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Rehabilitation interventions for oropharyngeal dysphagia in people with Parkinson's disease (Protocol)

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[Intervention Protocol]

Rehabilitation interventions for oropharyngeal dysphagia in people with Parkinson's disease

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effectiveness of rehabilitation interventions for oropharyngeal dysphagia in improving swallowing safety and efficiency in people with Parkinson's disease.

BACKGROUND

Parkinson's disease is estimated to affect 0.3% of people in industrialised countries, reaching 1% in people over 60 years old and 3% in people over 80 years (Balestrino 2020 ; Ball 2019 ; Hirsch 2016). Swallowing disorders (dysphagia) are highly prevalent and clinically significant symptoms in people with Parkinson's disease (Miller 2017 ; Suttrup 2016). A meta-analysis conducted by Kalf and colleagues reported a dysphagia prevalence of up to 82% in people with Parkinson's disease (Kalf 2012). Dysphagia in Parkinson's disease can lead to severe consequences: aspiration pneumonia, prolonged hospitalisation, increased mortality rate, and reduced quality of life (Dilmaghani 2022 ; Hobson 2018 ; Plowman-Prine 2009). Despite the high prevalence of dysphagia and its severe clinical sequelae in Parkinson's disease, there is a lack of scientific evidence on rehabilitation interventions. Since roughly 2013, there has been an increase in studies aiming to maintain or improve swallowing safety and efficiency, reduce associated health complications, and increase swallowing-related quality of life in people with Parkinson's disease (Battel 2020 ; Chang 2021 ; Cheng 2023).

Description of the condition

Dysphagia can be broadly categorised based on the anatomical location of the swallowing impairment. Oropharyngeal dysphagia refers to swallowing difficulty predominantly at the oral (mouth) and pharyngeal (upper portion of the throat known as the pharynx) phases, and it differs from oesophageal dysphagia, which affects the oesophagus. Oropharyngeal dysphagia seriously affects people with Parkinson's disease and it is recognised to be a fatal symptom, significantly increasing the risk of hospitalisation and death in this population (Akbar 2015 ; Dilmaghani 2022 ; Rinaldi 2023).

The clinical signs of oropharyngeal dysphagia differ enormously in people with Parkinson's disease. In the literature, it is widely accepted that major signs of oropharyngeal dysphagia, such as aspiration of food and fluid into the airway, occur in the advanced phase of the disease (Fabbri 2019 ; Müller 2001), but symptoms may also occur in the early stages of Parkinson's disease (Buhmann 2019). The neuropathological mechanism of swallowing disorders in Parkinson's disease is not yet clearly identified. Dysphagia seems to be caused by a degeneration of subcortical regions such as the basal ganglia and the swallowing central pattern generator in the medulla, as well as of cortical areas (Chaudhuri 2006 ; Hunter 1997 ; Suttrup 2016). One of the most severe signs of dysphagia is aspiration of food into the airway, as it increases the risk of developing pneumonia (Mandell 2019 ; Nienstedt 2019). Aspiration pneumonia is a lung infection caused by aspiration of food, fluids, or secretions into the airway (Mandell 2019). A recent retrospective study reported that people with Parkinson's disease had a 2.23 times higher risk for pneumonia than the general population (Won 2021). Furthermore, the presence of aspiration pneumonia was correlated with the mortality rate. Won 2021 found that nearly 24% of people with Parkinson's disease died within the first year of aspiration pneumonia occurrence, and 91.8% died five years following the diagnosis of aspiration pneumonia. However, the mechanism behind aspiration is complex. There is emerging evidence that reduced voluntary cough expiratory airflow and reflex cough parameters are significantly correlated with penetration and aspiration of bolus material (i.e. a small, rounded mass of chewed food and secretions) during swallowing, leading to aspiration pneumonia (Hegland 2014 ; Pitts 2010 ; Troche 2010 ; Troche 2016 ; Wheeler 2014). In other words, there seems to be an association between someone's ability to cough, both voluntarily and involuntarily, and the likelihood that particles of chewed food will be inhaled into the airway, leading to aspiration pneumonia.

In general, dysphagic symptoms are similar to those affecting the limb muscles, including bradykinesia (motor control impairment, slow movements, and 'freezing'), muscle rigidity, and prolonged initiation and reaction time (Miller 2017). The oral preparatory phase is particularly compromised in Parkinson's disease, resulting in difficulties in bolus formation, manipulation and control, and prolonged swallowing time. Hypotonia (decreased muscle tone) and bradykinesia of the facial muscles can result in difficulties with mastication (chewing) and increased drooling (Miller 2017 ; Simons 2017). Tongue tremors, lingual pumping, and festination (involuntary acceleration) movements impact oral transit time, mainly during swallowing solids rather than swallowing softer consistencies (Buhmann 2019 ; Pflug 2018 ; Troche 2008). As a result, the oral phase, which involves the propulsion of a bolus into the pharynx, can be severely compromised and prolonged (Fukuoka 2019 ; Troche 2008). Difficulties in the oral phase lead to an increase in pharyngeal bolus residues of both food and medication (Curtis 2020a ; Curtis 2020b ; Suttrup 2016 ; Warnecke 2016 ; Warnecke 2020). Pharyngeal residues could be caused by either pre-swallow spillage into the pharynx or post-swallow residue in the pharynx. A recent study showed the presence of medications in the pharynx in a sample of people with Parkinson's disease, suggesting the effects of dysphagia in reducing medication intake and increasing Parkinsonian symptoms (Battel 2022 ; Buhmann 2019). Masticatory difficulties and difficulties at mealtime are significantly correlated with the risk of malnutrition in this population (Pizzorni 2022). When oral food intake is severely compromised, an individual's nutrition can be supported by enteral nutrition methods, such as nasogastric tube or percutaneous endoscopic gastrostomy (PEG).

