

# Swallowing outcomes in dysphagia interventions in Parkinson's disease: a scoping review

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### Abstract

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To cite: Hirschwald J, Hofacker J, Duncan S, et al. BMJ Evidence-Based Medicine 2023;28:93–100. **Objectives** To identify all outcomes, their definitions, outcome measurement instruments (OMIs), timepoints and frequency of measurement applied in clinical trials in oropharyngeal dysphagia (OD) interventions in Parkinson's disease (PD). This scoping review is the first stage of a larger project establishing a core outcome set for dysphagia interventions in Parkinson's disease (COS-DIP).

### Design Scoping review.

Methods Six electronic databases and one trial registry were searched without language restrictions until March 2022. Bibliography lists of included studies were also reviewed. Study screening and data extraction were conducted independently by two reviewers using Covidence. The scoping review protocol is registered and published (http://hdl.handle.net/2262/97652). Results 19 studies with 134 outcomes were included. Trial outcomes were mapped to a recommended taxonomy for COSs and merged. 39 outcomes were identified. The most frequently measured were general swallowing-related outcomes, global quality-of-life outcomes and swallowing-related perceived health status outcomes. The applied outcomes, their definitions, OMIs, timepoints and frequency of measurement showed a high variability across all studies. Conclusions The high variability of outcomes emphasises the need for an agreed standardised COS. This will inform clinical trial design in OD in PD, increase the quality of OD trials in PD and facilitate synthesising and comparing study results to reach conclusion on the safety and effectiveness of OD interventions in PD. It will not prevent or restrict researchers from examining other outcomes.

Trial registration number The COS-DIP study, including the scoping review, was registered prospectively with the Core Outcome Measures in Effectiveness Trials Database on 24 September 2021 (www.comet-initiative.org, registration number: 1942).

### Introduction

Swallowing disorders (oropharyngeal dysphagia (OD)) are a common and clinically significant symptom in people with Parkinson's disease (PD).<sup>1</sup> The prevalence varies between 11% and 81% according to severity of the disease, definitions of OD and assessment tools used.<sup>2</sup> Nearly 50% of

# WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is a paucity of evidence on interventions for swallowing disorders (dysphagia) in Parkinson's disease (PD) and longer-term treatment effects and adverse events remain mostly unknown. One important reason for this is that studies examine different outcomes and use different methods of measurement making systematic reviews and meta-analyses difficult.

### WHAT THIS STUDY ADDS

⇒ This scoping review identified all outcomes, their definitions, outcome measurement instruments and timepoints and frequency of measurement in clinical trials in dysphagia in PD. The results will inform the next stages of a larger project to develop a core outcome set for dysphagia interventions in Parkinson's disease (COS-DIP).

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Ultimately, the COS-DIP will provide a minimum of clearly defined outcomes that should be measured systematically and reported in all clinical trials in dysphagia in PD. This will strengthen the evidence on dysphagia interventions in PD and reduce research waste.

people with PD experience aspiration,<sup>3</sup> increasing the risk of developing pneumonia, which is a leading cause of death in people with PD.<sup>4-6</sup>

OD interventions aim for safe, efficient and sufficient intake of food and fluids for patients while maximising quality of life (QoL) for the patient, their carers and their family.<sup>4</sup> Clinical decisions on the safety and effectiveness of interventions are based on selected outcomes, thus the choice of outcomes to be measured and reported in clinical trials is critical.<sup>7</sup>

Furthermore, synthesising and comparing study results to direct treatment for people with OD in PD is necessary. Two recently published systematic reviews by Gandhi and Steele<sup>8</sup> and López-Liria *et*  $al^9$  concluded that there is an ongoing significant lack of fundamental scientific evidence on the treatment of OD in PD. In an attempt to address this issue, Schindler *et al*<sup>10</sup> established a consensus on the treatment of OD in PD. One conclusion made by the authors is that in neurodegenerative conditions such as PD, longer-term treatment effects and adverse events must also be assessed.

These three published reports demonstrate not only a deficiency of evidence on OD interventions in PD but argue that longer-term treatment effects and adverse events should be assessed consistently. Despite being intricately linked, these studies focus on the efficacy and efficiency of OD interventions themselves rather than on the outcomes that are targeted by the interventions.

# Core outcome set for dysphagia interventions in Parkinson's disease (COS-DIP)

A solution to these challenges is the development and use of an agreed standardised COS-DIP devised by key stakeholders including patients, healthcare professionals and clinical trialists. This will result in higher quality meaningful trials, which will enhance synthesising and comparing individual study results to reach conclusions on the safety and effectiveness of the interventions. It will not prevent or restrict researchers from examining other outcomes.<sup>7 11</sup>

In order to establish the COS-DIP, the first step is a scoping review of the literature on the applied outcomes in clinical trials in OD in PD. A scoping review was chosen as the most appropriate method to systematically map the research done in this area, as well as to identify any existing gaps in knowledge.<sup>12</sup>

The objective of this scoping review was to report on all applied outcomes, their definitions, outcome measurement instruments (OMIs) and timepoints and frequency of measurement in (quasi-) randomised controlled trials (RCTs), controlled clinical trials (CCTs) and pilot/feasibility studies with control groups in OD in PD. This extracted information is brought together in a 'long list of outcomes' and will be used to inform the development of the COS-DIP. The following research questions were sought to be answered:

- 1. What are the outcomes of interest in clinical trials in OD in PD?
- 2. How are the outcomes in these clinical trials defined?
- 3. How are the outcomes in these clinical trials measured?
- 4. At which timepoints and at which frequency are the outcomes in these clinical trials measured?

### Patient and public involvement

We did not involve patients or members of the public in the design or conduct of this scoping review. For all following stages of the COS-DIP we have established a study steering committee that will lead and conduct the development of the COS-DIP and includes a public research partner with PD.

### Methods

### Study protocol and registration

This scoping review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Metaanalysis extension for Scoping Reviews (PRISMA-ScR) checklist (see online supplemental file 1).<sup>13</sup> A review protocol was devised beforehand and published online (http://hdl.handle.net/ 2262/97652). The COS-DIP study, including the scoping review, was registered prospectively with the Core Outcome Measures in Effectiveness Trials (COMET) Database on 24 September 2021 and

#### Searches

A comprehensive search strategy, including two search strings (1) dysphagia and (2) Parkinson's Disease, was devised with the assistance of a subject librarian. The databases AMED, CINAHL, EMBASE, MEDLINE, Web of Science, ProQuest Dissertations & Theses and trial registry Clinicaltrials.gov were searched from inception to 3 December 2021 and updated on 10 March 2022 (see online supplemental file 2). The reference lists of all included studies were screened for additional studies and study authors were contacted for additional information, if required.

### Study inclusion and exclusion criteria

Studies were included if (1) participants had a diagnosis of OD and PD, (2) clinical interventions were aimed at improving swallowing or feeding difficulties, (3) at least one swallowing (related) outcome was measured and (4) the study design included at least one intervention and one control group (RCT, quasi-RCT, CCT or feasibility/pilot study with control group). Only studies with control groups were included as ultimately the COS-DIP will inform clinical trial design with a focus on RCTs so that meta-analysis of clinical trials in OD and PD will be feasible in the future. In accordance with the patient, concept and context framework,<sup>13</sup> the following was applied:

- ▶ Patient: OD in idiopathic PD  $\ge$  18 years.
- Concept: any clinical intervention in OD in PD.
- Context: any clinical context (all countries and healthcare settings, eg, acute care, primary healthcare and community setting).

Studies were excluded if they did not fit into the conceptual framework of the study or if a heterogeneous participant population including people with PD was studied but data could not be extracted for the PD subgroup solely. Finally, studies were excluded if no full text was available, eg, a conference abstract only, and authors were unable to provide sufficient information. No date or language restrictions were applied.

#### Study selection

Following the search, all identified citations were collated and uploaded to an online platform (www.covidence.org), where duplicates were removed automatically. A pilot test of a random sample of 25 titles and abstracts was carried out by 2 independent reviewers (JHirschwald and JHofacker) and achieved an agreement of 96% (preset cut-off was set at 75%). Following, all abstracts and titles and thereafter full texts, were screened independently by JHirschwald and JHofacker against the inclusion criteria. Any disagreement that arose between the reviewers at each stage of the selection process was either resolved through discussion or with an additional reviewer (MWalshe).

### Data extraction strategy

Data was extracted independently from papers included in the scoping review by JHirschwald and JHofacker using a data extraction tool developed previously and applied by Hofacker.<sup>14</sup> The extracted data includes details about the first author's name, year of publication, country of origin, study design, population, sample size and applied outcomes. The data extraction form was trialled independently on three included sources by JHirschwald and JHofacker. As a result of discussion together with MWalshe, further parameters were added to the data extraction form: number of participants and dropouts, intention-to-treat analysis, age,

gender, PD severity, OD severity, intervention, comparator, OMIs, timepoints of measurement and frequency of measurement (see online supplemental file 3). Any disagreements that arose were resolved through discussion between JHirschwald and JHofacker, or with MWalshe in addition.

