



Review article

Underserved groups in dysphagia intervention trials in Parkinson's disease: A scoping review

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ABSTRACT

Background: Underserved groups in Parkinson's disease (PD) intervention studies are well recognised. However, it remains unclear whether these exclusions apply to oropharyngeal dysphagia (OD) intervention studies in PD. The aim of this scoping review was to identify characteristics of included participants and underserved groups in intervention studies in OD in PD.

Methods: Six electronic databases and one trial registry were searched without language restrictions. Screening of studies and data extraction were independently conducted by four reviewers.

Results: Of the 26 studies included, none fully reported the participants' ethnicity. Where data was available, 70% of participants were male with a mean age of 68 years, mean PD duration of 7.26 years, median Hoehn and Yahr stage of 2.5, mild OD and mostly recruited from movement disorders clinics. Underserved groups were younger people (< 50 years), older people (≥ 80 years), women, non-white people, people with severe OD and PD, longer PD duration, other neurological conditions, cognitive impairment/dementia, and depression.

Conclusions: Careful consideration of all characteristics of individuals with OD in PD is essential for improving the external validity of studies. This will enhance the generalisability of research findings to the broader PD population, ultimately strengthening the evidence base for OD interventions in PD.

1. Introduction

Results from randomised controlled trials (RCTs) are considered the most robust form of testing the efficacy, effectiveness and safety of health care interventions (Witham et al., 2020). Clinical practice decisions, policies and guidelines are often based on evidence from these trials. Thus, the included participants in clinical trials should represent the target population as these are the patients that could potentially gain from the intervention (Dawson et al., 2022). However, this is not always the case, and it is established that there are specific groups that tend to be underserved in clinical trials. Witham et al. (2020) found that older people, persons with multiple morbidities, ethnic minorities, people who are socioeconomically disadvantaged, persons who are not cared for in primary and secondary healthcare settings and people with

cognitive impairments were inadequately represented in clinical trials. Trivedi and Humphreys (2015) found that almost 75% of all screened neurological patients were considered ineligible to participate in a trial due to the study's exclusion criteria, thus posing a risk to the generalisability of the trial's results.

Research on underserved groups has been emerging especially in the last few years. For example, the INCLUDE ethnicity framework was created by the National Institute for Health Research (NIHR) in order to establish what an 'underserved group' is and to provide guidance for funders and researchers to improve their participant inclusion criteria and to overcome barriers to participation (Treweek et al., 2021; Witham et al., 2020). There is no single definition for an underserved group, however, those with lower inclusion in research than one would expect from population estimates, a high healthcare burden that is not matched

Abbreviations: BDI, Beck Depression Inventory; CCT, controlled clinical trial; DBS, deep brain stimulation; EOPD, early-onset Parkinson's disease; MMSE, Mini Mental State Examination; OD, oropharyngeal dysphagia; PD, Parkinson's disease; rTMS, repetitive transcranial magnetic stimulation; RCT, randomised controlled trial.

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by research and differences in how a group responds to interventions compared to other groups would typically fall within the category (Witham et al., 2020).

It is especially important to include underserved groups in research as different groups of participants may respond differently to interventions due to variables in demographics, physiology, or disease manifestation. Excluding these groups would compromise the external validity of the study, as the results would not be generalisable to the wider population (NIHR, 2020; Shepherd, 2020). Thus, an intervention might not work in clinical practice even though studies proved its efficacy and effectiveness, as the trial population does not match the clinical population. Additionally, an intervention that was deemed to be safe in clinical trials for the study group might be unsafe in clinical practice, as not all groups of the target population were included and therefore, the risks for underserved groups remain uncovered (Dawson et al., 2022).

Overall, eligibility criteria in clinical trials are intended to ensure the safety of participants, limit confounding variables and define the population. However, restrictive eligibility criteria can also serve as a barrier to recruitment and limit our understanding (Mathur et al., 2015).

2. Underserved groups in Parkinson's disease clinical trials

Research on people with Parkinson's disease (PD) is no exception in terms of restrictive eligibility criteria in research. Regarding age, Tosserams et al. (2018) found that people with PD were on average 10 years younger in clinical trials than in prevalence studies. In a meta-analysis it was found that the prevalence of PD increases with age regardless of the geographic location (Pringsheim et al., 2014). Nevertheless, older people with PD are being excluded from medical research on the basis of arbitrary upper age limits (Fitzsimmons et al., 2012). In 206 PD studies, almost half applied an arbitrary upper age limit. The mean age limit was 79.3 years, with a range of 64–95 years (Fitzsimmons et al., 2012) even though the highest prevalence of PD can be found in people aged 80 years and older (Pringsheim et al., 2014). It is estimated that an upper age limit of 75 years excludes about 75% of the PD population (Dorsey et al., 2018; Vaswani et al., 2020). Despite the use of upper age limits, which directly exclude older people with PD, medical and cognitive exclusion criteria, which indirectly exclude older people with PD because they are disproportionately affected, are widely used in clinical trials (Vaswani et al., 2020). This mainly is problematic due to the differences that occur between younger and older people with PD regarding physiology, pharmacodynamics, polypharmacy and co-morbidities (Fitzsimmons et al., 2012).