In addition to the nutritional implications, swallowing impairments can have psychological and social impacts on people with Parkinson's disease. In the literature, it is well documented that dysphagia has a direct impact on social life, decreasing mealtime enjoyment and reducing quality of life (Athukorala 2014 ; Manor 2013 ; Van Hooren 2014). These impacts have consequences not just for people with Parkinson's disease and oropharyngeal dysphagia but also for their families (Hirschwald 2022 ; Perry 2022 ; Plowman-Prine 2009).

Oropharyngeal dysphagia also impacts healthcare costs. According to data from two studies, there was a 40% higher expenditure on patients with oropharyngeal dysphagia compared to their non-dysphagic counterparts (Attrill 2018 ; Marin 2021). In people with Parkinson's disease, the length of stay in hospital has been reported to be 44% (95% confidence interval (CI) 1.43 to 1.45) longer, and inpatient costs were 46% higher (95% CI 1.44 to 1.47) when compared to costs for people without dysphagia (Di Luca 2021).

Description of the intervention

Rehabilitation interventions for oropharyngeal dysphagia have four interrelated aims: (1) improve swallowing safety by reducing penetration (when material stays above or contacts the vocal folds) and aspiration (when material enters the trachea and

goes below the vocal folds) of food and fluids (Rosenbek 1996); (2) improve swallowing efficiency by increasing oral and pharyngeal coordination during bolus swallowing; (3) improve overall swallowing ability to reduce the risk of malnutrition; and (4) improve quality of life and active participation.

The first-line treatment for movement disorders in Parkinson's disease is pharmacological: people with the disease take dopaminergic medications (drugs that increase the amount of dopamine in the brain), which are recognised as fundamental therapy for movement disorders. The effects of these medications on swallowing function are controversial. It seems that they do not directly affect swallowing, but they reduce rigidity, festination, or freezing episodes, which impact eating processes (Chang 2021 ; Gandhi 2022 ; Menezes 2009 ; Warnecke 2014).

Rehabilitation interventions for oropharyngeal dysphagia are complex interventions in keeping with the definition provided by the Medical Research Council (Craig 2008 ; Skivington 2021). They can be categorised into two main groups: behavioural treatments and stimulation interventions.

Behavioural treatments

Behavioural swallowing treatments involve compensatory strategies or exercise programmes, or both (Gandhi 2022 ; Kim 2023 ; Suttrup 2016 ; Winiker 2023).

Compensatory strategies include postural manoeuvres, changing swallowing behaviour (e.g. taking a smaller bolus), and changes to food and/or fluid consistency. These compensatory strategies can result in an immediate positive effect on swallowing (Cichero 2020 ; Da 2019 ; Matsuo 2020 ; Steele 2015). These strategies are usually applied at the first sign of oropharyngeal dysphagia. Modification of food/fluid consistencies is typically implemented to reduce difficulties in oral-pharyngeal swallow coordination. Thickened liquids are thought to reduce the risk of pre-swallowing entry of fluid into the airway. Recent systematic reviews on the effects of bolus viscosity on the safety and efficiency of swallowing concluded that, although increasing bolus viscosity can immediately impact the safety of swallowing, increasing fluid viscosity may also increase residue in the pharynx and heighten the risk for post-swallow aspiration. It can also have long-term effects on people's health (for example, by leading to malnutrition, dehydration, and urinary tract infections) (Flynn 2018 ; Logemann 2008 ; Newman 2016 ; Robbins 2008a). Modification of food to include softer, easier-to-chew foods may help swallowing in people with masticatory difficulties (Cichero 2020 ; Da 2019 ; Matsuo 2020 ; Steele 2015).

Exercise programmes aim to improve swallowing safety and efficiency by altering individuals' physiology (Langmore 2015 ; Robbins 2008b). Such exercise programmes can be broadly divided into two groups.

(1) Training that does not involve the act of swallowing but has positive effects on associated swallowing function. Examples of these exercises are respiratory and voice training (Cocks 2022 ; Reyes 2018 ; Troche 2010), or tongue strength exercises (Jenks 2019). Respiratory and voice training seems to increase swallowing safety (Hegland 2019 ; Miles 2017 ; Troche 2010). Accordingly, expiratory muscle strength training (EMST) has been applied to increase the airway protection mechanism during swallowing in people with Parkinson's disease (Troche 2010).

(2) Training that aims directly at increasing the skills and co-ordination involved in swallowing (Gandhi 2022 ; Kim 2023 ; Langmore 2015). These exercises incorporate the neuroplasticity principle of 'use it or lose it' (Martin 2009 ; Robbins 2008b). According to this principle, swallowing training may stimulate the cortical and subcortical areas responsible for deglutition (the action or process of swallowing) to promote recovery. These exercises include skill swallowing training or video-assisted therapy (Athukorala 2014 ; Manor 2013). Some of these rehabilitative interventions also include the use of biofeedback, which seems to be specifically beneficial in the recovery of swallowing function in people with Parkinson's disease and oropharyngeal dysphagia (Battel 2020 ; Huckabee 2018).