### Data analysis and presentation

As no taxonomy for categorisation of outcomes in OD interventions specifically exists, a widely used taxonomy by Dodd *et al*<sup>15</sup> was applied. This taxonomy was designed for trial outcomes and is applicable to all fields within medical research.<sup>7 16</sup> It includes 5 core areas (death, physiological/clinical, life impact, resource use and adverse events) and 38 outcome domains.<sup>15</sup>

The outcomes used in the included studies were extracted as verbatim following COS methodology as described in the COMET Handbook.<sup>7</sup> All extracted data were categorised in an Excel spreadsheet also previously developed and applied by Hofacker<sup>14</sup> and further adapted for the purpose of this study. It comprises information regarding core area of the outcome and outcome domain in accordance with the taxonomy by Dodd *et al*,<sup>15</sup> outcome description as reported verbatim by study authors, definition of outcome, OMIs and timepoints and frequency of measurement. Furthermore, the amount and percentages of used outcomes within the respective core area and outcome domain were calculated.

### **Results**

### Search results

The literature search identified 2587 studies. After removal of duplicates, further 2328 records were excluded during title/ abstract screening. Of the remaining 54 reports, 9 could not be retrieved as full texts and 27 did not meet the inclusion criteria in the full-text review (see online supplemental file 8). Additionally, two records were identified through citation searching, of

which one was included. In total, 19 studies were included in this scoping review. Of these, 18 were in English and one in Chinese. The Chinese study was translated with the help of a translator and Chinese speaking Speech and Language Therapist. The results of the search and the study inclusion process are outlined in the PRISMA-ScR flow diagram in figure 1.<sup>13 17</sup>

The included studies comprised 10 RCTs, 2 quasi-RCTs, 4 CCTs and 3 feasibility/pilot studies with control groups. Overall, 2124 participants were included with studies being published between the years 2000 and 2021, although all years were included in the search. Assessed interventions in the included studies were surface electrical stimulation (n=4), postural swallowing techniques (n=3), Expiratory Muscle Strength Training (n=3), application of biofeedback (n=2), repetitive transcranial magnetic stimulation (rTMS) (n=2), standardised swallowing training (n=2), deep brain stimulation (n=1), vocal training (n=1) and aural stimulation with capsaicin (n=1) (see online supplemental file 3 for the detailed characteristics of the included studies).

Within the 19 studies, 180 outcomes were identified. Of these, 46 outcomes were excluded for different reasons: (1) the outcomes were only assessed for determining whether the participants met the inclusion criteria for study participation but not the effect of the intervention, (2) neither the specific OMI nor results were reported or (3) due to missing information it was unclear what the outcome referred to (see online supplemental file 4).

#### **Outcome areas**

The majority of the 134 included outcomes belong to the outcome areas physiological/clinical (n=112; 83.58%) or life impact/functioning (n=19; 14.18%). One outcome was categorised to each of the outcome areas death, resource use and adverse events (n=1; 0.75% respectively).

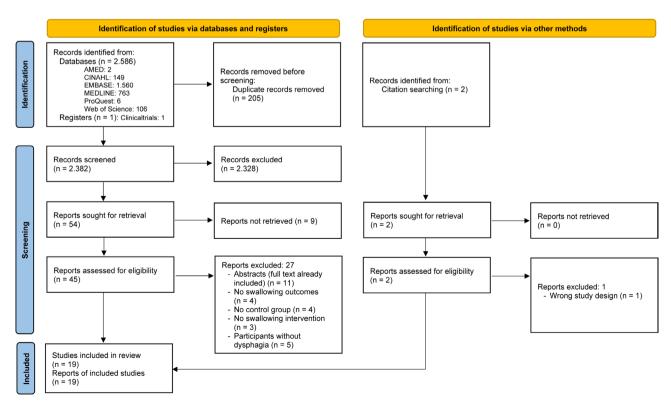


Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-analysis extension for Scoping Reviews flow diagram.

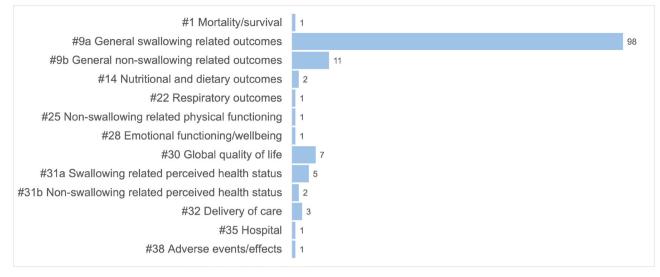


Figure 2 Outcome domains used in clinical trials in oropharyngeal dysphagia in Parkinson's disease.

### **Outcome domains**

As the taxonomy by Dodd *et al*<sup>15</sup> was developed for clinical trials in medical research in general but not specifically for OD interventions, the outcome domains were adapted for the purpose of this scoping review. Figure 2 depicts the outcome domains from the included studies and the number of outcomes mapped accordingly.

### **Outcome subdomains**

The outcome domain #9a comprises almost three quarters of all outcomes and the outcome domain #9b includes with over 8% the second most outcomes. In order to categorise these general outcome domains more precisely, recategorising according to subdomains was necessary. Outcome domain #9a was divided into the following five subdomains: (1) saliva management, (2) swallowing-related physiology, (3) swallow efficiency, (4) swallow safety and (5) neurological status. The outcome domain #9b was split into two subdomains: (1) neurological findings and (2) voice.

# Research question 1: what are the outcomes of interest in clinical trials in OD in PD?

The 134 included outcomes were merged to 39 outcomes due to overlaps or being identical. Table 1 presents the 'long list of outcomes' including the outcomes, subdomains, domains and outcome areas accordingly.

The outcome of most interest was penetration/aspiration measuring the depth of the entry of food and fluid into the larynx and airway. This was measured in 10 of the 19 studies. Oropharyngeal dysphagia severity was the second most often measured outcome (n=9). The top eight outcomes of interest in the included studies are depicted in figure 3. All other outcomes were measured one or two times.

Of these top eight outcomes, six belong to the outcome domain #9a general swallowing-related outcomes, whereas the other two belong to the outcome domain #30 global quality of life and #31a swallowing-related perceived health status.

# Research question 2: how are the outcomes in these clinical trials defined?

Most definitions of the outcomes in the included studies vary widely. Thereof, 17 outcomes were not defined at all in any study,

and 13 outcomes were defined by some studies but not by others. The outcomes swallowing-related hyoid bone movement and timing of oropharyngeal swallowing components were the most diverse defined outcomes. Each study used different parameters within these outcomes with either very specific or no definition. Outcomes that were assessed by using a scale or questionnaire were oftentimes not defined at all. Instead, the numerical scores from the scale or questionnaire were provided without explanation of what they related to. The outcome penetration/aspiration was defined in accordance with the definition by Rosenbek et al in 9 of 10 studies: 'Penetration is defined [...] as passage of material into the larynx that does not pass below the vocal folds. Aspiration is defined as passage of material below the level of the vocal folds.<sup>18</sup> There was no matching definition for any other outcome by at least two studies with different authors. The definitions of outcomes reported by Baijens et al19 20 were unsurprisingly in agreement given that both studies were conducted by the same main author group (see online supplemental file 5 for all definitions of outcomes).

# Research question 3: how are the outcomes in these clinical trials measured?

Overall, the applied OMIs show high variability. Most of the outcomes in the outcome domain #9a were measured using instrumental assessments and either validated scales or scales designed for the purpose of the according study during videofluoroscopic evaluation of swallowing (VFS) (also referred to Modified Barium Swallow Study) or Fibreoptic Endoscopic Evaluation of Swallowing (FEES) or measuring it in milliseconds during electromy-ography.

