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Austrian Institute for
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Pharyngeal electrical stimulation for neurogenic oropharyngeal dysphagia

Systematic Review

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Commissioned by the Austrian Ministry of Health, this report systematically assessed the intervention described herein as decision support for the inclusion in the catalogue of benefits.

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Content

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List of abbreviations

ALS .....amyotrophic lateral sclerosis
CE.....Conformité Européenne
CI.....confidence interval
DOSS .....Dysphagia Outcome and Severity Scale
DSRS.....Dysphagia Severity Rating Scale
EUnetHTA .....European Network for Health Technology Assessment
FEES .....flexible endoscopic evaluation of swallowing
FU .....follow up
GMDN .....Global Medical Device Nomenclature
GRADE.....Grading of Recommendations, Assessment, Development and Evaluations
ICD-11 .....International Classification of Diseases-11
IHE.....Institute for Health Economics
MCID.....minimal clinically important difference
MD .....mean difference
MeSH .....medical subject heading
MS .....multiple sclerosis
NMES .....neuromuscular electrical stimulation
OR .....odds ratio
PAS.....Penetration–Aspiration Scale
PD .....Parkinson's disease
PES.....pharyngeal electrical stimulation
RCT.....randomised controlled trial
RR .....risk ratio
s.s. .....statistisch signifikant
SD.....standard deviation
SMD .....standardised mean difference
SR .....systematic review
SWAL-QOL.....Swallowing Quality of Life Questionnaire
TBI .....traumatic brain injury
US FDA .....United States Food and Drug Administration
VFSS .....video fluoroscopic swallowing study

Executive Summary

Introduction

Health Problem

Swallowing is a complex process consisting of three sometimes overlapping phases – an initial voluntary oral phase, followed by involuntary pharyngeal and oesophageal phases – that work to propel a bolus of liquid or food from the mouth to the stomach, while protecting the airway from aspiration. Neurogenic oropharyngeal dysphagia is a complex syndrome that refers to any abnormality in the oropharyngeal phase of swallowing caused by diseases of the central and peripheral nervous system, neuromuscular transmission, or muscles. The most common conditions leading to oropharyngeal dysphagia include stroke, head and neck cancer, and progressive neurologic diseases such as dementia, amyotrophic lateral sclerosis, and Parkinson's disease.

Patients with neurogenic dysphagia experience gradually progressive difficulty in swallowing solid food and liquids. Dehydration, malnutrition, aspiration pneumonia, and airway obstruction are the most common serious consequences of dysphagia, with affected patients more often requiring long-term care and having an increased risk of debility and death. Dysphagia contributes to significant reductions in quality of life for both patients and caregivers. Among hospitalised patients, dysphagia is associated with an increased risk of aspiration pneumonia, prolonged mechanical ventilation, long-lasting severe disability, extended hospital and intensive care unit stay, prolonged rehabilitation, diminished quality of life, dependence upon discharge, and premature death.

The prevalence of oropharyngeal dysphagia in Europe is estimated at 45.7%. The global prevalence among stroke patients is 55.4%. Dysphagia occurs in approximately 50% of patients with Parkinson's disease, in 31% of those with multiple sclerosis, and in 38% to 65% of people with traumatic brain injury. The prevalence rate in people with dementia varies from 13% to 57%.

Description of Technology

Pharyngeal electrical stimulation (PES) involves passing a catheter through the nose into the throat to deliver small amounts of electrical current that travel via the sensory nerves in the pharyngeal wall to the brain. The applied current increases local levels of swallow-related neurotransmitters in the oropharynx and promotes neuroplastic changes in the brain networks responsible for controlling and coordinating the swallow process. PES is administered by trained healthcare professionals, primarily speech-language pathologists. A typical treatment cycle consists of ten minutes of electrical stimulation daily for three consecutive days, for up to two cycles (six days).

Methods

The aim of this report was to determine whether PES plus standard care is more effective and safer than standard care alone or neuromuscular electrical stimulation plus standard care in patients with neurogenic oropharyngeal dysphagia.

A systematic search was conducted to identify relevant systematic reviews (SRs), randomised controlled trials (RCTs), and case series studies (reporting safety data on ≥100 patients) published in English or German. The following databases were searched on 26 November 2025: Medline, Embase, the Cochrane Library, and the International Network of Agencies for Health Technology Assessment. Study selection, data extraction, and quality appraisal were carried out independently by at least two researchers. Any disagreements were resolved by an additional researcher. The quality of the included studies was assessed using the ROBIS tool for SRs and the Cochrane Risk of Bias (RoB) tool v.2 for RCTs. The strength of the evidence was rated according to the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) schema.

During the screening process, several potentially relevant SRs were identified. After cross-checking the literature search results with the studies included in these reviews, only one SR was comprehensive enough to justify further evaluation. This SR was found to have a low overall risk of bias for all four domains of the ROBIS tool. Consequently, it was used as the basis for an update. The only relevant RCT published after the search end date of the SR was a more comprehensive report of a study that was already included in the SR. Relevant outcomes with comparative data that were not included in the SR's pooled analyses were extracted from the original RCT publications.

Domain effectiveness

The following effectiveness-related outcomes were used as evidence to derive a recommendation: swallowing outcome, rate of decannulation, functional health status, and health-related quality of life.

Domain safety

Adverse events related to the treatment, procedure, or device were used as evidence to derive a safety recommendation.

Results

Available evidence

Thirteen unique studies on PES (12 RCTs and one quasi-RCT; 16 publications) and one multicentre prospective case series study published after the search end date of the SR met the inclusion criteria for this report.

Clinical effectiveness

Thirteen mostly small RCTs (≤30 patients) reported outcomes for PES (n=251) and sham treatment (n=215). This limited evidence suggested that PES plus standard care may improve swallow function more than sham treatment plus standard care up to three months after treatment (low certainty evidence). An improved rate of decannulation readiness was also observed after PES, compared with sham treatment (low certainty evidence). Evidence of low to very low certainty indicated that the effect of PES on health-related quality of life, and dependence and disability measures was not statistically significantly different from sham treatment. Although hospital stays were generally shorter for patients who received PES compared with sham treatment, regardless of whether they had a tracheostomy, there was no discernible difference between the two groups (low certainty evidence).

Safety

Eight RCTs included in the SR provided data on treatment- or device-related adverse events. The rates of treatment-related and device-related adverse events did not differ between PES and sham PES up to three months after treatment (moderate certainty and low certainty evidence, respectively). The only adverse event related directly to the PES procedure was transient pharyngeal discomfort, which did not occur in the sham treatment group (very low certainty evidence). One large case series study (very low certainty evidence) reported one serious occurrence of chest sepsis that was "possibly related" to catheter insertion over the two- to four-month follow-up period.

Upcoming evidence

Four ongoing RCTs were identified. One of two industry-sponsored RCTs will compare PES with the Phagenyx® System in 360 patients with oropharyngeal dysphagia after invasive mechanical ventilation. It has a primary completion date of September 2025. The other RCT, which has a completion date of May 2027 and a target enrolment of 800, will compare the Phagenyx® System with standard care in patients with post-stroke neurogenic dysphagia. The two non-industry RCTs include 56 and 82 patients and will compare PES with sham PES. Both studies are currently in the recruiting stage, but their primary completion dates are unknown.

Reimbursement

Currently, PES is not included in the hospital catalogue of benefits (LKF, leistungsorientierte Krankenanstaltenfinanzierung) and is not a fully reimbursable service in the Austrian healthcare system.

Discussion

The evidence base for PES is currently limited to mostly small studies in patients with post-stroke oropharyngeal dysphagia. The effectiveness of PES in other aetiologies or as an ongoing therapy for long-term stroke recovery or chronic progressive conditions is unknown. Some uncertainty also remains regarding the optimal protocol in terms of frequency and intensity of stimulation, duration of treatment, and anatomical positioning of the catheter, and whether these parameters vary across different dysphagia aetiologies. It is also unclear whether PES treatment is durable after an initial "dose" or whether patients require ongoing stimulation to maintain improvements in swallow function. The studies included in this review were mostly silent on the type of standard care administered to patients in conjunction with the PES treatments. Further research is required to determine whether PES is more effective alone or in combination with other treatment modalities such as swallow exercises, particularly in patients who do not have a tracheostomy and may be more capable of engaging in these active interventions.

Although the pooled standardised mean difference reported for swallow outcome would typically be considered moderate to large, it is unclear whether this degree of improvement would be clinically meaningful to patients. Thus, there is a significant gap in understanding whether improvements in physiological measures, such as swallow function scales, translate into meaningful changes in clinical outcomes such as rates of pneumonia, length of hospital stay, health-related quality of life, and disability.

Conclusion

The limited evidence indicates that PES may be a safe and effective adjunctive treatment for hastening decannulation in patients with post-stroke neurogenic oropharyngeal dysphagia. The effectiveness of PES in individuals with neurogenic oropharyngeal dysphagia due to progressive neurodegenerative disease or other aetiologies is unclear.

Zusammenfassung

Einleitung

Indikation und therapeutisches Ziel

Schlucken ist ein komplexer Prozess, der aus drei teils überlappenden Phasen besteht: vom Mund (willkürliche Phase) über den Rachen (unwillkürliche Phase) bis in die Speiseröhre. In diesen Phasen werden Nahrung und Flüssigkeit vom Mund in den Magen befördert und gleichzeitig vor dem Eindringen in die Atemwege und damit vor dem Verschlucken geschützt. Neurologisch bedingte Schluckstörung im Mund-Rachen-Bereich (neurogenic oropharyngeal dysphagia) ist ein komplexes Syndrom, das jede Störung der Schluckphase im Mund-Rachen-Bereich umfasst, die durch Erkrankungen des zentralen (Nerven innerhalb von Gehirn und Rückenmark) und des peripheren (Nerven außerhalb von Gehirn und Rückenmark) Nervensystems, der Signalübertragung von Nerven auf Muskeln oder der Muskulatur verursacht wird. Zu den häufigsten Ursachen zählen Schlaganfälle, Tumore im Kopf- und Halsbereich sowie fortschreitende neurologische Erkrankungen wie Demenz, eine Erkrankung der motorischen Nervenzellen (ALS, amyotrophe Lateralsklerose) und Morbus Parkinson.

Patient:innen mit neurologisch bedingten Schluckstörungen entwickeln bei der Zunahme fester Nahrung und Flüssigkeiten zunehmend ausgeprägtere Schluckstörungen. Dehydration, Mangelernährung, Lungenentzündung durch Eindringen von Nahrung oder Flüssigkeit in die Atemwege (Aspirationspneumonie) sowie Verschluss der Atemwege zählen zu den häufigsten schwerwiegenden Folgen. Betroffene Patient:innen benötigen häufig eine Langzeitpflege, weisen ein erhöhtes Erkrankungs- und Sterblichkeitsrisiko auf und erleben – ebenso wie ihre pflegenden Angehörigen – eine erhebliche Verringerung der Lebensqualität. Bei stationär behandelten Patient:innen sind Schluckstörungen mit schwerwiegenden Komplikationen assoziiert, darunter Aspirationspneumonie, verlängerte Krankenhausaufenthalte, verringerte Lebensqualität sowie erhöhte Sterblichkeit. Das therapeutische Hauptziel ist, die Schluckfunktion zu verbessern.

Die Häufigkeit von Schluckstörungen im Mund-Rachen-Bereich wird in Europa auf 46 % der untersuchten Risikogruppen geschätzt. Weltweit beträgt die Häufigkeit bei Schlaganfallpatient:innen 55 %. Schluckstörung tritt bei etwa 50 % der Patient:innen mit Morbus Parkinson, bei 31 % der Patient:innen mit Multipler Sklerose und bei 38 % bis 65 % der Patient:innen mit Schädel-Hirn-Trauma auf. Die Krankheitshäufigkeit bei Menschen mit Demenz liegt zwischen 13 % und 57 %.

Beschreibung der Technologie

Die elektrische Stimulation des Rachens (PES, pharyngeal electrical stimulation) ist ein Verfahren, bei dem ein Katheter über die Nase in den Rachen eingeführt wird, um geringe elektrische Ströme zu verabreichen, die über die sensorischen Nerven der Rachenwand zum Gehirn geleitet werden. Der zugeführte Strom erhöht die örtliche Konzentration von Botenstoffen, die am Schluckvorgang beteiligt sind, im Mund-Rachen-Bereich. Zudem fördert er Anpassungsprozesse in den Hirnnetzwerken, die für die Steuerung und Koordination des Schluckens verantwortlich sind. PES wird von geschultem Gesundheitspersonal, vorrangig von Logopäd:innen, durchgeführt. Ein typischer Behandlungszyklus umfasst täglich zehn Minuten elektrische Stimulation über drei aufeinanderfolgende Tage und umfasst bis zu zwei Zyklen (6 Tage). Das Phagenyx®-System zur Nervenstimulation ist derzeit das einzige in der EU zugelassene PES-System. Es ist in Europa zur Behandlung neurogener Schluckstörungen bei Erwachsenen zugelassen und in den USA für schwere Schluckstörungen nach einem Schlaganfall zugelassen.

Die Standardbehandlung umfasst unter anderem die Anpassung der Nahrungskonsistenz, Schluckmanöver, mundmotorische Übungen sowie Haltungsänderungen des Körpers und des Kopfes.

Methoden

Ziel des vorliegenden Berichts war es, die Wirksamkeit und Sicherheit von PES plus Standardbehandlung im Vergleich zur alleinigen Standardbehandlung oder zur elektrischen Muskelstimulation (NMES, neuromuskulärer Elektrostimulation) plus Standardbehandlung bei Patient:innen mit neurologisch bedingter Schluckstörung im Mund-Rachen-Bereich zu bewerten.

Im November 2025 wurde eine systematische Literatursuche in vier medizinischen Datenbanken (MEDLINE, Embase, Cochrane Library, INAHTA) nach systematischen Übersichtsarbeiten (SRs, systematic reviews), randomisierten kontrollierten Studien (RCTs) und Fallserien (≥100 Patient:innen für Sicherheitsdaten) in englischer oder deutscher Sprache durchgeführt.

Im Januar 2026 erfolgte eine Suche nach laufenden Studien in drei klinischen Studienregistern (ClinicalTrials.gov, WHO-ICTRP, EU Clinical Trials). Die Studienauswahl erfolgte von zwei Personen unabhängig voneinander. Die Datenextraktion und die Bewertung der methodischen Qualität erfolgten jeweils durch eine Autorin und wurden von einer zweiten Autorin verifiziert. Die Literaturauswahl folgte einem Ansatz der bestmöglichen Evidenz, wobei gut durchgeführte SRs gegenüber einzelnen Primärstudien bevorzugt wurden. Nach Abgleich der Literaturergebnisse mit den in den identifizierten SRs enthaltenen Studien erwies sich nur ein SR (Dai 2025) als qualitativ geeignet für eine weitergehende Bewertung. Dieser SR wies ein geringes Gesamtverzerrungsrisiko für alle vier Domänen des ROBIS-Tools auf und diente als Grundlage für ein Update. Die Bewertung der eingeschlossenen RCTs erfolgte mit dem Cochrane Risk of Bias Tool v.2. Die Vertrauenswürdigkeit der Evidenz wurde nach dem GRADE-Schema (Grading of Recommendations, Assessment, Development and Evaluations) eingestuft.