Stimulation interventions

In recent years, there has been an increasing interest in stimulation to improve swallowing. There are different types of stimulation, which can be divided into central and peripheral stimulation. Central stimulation involves devices that stimulate different parts of the brain, such as deep brain stimulation (DBS), transcranial magnetic stimulation (TMS), and transcranial direct current stimulation (tDCS). DBS is a type of central stimulation that continuously delivers electric current to the basal ganglia's deep structures. It is a recognised treatment for reducing motor symptoms in individuals with Parkinson's disease. Nevertheless, it seems not to increase swallow function and swallowing safety (Cheng 2023 ; Troche 2014). TMS and tDCS are brain stimulation interventions that modulate brain activities through electromagnetic and electrical induction. Some studies have suggested that repetitive TMS (rTMS) can induce long-lasting neural plasticity changes in the swallowing motor cortex, which plays a key role in the recovery of swallowing function (Cheng 2023 ; Khedr 2019 ; Sasegbon 2022). Several other stimulation interventions have emerged in recent years; in particular, pharyngeal electrical stimulation (PES) and neuromuscular electrical stimulation (NMES). PES stimulates the pharyngeal mucosa directly through intraluminal electrodes (Cheng 2023 ; Sasegbon 2022). NMES stimulates the skin around the neck or facial area through surface electrodes (Cheng 2023 ; Park 2018). Within the subgroup of peripheral stimulation interventions, there are peripheral sensory stimulations. These interventions include tactile, thermal, or other multimodal sensory stimulation approaches (Logemann 1991 ; Regan 2010 ; Rosenbek 1996) and carbonation (Krival 2008 ; Price 2023 ; Yang 2022). These deliver stimulation to peripheral nerves or structures that are involved in swallowing in order to initiate the pharyngeal swallow.

How the intervention might work

Recent systematic reviews have revealed that rehabilitation interventions for oropharyngeal dysphagia may potentially reduce the risk of aspiration and penetration of food and fluids into the trachea, by improving the timing of pharyngeal swallow initiation and hyolaryngeal excursion (closure of the airway through the movement of the hyoid bone and larynx) during swallowing (Battel 2020 ; Battel 2022 ; Cheng 2023 ; Gandhi 2022 ; Van Hooren 2014). These reviews also found that rehabilitation interventions improved the quality of life of people with Parkinson's disease. In a recent scoping review, Hirschwald and colleagues identified

core outcomes used for assessing dysphagia interventions in Parkinson's disease. The included studies on rehabilitation interventions for oropharyngeal dysphagia in Parkinson's disease primarily assessed the following outcomes (Hirschwald 2022):

- swallowing safety: reducing the risk of penetration and aspiration;
- swallowing-related physiology: increasing oral bolus control and transport, reducing the timing of oropharyngeal swallow;
- swallowing efficiency: reducing post-swallow oral pharyngeal residue and pooling, and reducing piecemeal deglutition;
- swallowing-related quality of life.

In addition, some studies reported the benefit of rehabilitation in enhancing airway protection and reducing aspiration pneumonia (Pitts 2009 ; Troche 2010). Swallowing interventions also increased saliva management in some studies, although few have measured it as an outcome (Battel 2022 ; Hirschwald 2022 ; McNaney 2019).

Hirschwald 2022 also analysed non-swallowing-related outcomes. Some studies showed that the swallowing treatment led to positive changes in neurological symptoms and voice (El Sharkawi 2002 ; Miles 2017). Furthermore, rehabilitation for oropharyngeal dysphagia seemed to impact life functioning, increasing perceived health status, well-being, and quality of life (Battel 2022 ; Van Hooren 2014). One study reported death and hospitalisation rates as outcome measures in people with Parkinson's disease (Robbins 2008a).

Why it is important to do this review

Oropharyngeal dysphagia is considered one of the main causes of death in people with Parkinson's disease, impacting negatively on their quality of life, activities of daily living, and participation in social life. People with Parkinson's disease, their caregivers, and healthcare professionals must have the evidence available regarding the most effective rehabilitation interventions for oropharyngeal dysphagia.

The last Cochrane systematic review on swallowing rehabilitation in people with Parkinson's disease was published in 2001 (Deane 2001). Deane and colleagues concluded that there was no evidence to support or refute the efficacy of non-pharmacological swallowing treatments for oropharyngeal dysphagia in Parkinson's disease, and they included no randomised controlled trials (RCTs) in their review. In the last two decades, there has been an increase in RCTs on rehabilitation interventions for oropharyngeal dysphagia in Parkinson's disease, including different approaches, from behavioural treatment to neuro-stimulation. Given the increase in prevalence of people living with Parkinson's disease and the severe complications of oropharyngeal dysphagia in this population, an up-to-date summary and synthesis of the available evidence on the effectiveness of rehabilitation interventions for oropharyngeal dysphagia in Parkinson's disease is needed.

OBJECTIVES

To assess the effectiveness of rehabilitation interventions for oropharyngeal dysphagia in improving swallowing safety and efficiency in people with Parkinson's disease.

