者 □申办者 □其他，请说明： 终止的主要原因是： □不良事件（已填写不良事件报告表） □违背试验方案 □失访 □被研究者终止 □其它，请说明：

研究者签名：　　填表日期：**20**|__|__|年|__|__|月|__|__|日

声 明

此病例报告表中的信息记录真实、准确，符合试验方案的要求，特此声明。

研究者签名：

年　　月　　日

Appendix 7. Assessment tools

Gugging Swallowing Screen, GUSS

1. Preliminary Investigation / Indirect Swallowing Test

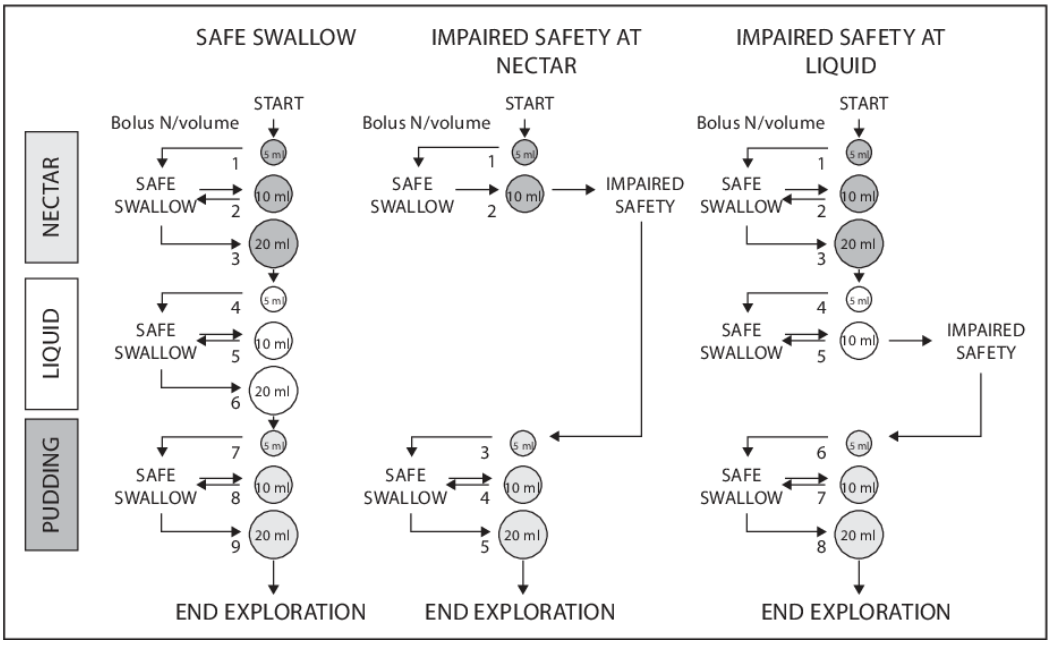
		YES	NO
VIGILANCE	The patient must be alert for at least 15 minutes	1	0
COUGHING and/or THROAT CLEARING	Voluntary cough: The patient should cough or clear his/her throat twice	1	0
SWALLOWING SALIVA • Swallowing successful	Conduct oral hygiene if the mouth is very dry If the patient coughs during or after swallowing saliva please tick „No“	1	0
• Drooling	Permanent severe saliva drooling	0	1
• Voice change after swallowing	Gurgling, wet hoarse voice since onset of stroke	0	1
	SUM:	(5)	
		1 – 4 = Stop the test see GUSS-Evaluation **5** = Continue with part 2	

2. Direct Swallowing Test (Material: Water, food thickener, teaspoon, cup, syringe, bread, biscuit)

In the following order	**SEMISOLID→**	**LIQUID→**	**SOLID**
	½ teaspoon of thickened water (IDDSI: Level 3) If there are no symptoms apply 3-5 more teaspoons Stop the investigation if one of the 4 aspiration criteria is observed	Offer 3, 5, 10, 20 ml of water in a cup followed by 50 ml of water. (sequential swallows) Stop the investigation if one of the 4 aspiration criteria is observed	Offer a piece of bread without crust and/or a piece of biscuit (max. 1.5 x 1.5cm) Stop the investigation if one of the 4 aspiration criteria is observed

DEGLUTITION			
• Swallowing not possible	0	0	0
• Swallowing delayed (semisolids, fluids > 2 sec. solids > 10 sec.)	1	1	1
• Swallowing successful	2	2	2
COUGHING (involuntary) *(before, during and after swallowing - until 3 minutes later)*			
• Yes	0	0	0
• No	1	1	1
DROOLING			
• Yes	0	0	0
• No	1	1	1
VOICE CHANGE *(Listen to the voice before and after swallowing - Patient should say „Ohhh")*			
• Yes	0	0	0
• No	1	1	1
SUM:	(5)	(5)	(5)
	1 – 4 = Stop the test see GUSS-Evaluation **5** = Continue „Liquid"	**1 – 4** = Stop the test see GUSS-Evaluation **5** = Continue „Solid"	
SUM: **(Indirect Swallowing Test AND Direct Swallowing Test)** ___(20)			