Klinische Wirksamkeit

Für die Bewertung der klinischen Wirksamkeit wurden folgende Endpunkte herangezogen: Schluckfunktion, Dekanülierungsrate (Entfernung des Atemröhrchens), funktioneller Gesundheitsstatus (Pflegeabhängigkeit und Beeinträchtigung) und gesundheitsbezogene Lebensqualität.

Sicherheit

Zur Bewertung der Sicherheit wurden folgende Endpunkte herangezogen: behandlungsbezogene, verfahrensbezogene und gerätebezogene unerwünschte Ereignisse.

Ergebnisse

Verfügbare Evidenz

Als Grundlage diente ein SR (Dai 2025), wovon 13 RCTs zu PES (16 Publikationen) in diesem Bericht berücksichtigt wurden. Darüber hinaus wurde eine nach dem Suchzeitraum des SR veröffentlichte, an mehreren Zentren durchgeführte prospektive Fallserie (Beobachtungsstudie ohne Kontrollgruppe) eingeschlossen. Die 13 RCTs berichteten Ergebnisse für PES (n=251) und Scheinbehandlung (n=215). Die Mehrzahl der Studien untersuchte Patient:innen mit neurologisch bedingter Schluckstörung im Mund-Rachen-Bereich nach einem Schlaganfall (mit oder ohne Luftröhrenschnitt). Das mittlere Alter der eingeschlossenen Patient:innen lag zwischen 40 und 76 Jahren. Die Nachbeobachtungszeiträume reichten von einer Stunde bis zu drei Monaten nach der Behandlung. In den meisten Studien wurde die PES täglich über zehn Minuten an drei aufeinanderfolgenden Tagen verabreicht. Sieben Studien setzten das Phagenyx®-System ein; die übrigen verwendeten verschiedene nicht näher spezifizierte Systeme.

Klinische Wirksamkeit

Hinsichtlich der **Schluckfunktion** zeigte die eingeschränkte Studienlage aus überwiegend kleinen RCTs (≤30 Patient:innen), dass PES plus Standardbehandlung die Schluckfunktion bis zu drei Monate nach der Behandlung wirksamer verbessern *kann* als Scheinbehandlung plus Standardbehandlung (standardisierte Mittelwertdifferenz: 0-2.99; 95 % Konfidenzintervall: −1.05, 4.34). Dieser Effekt war bei Patient:innen mit Luftröhrenschnitt nach Schlaganfall am stärksten ausgeprägt (p=0,05). Sieben der zehn

Studien zeigten jedoch keinen statistisch signifikanten Unterschied zwischen den beiden Gruppen (geringe Vertrauenswürdigkeit der Evidenz). Nach PES wurde im Vergleich zur Scheinbehandlung eine verbesserte Bereitschaft zur **Dekanülierung** beobachtet (p=0,05; geringe Vertrauenswürdigkeit der Evidenz).

Hingegen zeigte sich kein statistisch signifikanter Unterschied zwischen PES und Scheinbehandlung bei der **gesundheitsbezogenen Lebensqualität** (sehr geringe Vertrauenswürdigkeit der Evidenz), bei Maßen der **Pflegeabhängigkeit** und der **Beeinträchtigung** (geringe Vertrauenswürdigkeit der Evidenz) sowie bei der **Dauer des Krankenhausaufenthalts** (geringe Vertrauenswürdigkeit der Evidenz). Obwohl die Krankenhausaufenthalte bei Patient:innen, die PES erhielten, unabhängig vom Vorliegen eines Luftröhrenschnitts tendenziell kürzer waren, bestand kein statistisch signifikanter Unterschied zwischen den Gruppen.

Sicherheit

Bis zu drei Monate nach der Behandlung zeigte sich in acht RCTs kein Unterschied in der Anzahl **unerwünschter behandlungs- und gerätebezogener Ereignisse** zwischen PES und Scheinbehandlung (moderate bzw. geringe Vertrauenswürdigkeit der Evidenz). Das einzige direkt auf das **PES-Verfahren bezogene unerwünschte Ereignis** (sehr geringe Vertrauenswürdigkeit der Evidenz) waren vorübergehende Rachenbeschwerden, die in der Scheinbehandlungsgruppe nicht auftraten. Eine große Fallserie berichtete über einen schwerwiegenden Fall einer Blutvergiftung ausgehend vom Brustbereich, „die mit der Kathetereinführung in Zusammenhang stehen könnte“, über einen zwei- bis viermonatigen Nachbeobachtungszeitraum.

Laufende Studien

Es wurden vier laufende RCTs identifiziert. Einer von zwei industriegesponserten RCTs vergleicht das Phagenyx®-System bei 360 Patient:innen mit Schluckstörung im Mund-Rachen-Bereich nach künstlicher Beatmung über einen Beatmungsschlauch (geplanter Abschluss: September 2025). Der andere RCT (geplanter Abschluss: Mai 2027; Zielrekrutierung: 800 Patient:innen) vergleicht das Phagenyx®-System mit der Standardbehandlung bei Patient:innen mit neurologisch bedingter Schluckstörung nach Schlaganfall. Zwei nicht-industriegesponserte RCTs (56 bzw. 82 Patient:innen) vergleichen PES mit Scheinbehandlung; beide Studien befinden sich derzeit in der Rekrutierungsphase.

Kostenerstattung

PES ist im österreichischen Leistungskatalog (LKF, leistungsorientierte Krankenanstaltenfinanzierung) derzeit nicht enthalten. Daher wird diese Behandlung vom österreichischen Gesundheitssystem nicht vollständig erstattet.

Diskussion

Die Studienlage zu PES beschränkt sich derzeit vorwiegend auf kleine Studien bei Patient:innen mit Schluckstörung im Mund-Rachen-Bereich nach einem Schlaganfall. Die Wirksamkeit von PES bei anderen Krankheitsursachen als fortlaufende Therapie zur langfristigen Schlaganfallrehabilitation oder bei chronisch fortschreitenden Erkrankungen ist unbekannt. Unsicherheiten bestehen hinsichtlich des optimalen Stimulationsprotokolls (Frequenz und Intensität der Stimulation, Behandlungsdauer, Platzierung des Katheters) sowie der Frage, ob diese Parameter je nach Ursache der Schluckstörung variieren. Es ist zudem unklar, ob die PES-Behandlung nach einem einmaligen Behandlungszyklus dauerhaft wirkt oder ob Patient:innen eine fortlaufende Stimulation benötigen, um die Verbesserung der Schluckfunktion aufrechtzuerhalten. Die eingeschlossenen Studien machten kaum Angaben zu begleitenden Standardtherapien. Weiterer Forschungsbedarf besteht hinsichtlich der Frage, ob PES allein oder in Kombination mit anderen Behandlungsformen wie Schluckübungen wirksamer ist.

Obwohl die aus mehreren Studien zusammengefasste mittlere Effektgröße für die Schluckfunktion als moderat bis groß einzuordnen wäre, sind diese Effektschätzer aufgrund des sehr weiten Konfidenzintervalls mit erheblicher Unsicherheit behaftet. Da das Konfidenzintervall die Null einschließt, ist der Effekt statistisch nicht signifikant, was auf eine unzureichende statistische Power der zugrunde liegenden eher

kleinen Studien hinweisen könnte. Ob das Ausmaß der Verbesserung klinisch bedeutsam ist, bleibt daher unklar. Es besteht somit eine erhebliche Wissenslücke hinsichtlich der Frage, ob Verbesserungen physiologischer Messwerte (z. B. Schluckfunktionsskalen) zu bedeutsamen Veränderungen klinischer Ergebnisse wie der Häufigkeit von Lungenentzündungen, der Krankenhausverweildauer, der gesundheitsbezogenen Lebensqualität und der Beeinträchtigung führen.

Schlussfolgerung

Die eingeschränkte Studienlage mit niedriger Vertrauenswürdigkeit deutet darauf hin, dass PES eine sichere und wirksame Ergänzung zur Standardbehandlung zur schnelleren Entfernung des Atemröhrchens bei Patient:innen mit neurologisch bedingter Schluckstörung im Mund-Rachen-Bereich und Luftröhrenschnitt nach Schlaganfall sein kann, verglichen mit Scheinbehandlung plus Standardbehandlung. Die Wirksamkeit von PES bei Patient:innen mit neurologisch bedingter Schluckstörung aufgrund fortschreitender Erkrankungen des Nervensystems oder anderer Krankheitsursachen ist hingegen unklar. Ergebnisse aus zwei großen laufenden RCTs könnten die Effektschätzer potenziell beeinflussen und die betroffene Patient:innengruppe erweitern. Eine Re-Evaluierung wird daher für 2028 empfohlen.

1 Background

1.1 Overview of the disease, health condition and target population[1]

Zielgruppe

The target population for this assessment is patients of any age with neurogenic oropharyngeal dysphagia.

Schlucken als komplexer, phasenweise ablaufender Prozess

Swallowing, also known as deglutition, is a complex process involving the precise coordination of six cranial nerves, over 25 pairs of muscles in the mouth, pharynx, larynx and oesophagus, and cortical and subcortical brain signals. It consists of three sometimes overlapping phases – an initial voluntary oral phase, followed by involuntary pharyngeal and oesophageal phases – that work to propel a bolus of liquid or food from the mouth to the stomach, while protecting the airway from aspiration [1-4].

Schluckphase im Rachen: koordiniertes Zusammenspiel zum Schutz der Atemwege

The oropharynx comprises the soft palate, the side and back walls of the throat, the epiglottis and palatine tonsils, and the back one-third of the tongue [5]. In the pharyngeal phase of swallowing, the soft palate rises to close the nasopharynx, and the suprahyoid muscles pull the larynx up and forward. The epiglottis moves downward to cover the airway, while striated pharyngeal muscles contract to move the food bolus past the cricopharyngeus muscle. This swallowing reflex lasts approximately one second [6, 7]. The pharyngeal phase of swallowing ends once the food bolus descends through the upper oesophageal sphincter into the oesophagus and then to the stomach [7, 8].

neurologische Schluckstörung im Rachen als komplexes Syndrom bei Störungen des zentralen/peripheren Nervensystems

Neurogenic oropharyngeal dysphagia is a complex syndrome that refers to any abnormality in the oropharyngeal phase of swallowing caused by diseases of the central and peripheral nervous system, neuromuscular transmission, or muscles [9]. It has multiple clinical forms and pathogenetic mechanisms that can be categorised as: degenerative, such as multiple sclerosis, Parkinsonisms, dementia, motor neurone disease, myopathies, and peripheral neuropathies; nondegenerative, including stroke, trauma (head injury), and neoplasm (brain tumour); congenital (e.g., cerebral palsy); and iatrogenic (e.g., Tardive dyskinesia and dystonia), which is induced by medications, surgery, or radiation [2, 10, 11]. Neuromuscular abnormalities are the most common cause of oropharyngeal disorders [2].

vielfältige Symptome wie z. B. Husten/Würgen beim Schlucken, häufiges Räuspern, Schmerzen, Speichelfluss, Gewichtsverlust, Stimmveränderungen

Symptoms of oropharyngeal dysphagia arise from the dysfunctional transfer of a food bolus in the pharynx past the upper oesophageal sphincter into the oesophagus [7]. Patients with oropharyngeal dysphagia may display a variety of signs and symptoms including coughing or choking with swallowing, frequent throat clearing, difficulty initiating a swallow, painful swallowing, an abnormal sensation of food sticking in the back of the throat or upper chest, excessive drooling, unexplained weight loss, malnutrition and dehydration,

[1] This section addresses the following assessment elements:
A0002 – What is the disease or health condition in the scope of this assessment?
A0003 – What are the known risk factors for the disease or health condition?
A0004 – What is the natural course of the disease or health condition?
A0005 – What is the burden of disease for the patients with the disease or health condition?
A0006 – What are the consequences of the disease or health condition for the society?
A0007 – What is the target population in this assessment?
A0023 – How many people belong to the target population?

changes in dietary habits, aspiration pneumonia, changes in voice or speech, and nasal regurgitation. Cold foods often aggravate the problem. Presenting symptoms may also be subtle or absent, particularly in patients with silent aspiration [7, 12, 13].

relevante ICD-11-Codes für Schluckstörungen

The relevant International Classification of Diseases (ICD)-11 codes for dysphagia are listed in Table 1-1.

Table 1-1: Relevant ICD-11 codes for dysphagia

Category	ICD-11 code
Dysphagia	MD93
Functional swallowing disorder	DD90.1
Functions related to the digestive system	VV40
Dysphagia disorder (TM1)	SA50

Source: International Classification of Diseases 11th Revision [14]

1.1.1 Epidemiology

weltweite Prävalenz bei 44 %, in Europa 46 %

Since dysphagia spans many diseases and age groups, its true prevalence in adults is unclear and likely underestimated [15]. The global prevalence of oropharyngeal dysphagia is estimated at 44%, with a prevalence in Europe of 46%. It is slightly more common among men (55%) [12].

häufigste Ursachen: Schlaganfall, Kopf-Hals-Tumore, progressive neurologische Erkrankungen wie Parkinson und Demenz

The most common conditions leading to oropharyngeal dysphagia include stroke, head and neck cancer, and progressive neurologic diseases such as dementia, amyotrophic lateral sclerosis, and Parkinson's disease. Between 25% and 81% of patients experience swallow dysfunction within the first three days after a stroke, and the global prevalence among stroke patients is 55% [3, 9, 12]. Dysphagia occurs in approximately 50% of patients with Parkinson's disease, in 31% of those with multiple sclerosis, and in 38% to 65% of people with traumatic brain injury. The prevalence rate in people with dementia varies from 13% to 57%, whereas the global prevalence is 72% [11, 12, 16].

Alterungsprozess als Risikofaktor: weltweite Prävalenz bei älteren Menschen 48 %

The ageing process also contributes to an increased risk of oropharyngeal dysphagia. In addition to alterations in olfaction and gustatory sensation, sarcopenia can weaken the muscles used for swallowing, and many medications consumed by older adults exacerbate the problem by decreasing appetite and inducing muscle incoordination [1]. The global prevalence of oropharyngeal dysphagia among the elderly is 48% [12]. Dysphagia is found in 30% to 40% of independently living older people and in 30% to 50% of people in nursing homes [7, 9].

ö. Studie (n=3.174, ≥65 Jahre): 8 % haben Schluckerkrankungen, die Hälfte mit neurologischen Begleiterkrankungen

A study of 3,174 inpatients aged 65 years or older across 53 hospitals in Austria found the prevalence of dysphagia to be 7.6%. About half of these patients also suffered from a neurological disease. Patients with dysphagia were more likely to be malnourished, have more medical diagnoses, and to be more care dependent than those who did not suffer from dysphagia [17].

1.1.2 Burden of disease

schwerwiegende Folgen wie z. B. Dehydration, Mangelernährung, Atemwegsverschluss

Patients with neurogenic dysphagia experience gradually progressive difficulty in swallowing solid food and liquids. Dehydration, malnutrition, aspiration pneumonia, and airway obstruction are the most common serious consequences of dysphagia, with affected patients more often requiring long-term care and having an increased risk of debility and death [6, 7, 11]. Dysphagia contributes to significant reductions in quality of life for both patients and caregivers [7].