METHODS

Criteria for considering studies for this review

Types of studies

We will include eligible randomised controlled trials (RCTs) and cluster-randomised controlled trials (cluster-RCTs). We will include eligible cross-over randomised studies only if we can obtain separate data for the first study period from the study's publication or authors. We will exclude non-randomised studies of interventions, cross-sectional studies, case-control studies, and observational uncontrolled study designs.

Types of participants

We will include adults (aged 18 years and over) with a confirmed diagnosis of idiopathic Parkinson's disease with any duration or severity, according to guidelines defined by the Movement Disorders Society (Berg 2015). We will include participants experiencing oropharyngeal dysphagia as a consequence of Parkinson's disease. In the case of a mixed population, we will contact the study's authors to request separate data for people with Parkinson's disease, and we will exclude these studies if separate data are not available.

We will exclude studies involving participants with atypical parkinsonism and other neurological diseases potentially causing oropharyngeal dysphagia.

Types of interventions

We will include any rehabilitation intervention for oropharyngeal dysphagia. These include any of the following, alone or in combination with each other, with or without concurrent pharmacological treatments:

- behavioural interventions, such as swallowing exercise programmes, compensatory manoeuvres, and diet modifications;
- physical stimulation, such as thermal or tactile stimulation;
- neuromuscular electrical stimulation (NMES);
- pharyngeal electrical stimulation (PES);
- transcranial direct current stimulation (tDCS);
- transcranial magnetic stimulation (TMS);
- deep brain stimulation (DBS).

Eligible comparators may include:

- no intervention (e.g. waiting-list group);
- usual care: this may be described as standard treatment or usual treatment, and refers to the treatment usually available in the study locality. Usual care might include, for example, modified food consistencies or compensatory postures used by participants as a usual feeding method, compensatory manoeuvres, diet modifications, or combinations of these;
- a placebo/sham stimulation or attention control intervention;
- any other rehabilitation intervention: participants in the comparator group may receive another swallowing rehabilitation intervention, which is intended to influence the main outcomes of interest, but consists of different therapeutic components to the experimental intervention.

We will exclude pharmacological interventions alone.

Types of outcome measures

We will analyse the reliable outcome measures in Parkinson's disease at the end of treatment (at three months and at six months), and at the latest available follow-up. We will not use them as a basis for including or excluding studies. For each trial, we will analyse only the outcomes listed below and not all the outcomes reported in the trial.

In case of multiple outcome measures for the same outcome, we will select the one that is most clinically meaningful and that has better evidence of reliability and validity, if available.

Primary outcomes

- Swallowing efficiency (e.g. the Yale Pharyngeal Residue Severity Rating Scale (Neubauer 2015); bolus residue scale (Rommel 2015); Eisenhuber scale (Eisenhuber 2002))
- Swallowing safety (e.g. Penetration-Aspiration Scale (PAS) (Rosenbek 1996))

Secondary outcomes

- Dysphagia severity using validated outcome measures (e.g. the Dysphagia Outcome and Severity Scale (DOSS) (O'Neil 1999); the Dysphagia Severity Scale (DSS) (Tohara 2003); the Functional Oral Intake Scale (FOIS) (Crary 2005))
- Saliva management (change in frequency and severity of drooling and salivary pooling)
- Quality of life (e.g. Swallowing Quality of Life (Swal-QOL) (McHorney 2002))
- Respiratory outcomes (including chest infection or aspiration pneumonia; measurements of cough, such as peak expiratory flow rate, cough peak flow, reflex cough threshold, and reflex cough peak (Hegland 2014 ; Hegland 2019 ; Pitts 2010 ; Troche 2016))
- Nutritional and dietary outcome weight changes, using measures as well as validated scales (e.g. Malnutrition Universal Screening Tool (MUST) (Stratton 2004))
- Adverse events (hospitalisations, mortality)

Search methods for identification of studies

Electronic searches

We will search the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL; latest issue) (Appendix 1);
- MEDLINE (PubMed) (1946 to search date) (Appendix 2);
- Embase (Embase.com) (1947 to search date) (Appendix 3);
- Cumulative Index to Nursing and Allied Health Literature EBSCO (CINAHL) (1937 to search date) (Appendix 4);
- Web of Science (1900 to search date) (Appendix 5);
- Speech Pathology Database for Best Interventions and Treatment Efficacy (SpeechBite) (speechbite.com) (2008 to search date) (Appendix 6).

A review author (MJDF) developed detailed search strategies for each database. We will impose no language or publication date restrictions on the search strategies.

Searching other resources

We will also search the US National Institutes of Health Ongoing Trials register, ClinicalTrials.gov (www.clinicaltrials.gov) (Appendix 7) and the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (trialsearch.who.int) (Appendix 8) for ongoing studies and recently completed trials, and OpenGrey (System for Information on Grey Literature in Europe) (Appendix 9). We will manually review the reference lists of all included studies and of any relevant systematic reviews. We will perform a forward citation search of all included studies. We will contact the investigators of any known ongoing studies to try to obtain any relevant unpublished data.

Data collection and analysis

Selection of studies

Two review authors (IB and MJDF) will independently screen titles and abstracts. We will resolve any disagreements through discussion with a third review author (JH). We will retrieve the full-text articles of studies that appear to meet the inclusion criteria. Two review authors (IB and MJDF) will independently screen the articles for inclusion in the review. In the event of a disagreement between authors, we will involve a third review author (JH) to reach a final decision. We will use Covidence software for the screening process (Covidence). We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Page 2021). We will list studies that we judge are ineligible for inclusion in the 'Characteristics of excluded studies' table, together with reasons for their exclusion.