The volume-viscosity swallow test, V-VST



Standardized swallowing assessment，SSA

Step 1: Preliminary Assessment (8-23 points)	
（1）Level of consciousness	1= Alert
	2= Drowsy, can be aroused and responds verbally
	3= Responds to stimulation but remains with eyes closed and non-verbal
	4= Responds only to pain stimulation
（2）Head and trunk control	1= Can maintain normal sitting balance
	2= Can maintain sitting balance
	3= Cannot maintain sitting balance, but can partially control head balance
	4= Cannot control head balance
（3）Respiratory distress	1= Normal 2= Abnormal
（4）Drooling	1= Normal 2= Abnormal
（5）Range of tongue movement symmetry	1 = Normal 2 = Asymmetrical 3 = Unable to move
（6）Presence of articulation disorder, hoarse voice, wet phonation	1 = None 2 = Mild 3 = Severe
（7）Gag reflex	1 = Present 2 = Absent
（8）Voluntary cough ability	1 = Normal 2 = Reduced 3 = Absent
Total Score	
Step 2: Teaspoon Water Test (approximately 5ml), repeated 3 times (5-11 points)	
（9）Leakage from corner of mouth	1 = None/once 2 = >once
（10）Swallowing movement	1 = Present 2 = Absent
（11）Repeated swallowing	1 = None/once 2 = >once
（12）Shortness of breath, coughing during swallowing	1 = None 2 = Present

（13）Abnormal phonation after swallowing, such as wet voice, hoarseness	1 = Normal 2 = Reduced or hoarse voice 3 = Unable to phonate
Note: If >2 of the 3 swallowing trials in this step are completely normal, proceed to Step 3	
Step 3: Drinking a cup of water (approximately 60ml) (5-12 points)	
(14) Able to drink the entire amount	1 = Yes 2 = No
（15）Coughing during or after swallowing	1 = None 2 = Present
（16）Shortness of breath during or after swallowing	1 = None 2 = Present
（17）Abnormal phonation after swallowing, such as wet voice, hoarseness, etc.	1 = Normal 2 = Reduced or hoarse voice 3 = Unable to phonate
（18）Presence of aspiration	1 = None 2 = Possible 3 = Present

The Functional Oral Intake Scale, FOIS

Level 1	No oral intake
Level 2	Tube dependent with minimal/inconsistent oral intake
Level 3	Tube supplements with consistent oral intake
Level 4	Total oral intake of a single consistency
Level 5	Total oral intake of multiple consistencies requiring special preparation
Level 6	Total oral intake with no special preparation, but must avoid specific foods or liquid items
Level 7	Total oral intake with no restrictions

The Swallowing Quality of Life, SWAL-QOL

Please choose a number that best represents your personal opinion and draw a “√” on the corresponding number. 1: Strongly disagree, 2: Generally disagree, 3: Not sure, 4: Generally agree, 5: Strongly agree

Dimension	Item	1	2	3	4	5
Eating Desire	1 Most days, I don’t care if I eat or not					
	2 I’m rarely hungry anymore					
	3 I don’t enjoy eating anymore					
Food Selection	4 Figuring out what I can eat is a problem for me					
	5 It is difficult to find foods I both like and can eat					
Eating Duration	6 It takes me longer to eat than other people					
	7 It takes me forever to eat a meal					
Symptom Frequency	8 Coughing					
	9 Choking when you eat food					
	10 Choking when you take liquids					
	11 Coughing food/liquid out your mouth					
	12 Having thick saliva or phlegm					
	13 Gagging					
	14 Drooling					
	15 Problems chewing					
	16 Having excess saliva or phlegm					
	17 Having to clear your throat					
	18 Food sticking in your throat					
	19 Food sticking in your mouth					

	20 Food/liquid dribbling out your mouth					
	21 Food/liquid coming out your nose					
Burden	22 Dealing with my SP is very difficult					
	23 SP is a major distraction in my life					
Mental Health	24 My SP depresses me					
	25 Being so careful when I eat or drink annoys me					
	26 My SP frustrates me					
	27 I've been discouraged by my SP					
	28 I get impatient dealing with my SP					
Social	29 I do not go out to eat because of my SP					
	30 My usual activities have changed BOM SP					
	31 My role with family/friends has changed BOM SP					
	32 Social gatherings are not enjoyable BOM SP					
	33 My SP makes it hard to have a social life					
Sleep	34 Have trouble falling asleep					
	35 Have trouble staying asleep					
Fatigue	36 Feel exhausted					
	37 Feel weak					
	38 Feel tired					
Communication	39 People have a hard time understanding me					
	40 It's been difficult for me to speak clearly					

Fear	41 I fear I may start choking when I eat food					
	42 I worry about getting pneumonia					
	43 I am afraid of choking when I drink liquids					
	44 I never know when I am going to choke					

*SP= Swallowing problem; BOM= Because of my; The Swallowing Quality of Life Scale (SWAL-QOL) consists of 44 questions on 11 dimensions, namely swallowing-related quality of life (8 dimensions), swallowing symptoms (1 dimension) and general quality of life (2 dimensions). The “swallowing-related quality of life” included eight dimensions: psychological burden, eating time, appetite, food choice, verbal communication, fear of eating, mental health, and social interaction. The lowest score is 44 and the highest score is 220. The lower the score, the worse the swallowing function and the poorer the quality of life.

Mini Nutritional Assessment Short Form, MNA-SF

A. Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?