Another identified underserved group in PD research concerns women. Even though the overall prevalence of PD in women (46.9%) is slightly lower than in men (53.1%), it was found that less than 41% of participants recruited into the majority of large scale PD trials published between 2010 and 2016 were female (Tosserams et al., 2018). This sex imbalance is posing a challenge as women may experience different motor and non-motor symptoms to men. For example, women tend to be more tremor dominant, have a slower disease progression and experience more facial masking and levodopa-induced dyskinesias. Additionally, exacerbation of symptoms have been observed in premenstrual phases and pre menopause (Subramanian et al., 2022) and therefore might be different to men.

One major barrier in identifying whether ethnic minorities are adequately represented in PD trials is that most trials do not report on their participants' ethnicity. For example, Schneider et al. (2009) found that only 17% of US based RCTs reported racial/ethnic profiles of participants. Of those studies that included all ethnicities, only 5.6% of participants were non-white. In contrast, about 20% of people with PD in the USA are non-white (Ben-Joseph et al., 2020). One potential explanation for such a low rate of non-white participants with PD in clinical trials, is that the majority of PD trials are conducted at movement disorders clinics and many minority people with PD do not have adequate access to these clinics. This also affects geographic location of

these centres, excluding participants due to distance to a research setting (Vaswani et al., 2020).

Despite rare or inconsistent data on race and ethnicity, it is suggested that PD characteristics vary depending on geographical location, i.e., the Western Pacific Region, Europe, and North America. Possible explanations are genetic factors and environmental factors (Lim et al., 2019).

People with PD oftentimes have other medical comorbidities or non-motor symptoms associated with the condition. These include amongst others cognitive impairment/dementia, depression, cancer and stroke (Santiago et al., 2017). Mental illness, medical comorbidity, cognitive impairment, or a combination of these have been found to be among the most common exclusion criteria in clinical trials with people with neurological conditions (Trivedi and Humphreys, 2015). However, depression is present in approximately 35% of people with PD and often occurs in conjunction with impaired functioning and cognitive impairment (Aarsland et al., 2012). The prevalence of dementia in people with PD is increasing with PD duration and has been found to be present in 46% of people with PD within 10 years and 83% of people with PD within 20 years after PD diagnosis (Aarsland et al., 2021). Therefore, excluding people with PD and dementia indirectly excludes older people with PD (Vaswani et al., 2020) and people with a longer PD duration. Additionally, people with PD with African American and Hispanic descent have been found to have a higher prevalence of cognitive impairment/dementia compared to white people with PD and therefore have a higher chance to be excluded from a trial due to their cognitive status (Adriani and Fleisher, 2022; Di Luca et al., 2023).

2.1. Oropharyngeal dysphagia in PD

Oropharyngeal dysphagia (OD) is a common and relevant symptom in people with PD (Suttrup and Warnecke, 2016). OD has been shown to be prevalent in 72–87% of the PD population, when measured using instrumental assessments. Overall, people with PD are three times more likely to have OD than healthy controls (Kalf et al., 2012). Furthermore, OD can be present in all stages of PD but is not perceived subjectively by the majority of people with PD (Pflug et al., 2018; van Hooren et al., 2021).

Dehydration, malnutrition, weight loss and pneumonia are some common consequences of OD in PD, with pneumonia being a leading cause of death (Fernandez and Lapane, 2002; Groher and Cray, 2016; Hobson and Meara, 2018). As OD severity increases, quality of life oftentimes decreases (Leow et al., 2010) and there are frequent emotional and psychological reactions to having OD. Studies suggest that anxiety and depression can be associated with the condition (Carneiro et al., 2014).

Due to the high prevalence of OD in the PD population and its critical consequences, it is important that studies investigating the efficacy, effectiveness, and safety of OD interventions in PD produce accurate and generalisable results. For this, the inclusion of all participants that fall within the OD in PD population regardless of characteristics such as age, ethnicity and sex must be ensured. So far, it is unknown which groups are included in OD intervention studies in PD and whether, just like in other areas of PD intervention research, there are underserved groups. Therefore, the aim of this scoping review is to investigate if there are underserved groups excluded from OD intervention studies in PD and if so, to identify the features of this group in order to improve the design and applicability of future clinical trials in this area.