Folgen bei stationären Patient:innen z. B. Lungenentzündung durch Einatmen von Speiseresten, verlängerte Beatmung, künstliche Ernährung

Among hospitalised patients, dysphagia is associated with an increased risk of aspiration pneumonia, long-lasting severe disability, extended hospital and intensive care unit stay, prolonged rehabilitation, diminished quality of life, dependence upon discharge, and premature death [4, 18]. The presence of dysphagia often significantly prolongs mechanical ventilation and artificial nutrition and leads to problems with medication intake. Between 70% and 80% of patients requiring prolonged mechanical ventilation have, at least temporarily, significant swallowing impairment and aspiration after successful weaning. This has been linked to serious complications, such as pneumonia, the necessity for reintubation, and increased mortality [9].

wirtschaftliche Folgen: schwere Schluckstörungen als unabhängiger Kostentreiber

A recent study conducted in Germany found that the duration of artificial ventilation, length of hospital stay, and the presence of severe dysphagia were independent predictors of increased health insurance expenditures [19]. Patients with severe dysphagia incurred more than double the hospital costs of those with mild or no dysphagia (€25,643 versus €7,669). A study conducted in France and Switzerland found that patients with post-stroke dysphagia stayed longer in hospital (14.9 to 23.7 versus 8.9 to 11.8 days), compared with patients without dysphagia after stroke, with an associated increase in costs of €3,000 in France and Fr14,000 in Switzerland [20].

1.2 Current clinical practice[2]

1.2.1 Diagnosis and categorisation of dysphagia

klinische Diagnostik durch Logopäd:innen und Neurolog:innen:

The clinical evaluation of neurogenic oropharyngeal dysphagia is usually performed by a speech-language pathologist trained in the management of dysphagia and a neurologist. Assessment typically includes medical history, physical exam (clinical swallow examination), and instrumental examinations, including the following [1, 9, 11, 21]:

- **Anamnese, klinische Schluckuntersuchungen und instrumentelle Untersuchungen**

  Video fluoroscopic swallowing study (VFSS), also known as the digital fluoroscopic swallowing study or modified barium swallow. This is a contrast-based radiological examination in which various volumes and viscosities of barium are administered to visualise the entire swallowing process, including the oral, pharyngeal, and oesophageal stages.

[2] This section addresses the following assessment elements:
A0001 – For which health conditions, and for what purposes is the technology used?
A0024 – How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025 – How is the disease or health condition currently managed according to published guidelines and in practice?

- Flexible endoscopic evaluation of swallowing (FEES), which is routinely used to assess aspiration. It uses a flexible nasoendoscope passed through the nose and into the pharynx to visualise the pharyngeal and laryngeal anatomy and to directly observe various aspects of swallowing using coloured water and a solid bolus. FEES is recommended for individuals who are bedridden, severely motor impaired, or uncooperative.

kein einheitliches Klassifikationssystem zur Erfassung des Schweregrades

As there is no universally accepted framework for categorising dysphagia severity, a variety of assessment tools are available depending on the clinical goal. These include: the Dysphagia Outcome and Severity Scale (DOSS), Dysphagia Severity Rating Scale (DSRS), and Functional Oral Intake Scale (FOIS) for functional status and diet recommendations; the Dysphagia Numerical Rating Scale for symptom tracking; and the Dynamic Imaging Grade of Swallowing Toxicity (DIGEST) and Penetration–Aspiration Scale (PAS) for detailed evaluation of instrumental assessment results [9, 22].

1.2.2 Treatment

Therapieoptionen

Treatment options depend on the severity of the swallowing impairment, its underlying aetiology, and individual patient needs [9]. Interventions recommended for oropharyngeal dysphagia include both compensatory and rehabilitative methods, with the goal of improving swallow function and reducing the occurrence of aspiration, pneumonia, and choking.

kompensatorische Therapieverfahren (Symptomlinderung) wie z. B. Haltungsanpassung, Schlucktechniken, Kostanpassung oder bei schwerer Schluckstörung Ernährungssonden

Compensatory techniques minimise or eliminate the symptoms or adverse sequelae of dysphagia but do not change the underlying physiology of the swallow process. These approaches include oral care, postural changes, swallowing manoeuvres, pacing and feeding strategies, dietary modifications (including texture-modified foods and thickened liquids), and oral nutritional supplementation. Nasogastric tubes, percutaneous endoscopic gastrostomy tubes, and jejunostomy tubes are used to provide nutritional support in patients with moderate or severe dysphagia. Pharmacological treatment options include the adjunctive use of drugs, such as capsaicinoids and piperine, to stimulate afferent neural pathways in swallowing [1, 9, 23, 24].

Ziele rehabilitativer Therapieverfahren:

Verbesserung der Schluckbiomechanik durch Muskelkräftigung und Koordinationsverbesserung

Rehabilitative interventions aim to effect change in the biomechanics of swallowing by improving coordination of the swallowing motor sequence and strengthening or activating the muscles involved. These therapies include exercise regimens and behaviour training with or without biofeedback and electrical stimulation techniques [1, 25]. Electrical stimulation encompasses transcutaneous electrical stimulation, repetitive transcranial magnetic stimulation, transcranial direct current stimulation, and pharyngeal electrical stimulation (PES). Transcutaneous electrical stimulation activates the sensory nerves (sensory transcutaneous electrical stimulation) or muscles (neuromuscular electrical stimulation) involved in swallowing by stimulating axonal motor nerve endings and muscle fibres. In contrast, non-invasive brain stimulation aims to invoke changes in neuronal pathways to increase neural functioning. PES applies stimulation to pharyngeal structures, indirectly targeting the pharyngeal motor and sensory cortices and related brain areas involved in the swallow process, and possibly also the peripheral sensory afferent system [9, 26, 27]

europäische Leitlinienempfehlungen: elektrische Stimulation als Ergänzung zur Schlucktherapie

European and the Association of the Scientific Medical Societies in Germany guidelines recommend electrical stimulation therapies as adjuncts to behavioural swallowing therapy and other standard care interventions, preferably within a clinical trial setting [9, 26, 27]. PES, specifically, is recommended for accelerating decannulation in tracheotomised stroke patients with severe dysphagia [9, 26]. Recently published guidelines from the American Heart Association and the American Stroke Association also state that PES can be beneficial in patients with post-stroke dysphagia, particularly after ventilator weaning [28].

1.3 Features of the intervention and comparators[3]

1.3.1 Features of the comparators

Komparatoren:

Scheinbehandlung, Standardtherapie, neuromuskuläre Elektrostimulation

The comparator procedures for PES plus standard care are sham treatment plus standard care, standard care alone, or neuromuscular electrical stimulation (NMES).[4] Appropriately designed sham treatment involves using the exact same device, catheter placement, and treatment protocol as PES but delivering no electrical current. The sham procedure can more effectively mimic the active procedure if the threshold and tolerated level of stimulation are established before turning off the catheter [29, 30]. Although the underlying principle and clinical efficacy of NMES in dysphagia are controversial, it has been widely adopted in many clinical settings and is sometimes used as an active control in trials of electrical stimulation modalities [31, 32].

Ziel der neuromuskuläre Elektrostimulation:

Stärkung der Schluckmuskulatur mittels …

NMES aims to increase the effectiveness of swallowing therapy by strengthening the muscles involved in swallowing and is typically administered by a trained speech-language pathologist [33]. It involves placing electrodes on the skin of the head and neck over the muscles used for chewing and swallowing. Small electrical currents are then passed through the electrodes to stimulate the peripheral nerve supply of the pharyngeal or laryngeal muscles while the person swallows. A low level of stimulus intensity is used for sensory stimu-

[3] This section addresses the following assessment elements:
A0011 – How much are the technologies utilised?
A0020 – For which indications has the technology received marketing authorisation or CE marking?
A0021 – What is the reimbursement status of the technology?
B0001 – What is the technology and the comparator(s)?
B0002 – What is the claimed benefit of the technology in relation to the comparators?
B0003 – What is the phase of development and implementation of the technology and the comparator(s)?
B0004 – Who administers the technology and the comparators and in what context and level of care are they provided?
B0008 – What kind of special premises are needed to use the technology and the comparator(s)?
B0009 – What supplies are needed to use the technology and the comparator(s)?
D0001 – What is the expected beneficial effect of the technology on mortality?

[4] Expert clinical input confirmed that NMES is an appropriate comparator in the context of an RCT with an active control, that is, PES versus NMES. However, to determine the true treatment effect of PES, PES versus sham PES or PES plus standard care versus sham PES plus standard care would be the most appropriate comparison.

lation, whereas a higher level is used to trigger muscle contractions. Treatment duration varies by device but can be up to one hour. The mild electrical stimulation can produce feelings ranging from tingling and warmth to a 'grabbing' sensation. NMES is only viable for muscles with an intact nerve supply [33, 34].

There is a range of NMES devices that use different electrode designs, positions, and stimulus intensities. A list of the more commonly available systems in Europe is provided in Table 1-2.

… verschiedener verfügbarer Systeme

Table 1-2: Features of NMES devices commonly available in Europe [35-40]

Device name[a]/manufacturer	CE Mark	US FDA Approval	Class/GMDN code
Ampcare Effective Swallowing Protocol **Ampcare, LLC, Texas, USA**	Year unknown Re-education of muscles necessary for pharyngeal contraction	2013 Re-education of muscles necessary for pharyngeal contraction	Class II/IIa 46573
eSwallow **eSWALLOW LLC, Michigan, USA**	2012 Dysphagia	2013 Dsyphagia	Class II/IIa 46573
VitalStim Plus **Chattanooga®, Enovis Corporation, Delaware, USA**	2018 Re-education of muscles necessary for pharyngeal contraction	2001 Dsyphagia	Class II/IIa 46573

Abbreviations: GMDN … Global Medical Device Nomenclature; US FDA … United States Food and Drug Administration

[a] *This list is not exhaustive.*

1.3.2 Features of the intervention

PES involves passing a catheter through the nose into the throat to deliver small amounts of electrical current, which travels via the sensory nerves in the pharyngeal wall to the brain. The applied current increases local levels of swallow-related neurotransmitters in the oropharynx and promotes neuroplastic changes in the brain networks responsible for controlling and coordinating the swallow process [10, 41, 42].

elektrische Rachenstimulation (PES): Katheter über Nase in den Rachen und elektrischer Strom gelangt zum Gehirn

The Phagenyx® Neuromodulation System is the only proprietary PES delivery system currently available. It consists of a base station and a single-use nasogastric catheter (11.5 French outer diameter). The catheter, which has two electrodes on the outside, is inserted through the nose into the patient's pharynx; guide markings on the catheter ensure correct placement. The catheter is then connected to a portable base station that sends a small electric current (frequency of 5 Hz) to the pharynx through the electrodes. People may experience a mild fizzing, pulsing, or tingling sensation in the throat during the procedure. The stimulation level, which is usually set at 75% of the maximum tolerated intensity, is determined individually for each patient [10, 23, 42, 43]. A typical treatment cycle consists of ten minutes of electrical stimulation daily for three consecutive days, for up to two cycles. (six days). The catheter, which can be disconnected from the base station, can also be used as a feeding tube. Therefore, it can be left in place for the duration of treatment without needing to insert a separate catheter for feeding. Since PES is a passive treatment, it is particularly useful for patients with neurological disease or impairment that precludes them from treatments that require active engagement, such as exercise therapy [23, 41, 44]. The purported benefits of PES include improved swallowing function and airway protection, leading to reduced risk of death, faster recovery and tracheostomy decannulation, and shorter hospital stay [41, 44].

Phagenyx® System ist das einziges verfügbare PES-System

Behandlung: 10 Minuten täglich, 3 oder 6 aufeinanderfolgende Tage

erwartete Vorteile: verbesserte Schluckfunktion, Atemwegschutz, kürzerer Krankenhausaufenthalt, schnellere Entfernung des Luftröhrenschlauchs

Kontraindikationen

Contraindications for PES include presence of a permanent pacemaker or intracardiac defibrillator, being pregnant or breastfeeding, the inability to have a nasogastric tube passed safely, and having an active oropharyngeal infection [43].

Administration, investments, personnel and tools required to use the technology and the comparators

Durchführung durch geschulte Fachkräfte (Logopäd:innen, Neurolog:innen, Geriater:innen, Intensivmediziner:innen, HNO-Ärzt:innen)

10-minütige, meist stationäre Behandlung

The Phagenyx® System, which comprises the PES console and consumables, is administered by healthcare professionals, primarily speech-language pathologists, who have completed the on-site training program provided by the manufacturer. The healthcare professional must stay with the patient for the entire ten-minute treatment session. PES can be performed on an outpatient or inpatient basis [41, 43]. The submission materials indicate that in Austria, specialists in neurology, geriatrics, intensive care medicine, otolaryngology, or speech therapy would most likely deliver PES. Nursing staff with experience in tracheostomy tube management and dysphagia care may also be required, depending on the patient's needs. Inpatient administration is the most common, particularly for tracheotomised patients with dysphagia, for patients with acute neurological disease, after extubation in stroke units or intensive care units, and in neurological wards for stable patients with neurogenic dysphagia. Outpatient treatment is possible in cases of chronic dysphagia, but likely to be rare (fewer than five patients per hospital expected annually).

in Ö vorwiegend neurologische, geriatrische oder intensivmedizinische Stationen

The submission materials also suggested that any facility providing PES should have the capability of performing FEES to determine the severity and nature of the dysphagia before its application and to monitor changes in swallowing function and safety after treatment. In Austria, this would most likely be a neurological, geriatric, or intensive care wards with expertise in dysphagia diagnostics.

Regulatory & reimbursement status

CE-Kennzeichnung seit 2012 für neurologische Schluckstörungen im Rachen bei Erwachsenen

The Phagenyx® Neuromodulation System was Conformité Européenne (CE) marked in 2012 for the treatment of neurogenic dysphagia in adults (18 years or older) and has been in continuous use in Europe, Switzerland, and the United Kingdom since then (see Table 1-3) [41, 45]. It also received de novo clearance (Class II device) from the United States Food and Drug Administration in 2022 for use in conjunction with standard care in patients with severe post-stroke dysphagia [46].

PES derzeit nicht im LKF-Katalog

According to the submission materials, the expected average utilisation of PES by the three submitting hospitals is 77 interventions (range 50-100) per hospital per year. Currently, PES is not included in the hospital catalogue of benefits (LKF, leistungsorientierte Krankenanstaltenfinanzierung) and, hence, is not a fully reimbursable service in the Austrian healthcare system.

Table 1-3: Features of the Phagenyx® Neuromodulation System [41, 45, 46]

Device name/manufacturer	CE Mark	US FDA Approval	Class/GMDN code
Phagenyx® Neuromodulation System Phagenesis Ltd, Manchester, United Kingdom	2012 Neurogenic dysphagia in adults (≥ 18 years)	2022 Severe post-stroke dysphagia	Class II/IIa GMDN code: Not available

Abbreviations: GMDN … Global Medical Device Nomenclature; US FDA … United States Food and Drug Administration

2 Objectives and Scope

2.1 PICO question

PIKO-Frage

Is PES plus standard care in comparison with standard care alone or NMES plus standard care more effective or safe with respect to swallow outcomes, rates of decannulation, health-related quality of life, functional status, and adverse events in patients with neurogenic oropharyngeal dysphagia?

2.2 Inclusion criteria

Einschlusskriterien für relevante Studien

Inclusion criteria for relevant studies are summarised in Table 2-1.

Table 2-1: Inclusion criteria

Population	Patients of any age with neurogenic oropharyngeal dysphagia. *ICD-11 Codes:* MD93 Dysphagia; DD90.1 Functional swallowing disorder; VV40 Functions related to the digestive system; SA50 Dysphagia disorder (TM1) [14] *MeSH and Emtree Terms:* ■ Medline: Deglutition Disorders ■ Embase: Dysphagia, Swallowing **Rationale** Informed by information provided by the submitting hospitals and a scoping search of the literature.