0= severe decrease in food intake

1= moderate decrease in food intake

2= no decrease in food intake

B. Weight loss during the last 3 months

0 = weight loss greater than 3 kg (6.6 lbs)

1 = does not know

2 = weight loss between 1 and 3 kg (2.2 and 6.6 lbs)

3 = no weight loss

C. Mobility

0 = bed or chair bound

1 = able to get out of bed / chair but does not go out

2 = goes out

D. Has suffered psychological stress or acute disease in the past 3 months?

0 = yes

2 = no

E. Neuropsychological problems

0 = severe dementia or depression

1 = mild dementia

2 = no psychological problems

F1. Body Mass Index (BMI) (weight in kg) / (height in m) ^{2}

0 = BMI less than 19

1 = BMI 19 to less than 21

2 = BMI 21 to less than 23

3 = BMI 23 or greater

IF BMI IS NOT AVAILABLE, REPLACE QUESTION F1 WITH QUESTION F2. DO NOT ANSWER QUESTION F2 IF QUESTION F1 IS ALREADY COMPLETED.
F2. Calf circumference (CC) in cm 0 = CC less than 31 3 = CC 31 or greater
Screening score (max. 14 points) **12-14 points:** Normal nutritional status **8-11 points:** At risk of malnutrition **0-7 points:** Malnourished

Evaluation of the acceptability of an artificial intelligence-empowered video-game swallowing function rehabilitation system by patients with dysphagia

Dear patients and families:

Hello, I am a PhD student at the Hong Kong Polytechnic University, and I would like to thank you for filling out this questionnaire during your busy schedule.

Based on the high incidence of dysphagia in patients and the potential for multiple complications and serious consequences, it is important to provide swallowing rehabilitation training to patients in a timely manner. The purpose of this study is to find out your acceptability of the artificial intelligence-empowered video-game swallowing rehabilitation system after you have fully experienced it, so please fill in the questionnaire according to your true feelings.

This questionnaire will take you 5-10 minutes, and all information you provide is for academic research only and is absolutely private. Thank you very much for your help.

School of Nursing, The Hong Kong Polytechnic University

June 15, 2023

I. Your basic information

Age: _____years old Nursing home: _____ Gender: ① male ② female Height: _____cm, weight: _____kg Length of stay: _____(YYYY/MM/DD)	
Occupation Type	① Mainly mental work ② Mainly manual work ③ Partly mental work, partly manual work ④ Unemployed
Place of residence	① Rural/suburban ② Town/urban

Complications	① History of hypertension ② History of diabetes ③ History of coronary artery disease ④ Other: ____

II. Evaluation of the acceptability of the video-game based swallowing function rehabilitation system

Please answer the following questions based on your full experience of the training system (please just draw a tick "√" on the number code)

	Strongly disagree	**Basically disagree**	**Unsure**	**Basically agree**	**Strongly agree**
I. Perceived usefulness					
1. You feel that the video-game based swallowing training system helps to increase your initiative and motivation to exercise	1	2	3	4	5
2. You think the video-game based swallowing training system helps to improve the length and endurance of your exercise	1	2	3	4	5
3. You think the video-game based swallowing training system provides convenience and help for you to do swallowing exercise	1	2	3	4	5
II. Perceived ease of use					
1. You think the video-game equipment for swallowing training is easy to use	1	2	3	4	5
2. You find the video-game software for swallowing training easy to use	1	2	3	4	5
3. In general, you find the video-game based swallowing training system easy to implement	1	2	3	4	5
III. Perceived ease of learning					

1. You feel that it is easy to learn how to use the video-game equipment and software for swallowing training	1	2	3	4	5
2. You feel familiar with the video-game process for swallowing training very quickly	1	2	3	4	5
3. Even without training, you can learn to use this video-game equipment for swallowing training very quickly	1	2	3	4	5
IV. Perceived applicability					
1. You think the video-game based swallowing training system is suitable for your rehabilitation exercises in terms of the magnitude and intensity of the movements involved	1	2	3	4	5
2. You think that the video-game based swallowing training system is suitable for your rehabilitation exercises in terms of the interface and the form of interaction presented	1	2	3	4	5
3. In general, you think the video-game based swallowing training system is suitable for your swallowing rehabilitation	1	2	3	4	5
V. Perceived safety					
1. You believe that the video-game based swallowing training system will not increase your chance of pain or discomfort compared to traditional exercise programs	1	2	3	4	5
2. You believe that the video-game based swallowing training system does not increase your chances of exercise-related adverse events (such as	1	2	3	4	5

detachment, falls or coughing) compared to traditional exercise programs					
3. You believe that the video-game based swallowing training system is safer overall than traditional exercise programs	1	2	3	4	5
VI. Perceived satisfaction					
1. You feel happy in using the video-game based swallowing training system	1	2	3	4	5
2. You are satisfied with the results of the video-game based swallowing training system	1	2	3	4	5
3. You are happy to recommend the video-game based swallowing training system to other patients	1	2	3	4	5
VII. Intention to use					
1. You will take full advantage of the features of the video-game based swallowing training system	1	2	3	4	5
2. You look forward to extending the video-game based swallowing training system to clinical use	1	2	3	4	5
3. In general, you would like to continue using the video-game based swallowing training system	1	2	3	4	5

The questionnaire has been finished, please check the questionnaire again, check whether there are missing items or missing fill in. If you have any questions, please feel free to contact us: bohan.zhang@ .

Thank you again for your cooperation and participation, and wish you a happy life!

Evaluation of the satisfaction of an artificial intelligence based video-game based swallowing function rehabilitation system by patients with dysphagia

Dear patients and families:

Hello, I am a PhD student at the Hong Kong Polytechnic University, and I would like to thank you for filling out this questionnaire during your busy schedule.