The outcomes penetration/aspiration and swallowing-related quality of life were measured the most consistently. Eight of the ten studies used the Penetration–Aspiration–Scale (PAS) by Rosenbek *et al*<sup>18</sup> during VFS and/or FEES. One study<sup>21</sup> did not report the scale that was used to measure the outcome during VFS and another study<sup>22</sup> used a self-designed 4-point scale. The outcome swallowing-related quality of life was measured through the Swallowing Quality of Life (SWAL-QOL)<sup>23</sup> Questionnaire in six studies, whereas one study<sup>24</sup> additionally assessed this outcome through the MD Anderson Dysphagia Inventory.<sup>25</sup> The outcome self-perception of swallowing was measured by the Swallowing Disturbance Questionnaire<sup>26</sup> three times and the Dysphagia

Table 1 Long li	ist of outcomes included in clinical trials in oropharyngeal	dysphagia in Parkinson's	disease		
Outcome area	Outcome domain	Outcome subdomain	Outcome		
Death	1. Mortality/survival		Death		
	9a. General swallowing-related outcomes		Oropharyngeal dysphagia severity		
clinical		Saliva management	Drooling		
			Salivary pooling		
		Swallowing-related	Orolingual bolus control		
		physiology	Oral bolus transport		
			Swallowing-related lingual movement		
			Timing of oropharyngeal swallow components		
			Laryngeal elevation		
			Laryngeal sensation		
			Swallowing-related hyoid bone movement		
			Initiation of pharyngeal swallow		
		Swallow efficiency	Postswallow oral residue		
			Postswallow pharyngeal residue		
			Postswallow pharyngeal pooling		
			Piecemeal deglutition		
		Swallow safety	Penetration/aspiration		
		Neurological status	Cortical reorganisation		
			Motor evoked potential		
	9b. General non-swallowing-related outcomes	Neurological findings	Overall motor symptoms		
			Tremor		
			Rigidity		
			Bradykinesia		
			Axial symptoms		
			Freezing of gait		
		Voice	Phonation		
			Loudness		
	14. Nutritional and dietary outcomes		Level of oral intake		
	22. Respiratory outcomes		Aspiration pneumonia		
Life impact/	25. Non-swallowing-related physical functioning		Activities of daily living		
functioning	28. Emotional functioning/well-being		Pleasure of oral intake		
	30. Global quality of life		Swallowing-related quality of life		
	31a. Swallowing-related perceived health status		Self-perception of swallowing		
	31b. Non-swallowing-related perceived health status				
		Self-perception of activities of daily living			
	32. Delivery of care		Participant's satisfaction with intervention		
			Participant's adherence to intervention		
Resource use	35. Hospital		Hospitalisation		
Adverse events	38. Adverse events/effects		Adverse events		

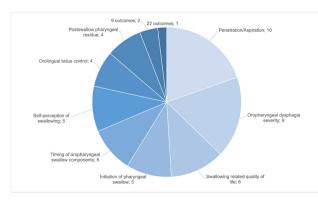


Figure 3 Number of studies measuring each outcome in clinical trials in oropharyngeal dysphagia in Parkinson's disease.

Severity Scale (DSS)<sup>27</sup> and Arabic Dysphagia Handicap Index<sup>28</sup> once each.

The outcome oropharyngeal dysphagia severity was the outcome measured most differently across all included studies. In order to assess the outcome either validated scales or self-designed scales for VFS and/or FEES, the Standardized Swallow Assessment<sup>29</sup> or a Clinical Swallow Evaluation were conducted. The OMIs of death and hospitalisation were not described and while it may seem self-explanatory, their methods of recording were not clear (see online supplemental file 6 for the applied OMIs).

# Research question 4: at which timepoints and at which frequency are the outcomes in these clinical trials measured?

In the outcome domains #1, #22, #35 and #38 only one study<sup>30</sup> assessed the outcomes death, aspiration pneumonia, hospitalisation and adverse events, respectively. These were measured

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continuously over a period of 3 months without further details provided by the authors. All remaining outcomes in the outcome area physiological/clinical were measured in the included studies one to five times either during or pre to post and/or with one to two follow-ups. The timepoints post intervention ranged from 5 min to 6 months.

The outcomes in the outcome area life impact/functioning were measured 1–36 times during, pre and/or post with follow-up assessments 2 weeks to 6 months post intervention. The outcome participant's adherence to intervention was assessed weekly over a period of 3 months, hence 36 times in 1 study.<sup>30</sup> The outcome self-perception of swallowing was measured differently at varying timepoints and frequency across the included studies. For example, 1 study<sup>24</sup> assessed the outcome through the DSS<sup>27</sup> after each session, hence 13–15 times, whereas the other 4 studies<sup>22 31–33</sup> assessed it 2, 3 or 5 times. Only the outcome participant's satisfaction with the intervention was measured once during or 2 weeks post intervention.

Overall, most outcomes were measured at least pre and post intervention with frequencies from one to four times. If the outcome was measured only once this was usually during the intervention, for example, rTMS (see online supplemental file 7 for all timepoints and frequency of measurements).

#### Discussion

In this scoping review, 19 clinical trials that investigated OD interventions in PD with 134 outcomes were included. Outcomes were merged to 39 final outcomes in 13 outcome domains. Outcomes of interest, definitions, OMIs, timepoints and frequency of measurement varied highly across the included studies. This scoping review identified relevant challenges within the included studies.

One major challenge in the included studies is the lack of information on outcomes, their definitions, and OMIs and omitted outcomes. For example, three studies did not report on outcomes in detail if there were no differences between the intervention and the control group.<sup>19 20 34</sup> In two other studies, the authors did not report why outcomes were omitted.<sup>24 35</sup> Incomplete reporting of research methods (eg, what was measured and how was it measured) and selective reporting of findings (eg, omitted outcomes) decrease the transparency of the research studies and raise questions about the applicability of the findings and study reporting practices. This heightens the risk that results lack credibility and studies are not easy to replicate and reproduce.<sup>36-38</sup> This is especially problematic in healthcare research involving OD interventions in PD where the outcomes of these clinical trials are essential for decision-making, such as the safety and effectiveness of the intervention.<sup>7</sup>

Another identified challenge in the included studies is that some of the outcomes that were previously identified in the literature as relevant for people with OD and PD were not or rarely assessed. Only one study<sup>39</sup> included the outcome voice as they assessed the effect of vocalisation training in improving drooling in people with PD. However, three pilot studies have previously shown that cross system effects through an intensive, evidencebased voice and speech treatment (Lee Silverman Voice Treatment, LSVT LOUD) in people with PD can improve swallowing.<sup>40-42</sup> These studies suggest that training voice and speech may improve swallow function as well. Concurrently, dysphagia therapy might affect voice and speech in PD. Therefore, voice as an outcome in clinical trials in OD in PD might be relevant to assess.

Just 6 of the 19 included studies assessed swallowing-related quality of life and five studies included self-perception of swallowing as patient-reported outcomes. This is a relatively small number, as patient-reported outcomes are considered critical for evidence-based practice and for assessing treatment effectiveness.<sup>43</sup> It should be noted that specifically in people with PD the self-assessment may differ from objective or investigator-reported outcomes due to sensorimotor deficits<sup>44 45</sup> and hence, both types of assessments should be included.

Outcomes that were not typically measured but may be considered relevant included parameters associated with cough, hydration and nutrition. People with OD in PD are at high risk of developing malnutrition and dehydration. This can further impair swallow function and delay the rehabilitation process. It can also increase the risk of medical complications or even mortality.<sup>46</sup> Furthermore, impaired cough (dystussia) reduces airway protection as material entering the airway might not be expelled effectively. Dystussia often coexists with OD in people with PD and therefore the risk of aspiration and pneumonia is increased, but also QoL can be decreased.<sup>47 48</sup> This is not surprising as both coughing and swallowing are sensorimotor behaviours that overlap in anatomy and neuroanatomical substrates.<sup>47</sup> Therefore, outcomes associated with hydration, nutrition and cough might be relevant to assess in future OD interventions in PD.

A further interesting finding in this review is that only one study<sup>30</sup> assessed outcomes pertaining to the outcome areas of death, resource use and adverse events. Assessing and reporting adverse events in RCTs is crucial for determining the safety of an intervention, but is less focused on than assessing and reporting efficacy and effectiveness in these trials.<sup>49</sup> The outcome area adverse events might comprise numerous outcomes, which typically are not predefined as they are usually unknown before commencing a study. Furthermore, only assessing if adverse events are present or absent is regarded as insufficient. Additional information on the severity, timing, duration and number of occurrences of the events is required and thus, making the assessment, reporting and analysis of these outcomes more laborious and possibly inconsistent.<sup>50</sup> Death might be incorporated as an outcome of adverse events. In OD interventions in PD, the assessment and reporting of death might be more relevant than currently considered. As stated before, dysphagia and dystussia increase the risk of aspiration and hence pneumonia, which is a leading cause of death in people with PD. Therefore, addressing this outcome area in future clinical trials in addition with adverse events might be relevant. The reporting of adverse events in clinical trials might further be improved by the adoption of the Consolidated Standards of Reporting Trials harm extension guideline.<sup>49</sup>

Following the Dodd *et al*<sup>15</sup> taxonomy, the outcome area resource use comprises the outcome domains economic, hospital, need for further intervention and societal/carer burden. Of these, only hospital in terms of length of hospital stay was assessed in one of the included studies. This outcome area might be underrepresented in OD in PD studies. A recent systematic review showed that the presence of dysphagia increases the hospital length of stay, regardless of admission cause. Furthermore, this also increases the monetary costs by over 40% in patients with dysphagia compared with non-dysphagic patients. In addition, pneumonia is one of the most common reasons for emergency hospital admission in patients with PD,<sup>51</sup> making patients with OD in PD more likely to be admitted to hospital and increase overall healthcare costs. Additionally, Perry et al<sup>52</sup> found that providing care for a person with OD in PD reduces the carer's QoL due to an increased burden. In future studies on OD in PD, it might be important to assess outcomes related to carer burden as ultimately, a less burdened carer might improve a PD person's health outcomes and QoL.<sup>52</sup>

Lastly, the use of unvalidated OMIs (in general or for the specific patient population) in the included studies comprised a further challenge.<sup>24 53</sup> Validated OMIs are important to ensure that the tool is measuring what it is supposed to measure, and hence, that the results are valid.