Data extraction and management

Using Covidence, we will record study data on data extraction forms that we have developed and tested in advance. Two review authors (IB and MJDF) will independently extract study information, and a third author (JH) will check the extracted information against the original study publications. Two review authors (CA and SGL) will independently extract outcome data and compare extractions. We will resolve any disagreements through discussion and involve a third review author (MW) if necessary. If contact details are available, we will contact the authors of published trials to clarify or provide additional information if required.

We will extract the following study characteristics.

- Methods: study design, study duration, number of study centres and location, study setting (i.e. inpatients, outpatients, home-based), withdrawals, and study date.
- Participants: number of participants, mean age, age range, gender, disease duration, the severity of the condition according to the Hoehn and Yahr Scale (Hoehn 1967) or Movement Disorder Society Unified Parkinson's Disease Rating (MDS-UPDRS) scale (Goetz 2007), swallowing-related baseline data, inclusion and exclusion criteria.
- Interventions: experimental intervention, comparison, co-interventions, concomitant pharmacological treatments, duration, frequency and dose of the interventions.
- Outcomes: primary and secondary outcomes specified and collected, and time points reported.
- Results: the number of events and participants per treatment group for dichotomous outcomes, means and standard deviations and the number of participants per treatment group

for continuous outcomes for each time point. If both final values and changes from baseline values are reported for the same outcome, we plan to extract the final values; if both unadjusted and adjusted values for the same outcome are reported, we plan to extract the adjusted values. If data are analysed based on an intention-to-treat (ITT) sample and another sample (e.g. per-protocol, as-treated), we plan to extract the data from the per-protocol analysis.

- Characteristics of the trial design, as outlined below in Assessment of risk of bias in included studies .
- Notes: funding for the trial, notable declarations of interest of trial authors, trial registration number.

Assessment of risk of bias in included studies

Two review authors (IB and MJDF) will independently assess the risk of bias using the Cochrane risk of bias 2 tool (RoB 2) (Sterne 2019), as described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023a). We will resolve any disagreements through discussion and by involving a third review author (CA), if necessary. We will assess the outcomes specified for inclusion in the summary of findings table(s) at the end of treatment and the latest available follow-up. For this review, we are interested in the effect of assignment to the interventions at baseline, regardless of whether the interventions are received as intended (i.e. the 'intention-to-treat' effect).

We will consider the following domains of bias:

- bias arising from the randomisation process;
- bias introduced by deviations from intended interventions;
- bias arising from missing outcome data;
- bias in measurement of the outcome;
- bias in selection of the reported result.

We will judge each domain as 'low risk of bias', 'high risk of bias', or 'some concerns'. The judgements will be facilitated by an algorithm that maps responses to the signalling questions with response options of 'yes', 'probably yes', 'probably no', 'no', and 'no information'. We will present an overall risk of bias judgement for each result based on the assessments across the five domains, considering the worst risk of bias in any of the domains. The overall risk of bias will be judged as 'low risk of bias', 'high risk of bias', or 'some concerns'. We will perform and document the risk of bias assessment using the RoB2 Excel tool (available at www.riskofbias.info).

If we include any cluster-RCTs, we will use the RoB 2 tool for cluster-randomised trials (available at www.riskofbias.info). This tool considers one additional domain to assess bias arising from the timing of identification and recruitment of participants. Following the guidance in Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* , we will assess the risk of bias when including variants of randomised trials (Higgins 2023b).

Measures of treatment effect

For dichotomous outcome data, we will calculate effect sizes as risk ratios (RR) with their respective 95% confidence intervals (CIs).

For continuous outcomes, when study authors use the same measures to assess the same outcome, we will calculate mean differences (MDs) with 95% CIs. When study authors use different measures to assess the same outcome, we will calculate standardised mean differences (SMDs) with 95% CIs, if we deem that pooling the results of different scales that measure the same outcome is appropriate and meaningful. We will classify the effect size measured by the SMD as very small or no effect (when the SMD is 0.00 to 0.19), small (SMD between 0.20 and 0.49), medium (SMD between 0.50 and 0.79), and large (SMD 0.80 or greater) (Cohen 1992).

Unit of analysis issues

Cluster-randomised trials

For cluster-RCTs, we will extract the intra-cluster correlation coefficient (ICC) when available; we will also record the number of clusters per group, the total size of clusters per group, and the unit of randomisation (e.g. household or institution). We will document the statistical methods used to analyse the trial results, along with details describing whether these methods were adjusted for clustering or other co-variables.

Using the generic inverse-variance random-effects method, we will pool cluster-RCT data that have been adjusted for clustering with data from trials that randomly assign individuals (individual-RCTs). When the results of a cluster-RCT have not been adjusted for clustering, we will adjust the data using the clustering effect (ICC) imputed from another study (Higgins 2023b).

Studies with multiple treatment groups

If a study compared two or more treatment groups eligible for inclusion in the review, we will label the arms separately in pair-wise analyses. To avoid including data for controls more than once in the same comparison, we will divide the number of events and number of participants in the control group into equal parts. Where suitable, we will combine multiple treatment arms representing the same intervention category, as defined for the purposes of the review, to create a single pair-wise comparison, according to the methods recommended in Chapters 6 and 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023c ; Higgins 2023b), and we will exclude irrelevant treatment arms.