Intervention	**Pharyngeal electrical stimulation (PES) plus standard care**
	Direct electrical stimulation of the pharyngeal mucosa via intraluminal catheters plus standard care (e.g., bolus modification, oromotor exercises, body and head postural adjustments, and swallow manoeuvres).
	Product name:
	Phagenyx®, Phagenesis, Manchester, United Kingdom
	Any generic or custom-built electrical stimulation device that uses intraluminal catheters to directly stimulate the pharyngeal mucosa.
	MeSH and Emtree Terms:
	■ Medline: Electric Stimulation, Electric Stimulation Therapy
	■ Emtree: electrotherapy
	Excluded
	■ Cortical stimulation techniques such as repetitive transcranial magnetic stimulation or transcranial direct current stimulation.
	■ Other peripheral neuromodulatory techniques, including:
	  ■ Neuromuscular electrical stimulation techniques using devices such as VitalStim® (Chattanooga®, Enovis Corporation, Delaware, USA), Ampcare Effective Swallowing Protocol (Ampcare, LLC, Texas, USA) and eSWALLOW (eSWALLOW LLC, Michigan, USA).
	  ■ Transcutaneous electrical stimulation
	  ■ Peripheral magnetic stimulation
	■ Insufficient description of the intervention to be able to determine whether PES or neuromuscular electrical stimulation was undertaken.
	Rationale
	Informed by information provided by the submitting hospitals and a scoping search of the literature [26, 27, 47].

Control	■ Standard care (e.g., bolus modification, oromotor exercises, body and head postural adjustments, or swallow manoeuvres) ■ Neuromuscular electrical stimulation plus standard care **Rationale** Informed by clinical practice guidelines [26, 27, 48].
Outcomes	
Effectiveness	*Critical outcomes:* ■ Swallowing outcomes ■ Rates of decannulation ■ Changes in health-related quality of life ■ Changes in functional health status (dependence and disability) *Important outcomes*: ■ Changes in oral intake and nutritional status ■ Length of hospital stay ■ Patient satisfaction **Excluded** Studies that did not report any of the primary outcomes. **Rationale** Informed by clinical practice guidelines and a scoping search of the literature [26, 27, 47].
Safety	■ Device-related adverse events, e.g. pneumonia, sepsis ■ Treatment-related adverse events, e.g. discomfort, pain ■ Serious adverse events **Rationale** Informed by clinical practice guidelines and a scoping search of the literature [26, 27, 47].
Study design	
Effectiveness Safety	*Effectiveness and safety:* ■ Well-conducted systematic reviews ■ RCTs (including sham-controlled trials) with ≥10 patients in each study arm A best-evidence approach to study selection was used, with recent, well-conducted systematic reviews selected over individual primary studies. Any eligible systematic reviews identified were updated, where necessary, with primary studies published after the review's search end date. If no systematic reviews are available, then RCTs will be included. If no RCTs are available, then prospective non-randomised comparative studies will be included provided they include ≥50 patients in each treatment arm, have a defined control arm, and are propensity score matched. *Safety:* Case series of ≥100 patients **Excluded** *Effectiveness:* Non-peer-reviewed studies, narrative reviews, letters to the editor and author responses, non-randomised comparative studies without propensity score-matching or with <50 patients in each treatment arm, case series, case reports, and conference abstracts. *Effectiveness and safety:* Non-peer-reviewed studies, narrative reviews, letters to the editor and author responses, non-randomised comparative studies without propensity score-matching or with <50 patients in each treatment arm, case series <100 patients, case reports, and conference abstracts. **Rationale** Informed by a scoping search of the literature.

Abbreviations: ICD-11 … International Classification of Diseases-11; MeSH … medical subject heading; RCTs … randomised controlled trials

3 Methods

3.1 Research questions

Assessment elements from the European Network for Health Technology Assessment (EUnetHTA) Core Model® for the production of Rapid Relative Effectiveness Assessments (Version 4.2) were customised to the specific objectives of this assessment [49]. Please refer to the Appendix (Table A-7 to Table A-10) for the detailed research questions.

Bewertung basierend auf EUnetHTA Core Model®

3.2 Clinical effectiveness and safety

3.2.1 Systematic literature search

The systematic literature search was conducted on 26 November 2025 in the following databases:

systematische Literatursuche in 4 Datenbanken

- Medline via Ovid
- Embase via Ovid
- The Cochrane Library
- The International Health Technology Assessment Database (International Network of Agencies for Health Technology Assessment)

The systematic search was limited to articles published in English or German.

After deduplication, 1,390 citations were included. The Medline search strategy is provided as an example in the Appendix. The report was registered on the Open Science Framework, and the other search strategies are published there (https://osf.io/y3ahb/).

1.390 Treffer

Registrierung auf Open Science Framework

Three clinical trials registries (ClinicalTrials.gov, WHO-ICTRP, and EU Clinical Trials) were searched on 14 January 2026 to identify ongoing and unpublished studies, which resulted in 22 potentially relevant hits.

Suche nach laufenden Studien

Phagenesis Ltd, the manufacturer of the Phagenyx® System, was contacted for information, which yielded two unpublished studies: a retrospective case series (n=131) and a retrospective matched cohort comparative study (n=38).

Hersteller kontaktiert: 2 unveröffentlichte Studien übermittelt

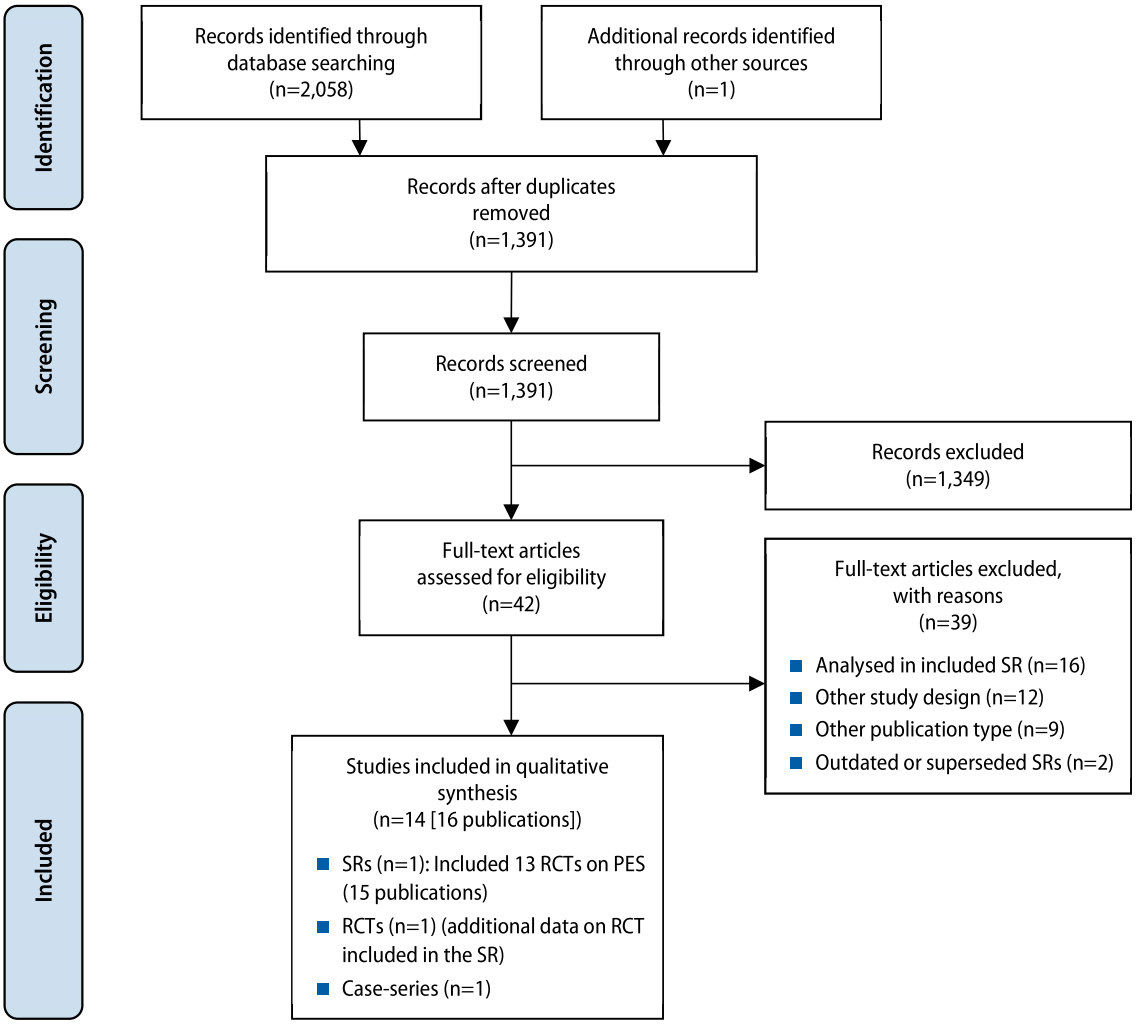
Handsearching identified one additional citation, resulting in a total of 1,391 hits.

manuelle Suche

3.2.2 Flow chart of study selection

Literaturauswahl

Overall, 1,391 unique citations were identified from the literature searches. The citations were screened by at least two independent researchers using Rayyan (Rayyan Systems Inc., USA). Any disagreements were resolved by consensus. In the case of unresolved disagreements, an additional researcher was consulted. The selection process is displayed in Figure 3-1.



Abbreviations: PES – pharyngeal electrical stimulation; RCTs – randomised controlled trials; SRs – systematic reviews

Figure 3-1: Flow chart of study selection (PRISMA Flow Diagram)

systematische Übersichtsarbeit (Dai 2025) als Basis für Update identifiziert

During the screening process, several potentially relevant systematic reviews (SRs) were identified. However, after cross-checking the literature search results with the studies included in these reviews, only one SR, conducted by Dai et al. 2025 [25] (hereafter referred to as the Dai 2025 SR), was comprehensive enough to justify further evaluation. The Dai 2025 SR also included one additional study that was not identified in the current literature searches (Youssef et al. 2015 [50]). This SR was assessed by two independent reviewers using the ROBIS tool [51] and found to have a low overall risk of bias

for all four domains. Consequently, the Dai 2025 SR was used as the basis for an update. Only one RCT [52] published after the search end date of the Dai 2025 SR was identified that met the inclusion criteria. This RCT was a more comprehensive report of a study by Suntrup-Krueger et al. 2023 [53], which was included in the Dai 2025 SR; therefore, both publications were listed for this single study, where applicable.

Verfahren zur Datenextraktion …

The Dai 2025 SR also included studies on gustatory stimulation and oral electrical stimulation of the faucial pillar using a finger-mounted electrode, but the data for these interventions were not extracted. Relevant outcomes with comparative data that were not included in the pooled analyses of the Dai 2025 SR were extracted from the original RCT publications. These included length of hospital stay after treatment, time to resumption of oral feeding or nasogastric tube removal, health-related quality of life, dependence and disability, patient satisfaction, and adverse events.

3.2.3 Analysis

… und Qualitätssicherung

Relevant data from included studies were extracted by one researcher into piloted data extraction tables and cross-checked by a second researcher for accuracy. In cases where pooled analyses from a systematic review (SR) combined results for PES with those of other interventions, the point estimate and 95% confidence interval (CI) for each of the PES studies were extracted. Other outcomes from the RCTs considered relevant to this review but not reported in the SRs were also extracted from the original study publications.

Verzerrungsrisiko und Evidenzqualität:

Bewertung der RCTs mittels Cochrane RoB v.2 und GRADE-Schema

One researcher assessed the RCTs for internal validity and risk of bias using the Cochrane Risk of Bias (RoB) tool v.2 [54] (see Table A-3 in the Appendix), and the GRADE (Grading of Recommendations Assessment, Development and Evaluation) schema [55] (see Table A-4 in the Appendix). Single-arm trials were classified as having a high risk of bias according to the methodological guidance by the HTA Coordination Group pursuant to the HTA Regulation, and as a result, they were not subject to further assessment [56]. A second researcher validated these assessments for accuracy. Any disagreements with respect to the data extraction or risk of bias analyses were resolved by consensus. Any relevant studies from included SRs were also assessed for internal validity and risk of bias in the same manner.

3.2.4 Synthesis

Ergebnisdarstellung

Results are summarised in the Appendix (Table A-1 and Table A-2). The research questions were answered in plain text format with reference to GRADE evidence Table A-4.

4 Results: Clinical effectiveness and Safety

4.1 Outcomes

4.1.1 Outcomes effectiveness

The following outcomes were defined as *critical* to derive a recommendation.

relevante Endpunkte:

- ***Swallowing outcomes:*** These are typically assessed with:

Schluckfunktion,

  - **Penetration-Aspiration Scale (PAS):** The only tool developed exclusively for assessment of airway protection. It contains a standardised, eight-point scale (higher score is worse) typically used with VFSS or FEES to measure the depth of food or fluid entry into the airway [57, 58].
  - **Dysphagia Severity Rating Scale (DSRS):** Commonly used in clinical trials, it is a seven-point scale that quantifies dysphagia severity by assessing required diet or fluid changes (e.g., thickened liquids, pureed foods) and supervision for safe oral intake (higher scores indicate more severe dysphagia) [59].
  - **Functional Oral Intake Scale (FOIS):** A seven-point ordinal scale that evaluates how well a patient can consume liquids (higher score is better) [59].
  - **Dysphagia Outcome and Severity Scale (DOSS):** A seven-point scale that rates the functional severity of dysphagia based on objective assessment (higher score is better) [60].
  - **Eating Assessment Tool-10:** A self-administered ten-item symptom questionnaire for dysphagia (lower score is better) [61].

- ***Rate of decannulation:*** This is an important outcome because severe dysphagia with related insufficient airway protection is often the main reason why decannulation is prolonged in tracheotomised patients who have been weaned from a respirator. The continued presence of a tracheotomy tube can delay rehabilitation, reduce patient comfort, and increase length of hospital stay and rate of hospital readmission [62, 63].

Entfernung des Luftröhrenschlauchs,

- ***Functional health status (dependence and disability):*** This is assessed with various tools, depending on the underlying health condition, including the following [59].

funktioneller Gesundheitsstatus,

  - **Barthel Index:** A ten-item scale that measures how well patients can function independently and how well they can perform activities of daily living (higher score is better).
  - **Modified Rankin Scale**: A seven-point scale that measures neurological disability, especially after stroke (lower score is better).

- ***Health-related quality of life:*** This is typically assessed with the Swallowing Quality of Life Questionnaire (SWAL-QOL), a 44-item tool that assesses ten quality-of-life concepts (higher score is better) [64, 65].

gesundheitsbezogene Lebensqualität

4.1.2 Outcomes safety

sicherheitsbezogene Endpunkte:

geräte-/ verfahrensbezogene und behandlungsbedingte unerwünschte Ereignisse

The following outcomes were defined as *critical* to derive a recommendation:

- Procedure or device-related adverse events defined as adverse events related to the use of a medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the installation, the operation, or any malfunction of the investigational medical device as well as any event that is a result of a use error or intentional misuse [66].
- Treatment-related or treatment-emergent adverse events defined as unexpected negative outcomes or events arising during the course of treatment that were not present beforehand or an already present condition or problem that appears to worsen following the treatment [67, 68].