### Strengths and limitations of the study

In order to categorise the outcomes, the taxonomy devised by Dodd *et al*<sup>15</sup> was applied as recommended by the COMET Handbook. This is widely implemented in outcome research and facilitates consistent use of clinical outcome terms.<sup>7 15</sup> However, the taxonomy was devised largely for medical research, making it less specific to OD interventions. Furthermore, a possible limitation in this review is the restriction of the review to include clinical trials only, but this was based on the fact that the focus of the COS-DIP is a COS for clinical trial design.

### Conclusion

This is the first scoping review that has systematically extracted and categorised all outcomes in clinical trials in OD interventions in PD. We identified high variability in included outcomes in addition to outcomes that were rarely measured or not measured at all. Furthermore, a lack of information on outcomes, such as definitions, OMIs and timepoints of measurement, was identified which can affect a study's replicability, credibility and decrease its validity. Additionally, in some of the included studies, outcomes mentioned as part of the study's research question were later omitted and hence pose a risk of reporting bias and skewing individual study results.

Through the development of the COS-DIP, the minimum core outcomes to be measured and reported in all future OD interventions in PD will be agreed on and advice on how and when to measure these will be provided. Ultimately, this will increase the quality of OD trials in PD and reduce research waste. It will not prevent or restrict researchers from examining other outcomes.

#### **Deviation from protocol**

In addition to (quasi-) RCTs and CCTs also, feasibility/pilot studies with control groups were included in this scoping review. This allows for inclusion of all clinical trial designs. No other deviations were made from the study protocol.

**Correction notice** This article has been corrected since it was first published. The open access licence has been updated to CC BY.

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**Contributors** JHirschwald drafted the manuscript. JHofacker was second reviewer. Discussions on inclusion/exclusion of studies were discussed and solved with MWalshe. The long list of outcomes was agreed on by all authors. All authors critically appraised and edited the manuscript. All authors read and approved the final manuscript. MWalshe is the guarantor for this study.

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Patient consent for publication Not applicable.

Ethics approval Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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## Additional file 1: PRIMSA-ScR Checklist

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	3-5
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	5
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	6
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	6-7
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	6
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	Additional file 2
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	7
Data charting 10 process‡		Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	8
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	Not applicable

Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	8-9
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	9
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	9
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	Not applicable
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	10-16
Synthesis of results 18		Summarize and/or present the charting results as they relate to the review questions and objectives.	10-16
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	16-18
Limitations	20	Discuss the limitations of the scoping review process.	18
Conclusions 21		Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	19
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	21

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

\* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

<sup>‡</sup> The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

*From:* Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. <u>doi: 10.7326/M18-0850</u>.

## Additional file 2: Search Strategy

AMED		
#	Search strategy	Results
S3	S1 AND S2	2
S2	SU parkinson disease OR TI ( idiopathic parkinson's disease OR idiopathic parkinsons disease OR idiopathic parkinsons' disease OR idiopathic parkinson disease ) OR AB ( idiopathic parkinson's disease OR idiopathic parkinsons disease OR idiopathic parkinsons' disease OR idiopathic parkinsons' disease OR idiopathic parkinsons' disease )	80
S1	SU dysphagia OR TI ( dysphagi* OR deglutition OR swallow* ) OR AB ( dysphagi* OR deglutition OR swallow* )	1.019
CINAHL		
S8	S5 AND S6 (Limiters - Exclude MEDLINE records)	149
S7	S5 AND S6	388
S6	S3 OR S4	24.108
S5	S1 OR S2	20
S4	T1 (idiopathic parkinson's disease OR idiopathic parkinsons disease OR idiopathic parkinsons' disease OR idiopathic parkinson disease ) OR AB (idiopathic parkinson's disease OR idiopathic parkinsons' disease OR idiopathic parkinsons' disease OR idiopathic parkinsons' disease OR idiopathic parkinson disease )	860
S3	(MH "Parkinson Disease")	
S2 S1	TI ( dysphagi* OR deglutition OR swallow* ) OR AB ( dysphagi* OR deglutition OR swallow* ) (MH "Deglutition Disorders"')	17.089
EMBASE		
	8 #7 AND (embase /lim NOT ((embasel/lim AND [medline]/lim)	1.560
	7 #3 AND #6	2.796
	6 #4 OR #5	174.509
	5 idiopathic parkinson/s disease':ab.ti OR 'idiopathic parkinsons disease':ab.ti OR 'idiopathic parkinsons/ disease':ab.ti OR 'idiopathic parkinson disease':ab.ti	4.939
	4 parkinson disease/exp	174.081
	3 #1 OR #2	126.373
	2 dysphagi*:ab.ti OR deglutition:ab,ti OR swallow*:ab,ti	92.668
	1 'dysphagia"/exp	85.162
ProQuest	noft(dysphagi* OR deglutition OR swallow*) AND noft(idiopathic parkinson's disease OR idiopathic parkinson disease OR idiopathic parkinson disease OR idiopathic parkinson disease)	6
PubMed		
#7	(("Parkinson Disease" [Mesh]) OR (idiopathic parkinson's disease[Title/Abstract] OR idiopathic parkinsons disease[Title/Abstract] OR idiopathic parkinsons' disease[Title/Abstract] OR idiopathic parkinson disease[Title/Abstract])) AND (("Deglutition Disorders"[Mesh]) OR (dysphagi*[Title/Abstract] OR deglutition[Title/Abstract] OR swallow*[Title/Abstract]))	763
#6	("Parkinson Disease" [Mesh]) OR (idiopathic parkinson's disease[Title/Abstract] OR idiopathic parkinsons disease[Title/Abstract] OR idiopathic parkinsons' disease[Title/Abstract] OR idiopathic parkinson disease[Title/Abstract])	74.422
#5	idiopathic parkinson's disease[Title/Abstract] OR idiopathic parkinsons disease[Title/Abstract] OR idiopathic parkinsons' disease[Title/Abstract] OR idiopathic parkinson disease[Title/Abstract]	336
#4	Parkinson Disease [Mesh]	73.538
#3	("Deglutition Disorders" [Mesh]) OR (dysphagi*[Title/Abstract] OR deglutition[Title/Abstract] OR swallow*[Title/Abstract])	94.511
#2	dysphagi*[Title/Abstract] OR deglutition[Title/Abstract] OR swallow*[Title/Abstract]	58.181
#1	Deglutition Disorders[Mesh]	55.955
Web of Scien	ce	
	3 (#1) AND #2	106
	2 TS=(idiopathic parkinson's disease OR idiopathic parkinsons disease OR idiopathic parkinsons' disease OR idiopathic parkinson disease)	7.220
	1 dysphagi* OR deglutition OR swallow* (Topic)	60.163
Clinicaltrials.	gov dysphagia   Interventional Studies   Parkinson Disease	24