Cross-over trials

We will include relevant eligible randomised cross-over trials in the review, but we will only use data gathered during the first period of the study, up to the point of the first cross-over. This should avoid any problems associated with any carry-over effect from the first to the second period of the study.

Dealing with missing data

If data on intervention groups, summary data, standard deviations on specific outcomes, or study design are missing, we will contact study authors or data owners to request these data.

For continuous outcomes, we will calculate the MD or SMD based on the number of participants analysed at the selected time point. If study authors do not report the number of participants analysed for each time point, we will use the number of randomised participants in each group at baseline.

Where possible, we will calculate missing standard deviations from other statistics, such as standard errors, confidence intervals, or P values, according to the methods recommended in Chapter 6 of

the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023c).

Assessment of heterogeneity

We will pool data if studies are similar in terms of their study populations, interventions, and outcomes (PICO elements). We will assess the presence of clinical heterogeneity within each pair-wise comparison by comparing the trial and study population characteristics across all eligible trials. For pair-wise analyses, we will inspect forest plots visually to detect heterogeneity. We will use the I^2 test to assess statistical heterogeneity, using the following rough guide to the interpretation of heterogeneity values set out in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2023) *:*

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: represents considerable heterogeneity.

These overlapping intervals reflect that the interpretation of the I^2 statistic depends on the value size and direction of the treatment effect and variance of the I^2 estimate.

Assessment of reporting biases

We will investigate the possibility of reporting biases, including publication bias, by visually assessing funnel plots for asymmetry where more than 10 studies are included in the meta-analysis (Sterne 2011).

In order to minimise the impact of reporting biases, we will conduct comprehensive searches of multiple databases and other sources, including clinical trial registries, to identify any unpublished studies (see Search methods for identification of studies). We will also look for outcome reporting bias in studies by recording all trial outcomes, planned and reported, and noting the absence of anticipated outcomes or less detailed reporting of non-significant outcomes. We will contact study authors to try to obtain any missing data.

Data synthesis

We plan to pool the results from the individual trials in meta-analyses, where possible (i.e. good comparability of types of participants, intervention, comparator, and outcomes between trials), with the DerSimonian and Laird method (DerSimonian 1986). We will employ a random-effects model, as we expect a certain degree of clinical heterogeneity amongst the included studies.

If, due to unacceptable heterogeneity, meta-analysis is not appropriate, we will present a narrative summary of study results, summarising effect estimates when possible, following guidance in Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (McKenzie 2023).

Subgroup analysis and investigation of heterogeneity

To investigate heterogeneity, we will plan to perform the following subgroup analyses.

- Severity of swallowing safety at baseline using instrumental examination (Penetration-Aspiration Scale (PAS) ≤ 5 versus PAS > 5) (Rosenbek 1996).
- Parkinson's disease onset: early onset at 50 years or younger versus older than 50 years (Camerucci 2021).
- Severity of Parkinson's symptoms/stage of disease according to the Hoehn and Yahr Scale (Mild 1-2; Moderate/Severe 3-5) (Hoehn 1967 ; Martinez-Ramirez 2015), or MDS-UPDRS scale (Part III: Mild/Moderate ≤ 58; Severe ≥ 59) (Goetz 2007 ; Martinez-Ramirez 2015).

We will compare subgroups using the formal test for subgroup differences in Review Manager (RevMan Web 2023). We will use caution in the interpretation of subgroup analyses, as advised in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2023).

Sensitivity analysis

We will check the robustness of the results of our primary analyses by conducting a sensitivity analysis restricted to the results of studies we rated as having either 'low risk' or 'some concerns' of bias overall.

Summary of findings and assessment of the certainty of the evidence

We will develop summary of findings tables to present summary effect estimates for the following outcomes:

- swallowing efficiency;
- swallowing safety;
- dysphagia severity;
- saliva management;
- quality of life;
- respiratory outcomes;
- adverse events.

For the critical outcomes, swallowing efficiency and swallowing safety, we will present summary effect estimates at the end of treatment (at three months and six months from the randomisation process) and end of follow-up. For the rest of the outcomes, we will present summary effect estimates at six months.

Considering the multicomponent characteristics of rehabilitation (Arienti 2021 ; Negrini 2022), we cannot specify a priori which are the most important comparisons we will present in the summary of findings tables. We will present those we consider to be clinically relevant.

We will use the GRADE approach to prepare the table(s) as needed. Two review authors (CA and SGL) will independently perform the evidence certainty assessment, with any disagreements resolved through discussion. We will assess the evidence across the following domains:

- study limitations (risk of bias);
- imprecision of results (wide confidence intervals for treatment effect);
- heterogeneity (large I^2 value);
- indirectness of evidence (variations in participants, interventions, comparisons, and outcomes);
- publication bias.

We plan to assess the overall certainty of the evidence for each outcome as 'high', 'moderate', 'low', or 'very low' according to the GRADE approach.

- High certainty: we are confident that the true effect lies close to that of the estimate of the 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.

We will follow the guidelines in the *Cochrane Handbook for Systematic Reviews of Intervention* s, Chapters 14 and 15 (Schünemann 2023a ; Schünemann 2023b), for interpreting results, and will be aware of distinguishing a lack of evidence of effect from a lack of effect. We will avoid making recommendations for practice. Our implications for research will suggest priorities for future research and will outline what the remaining uncertainties are in this area.