4.2 Included studies

4.2.1 Included studies effectiveness

eingeschlossene Studien

Study characteristics and results of included studies are displayed in the Appendix, Table A-1 and Table A-2, and in the evidence profile in Appendix, Table A-4.

4.2.2 Systematic reviews and RCTs

13 RCTs (16 Publikationen)

die meisten Patient:innen nach Schlaganfall ohne Luftröhrenschnitt (n=259)

zwischen 40 und 76 Jahren

Nachbeobachtung bis zu 3 Monate, meist ca. 2 Wochen nach Behandlung

Of the 15 articles on PES included in the Dai 2025 SR, two were secondary analyses of previously published clinical trials [69, 70]. The RCT [52] published after the search end date of the SR was also an additional publication relating to one of the trials included in the Dai 2025 SR. Therefore, the SR included 13 unique studies (16 publications) on PES (12 RCTs and one quasi-RCT [50]), of which, two were conducted in various countries (Austria, Denmark, France, Germany, Italy, Spain, and the United Kingdom [62, 71]) and the remainder were conducted in Germany (three studies [53, 63, 72]), Italy (one study [73]), Spain (one study [30]), the United Arab Emirates (one study [50]), and the United Kingdom (five studies [74-78]). Most studies used a parallel RCT design (ten trials, 77%), while three used a crossover RCT design where patients served as their own control separated by a washout period of at least one day [75] or one week [30, 76]. Seven of the studies focused on post-stroke patients without tracheostomy (n=259) [30, 50, 71, 74, 75, 77, 78], three on tracheotomised patients with severe post-stroke dysphagia (n=159) [53, 62, 63], and one each on patients with amyotrophic lateral sclerosis (n=20) [72], multiple sclerosis (n=20) [73], and Parkinson's disease (n=3) [76]. The mean age of the included patients was between 39.7 and 76.0 years. The follow-up periods ranged from within an hour up to three months or twelve weeks after treatment, although most studies assessed swallowing measurements around two weeks after the intervention.

Electrical stimulation was administered to the pharynx via a nasogastric tube in all studies. Seven studies used the Phagenyx® System [53, 62, 63, 71, 72, 76, 78], while the others used various unspecified intraluminal catheter and constant current generator combinations. In most studies, treatment was administered for ten minutes daily over three consecutive days; one study used a five-day protocol [73]. Four other studies administered only one 10-minute PES session [30, 75-77]. Sham stimulation involved either placing the intraluminal catheter in the pharynx but not applying any current or performing the optimisation procedure to establish the threshold and tolerated level of stimulation as for an active PES session before turning off the catheter [29, 30, 52, 63].

7 Studien mit Phagenyx®-System

meist 10 Minuten täglich über 3 aufeinanderfolgende Tage

Most studies utilised both clinical evaluation and instrumental assessment, primarily VFSS and FEES, to assess swallowing function. The main swallowing outcome measures reported were the PAS (eight studies [30, 50, 71-73, 75-77]) and the DSRS (two studies [74, 78]). Other relevant outcomes included the decannulation readiness or extubation failure rate, changes in measures of health-related quality of life or dependence and disability, time to resumption of oral feeding or nasogastric tube removal, and rates of adverse events.

Endpunkte der eingeschlossenen Studien: z. B. Schluckfunktion, Entfernung des Luftröhrenschlauchs, Lebensqualität, Pflegeabhängigkeit

4.2.3 Case series studies

One multicentre prospective case series study [29] that met the inclusion criteria was published after the search end date of the Dai 2025 SR. Per the PICO criteria, only safety data were extracted from this case series study. The study was conducted in 14 secondary and tertiary care centres across Austria, Germany, and the United Kingdom from March 2015 to September 2018. It included 245 patients (mean age 68 years; 71% men) with a mean DSRS score of 11.4 (twelve-point scale where twelve is most severe) and oropharyngeal dysphagia related to stroke, traumatic brain injury, and any other neurological cause. All patients underwent PES with the Phagenyx® System at 5 Hz for ten minutes daily for three consecutive days. The mean follow-up was three months (range 2-4). Reasons for the 21% (49/239) of patients lost to follow-up were provided.

eine multizentrische prospektive Fallserie (14 Zentren, n=245) zur Bewertung der Sicherheitsdaten eingeschlossen

4.3 Results[5]

4.3.1 Effectiveness outcomes

Thirteen RCTs reported outcomes for PES (n=251) and sham treatment (n=215).

13 RCTs eingeschlossen

Swallowing measurements

Among the ten studies (n=305) reporting continuous swallowing measurement data, the SMDs ranged from 0 to 2.99, with 95% CI lower and upper limits of −1.06 and 4.34 for PES compared with a sham procedure up to three months after treatment; seven of the ten studies showed no statistically significant difference between the two groups [25, 30, 50, 71-78].

Schluckfunktion: kein statistisch signifikanter (s.s) Unterschied in 7/10 Studien

Decannulation readiness

Pooled data indicated a trend in favour of PES for the rate of readiness for decannulation (three studies; n=159), with an odds ratio of 6.47 (95% CI 1.10, 38.04; p=0.05; I^2=3%) up to 90 days' follow-up (four publications: [25, 53, 62, 63]).

Entfernung des Luftröhrenschlauchs: s.s. Verbesserung nach PES

Health-related quality of life

Two studies measured health-related quality of life in patients with post-stroke dysphagia (without tracheostomy; n=113) and patients with amyotrophic lateral sclerosis (n=13) using the EQ-5D as health utility status, the European Quality of Life Visual Analogue, and the Swallowing Quality of Life scale [71, 72]. There were no statistically significant differences between PES and sham treatment for any of the scales up to twelve weeks after treatment.

gesundheitsbezogene Lebensqualität: kein s.s. Unterschied zwischen PES und Scheinbehandlung

Dependence/disability

Two studies assessed dependence or disability in patients with stroke, with (n=51 [62]) or without tracheostomy (n=134 [71]) using the National Institutes of Health Stroke Scale, the modified Rankin Scale, and the Barthel Index. There were no statistically significant differences between PES and sham treatment for any of the scales up to 90 days after treatment.

Pflegeabhängigkeit und Einschränkung: kein s.s. Unterschied

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[5] This section addresses the following assessment elements:
D0005 – How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?
D0006 – How does the technology affect progression (or recurrence) of the disease or health condition?
D0011 – What is the effect of the technology on patients' body functions?
D0012 – What is the effect of the technology on generic health-related quality of life?
D0013 – What is the effect of the technology on disease-specific quality of life?
D0016 – How does the use of technology affect activities of daily living?
C0002 – Are the harms related to dosage or frequency of applying the technology?
C0004 – How does the frequency or severity of harms change over time or in different settings?
C0007 – Are the technology and comparator(s) associated with user-dependent harms?
C0008 – How safe is the technology in comparison to the comparator(s)?

Length of hospital stay

Although there was a trend toward shorter hospital stays in five studies of 294 patients [53, 63, 71, 74, 78], the difference between groups was not statistically significant in patients with post-stroke dysphagia, regardless of whether they had a tracheostomy.

Trend zu kürzerer Krankenhausaufenthaltsdauer nach PES (nicht s.s.)

Time to resumption of oral feeding

Two studies of 95 patients with post-stroke dysphagia found that time to resumption of oral feeding or nasogastric tube removal was shorter after PES: mean 4.3 versus 10.2 days (60 patients [52, 53]) and median eight versus 14 days (eleven patients [78]). However, the difference was only statistically significant in the larger study (p=0.001).

kürzere Zeit bis zur oralen Ernährung (Sondenentfernung) in 1/2 Studien (s.s.)

Patient satisfaction

In one quasi-RCT (n=9), more patients were satisfied with active treatment than with the sham procedure, based on ratings weighted from zero (completely satisfied) to seven (completely unsatisfied) (mean 2.6 versus 3.8; p=0.046) [50].

höhere Patient:innenzufriedenheit nach PES (s.s.)

4.3.2 Safety outcomes

RCT evidence

Eight of the RCTs included in the Dai 2025 SR provided data on treatment- or device-related adverse events.

Sicherheitsdaten von 8 RCTs

There were no adverse or serious adverse events related to PES or sham treatment across 6 studies (n=314) [62, 63, 71, 75, 76, 78] at any point up to three months after the procedures.

keine behandlungsbezogene unerwünschte Ereignisse

Two studies noted device-related complications; one of the studies reported no complications occurring [63]. The other study found that the PES group experienced slightly more complications than the sham group (15/35 [14%] versus 2/34 [6%]), which mostly involved technical problems with the stimulation device and an inability to place the catheter, none of which were serious [62].

gerätebezogene Komplikationen in 1 Studie

Three studies (n=113) reported patients experiencing transient pharyngeal discomfort during or immediately after the procedure (8/57 [14%] versus 0/56 [0%]) [30, 62, 72].

vorübergehende Rachenbeschwerden nach PES in 3 Studien

Observational evidence

A case series study of 245 patients receiving PES with the Phagenyx® System reported one serious occurrence of chest sepsis that was “possibly related” to catheter insertion [29]. No other adverse events were reported over the two- to four-month follow-up period.

schwerwiegendes Ereignis (Fallserie): Blutvergiftung im Brustkorb

5 Certainty of evidence

Qualität der Evidenz nach GRADE

The strength of evidence was rated according to the GRADE (Grading of Recommendations Assessment, Development and Evaluation) schema [55] for each endpoint individually. Each study was rated by two independent researchers. In case of disagreement, a third researcher was involved to solve the difference. A more detailed list of criteria applied can be found in the recommendations of the GRADE Working Group [55].

GRADE uses four categories to rank the strength of evidence:

- **High** = We are very confident that the true effect lies close to that of the estimate of the effect;
- **Moderate** = We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different;
- **Low** = Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- **Very low** = Evidence either is unavailable or does not permit a conclusion.

For comparative data, ranking according to the GRADE schema for the research question can be found in the summary of findings table below (Table 5-1) and in the evidence profile in Appendix (Table A-4).

Dai 2025: niedriges Verzerrungsrisiko

Evidenzsicherheit der 13 RCTs: moderat bis sehr niedrig

3 Studien nicht registriert

eine Studie mit deutlichem Ungleichgewicht bei Studienabbrecher:innen (60 % PES vs. 10 % Scheinbehandlung)

The overall risk of bias of the Dai 2025 SR was assessed as low for all four domains of the ROBIS tool [51]. The study quality of the 13 RCTs included in the Dai 2025 SR was assessed independently with the RoB tool v.2 [54] for the following critical outcomes: swallowing measurements, decannulation readiness, health-related quality of life, dependence and disability, length of hospital stay, and adverse events. The certainty of the evidence ranged from moderate to very low. There were some concerns regarding randomisation and allocation concealment (methods not reported in some studies) and blinding. For the latter aspect, although the nature of the intervention prohibited blinding of the PES operators, it was possible for assessors reviewing patients after treatment to be blinded to the intervention received. In addition, the method used to administer the sham procedure in most of the studies meant that masking of patients was not guaranteed; one of the RCTs was completely open label. Three of the studies were not registered, which introduces the possibility of selective reporting, and one study had a significant imbalance in the number of patients lost to follow-up (60% for PES versus 10% for sham treatment) [72].

geringe Evidenzsicherheit für Wirksamkeit und Sicherheit

Overall, the certainty of evidence for the effectiveness and safety of PES plus standard care compared with sham PES plus standard care was low. There were no studies comparing PES plus standard care with either standard care alone or NMES plus standard care.

Fallserie: sehr niedrige Evidenzsicherheit

Although the case series study was well conducted, it was considered very low certainty evidence due to the lack of a comparator group. Additional issues included the lack of blinding of outcome assessors and the inability to determine whether patients were recruited consecutively.

Overall, the certainty of evidence for the safety of PES provided by the case series study was very low.

Table 5-1: Summary of findings table for PES versus sham PES in patients with neurogenic oropharyngeal dysphagia (randomised controlled trial evidence)

Outcome	Anticipated absolute effects (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Certainty	Comments
	Risk with PES	Risk with sham				
Swallowing measurements ≤3 months after treatment	NA	NA	SMD range 0–2.99; 95% CI lower and upper limits: −1.05, 4.34	305 (10)	⨁⨁◯◯ Low [a]	The SMDs appear to favour the intervention group. Seven of the ten studies showed no statistically significant difference between the two groups.
Decannulation readiness/ extubation failure rate ≤90 days after treatment	NA	NA	SMD 6.47 (1.10, 38.04)	159 (3)	⨁⨁◯◯ Low [b]	**Favours intervention (p=0.05)** [c]
Health-related quality of life ≤12 weeks after treatment	NA	NA	Not estimable Measured using different scales over different time periods	126 (2)	⨁◯◯◯ Very low [d]	p>0.05 for all scales over all time periods.
Dependence/disability ≤90 days after treatment	NA	NA	Not estimable Measured using different scales over different time periods	185 (2)	⨁⨁◯◯ Low [e]	p>0.05 for all scales over all time periods.
Length of hospital stay after treatment	NA	NA	SMD ranges: ■ Stroke without tracheostomy: change in mean −1 day (1 study); change in median −5 to −13 days (2 studies); ■ Stroke with tracheostomy: MD −2.45 (−9.11, 4.21) (2 studies)	294 (5)	⨁⨁◯◯ Low [f]	No difference between groups for either patient group (tracheostomy versus no tracheostomy).
Treatment-related adverse events ≤3 months after treatment	0	0	Not estimable	314 (6)	⨁⨁⨁◯ Moderate [g]	No difference between groups.
Device-related adverse events	9 per 100	5 per 100	RR 1.60 (0.30, 8.34)	99 (2)	⨁⨁◯◯ Low [h]	No difference between groups.
Procedure-related adverse events	14 per 100	0	RR 16.71 (0.99, 282.74)	113 (3)	⨁◯◯◯ Very low [i]	Appears to favour control group. Adverse events encompassed transient pharyngeal discomfort during or after PES.

Abbreviations: CI … confidence interval; RR … risk ratio; SMD … standardised mean difference; NA … not applicable; PES … pharyngeal electrical stimulation.

Note: Risk ratios for adverse events and the mean difference for length of hospital stay were calculated using RevMan (The Cochrane Collaboration).

Explanations

[a] *No blinding of participants, operators, or assessors (one study); method used to administer sham procedure meant that masking of patients not guaranteed (eightstudies); potential selective reporting (three studies); differential dropout >20% between PES and sham group (one study); wide CIs in individual study estimates; 95% CIs overlaps no effect (SMD=0) in most studies and CI fails to exclude important benefit or important harm; substantial heterogeneity.*

[b] *Method used to administer sham procedure meant that masking of patients not guaranteed (one study); few studies and/or small sample sizes.*

[c] *Cohen suggested that SMD values of 0.2, 0.5, and 0.8 represent small, medium, and large effect sizes, respectively [79].*

[d] *No blinding of participants, operators, or assessors (one study); method used to administer sham procedure meant that masking of patients not guaranteed (one study); differential dropout >20% between PES and sham group (one study); few studies and/or small sample sizes.*

[e] *Method used to administer sham procedure meant that masking of patients not guaranteed (one study); few studies and/or small sample sizes.*

[f] *Method used to administer sham procedure meant that masking of patients not guaranteed (three studies); point estimates and measures of variation vary widely.*

[g] *Method used to administer sham procedure meant that masking of patients not guaranteed (three studies); assessors likely not blinded to treatment allocation (three studies).*

[h] *Method used to administer sham procedure meant that masking of patients not guaranteed (one study); assessors likely not blinded to treatment allocation (one study); few studies and/or small sample sizes.*

[i] *No blinding of participants, operators, or assessors (one study); method used to administer sham procedure meant that masking of patients not guaranteed (two studies); assessors likely not blinded to treatment allocation (two studies); differential dropout >20% between PES and sham group (60% versus 10%) (one study); few studies and/or small sample sizes.*

6 Discussion

6.1 Summary of findings[6]

Bewertung von PES hinsichtlich der relevanten Endpunkte

This report aimed to determine whether pharyngeal electrical stimulation (PES) plus standard care, in comparison with standard care alone or neuromuscular electrical stimulation (NMES) plus standard care, is more effective or safe with respect to swallow outcomes, rates of decannulation, health-related quality of life, functional status, and adverse events in patients with neurogenic oropharyngeal dysphagia.