### Additional file 3: Data extraction chart

							Complete data	extraction				
1st author's name, year Country	Study desigr	n N (dropouts)	Intention to treat analysis	s Age	Gender	PD severity	OD severity	Intervention	Comparator	Applied outcome measures + way of measurement	Timepoints	Frequency
				(G: 62.0 (SD±11.5) CG1: 62.8		(G: 28 (SD±0.8) CG1: 25 (SD±0.7)	FOIS: IC:5.9 (SD ±1.3) CG1:6.8 (SD±0.5)		CG1: no intervention CG2: swallowing	> FOIS		
Ayres, 2017 Brazil	CCT	32 (8)	No	(SD±6.2) CG2: 64.5 (SD±5.6) m	n=18, f=6	CG2: 2.5 (SD±0.8)		Chin-down posture maneuver		> SWAL-QOL	pre, post (4w)	2
Baijens, 2012 Netherlands	Feasibilit/pilot study with control group		No	65.5 (46-81) m	1=14, f=6	median: 2 (1-3)	mild to severe	SES (VitalStim), 3 different electrode positions applied in random order per subject	Healthy controls with same intervention	VFS: moment of opening and closing of: glossopalatal junction, velopharyngeal junction, laryngeal vestibule, upper esophageal sphincter - PAS movement patterns of hyoid bone - extent of movement of hyoid bone - pre-swallow anterior spill - preswallow posterior spill - lingualpumping - swallow hostiancy - delayed initiation of the pharyngeal reflex - postswallow or all crail residue - postswallow valecular pooling - paskallow pyriform sinus pooling - PAS	during	1
Baijens, 2013 Netherlands		109 (19)	No	median:68 m	1=66, 1=24	median: 2(1-4)	mild to severe	<ul> <li>IG1: traditional logopedic dysphagia treatment + SES of submental region; motor-level stimulation;</li> <li>IG2: traditional logopedic dysphagia treatment + SES of submental region; sensory- level stimulation</li> </ul>		FEES:     Preswallow posterior spill     Presemaal degluition     Delayed initiation pharyngeal reflex     Postwallow vallecular pooling     Postwallow priform sinus pooling     PAS     VFS:     Preswallow anterior spill     Lingual pumping     Svallow hositancy     Presemalow posterior spill     Delayed initiation pharyngeal reflex     Postwallow oral residue     Postwallow voral residue     Postwallow poing     Postemalow poing	pre. post (15d)	2

Byeon, 2016	Korea	RCT	33 (N/S)	No	IG: 63.8 (SD ± 8.2) CG: 65.1 (SD ± 9.5	m=31, f=2	IG: 15 ≤ H&Y 3; 3 > H&Y 4 CG: 11 ≤ H&Y 3; 4 > H&Y 4	N/S	Postural techniques + EMST	EMST	> VFS: - Functional Dysphagia Scale (FDS)	pre, post (4w)	
laus, 2021	Germany	RCT	53 (8)	Νο	(G: 67.3 (54-83; SD ± 9.5) CG: 67.1 (49-82; SD ± 7.7)	IG: m=19, f=5 CG: m=18. f=3	IG: 2.5 (2-4), CG: 2.6 (2-4)	N/S	EMST (calibrated)	EMST (sham)	> FEES (5-point scales): - premature spillage - penetration aspiration events - residue - total FEES score (0-108) - SWAL-OCL (German) - SWALOCL (German) - SWallowing Disturbance Questionnaire (SDQ) (German) - MEG (onty 22 patients, sub-group): - frequency bands: theta[4-8 Hz), alpha (6-13 Hz), beta (13-30 Hz), low-gamma, (30-60 Hz), and high-gamma (60-80 Hz) - in all frequency bands: source localization of each subjects swallowing-associated event-related desynchronization (ERD) of cortical Hythms	pre, post (4w, 3m)	)
ang, 2019	China	ССТ	60 (N/S)	No	IG: 65.20 (SD ± 6.84) (54.84) CG: 64.66 (SD ± 5.27) (56-75)		N/S	>18 on the SSA (inclusion criterium)	Vocal training + conventional	Conventional	> SSA > Evaluation of salivation: - UPDRS II - Drocling Sevently and Frequency Scale (DSFS) > Voice evaluation - Maximum phonation firme (MPT) - Maximum phonation decibel	pre, post (4w)	
eijnen, 2012	Netherlands	quasi-RCT	109 (21)	No	Median 68 (42-81)	m=65, f=23	Median 2 (1-4)	FOIS: median 7 (1-7	Traditional logopedic dysphagia treatment + NMES (VitalStim) of the supra hyoid musculature; Group 2 (NMES- M): motor level, Group 3 ( NMES-S): sensory level	Group 1: traditional logopedic dysphagia treatment	<ul> <li>FOIS</li> <li>SWAL-QOL (Dutch)</li> <li>MD Anderson Dysphagia Inventory (MDADI) (Dutch)</li> <li>Dysphagia Severity Scale (DSS)</li> <li>FEES</li> <li>VFS</li> </ul>	pre, post, 3m (DSS post each treatment session)	3 (15)
hedr, 2019	Egypt	RCT	33 (3)	No	IG:60.7 (SD ± 8.8) CG:574 (SD ± 10.0)	N/S	IG: 3.1 (SD ±1.1) CG: 3.5 (SD ±1.0)	SDQ: [G: 17.4 (SD ±6.1) CG: 16.2 (SD ±5.8)	Repetitive Transcraniai Magnet Stimulation	Sham	> H&Y > UPDRS III > Instrumental Activities of Daily Living (IADL) > Selfassessment scale of swallowing > SDQ > Arabic DHI > VFS (for 9 In K0, 6 in CG, pre, post) - pharyngeal transit time (PTT) - time of tint superior-anterior movemnt of hyoid bone H1 - time valing to max, elevation the - time required for max, elevation the - postswallow residue	pre, post (2w, 1m, 2m, 3m)	,
ondo, 2017		RCT	20, thereof 3 with PD (N(S)	No	(G: 80.4 (SD ±9.5) CG: 80.1 (SD ±5.9)	m=19, f=1	NS	N/S	Aural stimulation with capsaiclin ointment		> Endoscopic swallowing scoring: - Salivary pooling in vallecula and pyriform sinuses - The response of olotal closure reflex induced by touching epiglottis with endoscope - The tocation of the bolus at the time of swallow onset assessed by endoscopic whileout - The stent of pharyngeal clearance after swallowing of blue-dyed water - Total swallowing function - Sensory-Motor-Reflex-Clearance (SMRC) scale: - Sensory-Initiation of swallowing reflex as assessed by endoscopic whiteout - Motion: holding bolus in oral cavity and inducing laryngeal elevation according to instructions - Reflex: glotal closure and cough reflexes induced by touching epiglottis or arytenoids with endoscope - Clearance: pharyngeal dearance of bolus after swallowing		
gemann,	·		742, thereof 360					Aspiration of water on VFS (inclusion	Chin-down posture while	No postural adjustment during swallows of nectar and honey-thickened	> VFS: - Aspiration		
008	United States	DOT	with PD (31)	No	range: 50-95	m=498, f=213	N/C	criterium)	consuming thin liquids	liquids	Preference for different interventions	during	

							IG: 2.21 (SD ±0.79)		Video assisted swallowing therapy (VAST) with		> SDQ > FEES: - FEES: - bolus flow time - bolus location when the swallowing reflex is triggered - residue location - penetration before/after swallowing - appriaton before/after swallowing > SWAL-OXL - SWAL-OXL - SWAL-OXE	pre.post (2w, 4w,
Manor, 2013	Israel	RCT	42 (N/S)	No	68.8 (SD ±8.1)	m=24, f=18 m=8, f=14	CG: 2.19 (SD ±0.84)	N/S	conventional therapy	Conventional therapy	> Pleasure of Eating (POE) Scale	6 m) 4
Nagaya, 2000	Japan	CCT	24, thereof 10 with PD (N/S)	No	IG: 70.5 (53-80) CG: 72 (47-93)	IG: m=5, f=5 CG: m=3, f=6	H&Y III = 8x, H&Y IV = 2	N/S	Swallowing training in PwPD		<ul> <li>&gt; Electromyography in submental muscles</li> <li>- premotor time (PMT)</li> </ul>	pre, post 2
	Korea	RCT	18 (0)	No	IG: 63.44 (SD ±13.55) CG: 54.67 (SD ±13.82)	m=8, f=10	< H&Y III	N/S	NMES (VitalStim) with effortful swallowing + conventional therapy	Sham NMES (VitalStim) with	<ul> <li>&gt; VFS:</li> <li>- horizontal displacement of the hyoid bone</li> <li>- vertical displacement of the hyoid bone</li> <li>- Videofluoroscopic dysphagia scale (VDS) total</li> <li>- VDS - oral phase</li> <li>- VDS - pharyngeal phase</li> </ul>	pre, post (4w) 2
Robbins, 2008			515, thereof 255 with PD (213)	Yes	IG: 81 CG: 80	m=359.f=156		Aspiration of water on VFS (inclusion criterium)	Chin-down posture with thin liquids	(nectar thick or	> Pneumonia > Death > Adverse events > Hospitalization > Adherence to intervention	continuously during 3m, intervention adherence continuously, weekly 36
Sasegbon,		Feasibilit/pilot study with					1 Hz: 2.9 (±0.3) 5 Hz: 2.1 (±0.6)				> VFS: - PAS - Oral transit time (OTT) - Pharyngeal transit time (PTT) Pharyngeal responses time (PRT) > EMG: - Pharyngeal motor evoked potential (MEP) amplitudes	pre, post (0min;
2021	UK	control group	12 (N/S)	No	70 (SD ±8)	m=10, f=2	PES: 1.8 (±0.3)	PAS≥2	1 Hz rTMS, 5 Hz rTMS, PES	Sham	- MEP latencies	for MEP 30min) 2 to 3
Silva-Arone, 2021	Brazil	Feasibilit/pilot study with control group	6 (N/S)	No	73.1 (64-83) (SD ±6.2)	m=6, f=0	2.3 (2-3)	FOIS: 6.5 (6-7)	Prophylactic speech-language therapy associated with EMG biofeedback		- Dysphagia Outcome and Severity Scale (DOSS) > SWAL-QOL > FOIS	pre, post (3m, 6m) 3
					IG: 66.7 (SD ±8.9)						> VFS: - PAS - duration of hyoid movement - onsert obolus transit - UES-opening - UES-viduset - UES-dosure - laryngeal closure - max karyngeal closure - max karyngeal closure - laryngeal closure	
Troche, 2010	United States	RCT	68 (8)	Yes	CG: 68.5 (SD ±10.3)	m=47, f=13	range II-IV	mild to moderate	EMST (calibrated) Standardized out-of-hospital management: education, skill training (oral muscle exercises, effective cough training, pronunciation training, eating training,	EMST (sham) Face and tongue training, eating considerations and dysphagia	> SWAL-QOL	pre, pre, post (4w) up to 3
Wei, 2017	China	CCT	217 (N/S)	No	IG: 71.4 (SD ±12.7) CG: 69.3 (SD ±11.3)	m=130, f=87	N/S	Level 6-3 (unspecified scale)	compensatory training with video and presentation)	rehabilitation guidance	> Dysphagia > Mis-inhalation	post (6m) 1
Vic. 0040					005/00 (50)	- 0 ( 0			3 DBS conditions (sequence random order of 130 Hz, 60Hz	order of 130 Hz,	> VFS: - Aspiration > SDQ > UPDRS III > FOG spells > FOG time	V1: during, SDQ post 30 min V2 (at least 6m later): during,
Xie, 2018	United States	RCI	11 (1)	No	68.5 (SD ± 5.9)	m=9, f=2	N/S	N/S	DBS off)	60Hz, DBS off)	> Walking difficulty perception	SDQ post 30 min 2