Based on the high incidence of dysphagia in patients and the potential for multiple complications and serious consequences, it is important to provide swallowing rehabilitation training to patients in a timely manner. The purpose of this study is to investigate your satisfaction of the video-game based swallowing rehabilitation system after you have fully used it, so please fill in the questionnaire according to your true feelings.

This questionnaire will take you 5-10 minutes, and all information you provide is for academic research only and is absolutely private. Thank you very much for your help.

School of Nursing, The Hong Kong Polytechnic University

June 15, 2023

Please answer the following questions based on your full experience of the training system (please just draw a tick "√" on the number code)

	Strongly disagree	**Basically disagree**	**Unsure**	**Basically agree**	**Strongly agree**
I. Training mode content setting					
1. You think the video-game based swallowing training system game design is interesting	1	2	3	4	5

2. You think the difficulty setting of the video-game based swallowing training system game is appropriate	1	2	3	4	5
3. You think the feedback of the video-game based swallowing training system is clear and easy to understand	1	2	3	4	5
4. You think the game content of video-game based swallowing training system meets the swallowing rehabilitation related content	1	2	3	4	5
5. You think the video-game based swallowing training system game content can stimulate your interest in rehabilitation training	1	2	3	4	5
II. Training mode format setting					
1. You think the video-game format for swallowing training is innovative and interesting	1	2	3	4	5
2. You think the video-game for swallowing training is visually appealing and easy to use	1	2	3	4	5
3. You think the video-game for swallowing training has enough tips and help	1	2	3	4	5
4. You think the video-game for swallowing training runs smoothly	1	2	3	4	5
5. You think the video-game for swallowing training is easy to use	1	2	3	4	5
III. Self-subjective feeling					
1. You feel that your dysphagia has improved by using the video-game based swallowing training system	1	2	3	4	5
2. You feel comfortable and relaxed when using the video-game based swallowing training system	1	2	3	4	5
3. You feel that the Video game-based swallowing training system is very helpful for dysphagia rehabilitation	1	2	3	4	5

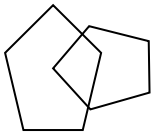
4. You would like to continue to use the video-game based swallowing training system for swallowing rehabilitation	1	2	3	4	5
5. You would recommend the video-game based swallowing training system to others	1	2	3	4	5

The questionnaire has been finished, please check the questionnaire again, check whether there are missing items or missing fill in. If you have any questions, please feel free to contact us: bohan.zhang@ .

Thank you again for your cooperation and participation, and wish you a happy life!

Mini-mental State Examination, MMSE

Maximum	Score	
		Orientation
5	( )	What is the (year) (season) (date) (day) (month)?
5	( )	Where are we (state) (country) (town) (hospital) (floor)?
		Registration
3	( )	Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he/she learns all 3. Count trials and record. Trials _____
		Attention and Calculation
5	( )	Serial 7's. 1 point for each correct answer. Stop after 5 answers. Alternatively spell "world" backward.
		Recall
3	( )	Ask for the 3 objects repeated above. Give 1 point for each correct answer.
		Language
2	( )	Name a pencil and watch
1	( )	Repeat the following "No ifs, ands, or buts"
3	( )	Follow a 3-stage command: "Take a paper in your hand, fold it in half, and put it on the floor."

1	( )	Read and obey the following: CLOSE YOUR EYES
1	( )	Write a sentence.
1	( )	Copy the design shown. 
Total Score	( )	

*e. The maximum score is 30. A score of 23 or lower is indicative of cognitive impairment

Rehabilitation training diary

Name: _____

Age: _____

Training Day_____ Date:_____(YYYY/MM/DD)
Did you complete dysphagia rehabilitation training today? □ Yes Start time: _____ : _____ (24-hour format) End time: _____ : _____ (24-hour format) Total training duration today: _____ minutes □ No
Did you experience any choking, vomiting, or similar symptoms during training? □ Yes □ No
Did you experience any choking, vomiting, or similar symptoms while eating today? □ Yes □ No
Did you feel any discomfort during training (other than choking, vomiting)? □ Yes □ No If yes, please describe: _____

Appendix 8. Assessment tools (Chinese version)

Gugging 吞咽功能评估量表 (Gugging Swallowing Screen，GUSS)

Gugging 吞咽功能评估量表（Gugging Swallowing Screen，GUSS）是通过间接吞咽试验、直接吞咽试验来全面评估患者对各种性状食物的吞咽情况，并进行打分。

1. 间接吞咽试验

初步检查/间接吞咽测试（患者取坐位，至少 60 度）

		是	否
警惕（病人是否有能力保持 15 分钟注意力）		1	0
主动咳嗽/清嗓子（病人应该咳嗽或清嗓子两次）		1	0
吞咽口水	成功吞咽	1	0
	流口水	0	1
	声音改变（嘶哑、过水声、含糊、微弱）	0	1
总计			
分析		1~4 分停止下一步检查 5 分：进入第二步	

2. 直接吞咽测试（材料：水，茶匙，食物添加剂，面包）

按下面的顺序：	1	2	3
	糊状食物★	液体食物★★	固体食物★★★
吞咽： · 不能 · 延迟（大于 2s，固体大于 10s） 成功吞咽	0 1 2	0 1 2	0 1 2
咳嗽（不由自主）： （在吞咽前-吞咽时-吞咽后 3 分钟） · 是 · 否	0 1	0 1	0 1
流口水 · 是 · 否	0 1	0 1	0 1
总计	___分	___分	___分
	1-4 分：不再进入第二步；记录分数 5 分，继续用液体	1-4 分：不再进入第二步；记录分数 5 分，继续用固体	
总合计（直接和间接吞咽测试）：_____（20 分）			