13 überwiegend kleine RCTs mit niedriger Evidenzsicherheit: mögliche Verbesserung der Schluckfunktion

kein Unterschied bei Lebensqualität und Pflegeabhängigkeit und Trend zu kürzerem Krankenhausaufenthalt

vorübergehende Rachenbeschwerden als Nebenwirkung

Limited evidence from 13 mostly small randomised controlled trials (RCTs) (≤30 patients) suggested that PES plus standard care may improve swallow function more than sham treatment plus standard care up to three months after treatment (low certainty evidence). An improved rate of decannulation readiness was also observed after PES, compared with sham treatment (low certainty evidence). Evidence of low to very low certainty indicated that the effect of PES on health-related quality of life, and dependence and disability measures was no different from sham treatment. Although hospital stays were shorter for patients who received PES, regardless of whether they did or did not have a tracheostomy, there was no discernible difference between the groups (low certainty evidence). The rates of treatment-related and device-related adverse events did not differ between PES and sham PES up to three months after treatment (moderate certainty and low certainty evidence, respectively). The only adverse events related directly to the PES procedure was transient pharyngeal discomfort, which did not occur in the sham treatment group (very low certainty evidence).

Blutvergiftung im Brustraum möglicherweise aufgrund von PES

One large case series study (very low certainty evidence) reported one serious occurrence of chest sepsis that was "possibly related" to catheter insertion over the two- to four-month follow-up period.

Subgruppenanalysen:

stärkste Verbesserung bei Patient:innen mit Luftröhrenschnitt und Schluckstörungen nach Schlaganfall

Schluckverbesserung nicht unmittelbar nach Behandlung erkennbar, sondern erst nach einer Woche

anhaltender Nutzen bei 2-3 Wochen

Subgroup analyses conducted in the Dai 2025 systematic review (SR) suggested that the effects of PES on swallow outcomes were not immediately obvious (three studies, n=42; all not statistically significant [30, 75, 76]) after treatment but became more apparent within one week (three studies, n=159; SMD 1.03; 95% CI 0.05, 2.01; p=0.05; I^2=6% [53, 62, 63]) (see Table A-1 in the Appendix). Sustained benefit was observed by two to three weeks after treatment in four of seven studies (n=260); SMDs ranged from 0 to 2.99 and 95% CI lower and upper limits of −1.06 and 4.34, respectively, across the seven studies [50, 71-74, 77, 78]. Another subgroup analysis of swallow measurement results revealed that improvement was most pronounced in tracheotomised patients with post-stroke dysphagia (three studies, n=159), with an SMD of 1.03 (95% CI 0.05, 2.01; p=0.05, I^2=6%) up to 90 days after PES [53, 62, 63]. However, there was no discernible difference between PES and sham PES among individuals with neurogenic oropharyngeal dysphagia due to progressive neurodegenerative conditions (three studies, n=43 [72, 73, 76]) or among those with post-stroke dysphagia who did not have a tracheostomy (n=259; five of seven studies showed no discernible difference between the two groups [30, 50, 71, 74, 75, 77, 78]). However, these post hoc between-study analyses require prospective confirmation and should be interpreted with caution.

[6] This section addresses the following assessment elements:
D0017 – Was the use of the technology worthwhile?

6.2 Interpretation

Internal validity, external validity and evidence gaps

eingeschränkte interne Validität der Studien wie z. B. fehlende Angaben zu Randomisierung, fehlende Verblindung, überwiegend kleine Studien

The results of this review should be interpreted cautiously due to concerns with the internal validity of the studies. The main issues for the RCTs were a lack of information regarding randomisation and allocation concealment methods, and the lack of blinding to treatment allocation of assessors conducting post-treatment measurements. Most of the RCTs were small and likely underpowered to detect a clinically significant difference in the primary endpoint. In many cases, the method used to administer the sham procedure meant that masking of patients was not guaranteed. The most significant problem for the case series study, aside from the absence of a comparator group, was the lack of blinding of outcome assessors and the potential for selective recruitment.

überwiegend Schlaganfallpatient:innen mit neurologischen Schluckstörungen im Rachen; eingeschränkte Übertragbarkeit auf andere Erkrankungen

In terms of external validity, most of the study participants comprised patients with neurogenic oropharyngeal dysphagia due to stroke (with or without tracheostomy). While this reflects the type of patients who would undergo PES in the Austrian health system, the results pertaining to these patient groups are not necessarily applicable to individuals who have neurogenic oropharyngeal dysphagia due to other causes (see Table A-5 in the Appendix). The effectiveness of PES in other aetiologies or as an ongoing therapy for long-term stroke recovery or for chronic progressive conditions, such as multiple sclerosis, is unknown.

unklar sind optimales Stimulationsprotokoll, Langzeitwirkung und Notwendigkeit einer Dauerstimulation

Significant uncertainty also remains regarding the optimal stimulation protocol in terms of frequency and intensity of stimulation, duration of treatment, and anatomical positioning of the catheter, and whether these parameters vary with different dysphagia aetiologies [29, 80]. It is also unclear whether PES treatment is durable after an initial "dose" or whether patients require ongoing stimulation to maintain improvements in swallow function.

weiterer Forschungsbedarf bei Patient:innen ohne Luftröhrenschnitt

The studies included in this review were mostly silent on the type of standard care administered to patients in conjunction with the PES treatments. Further study is required to determine whether PES is more effective alone or in combination with other treatment modalities such as swallow exercises, particularly in patients who do not have a tracheostomy and may be more capable of engaging in these active interventions.

Schluckendpunkte überwiegend von Kliniker:innen berichtet

The minimal clinically important difference (MCID) is defined as the smallest change in an outcome that would be perceived – by the patient or the clinician – as clinically meaningful [81, 82]. These differences are usually calculated for patient-reported outcomes, such as the MD Anderson Dysphagia Inventory score used to measure swallowing-related quality of life for patients with head and neck cancer [83]. However, the swallow outcomes measured in the included studies comprised clinician-reported outcomes such as the Penetration and Aspiration Scale (nine studies), the Dysphagia Severity Rating Scale (DSRS; two studies), and an algorithm for decannulation readiness based on the flexible endoscopic evaluation of swallowing (three studies). Of these, only the Dysphagia Severity Rating Scale has a validated MCID [84]. Since only two small studies used this scale, re-expressing the pooled standardised mean difference in the units of the DSRS is not particularly helpful.

nur eine Bewertungsskala mit MCID

klinische Bedeutsamkeit der Ergebnisse unklar

Consequently, although the pooled standardised mean difference for swallow outcome would typically be considered moderate to large [79], it is unclear whether this degree of improvement would be clinically meaningful to

patients. Thus, there is still a significant gap in understanding whether improvements in physiological measures such as swallow function scales translate to meaningful changes in clinical outcomes such as rates of pneumonia, length of hospital stay, health-related quality of life, and disability.

Embedding our findings into existing knowledge

Ergebnisse weitgehend konsistent mit früheren systematischen Übersichtsarbeiten zu PES

The results of this report generally align with previously published systematic reviews on PES, which often focused on specific subpopulations such as patients with acquired brain injury and tracheostomy or post-stroke dysphagia and consequently included various subsets of the studies cited in the Dai 2025 systematic review (SR) [23, 32, 80, 85, 86]. The review authors similarly noted the heterogeneity across the studies with respect to outcome measures (percentage of people decannulated, Penetration and Aspiration Scale, DSRS), dysphagia aetiologies, and intervention doses and treatment regimens. The current review updates the Dai 2025 SR and includes safety data from the largest published case series study on PES to date, providing the most up to date evidence on the effectiveness and safety of PES for neurogenic oropharyngeal dysphagia.

Ongoing randomised controlled trials

4 relevante laufende RCTs

Four relevant RCTs were identified and are summarised in the Appendix, Table A-6. There are three ongoing single-blind (patients or outcome assessors) and one double-blind RCT, which aim to compare PES with either sham PES (three studies) or standard care (one study). One of the two industry-sponsored RCTs will compare PES with the Phagenyx® System in patients with oropharyngeal dysphagia after invasive mechanical ventilation. It has a target enrolment of 360 patients and a primary completion date of September 2025, although recruitment is still underway. The other RCT, which has a completion date of May 2027 and a target enrolment of 800, is comparing the Phagenyx® System with standard care in patients with post-stroke neurogenic dysphagia. The two non-industry RCTs include 56 and 82 patients and will compare PES with sham PES; one study has an additional transcranial direct current stimulation comparison group. Both studies are currently in the recruiting stage, but their primary completion date is unknown.

6.3 Limitations

Best-Evidence-Ansatz

To reduce uncertainty in the evidence base, a best evidence approach to study selection was used, preferentially including SRs and RCTs with at least ten patients in each study arm. This led to the exclusion of one quasi-RCT of 60 patients and one RCT of 17 patients with post-stroke dysphagia [87, 88]. Given the small sample size and large imbalance in patient numbers in one study (15 PES versus two sham treatment [87]) and the potential for confounding in the other study [88], it is unlikely that excluding these RCTs led to the loss of any data that would have changed the outcome of this assessment. In addition, while excluding case series studies with fewer than 100 participants may have led to rare safety events being missed, this seems unlikely given the relative safety of the PES procedure.

Limitationen der Literaturrecherche wie z. B. Spracheinschränkung

Although a comprehensive search of medical literature databases was conducted, an extensive grey literature search was not undertaken. In addition, some relevant articles may have been overlooked by restricting the searches to studies published in the English or German language. However, clinical trial databases were searched, the references of all retrieved studies (including systematic and narrative reviews) were hand searched, and the manufacturer of the Phagenyx® System was contacted for additional information, so it is unlikely that any significant studies were missed. In addition, results from a recent meta-epidemiological study suggest that excluding non-English publications from systematic reviews on clinical interventions has little effect on the overall conclusions [89].

6.4 Conclusion

begrenzte Evidenz: PES möglicherweise sichere und wirksame Ergänzungstherapie

The limited evidence indicates that PES may be a safe and effective adjunctive treatment for hastening decannulation in patients with post-stroke neurogenic oropharyngeal dysphagia. The effectiveness of PES in individuals with neurogenic oropharyngeal dysphagia due to progressive neurodegenerative disease or other aetiologies is unclear.

7 Evidence-based conclusions

Empfehlung

In Table 7-1 the scheme for evidence-based conclusion is displayed and the according choice is highlighted.

Table 7-1: Evidence based conclusions

	1	Strong evidence for added benefit in routine use.
	2a	Evidence indicates added benefit only in specific indications.
X	2b	**Less robust evidence indicating an added benefit in routine use or in specific indications**
	3	No evidence or inconclusive evidence available to demonstrate an added benefit of the intervention of interest.
	4	Strong evidence indicates that intervention is ineffective and or harmful.

Reasoning:

Begründung

Low certainty evidence indicated that PES may be a safe and effective adjunct to standard care for tracheotomised patients with post-stroke neurogenic oropharyngeal dysphagia, compared with sham treatment plus standard care. Results from two large ongoing RCTs may potentially influence the effect estimate and expand the indicated patient group.

Therefore, the re-evaluation is recommended in 2028.

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Appendix

Evidence tables of individual studies included for clinical effectiveness and safety

Table A-1: PES: Study characteristics and effectiveness and safety results from the systematic review and meta-analysis

Author, year	Dai 2025 [25]
Country	China, United Kingdom
Funding	National Natural Science Foundation of China and the Third Affiliated Hospital of Sun Yat-Sen University, China
Conflicts of interest	One of the five authors is the chief scientific officer and holds stocks/shares of Phagenesis Ltd; the other authors declared no conflicts of interest
Literature databases	PubMed, EMBASE (via Ovid), CINAHL, Web of Science, the Cochrane Library; reference checking and additional citation searching
Search end date	January 1970 to January 2025
Inclusion criteria	■ RCTs (including crossover, cluster-RCTs), quasi-RCTs comparing oropharyngeal sensory stimulation for neurogenic dysphagia with either sham, no treatment, or standard care ■ Trials that combined oropharyngeal sensory stimulation with other swallowing interventions were eligible if study groups differed solely in applying the specific oropharyngeal sensory stimulation. ■ Trials that reported swallowing ability (functional evaluation scales based on clinical or instrumental assessments and validated self-reported dysphagia questionnaires) or decannulation and reintubation rates
Exclusion criteria	■ Patients with neurogenic oropharyngeal dysphagia resulting from central or peripheral nervous system damage that was diagnosed clinically or through validated self-report questionnaires, regardless of the timing of symptom onset ■ Animal studies, case studies, open-label trials, observational studies, retrospective analyses, studies lacking original data, and non-English-language publications ■ Studies with only healthy participants, patients without dysphagia, or those with dysphagia without neurogenic conditions, and dysphagia in elderly patients without any neurogenic diseases ■ Studies that used non-validated subjective ratings to assess swallowing ability
Number of studies	15 RCTs: [a] [30, 50, 53, 62, 63, 69-78] ■ Parallel (k=12) crossover design (k=3) [30, 75, 76] ■ Two studies were secondary analyses of previously published clinical trials on PES [69, 70]
Intervention	Oropharyngeal sensory stimulation administered for (13 unique studies; 15 publications): ■ 10 minutes daily over 3 (8 studies) or 5 consecutive days (1 study) ■ One 10-minute session (4 studies)
Comparator	Sham PES (15 studies)
Population	Patients with neurogenic oropharyngeal dysphagia resulting from: ■ Stroke with (3 studies) or without tracheostomy (9 studies) ■ Amyotrophic lateral sclerosis (1 study) ■ Multiple sclerosis (1 study) ■ Parkinson's disease (1 study)
Number of patients	N=496 ■ Stroke with (n=159) or without tracheostomy (n=278) ■ Amyotrophic lateral sclerosis (n=20) ■ Multiple sclerosis (n=20) ■ Parkinson's disease (n=3)
Mean age of patients (yrs)	Range: 39.7-76.0
Outcomes	Penetration-Aspiration Scale (9 studies), Dysphagia Severity Rating Scale (5 studies); the Functional Oral Intake Scale (FOIS) (3 studies)
Follow-up (months)	Range: 0 to 3 months/12 weeks [b]
Loss to follow-up, n (%)	Not reported