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APPENDICES

Appendix 1. Search strategy for CENTRAL (via Cochrane Library)

1. MeSH descriptor: [Parkinson Disease] explode all trees
2. MeSH descriptor: [Parkinsonian Disorders] explode all trees
3. (parkinson*):ti,ab,kw
4. #1 OR #2 OR #3
5. MeSH descriptor: [Deglutition Disorders] explode all trees
6. MeSH descriptor: [Deglutition] this term only
7. (dysphag*):ti,ab,kw
8. (((swallow* OR deglutit* OR pharyn* OR oropharyn*) near/3 (disturbance* OR disorder* OR difficult* OR dysfunction* OR impair* OR condition* OR abnormal* OR damage* OR injur*))):ti,ab,kw
9. #5 OR #6 OR #7 OR #8
10. #4 AND #9 – in Trials

Appendix 2. Search strategy for MEDLINE PubMed (via pubmed.ncbi.nlm.nih.gov/)

1. "Parkinson disease"[Mesh] OR "Parkinsonian Disorders" [Mesh]
2. Parkinson*[tiab]
3. #1 OR #2
4. "Deglutition Disorders"[Mesh]
5. (dysphag* [tiab] OR ((swallow*[tiab] OR deglutit*[tiab] OR pharyn*[tiab] OR oropharyn*[tiab]) AND (disturbance*[tiab] OR disorder*[tiab] OR difficult*[tiab] OR dysfunction*[tiab] OR impair*[tiab] OR condition*[tiab] OR abnormal*[tiab] OR damage*[tiab] OR injur*[tiab])))
6. #4 OR #5
7. "randomized controlled trial"[pt]
8. "controlled clinical trial"[pt]
9. randomized[tiab]
10. placebo[tiab]
11. "clinical trials as topic"[mesh:noexp]

12.randomly[tiab]
13.trial[ti]
14.#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13
15.animals [mh] NOT humans [mh]
16.#14 NOT #15
17.#3 AND #6 AND #16

Appendix 3. Search strategy for Embase (via Embase.com)

1. 'Parkinson disease'/exp OR 'parkinsonism'/exp
2. parkinson*:ti,ab,kw
3. #1 OR #2
4. 'dysphagia'/exp OR 'swallowing'/exp
5. (dysphag* OR ((swallow* OR deglutit* OR pharyn* OR oropharyn*) NEAR/3 (disturbance* OR disorder* OR difficult* OR dysfunction* OR impair* OR condition* OR abnormal* OR damage* OR injur*))):ti,ab,kw
6. #4 OR #5
7. 'randomized controlled trial'/de
8. 'controlled clinical trial'/de
9. random*:ti,ab,tt
10. 'randomization'/de
11. 'intermethod comparison'/de
12. placebo:ti,ab,tt
13. (compare:ti,tt OR compared:ti,tt OR comparison:ti,tt)
14. ((evaluated:ab OR evaluate:ab OR evaluating:ab OR assessed:ab OR assess:ab) AND (compare:ab OR compared:ab OR comparing:ab OR comparison:ab))
15. (open NEXT/1 label):ti,ab,tt
16. ((double OR single OR doubly OR singly) NEXT/1 (blind OR blinded OR blindly)):ti,ab,tt
17. 'double blind procedure'/de
18. (parallel NEXT/1 group*):ti,ab,tt
19. (crossover:ti,ab,tt OR 'cross over':ti,ab,tt)
20. ((assign* OR match OR matched OR allocation) NEAR/6 (alternate OR group OR groups OR intervention OR interventions OR patient OR patients OR subject OR subjects OR participant OR participants)):ti,ab,tt
21. (assigned:ti,ab,tt OR allocated:ti,ab,tt)
22. (controlled NEAR/8 (study OR design OR trial)):ti,ab,tt
23. (volunteer:ti,ab,tt OR volunteers:ti,ab,tt)
24. 'human experiment'/de
25. trial:ti,tt
26. #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25
27. (((random* NEXT/1 sampl* NEAR/8 ('cross section*' OR questionnaire* OR survey OR surveys OR database or databases)):ti,ab,tt) NOT ('comparative study'/de OR 'controlled study'/de OR 'randomised controlled':ti,ab,tt OR 'randomized controlled':ti,ab,tt OR 'randomly assigned':ti,ab,tt))
28. ('cross-sectional study'/de NOT ('randomized controlled trial'/de OR 'controlled clinical study'/de OR 'controlled study'/de OR 'randomised controlled':ti,ab,tt OR 'randomized controlled':ti,ab,tt OR 'control group':ti,ab,tt OR 'control groups':ti,ab,tt))
29. ('case control*':ti,ab,tt AND random*:ti,ab,tt NOT ('randomised controlled':ti,ab,tt OR 'randomized controlled':ti,ab,tt))
30. ('systematic review':ti,tt NOT (trial:ti,tt OR study:ti,tt))
31. (nonrandom*:ti,ab,tt NOT random*:ti,ab,tt)
32. 'random field*':ti,ab,tt
33. ('random cluster' NEAR/4 sampl*):ti,ab,tt
34. (review:ab AND review:it NOT trial:ti,tt)
35. ('we searched':ab AND (review:ti,tt OR review:it))
36. 'update review':ab
37. (databases NEAR/5 searched):ab
38. ((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de)