A-DHI: Arabic Dysphagia Handicap Index; CCT: Controlled Clinical Trial; CG: Control Group; CSE: Clinical Swallow Evaluation; DBS: Deep Brain Stimulation; DOSS: Dysphagia Outcome and Severity Scale; DSFS: Drooling Severity and Frequency Scale; DSS: Dysphagia Severity Scale; EMG: Electromyography; EMST: Expiratory Muscle Strength Training; FDS: Functional Dysphagia Scale; FEES: Fibreoptic Endoscopic Evaluation of Swallowing; f: female; FOG: Freezing of Gait; FOIS: Functional Oral Intake Scale; H&Y: Hoehn&Yahr; IADL: Instrumental Activities of Daily Living; IG: Intervention group; m: male; MDADI: MD Anderson Dysphagia Inventory; NMES: Neuromuscluar Electrical Stimulation; N/S: not specified; OD: Oropharyngeal Dysphagia; PAS: Penetration-Aspiration-Scale; PD: Parkinson's Disease; POE: Pleasure of Eating; rTMS: repetitive Transcranial Magnetic Stimulation; SDQ: Swallowing Disturbance Questionnaire; SUAL-CARE: Swallowing Quality of Care Questionnaire; SWAL-QOL: Swallowing Quality of Life Questionnaire; SUAL-CARE: Swallowing Quality of Care Questionnaire; SVAL-QOL: Swallowing Quality of Life Questionnaire; SCI: Quality of Life; RCT: Randomized Controlled Trial; UPDRS: Unified Parkinson's Disease Rating Scale; VDS: Videofluoroscopic Dysphagia Scale; VFS: Videofluoroscopy of Swallowing; V1 / V2: Visit 1 / Visit 2

### Additional file 4: Excluded outcomes

#	Author, Year	Verbatim	Definition	Measure- ment	Timepoints	Frequency	Reason for exclusion
1	Ayres, 2017	Prior state of secretion in nasopharyngeal structures, oropharynx, laryngopharynx	N/S	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
2	Ayres, 2017	Thickening on the posterior laryngeal wall	Presence/absence of thickening on the posterior laryngeal wall	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
3	Ayres, 2017	Tremor in structures (BOT, vallecula)	Presence/absence of tremor in structures (BOT, valleculae)	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
4	Ayres, 2017	Early escape	Characterized by the presence of food in the hypopharynx or larynx before the swallowing reflex was triggered	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
5	Ayres, 2017	Vallecular stasis in glossoepiglottic folds and pyriform sinus	Characterized by accumulation of food after the third swallowing on the mentioned structures	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
6	Ayres, 2017	Penetration	Characterized by the presence of food in the laryngeal vestibule	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
7	Ayres, 2017	Tracheal aspiration	Characterized by food intake in the region located below the vocal folds, in the subglottic region and in the trachea, at any time of swallowing	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
8	Ayres, 2017	Cough reflex	Presence/absence	FEES	pre, post (4w)	2	Observations that were made, but not measured and not reported
9	Ayres, 2017	Ability to manipulate flows	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
10	Ayres, 2017	Postural control	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
11	Ayres, 2017	Fatiguability	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
12	Ayres, 2017	Anatomy and oral, pharyngeal and laryngeal physiology	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
13	Ayres, 2017	Orofacial tones	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
14	Ayres, 2017	Oral apraxia	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
15	Ayres, 2017	Orofacial sensitivity	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
16	Ayres, 2017	Gag pharyngeal contraction	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported

17	Ayres, 2017	Saliva swallowing	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not
17	Ayres, 2017	Saliva Swallowing	Flesence/absence	USE	pre, post (4w)	2	measured and not reported
18	Ayres, 2017	Cough and hawk	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
19	Ayres, 2017	Swallowing apraxia	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
20	Ayres, 2017	Oral residue	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
21	Ayres, 2017	Delayed swallowing reflex	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
22	Ayres, 2017	Reduction in laryngeal elevation	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
23	Ayres, 2017	Wet voice	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
24	Ayres, 2017	Multiple swallowing	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
25	Ayres, 2017	History of aspiration pneumonia	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
26	Ayres, 2017	Intake of food	Level of oral food intake	FOIS	pre, post (4w)	2	Observations that were made, but not measured and not reported
27	Ayres, 2017	Interaction attention/ability	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
28	Ayres, 2017	Alert state	presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
29	Ayres, 2017	Awareness of the swallowing problem	Presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
30	Ayres, 2017	Awareness of secretion	presence/absence	CSE	pre, post (4w)	2	Observations that were made, but not measured and not reported
 31	Feng, 2019	Consciousness	N/S	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
32	Feng, 2019	Head and trunk control	N/S	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
33	Feng, 2019	Lip closure	N/S	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
34	Feng, 2019	Voice strength	N/S	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
35	Feng, 2019	Gag reflex	N/S	SSA	pre, post (4w)	2	Observations that were made for overall SSA score

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36	Feng, 2019	Laryngeal movement	Presence/absence by observation of the patient drinking (scale from 18-46)	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
37	Feng, 2019	Repetitve swallowing	Presence/absence by observation of the patient drinking (scale from 18-46)	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
38	Feng, 2019	Laryngeal function after swallowing	Presence/absence by observation of the patient drinking (scale from 18-46)	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
39	Feng, 2019	Time required to swallow	Presence/absence by observation of the patient drinking (scale from 18-46)	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
40	Feng, 2019	Breathing	clinical examination (scale from 18-46)	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
41	Feng, 2019	Wheezing during swallowing	presence/absence by observation of the patient drinking (scale from 18-46)	SSA	pre, post (4w)	2	Observations that were made for overall SSA score
42	Heijnen, 2012	N/S	N/S	FEES	N/S	N/S	No specification of outcomes being measured
43	Heijnen, 2012	N/S	N/S	VFS	N/S	N/S	No specification of outcomes being measured
44	Khedr, 2019	Diagnosis of dysphagia	<ul> <li>N/S (a score on the SDQ of ≥ 11 indicates dysphagia.)</li> </ul>	SDQ	pre	1	Is reported as an outcome but was only conducted for assessing dysphagia pre treatment for inclusion
45	Silva-Arone, 2021	N/S	N/S	VFS: Eisenhuber scale	pre, post (3m, 6m)	3	No specification, outcome was only reported in unpublished Master thesis, referenced by Battel et al. (2020)
46	Wei, 2017	Mis-inhalation	N/S	N/S	post (6m)	1	No definition of the outcome, unclear to what this relates and what was measured