Author, year	Dai 2025 [25]
Outcomes	
Effectiveness outcomes from RCTs included in pooled analyses in Dai 2025 [25] [c]	
Swallowing measurements	
Overall, SMD (95% CI)	n=305; 10 studies I [n=70], C [n=56]: 0.00 (−0.35, 0.35) [71] I [n=12], C [n=12]: 0.51 (−0.31, 1.33) [30] I [n=10], C [n=6]: 0.90 (−0.18, 1.98) [77] I [n=7], C [n=10]: 0.54 (−0.36, 1.44) [72] I [n=16], C [n=12]: 0.83 (0.05, 1.61) [74] I [n=6], C [n=6]: 0.29 (−0.85, 1.43) [75] I [n=10], C [n=10]: 2.99 (1.64, 4.34) [73] I [n=3], C [n=3]: 0.67 (−1.06, 2.39) [76] I [n=18], C [n=17]: 0.11 (−0.56, 0.78) [78] I [n=9], C [n=9]: 2.16 (0.94, 3.38) [50]
By condition (between-study subgroup analysis from Dai 2025 [25])	
Stroke without tracheostomy, SMD (95% CI)	n=259; 7 studies (FU ≤3 months) I [n=70], C [n=56]: 0.00 (−0.35, 0.35) [71] I [n=12], C [n=12]: 0.51 (−0.31, 1.33) [30] I [n=10], C [n=6]: 0.90 (−0.18, 1.98) [77] I [n=16], C [n=12]: 0.83 (0.05, 1.61) [74] I [n=6], C [n=6]: 0.29 (−0.85, 1.43) [75] I [n=18], C [n=17]: 0.11 (−0.56, 0.78) [78] I [n=9], C [n=9]: 2.16 (0.94, 3.38) [50]
Stroke with tracheostomy, SMD (95% CI)	1.03 (0.05, 2.01); p=0.05, I^2=6% (n=159; 3 studies; FU ≤90 days) [53, 62, 63]
Neurodegenerative diseases SMD (95% CI)	1.39 (−2.04, 4.82); p=0.22, I^2=77% (n=43; 3 studies [d]; FU ≤3 months) [72, 73, 76]
By follow-up period (between-study subgroup analysis from Dai 2025 [25])	
Immediate (30-120 minutes), SMD (95% CI)	n=42; 3 studies I [n=12], C [n=12]: 0.51 (−0.31, 1.33) [30] I [n=6], C [n=6]: 0.29 (−0.85, 1.43) [75] I [n=3], C [n=3]: 0.67 (−1.06, 2.39) [76]
Within 1 week, SMD (95% CI)	1.03 (0.05, 2.01); p=0.05, I^2=6% (n=159; 3 studies) [53, 62, 63]
>1 week (2-3 weeks), SMD (95% CI)	n=260; 7 studies I [n=70], C [n=56]: 0.00 (−0.35, 0.35) [71] I [n=10], C [n=10]: 0.90 (−0.18, 1.98) [77] I [n=7], C [n=6]: 0.54 (−0.36, 1.44) [72] I [n=16], C [n=12]: 0.83 (0.05, 1.61) [74] I [n=10], C [n=10]: 2.99 (1.64, 4.34) [73] I [n=18], C [n=17]: 0.11 (−0.56, 0.78) [78] I [n=9], C [n=9]: 2.16 (−0.94, 3.38) [50]
By swallowing assessment method (between-study subgroup analysis from Dai 2025 [25])	
Penetration and Aspiration Scale, SMD (95% CI)	n=239; 8 studies (FU ≤3 months) I [n=70], C [n=56]: 0.00 (−0.35, 0.35) [71] I [n=12], C [n=12]: 0.51 (−0.31, 1.33) [30] I [n=10], C [n=10]: 0.90 (−0.18, 1.98) [77] I [n=7], C [n=6]: 0.54 (−0.36, 1.44) [72] I [n=6], C [n=6]: 0.29 (−0.85, 1.43) [75] I [n=10], C [n=10]: 2.99 (1.64, 4.34) [73] I [n=3], C [n=3]: 0.67 (−1.06, 2.39) [76] I [n=9], C [n=9]: 2.16 (−0.94, 3.38) [50]
Dysphagia Severity Rating Scale, SMD (95% CI)	0.44 (−4.12, 5.00); p=0.44, I^2=47% (n=63; 2 studies; FU ≤3 months) [74, 78]

Author, year	Dai 2025 [25]
FEES-based algorithm for decannulation readiness, SMD (95% CI)	1.03 (0.05, 2.01); p=0.05, I^2=6% (n=159; 3 studies; FU ≤90 days) [53, 62, 63]
Other effectivenessoutcomes	
Decannulation readiness/ extubation failure rate, OR (95% CI)	6.47 (1.10, 38.04); p=0.05, I^2=3% (n=159; 3 studies; FU ≤90 days) [53, 62, 63]
Effectiveness: outcomes from RCTs in Dai 2025 [25] not included in pooled analyses [f]	
Health-related quality of life, MD (95% CI)	*EQ-5D as Health Utility Status* I and C [n=113]: 0.13 (0.00, 0.27); p=0.054 (FU 12 weeks) [71] *European Quality of Life Visual Analogue scale* I and C [n=105]: −4.17 (−15.22, 6.88); p=0.46 (FU 12 weeks) [71] *Swallowing Quality of Life* I [n=4], C [n=9]: p>0.05 (FU 3 months) [72] *Amyotrophic Lateral Sclerosis Functional Rating Scale Revised scale* I [n=4], C [n=9]: p>0.05 (FU 3 months) [72]
Dependence/disability, MD (95% CI)	*National Institutes of Health Stroke Scale* I and C [n=134]: −0.05 (−1.42, 1.32); p=0.94 (FU 2 weeks) [71] I and C [n=16]: −6.75 (−16.28, 2.78); p=0.15 (FU 90 days) [62] *Modified Rankin Scale* I and C [n=134]: 0.53 (0.23, 1.22); p=0.14 (FU 2 weeks) [71] I and C [n=51]: −0.20 (−0.73, 0.32); p=0.44 (FU 90 days) [62] *Barthel Index* I and C [n=134]: 1.57 (−3.60, 6.73); p=0.55 (FU 2 weeks) [71]
Length of hospital stay after treatment, days	n=294; 5 studies *Stroke without tracheostomy* I [n=16]: median 21 (95%CI 18, 24); C [n=12]: median 26 (95%CI 21, 31); p=0.038 [74] I [n=18]: median 39; C [n=18]: median 52; HR 1.2 (95% CI 0.55, 2.6); p=0.62 [78] I [n=78]: mean 27.7 (SD 22.7); C [n=63]: mean 28.7 (SD 23.0); p=0.83 [71] *Stroke with tracheostomy* I [n=20]: mean 16.3 (SD 12.2); C [n=10]: mean 18.75 (SD 6.4); p=0.55 [63] I [n=30]: mean 17.0 (SD 7.9); C [n=30]: mean 24.3 (SD 12.4); p=0.01 [53]
Time to resumption of oral feeding/nasogastric tube removal, days	n=95; 2 studies I [n=30]: mean 4.3; C [n=30]: 10.2; p=0.001 [52, 53] I [n=7]: median 8; C [n=4]: median 14; HR 2.0 (95% CI 0.51, 7.9) [78]
Patient satisfaction with treatment, mean (SD) [e]	I [n=9]: mean 2.6 (1.19); C [n=9]: 3.8 (1.71); p=0.046 (FU 2 weeks) [50]
Safety: outcomes from RCTs included in Dai 2025 [25] [f]	
Serious adverse events related to PES treatment, n (%)	n=231; 2 studies I [n=87]: 0; C [n=75]: 0 (FU 12 weeks) [71] I [n=35]: 0; C [n=34]: 0 (FU 90 days) [62]
Adverse events related to PES treatment, n (%)	n=83; 4 studies I [n=6]: 0; C [n=6]: 0 (FU day of intervention) [75] I [n=3]: 0; C [n=3]: 0 (FU day of intervention) [76] I [n=20]: 0; C [n=10]: 0 (FU ≤mean 18.75 days) [63] I [n=18]: 0; C [n=17]: 0 (FU 3 months) [78]
Device-related complication, n (%)	n=99; 2 studies I [n=35]: 5 (14); C [n=34]: 2 (6) (FU 90 days) [62] I [n=20]: 0; C [n=10]: 0 (FU ≤mean 18.75 days) [63]
Pharyngeal discomfort during procedure, n (%)	n=93; 2 studies I [n=12]: 5 (42); C [n=12]: 0 (FU day of intervention) [30] I [n=35]: 1 (3); C [n=34]: 0 (FU 90 days) [62]
Pharyngeal discomfort after procedure, n (%)	n=20; 1 study I [n=10]: 2 (20); C [n=10]: 0 (FU 3 months) [72]

Abbreviations: CI … confidence interval; FEES … fibreoptic endoscopic evaluation of swallowing; FU … follow up; MD … mean difference; OR … odds ratio; PES … pharyngeal electrical stimulation; RCT … randomised controlled trial; SMD … standardised mean difference; SD … standard deviation

Explanations: [a] *Three additional studies reported on gustatory stimulation with capsaicin, one of which also included a PES and sham comparison. A fourth study reported on oral electrical stimulation of the faucial pillar using a finger-mounted electrode. Only data pertaining to PES interventions with an intraluminal catheter were extracted from the studies.*

[b] *Most studies assessed swallowing measurements around two weeks after treatment.*

[c] *In cases where pooled analyses from Dai et al. 2025 [25] combined results for PES with those of other interventions, the SMD and 95% CIs for the individual studies were extracted. Dai et al. 2025 standardised the directionality of outcome measures that increased with disease severity by multiplying the mean values by -1.*

[d] *One study each on amyotrophic lateral sclerosis, multiple sclerosis, and Parkinson's disease*

[e] *Seven-point scale weighted from zero (completely satisfied) to seven (completely unsatisfied)*

[f] *Data were extracted from the original RCT publications.*

Table A-2: PES: Study characteristics and safety results from the case series study

Author, year	**Bath 2020 [29]**
Country	Austria, Germany, United Kingdom
Funding	Phagenesis Ltd (Manchester, United Kingdom)
Conflicts of interest	Six of the 22 authors reported conflicts of interest. Two employees are authors and managed much of the study. The funder was involved in the design and conduct of the study, data management, compensated sites for data collection, and reviewed and approved the manuscript.
Study design	Multicentre prospective cohort (14 secondary/tertiary care centres)
Time period	March 2015 to September 2018
Intervention	
Device	Phagenyx® Base Station and Phagenyx® Catheter (Phagenesis Ltd, Manchester, United Kingdom)
Stimulation	5 Hz for 10 minutes on each of three consecutive days; intensity set at 75% of the tolerable limit above sensory threshold
Cointerventions	Not stated
Inclusion criteria	Adults with a DSRS score ≥6 and oropharyngeal dysphagia related to: A. stroke not requiring mechanical ventilation B. stroke requiring mechanical ventilation and tracheotomy C. mechanical ventilation in non-stroke, non-TBI D. TBI with or without the need for mechanical ventilation and tracheotomy E. any other neurological cause not needing mechanical ventilation and tracheotomy
Exclusion criteria	Non-neurogenic dysphagia (e.g. cancer), presence of an implanted cardiac pacemaker or cardioverter defibrillator, pregnancy or a nursing mother
Number of patients	245 (6 were intolerant of catheter and did not receive treatment) Diagnostic subgroups that received treatment (n=239): A: 79; B: 98; C: 35; D: 24; E: 3
Mean age of patients, years (SD)	68 (14)
Sex, male, n/N (%)	173 (71)
Mean DSRS (total score 12)	11.4
Feeding status	
Nasogastric or nasojejunal tube n/N (%)	151 (62)
Gastrostomy tube, n/N (%)	76 (31)
Mean follow-up, months (range)	3 (2-4)
Loss to follow-up, n (%)	49/239 (21) Diagnostic subgroups: A: 23/79 (29); B: 17/98 (17); C: 5/35 (14); D: 4/24 (17); E: 0/3 (0)
Safety outcomes	
Serious adverse events related to PES treatment, n (%)	1/245 (0.4)[a]

Abbreviations: DSRS … Dysphagia Severity Rating Scale; PES … pharyngeal electrical stimulation; SD … standard deviation; TBI … traumatic brain injury

Explanation: [a] *Chest sepsis "possibly related" to catheter insertion*

Risk of bias tables and GRADE evidence profile

Internal validity of the included studies was judged by two independent researchers. In case of disagreement a third researcher was involved to solve the differences. A more detailed description of the criteria used to assess the internal validity of the individual study designs can be found in the Internal Manual of the AIHTA and in the Guidelines of EUnetHTA [90, 91].

Table A-3: Risk of bias – randomised controlled trials on PES included in the Dai 2025 systematic review [25], see [54]

Trial	Endpoints	Bias arising from the randomisation process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall risk of bias
Bath 2016 [71], Everton 2021 [70]	Swallow assessment	Some concerns [a,b]	Some concerns [c]	Low	Low	Low	Some concerns
	Time to discharge after treatment	Some concerns [a,b]	Some concerns [c]	Low	Low	Low	
	Health-related quality of life	Some concerns [a,b]	Some concerns [c]	Low	Low	Low	
	Dependence/disability	Some concerns [a,b]	Some concerns [c]	Low	Low	Low	
	Serious adverse events	Some concerns [a,b]	Low	Low	Some concerns [d]	Low	
Cabib 2020 [30]	Swallow assessment	Some concerns [a,b]	Some concerns [c]	Low	Low	Low	Some concerns
	Adverse events	Some concerns [a,b]	Low	Low	Some concerns [d]	Low	
Dziewas 2018 [62]	Swallow assessment	Some concerns [a]	Some concerns [e]	Low	Low	Low	Some concerns
	Dependence/disability	Some concerns [a]	Some concerns [e]	Low	Low		
	Adverse events	Some concerns [a]	Some concerns [e]	Low	Low	Low	
Fraser 2002 [77]	Swallow assessment	Some concerns [a,f]	Some concerns [e]	Low	Some concerns	Some concerns [g]	High
Herrmann 2022 [72]	Swallow assessment	Some concerns [h]	Some concerns [c,e]	Some concerns [i]	Low	Low	High
	Health-related quality of life	Some concerns [h]	Some concerns [e]	Some concerns [i]	Low	Low	
	Adverse events	Some concerns [h]	Some concerns [c,e]	Some concerns [i]	Some concerns [d]	Low	
Jayasekeran 2010 [74]	Swallow assessment	Some concerns [a,b]	Some concerns [e]	Low	Low	Low	Some concerns
	Length of hospital stay after treatment	Some concerns [a,b]	Some concerns [e]	Low	Low	Low	
Michou 2014 [75]	Swallow assessment	Some concerns [a,b]	Some concerns [e]	Low	Low	Low	Some concerns
	Adverse events	Some concerns [a,b]	Some concerns [e]	Low	Low	Low	
Restivo 2013 [73]	Swallow assessment	Some concerns [a,b,f]	Some concerns [e]	Low	Low	Some concerns [g]	High
Sasegbon 2022 [76]	Swallow assessment	Some concerns [a,b,f]	Some concerns [e]	Low	Low	Low	Some concerns
	Adverse events	Some concerns [a,b,f]	Some concerns [e]	Low	Some concerns [d]	Low	