39.('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))
40.#27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39
41.#26 NOT #40
42.#3 AND #6 AND #41

Appendix 4. Search strategy for CINAHL (via EBSCOhost)

1. (MH "Parkinson Disease" OR MH "Parkinson Disorders+")
2. TI (Parkinson*) OR AB (Parkinson*) OR SU (Parkinson*)
3. #1 OR #2
4. (MH "Deglutition Disorders" OR MH "Deglutition")
5. TI ((dysphag*) OR ((swallow* OR deglutit* OR pharyn* OR oropharyn*) N3 (disturbance* OR disorder* OR difficult* OR dysfunction* OR impair* OR condition* OR abnormal* OR damage* OR injur*))) OR AB ((dysphag*) OR ((swallow* OR deglutit* OR pharyn* OR oropharyn*) N3 (disturbance* OR disorder* OR difficult* OR dysfunction* OR impair* OR condition* OR abnormal* OR damage* OR injur*))) OR SU ((dysphag*) OR ((swallow* OR deglutit* OR pharyn* OR oropharyn*) N3 (disturbance* OR disorder* OR difficult* OR dysfunction* OR impair* OR condition* OR abnormal* OR damage* OR injur*)))
6. #4 OR #5
7. MH randomized controlled trials
8. MH double-blind studies
9. MH single-blind studies
10. MH random assignment
11. MH pretest-posttest design
12. MH cluster sample
13. TI (randomised OR randomized)
14. AB (random*)
15. TI (trial)
16. MH (sample size) AND AB (assigned OR allocated OR control)
17. MH (placebos)
18. PT (randomized controlled trial)
19. AB (control W5 group)
20. MH (crossover design) OR MH (comparative studies)
21. AB (cluster W3 RCT)
22. MH animals+
23. MH (animal studies)
24. TI (animal model*)
25. #22 OR #23 OR #24
26. MH (human)
27. #25 NOT #26
28. #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21
29. #28 NOT #27
30. #3 AND #6 AND #29

Appendix 5. Search strategy for Web of Science

1. TS=(Parkinson*)
2. TS=((dysphag*) OR ((swallow* OR deglutit* OR pharyn* OR oropharyn*) NEAR/3 (disturbance* OR disorder* OR difficult* OR dysfunction* OR impair* OR condition* OR abnormal* OR damage* OR injur*)))
3. TS=(random* or RCT or RCTs)
4. TS=(controlled NEAR/5 (trial* or stud*))
5. TS=(clinical* NEAR/5 trial*)
6. TS=((control or treatment or experiment* or intervention) NEAR/5 (group* or subject* or patient*))
7. TS=((control or experiment* or conservative) NEAR/5 (treatment or therapy or procedure or manage*))
8. TS=((singl* or doubl* or tripl* or trebl*) NEAR/5 (blind* or mask*))
9. TS=(cross-over or cross over or crossover)
10. TS=(placebo* or sham)

11.TS=trial
12.#3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11
13.#1 AND #2 AND #12

Appendix 6. Search strategy for Speech Pathology Database for Best Interventions and Treatment Efficacy (SpeechBite)

1. Speech Pathology Practice Area: Dysphagia
2. Type of interventions: Swallowing/feeding intervention
3. Within this population: Degenerative disorders/diseases

Appendix 7. Search strategy for ClinicalTrials.gov

Other terms: ("Parkinson Disease" OR "Parkinsonian Disorders" OR Parkinson) AND (Dysphagia OR "Deglutition Disorders" OR "Swallowing Disorder" OR Pharynx)

Appendix 8. Search strategy for World Health Organization International Clinical Trials Registry Platform (WHO ICTRP)

Parkinson* AND dysphag* OR Parkinson* AND Swallow* OR Parkinson* AND Deglutition Disorder* OR Parkinson* AND Oropharyn* OR Parkinson* AND Pharyn*

Appendix 9. Search strategy for OpenGrey (system for information on grey literature in Europe)

("parkinson*") AND ("dysphagia" OR “deglutition disorders” OR “swallowing disorder”)

CONTRIBUTIONS OF AUTHORS

Irene Battel : developed and co-ordinated the protocol; made an intellectual contribution to the protocol in writing about the background, objectives, and methods; approved the final version of the protocol before submission.

Chiara Arienti : made an intellectual contribution to the protocol in writing about the methods, data collection, and analysis; approved the final version of the protocol before submission.

Matteo Johann Del Furia : developed and advised on the protocol; completed the first draft of the protocol; made an intellectual contribution to the protocol in writing about the background, objectives, and methods; approved the final version of the protocol before submission.

Julia Hirschwald : made an intellectual contribution to the protocol; approved the final version of the protocol before submission.

Stefano Giuseppe Lazzarini : made an intellectual contribution to the protocol in writing about the methods, data collection, and analysis; approved the final version of the protocol before submission.

Margaret Walshe : developed the protocol; made an intellectual contribution to the protocol in writing about the background, objectives, and methods; approved the final version of the protocol before submission.

DECLARATIONS OF INTEREST

Irene Battel declares that she has no conflicts of interest.

Chiara Arienti declares that she has no conflicts of interest.

Matteo Johann Del Furia declares that he has no conflicts of interest.

Julia Hirschwald declares that she has no conflicts of interest.

Stefano Giuseppe Lazzarini declares that he has no conflicts of interest.

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