★	首先给予病人 1/3~1/2 勺类似布丁的糊状食物。如果给予 3~5 勺（1/2）勺没有任何症状，则进行下面的评估
★★	3,5,10,20 毫升水——如果没有症状继续给 50 毫升水，应以患者最快速度进食，评估和调查时得出的一个标准
★★★	临床：一小片干面包，撕下一小片，嘱患者吞咽，重复 5 次。10s 时间限制，包括口腔准备期

容积-黏度吞咽测试（The volume-viscosity swallow test, V-VST）

1、黏度

微稠（1%）：300ml 水+1 条舒食素（3g）

中稠（2%）：150ml 水+1 条舒食素（3g）

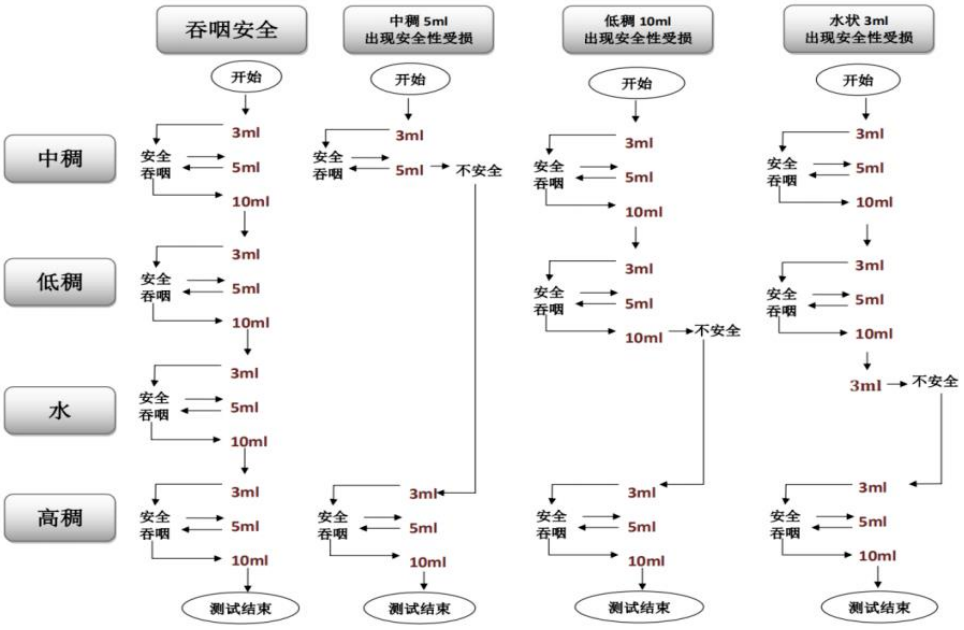
高稠（3%）：100ml 水+1 条舒食素（3g）

2、测试顺序

中稠（2%） 微稠（1%） 高稠（3%）

黏度-一口量		中稠			微稠			高稠		
相关指标		3ml	5ml	10ml	3ml	5ml	10ml	3ml	5ml	10ml
安全性指标	咳嗽									
	音质改变									
	血氧饱和度下降									
有效性指标	食物外溢									
	口腔残留									
	分次吞咽									

	咽腔残留									
受试者主观指标	顺滑性									
	适口性									
	喜食度									



3、记录

安全性指标：咳嗽、音质改变、氧饱下降 3%

有效性指标：食物外溢、 口腔残留、分次吞咽、 启动延迟。

受试者主观感受：顺滑性、喜食性、适口性

4、结果

（1）无安全性/有效性受损

评估结果：患者无口咽性吞咽障碍。

（2）有效性受损，但无安全性受损

评估结果：患者有口咽性吞咽障碍。患者可安全吞咽，但有效性受损，这可能危及患者的营养和补水状况。

（3）安全性受损（伴/不伴相关有效性问题）

评估结果：患者有口咽性吞咽障碍。吞咽过程的安全性下降提示该患者可能已经发生误吸。

标准吞咽功能评价量表（standardized swallowing assessment，SSA）

第一步 初步评价（8-23 分）	
（1）意识水平	1=清醒
	2=嗜睡，可唤醒并做出言语应答
	3=呼唤有反应，但闭目不语
	4=仅对疼痛刺激有反应
（2）头部和躯干部控制	1=能正常维持坐位平衡
	2=能维持坐位平衡
	3=不能维持坐位平衡，但能部分控制头部平衡
	4=不能控制头部平衡
（3）有无呼吸困难	1=正常 2=异常
（4）有无流涎	1=正常 2=异常
（5）舌的活动范围是否对称	1=正常 2=不对称 3=无法活动
（6）有无构音障碍、声音嘶哑、湿性发音	1=无 2=轻度 3=重度
（7）咽反射是否存在	1=存在 2=缺乏
（8）自主咳嗽能力	1=正常 2=减弱 3=缺乏
合计	得分
第二步 饮一匙水（量约 5ml），重复 3 次（5-11 分）	
（9）口角流水	1=无/1 次 2=>1 次
（10）吞咽动作	1=有 2=无
（11）重复吞咽	1=无/1 次 2=>1 次
（12）吞咽时气促、咳嗽	1=无 2=有
（13）吞咽后发音异常如湿性发音、声音嘶哑	1=正常 2=减弱或声音撕哑 3=发音不能
注:如果该步骤的 3 次吞咽中有>2 次完全正常，则进行下面第三步	