Trial	Endpoints	Bias arising from the randomisation process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall risk of bias
Suntrup 2015 [63]	Swallow assessment	Some concerns [a]	Low	Low	Low	Low	Some concerns
	Length of hospital stay after treatment	Some concerns [a]	Low	Low	Low	Low	
	Adverse events	Some concerns [a]	Low	Low	Some concerns [d]	Low	
Suntrup-Krueger 2023 [53], Suntrup-Krueger 2025 [52]	Swallow assessment	Some concerns [a]	Low	Low	Low	Low	Some concerns
	Length of hospital stay after treatment	Some concerns [a]	Low	Low	Low	Low	
	Time to resumption of oral feeding	Some concerns [a]	Low	Low	Low	Low	
Vasant 2016 [78], Essa 2017 [69]	Swallow assessment	Some concerns [a]	Some concerns [e]	Low	Low	Low	Some concerns
	Length of hospital stay after treatment	Some concerns [a]	Some concerns [e]	Low	Low	Low	
	Time to nasogastric tube removal	Some concerns [a]	Some concerns [e]	Low	Low	Low	
	Adverse events	Some concerns [a]	Some concerns [e]	Low	Low	Low	
Youssef 2015 [50]	Swallow assessment	Some concerns [a,b,f]	Some concerns [e]	Low	Low	Some concerns [g]	High
	Patient satisfaction	Some concerns [a,b,f]	Some concerns [e]	Low	Low	Some concerns [g]	

Explanations:

[a] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation.*

[b] *Unclear how allocation concealed but no obvious baseline imbalances.*

[c] *Some deviations but balanced between treatment groups.*

[d] *Assessors likely not blinded to treatment allocation.*

[e] *Method used administer sham procedure meant that masking of patients not guaranteed because patients could potentially feel whether PES was applied.*

[f] *No information about randomisation process but no obvious baseline imbalances.*

[g] *Study not registered.*

[h] *No blinding of participants, operators, or assessors.*

[i] *Differential dropout >20% between PES and sham group (60% versus 10%).*

Table A-4: Evidence profile: effectiveness and safety of PES versus PES sham in patients with neurogenic oropharyngeal dysphagia

Quality assessment							Summary of findings				
Number of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Number of patients		Effect		Certainty of evidence
							PES	Sham PES	Relative (95% CI)	Absolute (95% CI)	
Swallowing measurements (≤3 months after treatment): patients with neurogenic oropharyngeal dysphagia											
10 [30, 50, 53, 62, 63, 69-78]	RCT (9); quasi-RCT (1)	Serious [a]	Not serious	Not serious	Serious [b]	None	164	141	SMD range 0–2.99; 95% CI lower and upper limits: −1.06, 4.34		⨁⨁◯◯ Low
Decannulation readiness/extubation failure rate (≤90 days after treatment): patients with neurogenic oropharyngeal dysphagia											
3 [53, 62, 63]	RCT	Serious [c]	Not serious	Not serious	Serious [d]	None	85	74	SMD 6.47 (1.10, 38.04); p=0.05, I^2=3%		⨁⨁◯◯ Low
Health-related quality of life (≤12 weeks after treatment): patients with neurogenic oropharyngeal dysphagia											
2 [71, 72]	RCT	Very serious [e]	Not serious	Not serious	Serious [d]	None	126 (both groups)		Measured using different scales over different time periods p>0.05 for all scales over all time periods		⨁◯◯◯ Very low
Dependence/disability (≤90 days after treatment): patients with neurogenic oropharyngeal dysphagia											
2 [62, 71]	RCT	Serious [f]	Not serious	Not serious	Serious [d]	None	185 (both groups)		Measured using different scales over different time periods p>0.05 for all scales over all time periods		⨁⨁◯◯ Low
Length of hospital stay after treatment: patients with neurogenic oropharyngeal dysphagia											
5 [53, 63, 71, 74, 78]	RCT	Serious [g]	Not serious	Not serious	Serious [h]	None	162	132	SMD ranges: ■ Stroke without tracheostomy: change in mean −1 day (1 study); change in median −5 to −13 days (2 studies) ■ Stroke with tracheostomy; change in mean −2.5 to −7.3 days (2 studies)		⨁⨁◯◯ Low
Treatment-related adverse events (≤3 months after treatment): patients with neurogenic oropharyngeal dysphagia											
6 [62, 63, 71, 75, 76, 78]	RCT	Serious [i]	Not serious	Not serious	Not serious	None	169	145	0% for both groups		⨁⨁⨁◯ Moderate
Treatment-related adverse events (mean 3 months after treatment): patients with neurogenic oropharyngeal dysphagia											
1 [29]	Case series	Very serious [j]	Not applicable	Not serious	Not serious	None	245	Not applicable	1/245 (0.4%)		⨁◯◯◯ Very low
Device-related adverse events: patients with neurogenic oropharyngeal dysphagia											
2 [62, 63]	RCT	Serious [k]	Not serious	Not serious	Serious [d]	None	55	44	RR 1.60 (0.30, 8.34) **3 more per 100** (from 3 fewer to 33 more)		⨁⨁◯◯ Low
Procedure-related adverse events: patients with neurogenic oropharyngeal dysphagia											
3 [30, 62, 72]	RCT	Very serious [l]	Not serious	Not serious	Serious [d]	None	57	56	RR 16.71 (0.99, 282.74) **0 fewer per 1,000** (from 0 fewer to 0 fewer)		⨁◯◯◯ Very low

Abbreviations: ALS … amyotrophic lateral sclerosis; CI … confidence interval; FEES … fibreoptic endoscopic evaluation of swallowing; FU … follow up; MS … multiple sclerosis; PD … Parkinson's disease; PES … pharyngeal electrical stimulation; RCT … randomised controlled trial; SMD… standardised mean difference.

Comments:

[a] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (ten studies); unclear how allocation concealed but no obvious baseline imbalances (seven studies); no blinding of participants, operators, or assessors (one study); method used to administer sham procedure meant that masking of patients not guaranteed (eight studies); no information about randomisation process but no obvious baseline imbalances (four studies); potential selective reporting (three studies); differential dropout >20% between PES and sham group (60% versus 10%) (one study).*

[b] *Wide CIs in individual study estimates; 95% CIs overlaps no effect (SMD=0) in most studies and CI fails to exclude important benefit or important harm; substantial heterogeneity.*

[c] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (three studies); method used to administer sham procedure meant that masking of patients not guaranteed (one study).*

[d] *Few studies and/or small sample sizes.*

[e] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (one study); unclear how allocation concealed but no obvious baseline imbalances (one study); no blinding of participants, operators, or assessors (one study); method used to administer sham procedure meant that masking of patients not guaranteed (one study); differential dropout >20% between PES and sham group (60% versus 10%) (one study).*

[f] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (two studies); unclear how allocation concealed but no obvious baseline imbalances (one study); method used to administer sham procedure meant that masking of patients not guaranteed (one study).*

[g] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (five studies); unclear how allocation concealed but no obvious baseline imbalances (2 studies); method used to administer sham procedure meant that masking of patients not guaranteed (three studies).*

[h] *Point estimates and measures of variation vary widely.*

[i] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (six studies); unclear how allocation concealed but no obvious baseline imbalances (three studies); method used to administer sham procedure meant that masking of patients not guaranteed (three studies); no information about randomisation process but no obvious baseline imbalances (one study); assessors likely not blinded to treatment allocation (three studies).*

[j] *Single arm open label study; unclear if patients recruited consecutively.*

[k] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (two studies); method used to administer sham procedure meant that masking of patients not guaranteed (one study); assessors likely not blinded to treatment allocation (one study).*

[l] *Blinding of operators not possible due to the nature of the intervention, but possible to blind assessors conducting post-treatment measurements to treatment allocation (three studies); unclear how allocation concealed but no obvious baseline imbalances (one study); no blinding of participants, operators, or assessors (one study); method used to administer sham procedure meant that masking of patients not guaranteed (two studies); assessors likely not blinded to treatment allocation (two studies); differential dropout >20% between PES and sham group (60% versus 10%) (one study).*

Nomenclature for GRADE table:

Limitations: 0: no limitations or no serious limitations; -1: serious limitations

Inconsistency: NA: Not applicable (only one trial); 0: no important inconsistency; -1: important inconsistency

Indirectness: 0: direct, no uncertainty, -1: some uncertainty, -2 major uncertainty

Other modifying factors: publication bias likely (-1), imprecise data (-1), strong or very strong association (+1 or +2), dose-response gradient (+1), Plausible confounding (+1)

GRADE Working Group grades of evidence [55]:

⊕⊕⊕⊕ ***High certainty:*** *We are very confident that the true effect lies close to that of the estimate of effect.*

⊕⊕⊕◯ ***Moderate certainty:*** *We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.*

⊕⊕◯◯ ***Low certainty:*** *Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.*

⊕◯◯◯ ***Very low certainty:*** *We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.*

Applicability table

Table A-5: Summary table characterising the applicability of a body of studies

Domain	Description of applicability of evidence
Population	The participants in the studies comprised patients with neurogenic oropharyngeal dysphagia due to stroke (with or without tracheostomy), amyotrophic lateral sclerosis, multiple sclerosis, or Parkinson's disease. This reflects the type of patients who would undergo PES in the Austrian health system. However, the results pertaining to these patient groups are not necessarily applicable to individuals who have neurogenic oropharyngeal dysphagia due to other causes.
Intervention	The Phagenyx® system used in some of the studies is commonly available in Europe and has the CE mark. Other studies used generic stimulation devices with intraluminal electrodes to deliver PES, which is not necessarily a limiting factor in terms of applicability.
Comparators	The only comparator reported in the studies was sham treatment, which would not have contravened recommended standard care for patients with neurogenic oropharyngeal dysphagia.
Outcomes	The critical outcome of swallow function was reported in all studies over periods ranging from within one hour to three months after treatment, although most studies assessed swallowing measurements around two weeks after the intervention. Three studies reported on decannulation rates in patients with a tracheostomy. Considering that the main purpose of PES is to improve swallow function in patients with severe dysphagia and to expedite decannulation, these outcomes are appropriate. However, follow-up periods of around two weeks may not be long enough to track the durability of the procedure. The other critical outcomes of rates of treatment- or procedure-related adverse events and changes in functional health status and health-related quality of life were not well reported.
Setting	The studies were conducted in Denmark, France, Germany, Italy, Spain, the United Arab Emirates, and the United Kingdom. PES was conducted in hospitals by personnel with experience in pharyngeal catheter placement. This is reflective of the likely utilisation of the device in Austria.

Abbreviation: PES … pharyngeal electrical stimulation

List of ongoing randomised controlled trials

Table A-6: List of relevant ongoing trials on PES

Identifier/ Trial name/Country	Study design	Condition	Target enrollment	Intervention	Comparator	Primary outcome	Primary completion date/Status	Sponsor
NCT03840395 (PhINEST Study) Austria, Finland, Germany, Switzerland	Prospective, multicentre, single-blind (outcome assessor) RCT	Oropharyngeal dysphagia after invasive mechanical ventilation of any duration	360	PES with Phagenyx® system	Sham PES	Penetration-Aspiration Scale scores Dysphagia Outcome and Severity Score scores	September 2025 Recruiting	Phagenesis Ltd
ISRCTN98886991 (PhEAST) Austria, Denmark, England, Germany, Northern Ireland, Scotland, Wales	Prospective, multicentre, single-blind (outcome assessor) RCT	Post-stroke neurogenic dysphagia	800	PES with Phagenyx® system	Standard care	Dysphagia Severity Rating Scale scores Functional Oral Intake Scale scores	May 2027 Ongoing	University of Nottingham Phagenesis Ltd
ChiCTR2100054548 China	Prospective single-blind (patient) RCT	Neurogenic dysphagia	56	PES	Sham PES	Functional Oral Intake Scale scores	Not reported Recruiting	Third Affiliated Hospital of Sun Yat-Sen University
DRKS00016845 Germany	Prospective double-blind RCT	Post-stroke neurogenic dysphagia	82	PES	Sham PES Transcranial direct current stimulation	Penetration-Aspiration Scale scores	Not reported Recruiting	Schön Klinik Bad Aibling

Abbreviations: PES … pharyngeal electrical stimulation; RCT … randomised controlled trial

Research questions

Table A-7: Health problem and current use

Element ID	Research question
A0001	For which health conditions, and for what purposes is the technology used?
A0002	What is the disease or health condition in the scope of this assessment?
A0003	What are the known risk factors for the disease or health condition?
A0004	What is the natural course of the disease or health condition?
A0005	What is the burden of disease for the patients with the disease or health condition?
A0006	What are the consequences of the disease or health condition for the society?
A0024	How is the disease or health condition currently diagnosed according to published guidelines and in practice?
A0025	How is the disease or health condition currently managed according to published guidelines and in practice?
A0007	What is the target population in this assessment?
A0023	How many people belong to the target population?
A0011	How much are the technologies utilised?

Table A-8: Description of the technology

Element ID	Research question
B0001	What is the technology and the comparator(s)?
A0020	For which indications has the technology received marketing authorisation or CE marking?
B0002	What is the claimed benefit of the technology in relation to the comparators?
B0003	What is the phase of development and implementation of the technology and the comparator(s)?
B0004	Who administers the technology and the comparators and in what context and level of care are they provided?
B0008	What kind of special premises are needed to use the technology and the comparator(s)?
B0009	What supplies are needed to use the technology and the comparator(s)?
A0021	What is the reimbursement status of the technology?

Table A-9: Clinical effectiveness

Element ID	Research question
D0001	What is the expected beneficial effect of the technology on mortality?
D0005	How does the technology affect symptoms and findings (severity, frequency) of the disease or health condition?
D0006	How does the technology affect progression (or recurrence) of the disease or health condition?
D0011	What is the effect of the technology on patients' body functions?
D0012	What is the effect of the technology on generic health-related quality of life?
D0013	What is the effect of the technology on disease-specific quality of life?
D0016	How does the use of technology affect activities of daily living?
D0017	Was the use of the technology worthwhile?

Table A-10: Safety

Element ID	Research question
C0008	How safe is the technology in comparison to the comparator(s)?
C0002	Are the harms related to dosage or frequency of applying the technology?
C0004	How does the frequency or severity of harms change over time or in different settings?
C0007	Are the technology and comparator(s) associated with user-dependent harms?

Literature search strategies

Search strategy for Medline via Ovid

Search Name: Ovid MEDLINE(R) ALL<1946 to 25 November 2025>	
Search date: 25 November 2025	
ID	Search
#1	Deglutition Disorders/ (26255)
#2	((deglutition or swallow*) adj3 (difficult* or problem* or disorder*)).mp. (32075)
#3	dysphagia*.mp. (41152)
#4	1 or 2 or 3 (55336)
#5	Electric Stimulation/ (118384)
#6	Electric Stimulation Therapy/ (23303)
#7	((electr* or galvan*) adj3 stimul*).mp. (192948)
#8	galvano?stimul*.mp. (1)
#9	galvano-stimul*.mp. (1)
#10	electro?stimul*.mp. (4102)
#11	electro-stimul*.mp. (405)
#12	EST.ti,ab. (31451)
#13	electro?therap*.mp. (2803)
#14	electro-therap*.mp. (113)
#15	(pharyn* adj3 stimul*).mp. (319)
#16	PES.ti,ab. (14309)
#17	EPS.ti,ab. (18782)
#18	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (259027
#19	4 and 18 (702)
#20	Phagenyx*.mp. (1)
#21	Phagenesis*.mp. (2)
#22	19 or 20 or 21 (702)
#23	exp animals/ not humans.sh. (5399251)
#24	22 not 23 (664)
#25	limit 24 to (english or german) (602)
Total hits: 602	

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