CSE: Clinical Swallow Evaluation; FEES: Fibreoptic Evaluation of Swallowing; N/S: not specified; SDQ: Swallowing Disturbance Questionnaire; SSA: Standardized Swallow Assessment; VFS: Videofluorscopy of Swallowing; w: weeks

### Additional file 5: Definitions of outcomes

Outcome	Definition				
Death	N/S				
Oropharyngeal dysphagia severity	N/S				
Drooling	Severity and frequency of drooling				
Salivary pooling Salivary pooling in vallecula and pyriform sinuses					
Orolingual bolus control	3x N/S; Preswallow loss of bolus from lips/into pharynx; Premature spillage: materials spilled over the base of the tongue into the hypopharynx (including the valleculae, the lateral channels, and the piriform sinus) too early during the oral swallowing stage, meaning before the pharyngeal swallow was initiated.				
Oral bolus transport	Swallow hesitancy; delayed onset oral transport				
Swallowing related lingual movement pattern	Preswallow involuntary repetitive tongue movements				
Timing of oropharyngeal swallow components	GPJo (glossopalatal junction opening): N/S				
	GPJc (glossopalatal junction closure): N/S				
	VPJo (velopharyngeal junction opening): Moment of separation of soft palate and posterior pharyngeal wall with re-entry of air in retrolingual space from nasopharynx (in seconds)				
	VPJc (velopharyngeal junction closure): Moment of separation of soft palate and posterior pharyngeal wall with re- entry of air in retrolingual space from nasopharynx (in seconds)				
	VPJd (velopharyngeal junction duration): ▲T between VPFc and VPJo (in seconds)				
	Lvo (laryngeal vestibule opening): Moment of separation of arytenoid cartilages and underside of epiglottis with re entry of air in laryngeal vestibule (in seconds)				

LVc (laryngeal vestibule closure): Moment when laryngeal elevation results in making contact between arytenoid cartilages and underside of epiglottis (in seconds)

LVd (laryngeal vestibule duration): A T between LVc and LVo (in seconds)

UESo (upper esophageal sphincter opening): N/S

UESc (upper esophageal sphincter closure): Moment of closure of esophagus after bolus transport (in seconds)

GPJo (glossopalatal junction opening) – LVc (laryngeal vestibule closure): ▲T between GPJo and LVc (in seconds)

Duration horizontal hyoid motion: Duration between initiation of swallow and moment of maximum horizontal (anterior) motion (in seconds)

Duration vertical hyoid motion: Duration between initiation of swallow and moment of maximum vertical motion (in seconds)

Pharyngeal transit time (PTT): From the point where the bolus head moved from the hold position and passed the posterior nasal spine until it fully entered the esophagus after the closure of the upper esophageal sphincter (in seconds)

Time required for max elevation of the hyoid bone: H2-H1: The time of the first superior-anterior movement of the hyoid bone was assigned as H1, and the time when the hyoid bone reached its maximum elevation was assigned as H2.

Bolus flow time: Measurement of the time when the bolus is seen in the hypopharynx until it triggers the swallowing reflex (0 = 0.1 s, 1 = 2.4 s, 2 = 5.7 s, 3 = 8 + s)

Oral transit time (OTT): N/S

Pharyngeal transit time (PTT): N/S

Pharyngeal response time (PRT): N/S

Duration of hyoid movement: measurement tags at 1) the initiation of hyoid movement which resulted in the swallow and 2) the point when the hyoid returned to rest following the completion of the swallow. These tags were then used to calculate the duration of hyoid (in seconds) movement.

Laryngeal elevation	N/S
Laryngeal sensation	The response of glottal closure reflex induced by toughing epiglottis with endoscope; Glottal closure and cough reflexes induced by touching epiglottis or arytenoids with endoscope
Piecemeal deglutition	Sequential swallowing of same bolus
Swallowing related hyoid bone movement	Movement patterns of hyoid bone: Anterior/superior corner of hyoid bone (x axis), anterior/inferior corner of third and fifth cervical vertebral bodies (y axis)
	Extent of movement of hyoid bone: Extent of movement in x-y coordinate system over time
	Vertical hyoid motion: Maximum vertical motion during swallowing act (in mm)
	Horizontal displacement of the hyoid bone: The distance (in cm) from the resting position to the maximal excursion position during swallowing; the most supero-anterior point of the hyoid indicates maximum displacement after swallowing
	Vertical displacement of the hyoid bone: The distance (in cm) from the resting position to the maximal excursion position during swallowing; the most supero-anterior point of the hyoid indicates maximum displacement after swallowing
	Hyoid displacement - Onset of bolus transit: Bolus head arrival at posterior edge of ramus of mandible
	Hyoid displacement - UES-opening: Forward displacement of cricoid cartilage from posterior pharyngeal wall
	Hyoid displacement - UES-widset: Widest part of bolus head passing through UES
	Hyoid displacement - UES-closure: Last point when UES is open
	Hyoid displacement - Laryngeal closure: Forward displacement of arytenoid cartilage to epiglottic petiole
	Hyoid displacement - Max laryngeal closure: Maximum contact of arytenoid cartilages with epiglottic petiole
	Hyoid displacement - Laryngeal opening: First separation of arytenoid cartilages from epiglottic petiole

Initiation of pharyngeal swallow	Delayed initiation pharyngeal triggering; the location of the bolus at the time of swallow onset; Initiation of swallowing reflex; Bolus location when the swallowing reflex is triggered; Initiation time of the swallowing reflex
Postswallow oral residue	1x N/S, Pooling in oral cavity after the swallow
Postswallow pharyngeal residue	1x N/S; Material was insufficiently cleared from the hypopharynx during swallowing and remained after swallowing; The extent of pharyngeal clearance after swallowing; Residue location of the food
Postswallow pharyngeal pooling	Postswallow pooling in valleculae; Pooling in valleculae after the swallow; Pooling in pyriform sinuses after the swallow
Piecemeal deglutition	Sequential swallowing of same bolus
Penetration/Aspiration	2x N/S; Definitions of penetration and aspiration according to Rosenbek et al. 1996, Penetration and/or aspiration; Penetration: material entered the laryngeal vestibule (defined by Langmore's epiglottis level 3) but remained at or above the level of the vocal cords; Aspiration: material entered the airway below the vocal cords; Penetration/aspiration of food/liquid before/after swallowing
Cortical reorganization	N/S
Motor evoked potential (MEP)	Amplitude: N/S Latency: the time in milliseconds from the point at which a TMS pulse was delivered to the onset of a MEP
Overall motor symptoms	N/S
Tremor	N/S
Rigidity	N/S
Bradykinesia	N/S
Axial symptoms	N/S
Freezing of gait	Number of Freezing of gait spells, time to complete test
Phonation	N/S
Loudness	N/S
Level of oral intake	N/S

Aspiration pneumonia	Chest radiography: evidence of pneumonia Clinical evaluation: 3 or more of the following: sustained fever (temperature > 100 °F [38 °C]), rales or rhonchi on chest auscultation, sputum Gram stain showing substantial leukocytes, or sputum culture showing a respiratory pathogen
Acitivities of daily living	N/S
Pleasure of oral intake	Patient's degree of enjoyment from food
Swallowing related quality of life	N/S
Self-percepetion of swallowing	4x N/S; Changes in patient subjective dysphagia symptoms as well as swallowing-related quality of life
Self-perception of walking	Patient's perception of walking difficulty
Self-perception of activities of daily living	N/S
Patient's satisfaction with intervention	1x N/S; Preference for different interventions
Patient's adherence to intervention	N/S
Hospitalization	N/S
Adverse events	Any clinically significant event possibly related to the assigned intervention (for example, dehydration), no report of events expected as part of the participant's disease progression or aging process (for example, worsening of Parkinson disease symptoms), all adverse events were rated as mild, moderate, severe, or life-threatening

N/S: not specified; T: time; TMS: Transcranial Magnetic Stimulation; UES: upper esophageal sphincter