第三步饮一杯水（量约 60ml） （5-12 分）	
（14）能否全部饮完	1=是 2=否
（15）吞咽中或后咳嗽	1=无 2=有
（16）吞咽中或后喘息	1=无 2=有
（17）吞咽后有无发音异常如湿性发音、声音嘶哑等	1 正常 2=减弱或声音嘶 3=发音不能
（18）误咽是否存在	1=无 2=可能 3=有

*2 分制的条目：1 分为正常，2 分为异常；3 分或 4 分制的条目：1-2 分为正常，3 分以上为异常。

**每个步骤（共三大步骤：初步评价，第二步饮 5ml 水 3 次，第三步饮 60ml 水）正常和异常的界定：

1 个条目异常，则该步骤异常；所有条目都正常，则该步骤为正常。

***评价原则：

a）初步评价异常，就不进行后续评价。判定误吸风险为 IV 级，分数为初步评价各项目的分数＋第二步最高分（11 分）＋第三步最高分（12 分）；

b）初步评价正常，第二步评价异常（饮 3 次水有至少 2 次异常），就不进行第三步评价。判定误吸风险为 III 级，分数为初步评价各项目的分数＋第二步各项目的分数＋第三步最高分（12 分）；

c）初步评价正常，第二步评价正常（饮 3 次水有至少 2 次正常），第三步评价异常。判定误吸风险为 II 级，分数为初步评价各项目的分数＋第二步各项目的分数＋第三步项目分数；

d）初步评价正常，第二步评价正常（饮 3 次水有至少 2 次正常），第三步评价正常。判定误吸风险为 I 级。不计算评分。

功能性经口摄食量表（the Functional Oral Intake Scale, FOIS）

Level 1	不能经口进食，完全依赖管饲或禁食
Level 2	依赖管饲进食，最小量的尝试进食食物或液体
Level 3	依赖管饲进食，经口进食单一质地的食物或液体
Level 4	完全经口进食单一质地的食物
Level 5	完全经口进食多种质地的食物，但需要特殊的准备或代偿
Level 6	完全经口进食不需要特殊的准备，但有特殊的食物限制
Level 7	完全经口进食没有限制

吞咽生存质量量表(the Swallowing Quality of Life, SWAL-QOL)

请您根据自身情况，选择一个最能代表您个人看法的数字，在相应数字上画“√”。1：非常不同意，2：一般不同意，3：不确定，4：一般同意，5：非常同意

维度	条目	1	2	3	4	5
食欲	1 大部分时间我都不关心我有没有吃东西					
	2 我几乎很少感觉到饥饿					
	3 我不再喜欢进食					
食物选择	4 什么我能吃，什么我不能吃是一个难题					
	5 很难发现我喜欢吃且能吃的东西					
进食时间	6 我比其他人用更长的时间进食					
	7 无论多长时间我都不能吃完一顿饭					
症状频率	8 咳嗽					
	9 吃东西时呛咳					
	10 吃糊状的东西时呛咳					
	11 吃液体的东西时呛咳					
	12 有浓稠的唾液或者痰液					
	13 窒息					
	14 流涎					
	15 咀嚼问题					
	16 过量的唾液或痰液					
	17 必须清喉咙					
	18 食物黏在喉部					
	19 食物黏在口腔里					
	20 食物或者液体从口腔流出					
	21 食物或者液体从鼻腔流出					
心理负担	22 我的吞咽功能存在问题					

	23 我生活中最大的困难是吞咽障碍					
心理健康	24 我的吞咽问题使我感到郁闷					
	25 进食时我必须非常小心，这使我很愤怒					
	26 我的吞咽问题使我很伤心					
	27 我的吞咽问题使我无能为力					
	28 我非常厌恶去处理我的吞咽问题					
社会交往	29 由于吞咽障碍使我不愿意出去吃饭					
	30 吞咽障碍已经影响到了我的生活					
	31 吞咽障碍已经影响到了我的家人和朋友					
	32 由于吞咽障碍使我不愿意社交活动					
	33 吞咽障碍给我的社会生活带来困难					
睡眠	34 入睡困难					
	35 睡眠时间缩短					
疲劳程度	36 经常感到虚弱					
	37 经常感到疲倦					
	38 经常感到筋疲力尽					
言语交流	39 他人很难理解我的语言					
	40 我很难清楚说话					
恐惧	41 当我吃东西时经常感到害怕咀嚼					
	42 我担心自己出现肺部感染					
	43 我害怕吃液体状食物					
	44 我不知道自己什么时候开始咀嚼					

微型营养评价简表 (Mini Nutritional Assessment Short Form, MNA-SF)

项目	筛查内容	分值
A	既往 3 个月内，是否因食欲下降、咀嚼或吞咽等消化问题导致食物摄入减少？	0=严重的食欲减退 1=中等程度食欲减退 2=无食欲减退
B	最近 3 个月内体重是否减轻？	0=体重减轻超过 3kg 1=不知道 2=体重减轻 1kg~3kg 3=无体重下降
C	活动情况如何？	0=卧床或长期坐着 1=能离床或椅子，但不能出门 2=能独立外出
D	在过去 3 个月内是否受过心理创伤或罹患急性疾病？	0=是 2=否
E	是否有神经心理问题	0=严重痴呆或抑郁 1=轻度痴呆 2=无心理问题
F1	BMI（kg/m^2）是多少？	0=＜19 1=19~21 2=21~23 3=＞23
F2	小腿围 CC（cm）是多少？	0=CC＜31cm 3=CC≥31cm
合计	筛查分值	

说明：由于老年患者的特殊性，常存在不易获得 BMI 的情况，如卧床或昏迷患者，可用小腿围代替。

吞咽障碍患者对基于人工智能的视频游戏的吞咽功能康复系统的接受度评价

尊敬的患者及家属：

您好!我是香港理工大学的博士研究生，感谢您能在百忙中填写本问卷。

基于患者吞咽障碍发生率很高，并可能引发多种并发症及严重后果，因此及时对患者进行吞咽功能康复训练至关重要。本研究旨在了解您在充分体验基于人工智能视频游戏的吞咽功能康复系统后，对该系统的接受度，请您依照真实感受填写。

本问卷将花费您 5-10 分钟，您提供的一切资料仅供学术研究，绝对保密，敬请放心，谢谢您的支持!

香港理工大学护理学院

2023 年 10 月 1 日

一、您的基本资料

年龄：____岁 性别：①男　②女　身高：_____cm，体重：_____kg 入住时间：____年____月____日 患病时间：____年____月____日	
职业类型	② 以脑力劳动为主　②以体力劳动为主 ③部分脑力劳动，部分体力劳动　④无业
居住地	② 农村/郊区　②城镇/市区
合并症	② 高血压病史 ②糖尿病史 ③冠心病史 ④其他：____

二、参与者对基于人工智能视频游戏的吞咽功能康复系统的接受度评价

请您在充分体验该训练系统的基础上，回答下述问题（请在数字代号上画√即可）

	非常不同意	基本不同意	不确定	基本同意	非常同意
一、感知有用性					
1.您觉得基于人工智能的视频游戏的吞咽训练系统有助于提高您锻炼的主动性和积极性	**1**	**2**	**3**	**4**	**5**
2.您觉得基于人工智能的视频游戏的吞咽训练系统有助于提高您锻炼的时长和耐力	**1**	**2**	**3**	**4**	**5**
3.您觉得基于人工智能的视频游戏的吞咽训练系统为您进行吞咽锻炼提供了方便和助力	**1**	**2**	**3**	**4**	**5**
二、感知易用性					
1.您觉得用于吞咽训练的人工智能的视频游戏设备很容易使用	**1**	**2**	**3**	**4**	**5**
2.您觉得用于吞咽训练的人工智能的视频游戏软件很容易使用	**1**	**2**	**3**	**4**	**5**
3.总体上，您觉得基于人工智能的视频游戏的吞咽训练系统很容易实施	**1**	**2**	**3**	**4**	**5**
三、感知易学性					
1.您觉得用于吞咽训练的人工智能的视频游戏设备和软件的操作方法很容易学会使用	**1**	**2**	**3**	**4**	**5**
2.您觉得用于吞咽训练的人工智能的视频游戏流程很快能熟悉	**1**	**2**	**3**	**4**	**5**

3.即使没有培训，对于这个用于吞咽训练的人工智能的视频游戏设备，您也能很快学会使用	**1**	**2**	**3**	**4**	**5**
四、感知适用性					
1.您觉得基于人工智能的视频游戏的吞咽训练系统，涉及到的运动幅度和强度，适用于您进行康复运动	**1**	**2**	**3**	**4**	**5**
2.您觉得基于人工智能的视频游戏的吞咽训练系统，呈现的界面和互动形式，适用于您进行康复运动	**1**	**2**	**3**	**4**	**5**
3.总体上，您觉得基于人工智能的视频游戏的吞咽训练系统适用于您的吞咽功能康复	**1**	**2**	**3**	**4**	**5**
五、感知安全性					
1.您认为基于人工智能的视频游戏的吞咽训练系统，与传统运动方案相比，不会增加您痛苦或不适的几率	**1**	**2**	**3**	**4**	**5**
2.您认为基于人工智能的视频游戏的吞咽训练系统，与传统运动方案相比，不会增加您发生运动相关不良事件（如脱管、跌倒、呛咳等）的几率	**1**	**2**	**3**	**4**	**5**
3.您认为基于人工智能的视频游戏的吞咽训练系统，与传统运动方案相比，整体安全性更高	**1**	**2**	**3**	**4**	**5**
六、感知满意度					
1.在使用基于人工智能的视频游戏的吞咽训练系统的过程中，您感觉愉快	**1**	**2**	**3**	**4**	**5**
2.对于基于人工智能的视频游戏的吞咽训练系统所能带来的效果，您感到很满意	**1**	**2**	**3**	**4**	**5**
3.您乐于将人工智能的基于视频游戏的吞咽训练系统推荐给其他患者使用	**1**	**2**	**3**	**4**	**5**
七、使用意向					
1.您会充分利用基于人工智能的视频游戏的吞咽训练系统所能实现的各项功能	**1**	**2**	**3**	**4**	**5**

2.您期待把这个基于人工智能的视频游戏的吞咽训练系统推广到临床使用	**1**	**2**	**3**	**4**	**5**
3.总体上，您将愿意继续使用这个基于人工智能的视频游戏的吞咽训练系统	**1**	**2**	**3**	**4**	**5**