### Additional file 6: Outcome measurement instruments

Outcome	Measurement
Death	N/S
Oropharyngeal dysphagia severity	VFS: DOSS (O'Neil et al., 1999); FDS (Han et al., 1999) VDS-total; -oral; -pharyngeal (Kim et al., 2012) FEES: score 0-108; sum of 5 scores; sum of 4 scores Dysphagia scale (no reference, from Wei et al. 2017); SSA (Perry et al., 2001); CSE
Drooling	UPDRS II: 5-point scale DSFS: 5- and 4-point scale (Thomas-Stonell & Greenberg, 1988)
Salivary pooling	FEES: 4-point scale
Orolingual bolus control	VFS: 5-point scale FEES: 3-point-scale, 5-point scale
Oral bolus transport	VFS: 3-point scale
Swallowing related lingual movement	VFS: 5-point scale
Timing of oropharyngeal swallow components	VFS FEES: 4-point scale
Laryngeal elevation	FEES: 3-point scale
Laryngeal sensation	FEES: touching epiglottis or arytenoids with endoscope, 4-point scale
Swallowing related hyoid bone movement	VFS: in milli- or centimeters
Initiation of pharyngeal swallow	VFS: 3-point scale FEES: endoscopic whiteout, 4-point scale; 3-point scale EMG (submental muscles) in milliseconds
Postswallow oral residue	VFS: 5-point scale
Postswallow pharyngeal residue	VFS: 3-point scale FEES: 4-point scale; 5-point scale
Postswallow pharyngeal pooling	VFS: 3-point scale FEES: 3-point scale
Piecemeal deglutition	VFS: 5-point scale FEES: 5-point scale
Penetration/Aspiration	VFS: PAS, 8-point scale (Rosenbek et al., 1996) FEES: PAS, 8-point scale (Rosenbek et al., 1996); penetration/aspiration before/after swallowing, 4-point scale
Cortical reorganization	Magnetoencephalography: data filtered within theta (4–8 Hz), alpha (8–13 Hz), beta (13–30 Hz), low-gamma, (30- 60 Hz), high-gamma (60–80 Hz) frequency bands; in all frequency bands, performance of source localization of each subject's swallowing-associated event-related desynchronization (ERD) of cortical rhythms
Motor evoked potential	Electromyography
Overall motor symptoms	H&Y UPDRS III

Tremor	UPDRS III
Rigidity	UPDRS III
Bradykinesia	UPDRS III
Axial symptoms	UPDRS III
Freezing of gait	Stand-walk-test (no reference, from Xie et al., 2018)
Phonation	Maximum phonation time on /aa/ in seconds
Loudness	Maximum phonation decibel (dB) on /aa/
Level of oral intake	FOIS (Crary et al., 2005)
Aspiration pneumonia	Chest radiography Clinical evaluation: ≥ 3 of the following: sustained fever (temperature > 100 °F [38 °C]), rales or rhonchi on chest auscultation, sputum Gram stain showing substantial leukocytes, or sputum culture showing a respiratory pathogen
Activities of daily living	IADL (Lawton et al., 1969)
Pleasure of oral intake	POE (Manor et al., 2013)
Swallowing related quality of life	SWAL-QOL (McHorney et al., 2002), MDADI (Chen et al., 2001)
Self-perception of swallowing	SDQ (Manor et al., 2007), DSS (Tohara et al., 2003), A- DHI (Farahat et al., 2014)
Self-perception of walking	FOG questionnaire (Giladi et al., 2009)
Self-perception of activities of daily living	Activities of Daily Living Scale (Brown et al., 1989)
Patient's satisfaction with intervention	Interview: rated as easy/pleasant, average, or difficult/unpleasant SWAL-CARE (McHorney et al., 2002)
Patient's adherence to intervention	Assessed across meals, classified monthly as 0% - 25%, 26% - 50%, 51% - 75%, or 76% - 100%
Hospitalization	N/S
Adverse events	Clinical evaluation

A-DHI = Arabic Dysphagia Handicap Index, CSE = Clinical Swallow Evaluation, DOSS = Dysphagia Outcome and Severity Scale, DSFS = Drooling Severity and Frequency Scale, DSS = Dysphagia Severity Scale, EMG = Electromyography, FDS = Functional Dysphagia Scale, FEES = Fibreoptic Endoscopic Evaluation of Swallowing, FOG = Freezing of Gait, FOIS = Functional Oral Intake Scale, H&Y = Hoehn & Yahr, IADL = Instrumental Activities of Daily Living, MDADI = MD Anderson Dysphagia Inventory, N/S = not specified, PAS = Penetration-Aspiration-Scale, POE = Pleasure of Eating, SDQ = Swallowing Disturbance Questionnaire, SSA = Standardized Swallowing Assessment, SWAL-CARE = Swallowing Quality of Care Questionnaire, SWAL-QOL = Swallowing Quality of Life Questionnaire, UPDRS = Unified Parkinson's Disease Rating Scale, VDS = Videofluoroscopic Dysphagia Scale, VFS = Videofluorscopic Evaluation of Swallowing

## Additional file 7: Timepoints and frequency of measurement

Outcome	Timepoints of measurement	Frequency of measurement
Death	continuously during 3m	continously
Oropharyngeal dysphagia severity	pre, post (5min, 30min, 60min, 2w, 1m, 3m, 6m)	1 to 3
Drooling	pre, post (4w)	2
Salivary pooling	pre, post (5min, 30min, 60min)	4
Orolingual bolus control	during, pre, post (5min, 30min, 60min, 15d, 1m, 3m)	1 to 4
Oral bolus transport	during, pre, post (15d)	1 to 2
Swallowing related lingual movement	pre, post (15d)	2
Timing of oropharyngeal swallow components	during, pre, post (0min, 2w, 4w)	1 to 2
Laryngeal elevation	pre, post (5min, 30min, 60min)	4
Laryngeal sensation	pre, post (5min, 30min, 60min)	4
Swallowing related hyoid bone movement	during, pre, post (4w)	1 to 2
Initiation of pharyngeal swallow	during, pre, post (0d, 5min, 30min, 60min, 15d, 2w)	1 to 4
Postswallow oral residue	during, pre, post (15d)	1 to 2
Postswallow pharyngeal residue	pre, post (5min, 30min, 60min, 2w, 1m, 3m)	2 to 4
Postswallow pharyngeal pooling	during, pre, post (15d)	1 to 2
Piecemeal deglutition	during, pre, post (15d)	1 to 2
Penetration/Aspiration	during, pre, post (0min, 15d, 2w, 1m, 3m) V1: during; V2 (at least 6m later): during	1 to 2
Cortical reorganization	pre, post (1m)	2
Motor evoked potential (MEP)	pre, post (0min, 30min)	3
Overall motor symptoms	pre, post (2w, 1m, 2m, 3m) V1: during; V2 (at least 6m later): during	2 to 5
Tremor	V1: during; V2 (at least 6m later): during	2
Rigidity	V1: during; V2 (at least 6m later): during	2
Bradykinesia	V1: during; V2 (at least 6m later): during	2
Axial symptoms	V1: during; V2 (at least 6m later): during	2
Freezing of gait	V1: during; V2 (at least 6m later): during	2
Phonation	pre, post (4w)	2
Loudness	pre, post (4w)	2
Level of oral intake	pre, post (3m, 6m)	3
Aspiration pneumonia	continuously during 3m	continously
Acitivities of daily living	pre, post (2w, 1m, 2m, 3m)	5
Pleasure of oral intake	pre, post (2w, 4w)	3
Swallowing related quality of life	pre, post (1m, 3m, 6m)	2 to 3
Self-percepetion of swallowing	pre, post (2w, 1m, 2m, 3m, 6m) 2 x pre, after each session (13-15), 2 x post V1: post (30 min); V2 (at least 6m later): post (30min)"	2 to 15
Self-perception of walking	V1: during; V2 (at least 6m later): during	2
Self-perception of activities of daily living	pre, post (2w, 1m, 2m, 3m)	5
Patient's satisfaction with intervention	during, post (2w)	1
Patient's adherence to intervention	weekly	36
Hospitalization	continuously during 3m	continously
Adverse events	continuously during 3m	continously

min: minutes; d: days; w: weeks; m: months; V1: visit 1; V2: visit 2

### Additional file 8: Excluded reports with reasons for exclusion

#	Study	Reason for exclusion
1	Antonello, N., & Grecchi, B. (2019). EFFECTIVENESS OF AN EXPIRATORY FLOW ACCELERATION DEVICE IN DYSPHAGIC PATIENTS WITH PARKINSON DISEASE. Chest, 156(4), A1784–A1785. https://doi.org/10.1016/j.chest.2019.08.1549	Congress abstract of Riboldazzi et al. 2020
2	Baijens, L., Speyer, R., & Pilz, W. (2011). The effect of surface electrical stimulation on swallowing in Parkinson's disease. Dysphagia, 26(4), 462. https://doi.org/10.1007/s00455-011-9345-1	Congress abstract on Baijens et al. 2012
3	Baijens, L. W. J., Speyer, R., Passos, V. L., Pilz, W., Van Der Kruis, J., Haarmans, S., & Desjardins- Rombouts, C. (2014). Surface electrical stimulation in dysphagic parkinson patients: A Randomized clinical trial. Dysphagia, 29(3), 404. https://doi.org/10.1007/s00455-014-9536-7	Comment on Baijens et al. 2013
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