问卷已结束，请您再次查看问卷，检查是否有漏项、漏填等，有任何问题请随时与我们联系：bohan.zhang@ 。再次感谢您的配合与参与，祝您生活愉快！

吞咽障碍患者对基于人工智能的视频游戏的吞咽功能康复系统的满意度评价

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本问卷将花费您 5-10 分钟，您提供的一切资料仅供学术研究，绝对保密，敬请放心，谢谢您的支持！

香港理工大学护理学院

2023 年 10 月 1 日

请您回答下述问题（请在数字代号上画√即可）

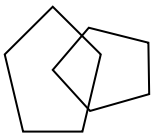
	非常不同意	基本不同意	不确定	基本同意	非常同意
一、训练内容设置					
1.您觉得基于人工智能的视频游戏的吞咽训练系统游戏设计丰富有趣	**1**	**2**	**3**	**4**	**5**
2.您觉得基于人工智能的视频游戏的吞咽训练系统游戏难度设置合适	**1**	**2**	**3**	**4**	**5**
3. 您觉得基于人工智能的视频游戏的吞咽训练系统内容反馈清晰易懂	**1**	**2**	**3**	**4**	**5**

4.您觉得基于人工智能的视频游戏的吞咽训练系统游戏内容满足吞咽康复相关内容	**1**	**2**	**3**	**4**	**5**
5.您觉得基于人工智能的视频游戏的吞咽训练系统游戏内容可以激发您进行康复训练的兴趣	**1**	**2**	**3**	**4**	**5**
二、训练形式设置					
1.您觉得用于吞咽训练的人工智能的视频游戏形式新颖有趣	**1**	**2**	**3**	**4**	**5**
2.您觉得用于吞咽训练的人工智能的视频游戏画面直观易用	**1**	**2**	**3**	**4**	**5**
3.您觉得用于吞咽训练的人工智能的视频游戏有足够的提示和帮助	**1**	**2**	**3**	**4**	**5**
4.您觉得用于吞咽训练的人工智能的视频游戏运行流畅	**1**	**2**	**3**	**4**	**5**
5.您觉得用于吞咽训练的人工智能的视频游戏操作方便	**1**	**2**	**3**	**4**	**5**
三、自我主观感受					
1.您觉得通过使用基于人工智能的视频游戏的吞咽训练系统，自己的吞咽障碍得到了改善	**1**	**2**	**3**	**4**	**5**
2.您在使用基于人工智能的视频游戏的吞咽训练系统时，感到舒适和自在	**1**	**2**	**3**	**4**	**5**
3.您觉得基于人工智能的视频游戏的吞咽训练系统对吞咽障碍康复很有帮助	**1**	**2**	**3**	**4**	**5**
4.您愿意继续使用基于人工智能的视频游戏的吞咽训练系统进行吞咽康复训练	**1**	**2**	**3**	**4**	**5**
5.您愿意向其他人推荐基于人工智能的视频游戏的吞咽训练系统	**1**	**2**	**3**	**4**	**5**

问卷已结束，请您再次查看问卷，检查是否有漏项、漏填等，有任何问题请随时与我们联系：bohan.zhang@ 。再次感谢您的配合与参与，祝您生活愉快！

简易智能精神状态检查量表（Mini-mental State Examination, MMSE）

维度	序号	项目	评分	
定向力	1	今年的年份？	1	0
	2	现在是什么季节？	1	0
	3	今天是几号？	1	0
	4	今天是星期几？	1	0
	5	现在是几月份？	1	0
	6	你现在在哪一省（市）？	1	0
	7	你现在在哪一县（区）？	1	0
	8	你现在在哪一乡（镇、街道）？	1	0
	9	你现在在哪一层楼上？	1	0
	10	这里是什么地方？	1	0
记忆力	11	复述：皮球	1	0
	12	复述：国旗	1	0
	13	复述：树木	1	0
注意力和计算力	14	100－7 是多少？	1	0
	15	93－7	1	0
	16	86－7	1	0
	17	79－7	1	0
	18	72－7	1	0
回忆能力	19	回忆：皮球	1	0
	20	回忆：国旗	1	0
	21	回忆：树木	1	0
语言能力	22	辨认：铅笔（这个东西叫什么）	1	0
	23	辨认：手表（这个东西叫什么）	1	0
	24	复述：四十四只石狮子	1	0

	25	请您看看这句话(“闭上你的眼睛”)，并且按它的意思去做	1	0
	26	用右手拿纸	1	0
	27	将纸对折	1	0
	28	放在大腿上	1	0
	29	说一回完整句子（主谓宾）	1	0
	30	按样作图 	1	0

康复训练日记

姓名：_____

年龄：_____

运动第_____天　　_____年_____月____日
您今天是否完成吞咽障碍康复训练？ □是，开始训练时间：_____时_____分（24 小时制） 结束训练时间：_____时_____分（24 小时制） 今日共计训练时长：_____分钟 □否
训练时是否出现呛咳、呕吐等症状？ □是　　□否
今日进食是否出现呛咳、呕吐等症状？ □是　　□否
训练时是否感觉任何不适（除呛咳、呕吐）？□是　　□否 若选择是，请记录：_____

运动第_____天　　_____年_____月____日
您今天是否完成吞咽障碍康复训练？ □是，开始训练时间：_____时_____分（24 小时制） 结束训练时间：_____时_____分（24 小时制） 今日共计训练时长：_____分钟 □否
训练时是否出现呛咳、呕吐等症状？ □是　　□否
今日进食是否出现呛咳、呕吐等症状？ □是　　□否
训练时是否感觉任何不适（除呛咳、呕吐）？□是　　□否 若选择是，请记录：_____