The following research questions were formulated: (1) What are the characteristics (e.g. ethnicity, age, sex, PD duration, PD severity, OD severity, cognitive and psychological status) of people with OD in PD recruited into OD intervention studies? (2) Are there underserved groups in OD intervention studies in PD and if so, what are the characteristics of these groups?

3. Methods

A scoping review rather than a systematic review was considered as appropriate for the project to meet the wide scope of the research aims (Munn et al., 2018). The Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for scoping reviews (PRISMA-ScR) checklist (Tricco et al., 2018) (supplemental material 1) was followed.

3.1. Eligibility criteria

The following eligibility criteria were applied: (1) participants with OD in PD, (2) interventions aiming at improving swallowing or feeding difficulties, (3) at least one swallowing (related) outcome was measured and (4) intervention trials including RCTs, quasi-RCTs, non-randomised trials, controlled clinical trials (CCTs), pilot/feasibility studies (with and without control groups), crossover study designs, before-and-after studies and single case studies. No language or date restrictions were applied. Therefore, based on the participant, concept and context framework (Tricco et al., 2018), the following was considered:

- Participant: OD in idiopathic PD $\geq$ 18 years
- Concept: any OD intervention in PD
- Context: any clinical context

Exclusion criteria were the following: the conceptual framework was not matched, individual PD data could not be retrieved (e.g., a heterogeneous participant population was included), only conference abstracts without a retrievable full text, (e.g., inaccessible online) and authors are unable to provide it.

3.2. Search and information sources

Two search strings (1) dysphagia and (2) Parkinson's disease were used to search six databases (AMED, CINAHL, EMBASE, MEDLINE, Web of Science and ProQuest Dissertations & Theses) and one trial registry (www.clinicaltrials.gov) from inception to March 2022 and updated in October 2022 (supplemental material 2). Reference lists of all included reports were searched as well and, where needed, the corresponding study authors were contacted for further information.

3.3. Study selection

After the search, the identified reports were uploaded to the online platform Covidence (www.covidence.org), where duplicates were automatically removed. A random sample of 25 titles and abstracts was screened by two reviewers (JHirschwald, JHofacker) as part of a pilot test to ensure inter-rater reliability. The sample was assessed against the inclusion criteria for the review with a pre-set cut-off agreement of 75%. A consensus of 96% was achieved. Subsequently, the complete abstracts and titles, and thereafter full texts, were independently reviewed by four reviewers according to the eligibility criteria. Disagreements between the reviewers at any of the selection stages were resolved through discussion or with an additional reviewer (MWalshe).

3.4. Data charting process

A data extraction sheet was developed based on the guidance from the INCLUDE project (NIHR, 2020). Data were extracted and categorised into an Excel spreadsheet by one reviewer (LFinnegan) and verified by a second reviewer (JHirschwald) (supplemental material 3). The following information was included: first author's name and year of publication, country of study origin, recruitment setting, study design, total number of PD participants, age, sex, ethnicity, duration of PD, severity of PD, severity of OD, other neurological conditions, cognitive status, psychological status, and additional exclusion criteria.

3.5. Synthesis of results

Data were synthesised regarding the studies' participant characteristics and according to in- and exclusion criteria. Mean, range, and percentage were calculated, where data were available from included studies. As recommended by the Movement Disorders Society Task Force (Goetz et al., 2004) the median instead of the mean was reported for the Hoehn and Yahr (H&Y) scale (Hoehn and Yahr, 1967).

4. Results

4.1. Search results

The literature search identified 2587 studies. Duplicates were removed and a further 2317 were excluded during the title/abstract screening process. Of the remaining 65 reports, no full text could be found for nine studies and 31 did not meet the inclusion criteria. Citation searching identified an additional two records, one of which was included. 26 studies were included in this scoping review. The results of the search along with the study inclusion process are outlined in the PRISMA-ScR flow diagram in supplemental material 4.

Of these, 25 were published in English and one in Chinese (Feng et al., 2019). The Chinese study was translated with assistance from a Chinese speaking speech and language therapist.

The included studies comprised six RCTs, six before-and-after studies, six pilot/feasibility studies (three with and three without a control group), four CCTs, two quasi-RCTs, one single case study and one non-randomised trial. In total, 849 participants with PD were included across the studies and all studies were published between the years 2000 and 2022, although all years were included in the search (supplemental material 3).

4.2. Ethnicity

Only one (Xie et al., 2018) of the 26 studies partially described the ethnicity of the included participants. Therein, the authors report that six participants were white (Xie et al., 2018). A description of the ethnicity of the remaining five participants is not provided. Another study (El Sharkawi et al., 2002) stated that participants were recruited regardless of any minority status. However, no information on the characteristics of the participants' ethnicities is reported, so it remains unclear whether or not the researchers included participants with minority status. All other 25 studies did not report on their participants' ethnicity.

4.3. Country of origin

There was a total of 13 countries from which the included studies originated. The most studies were conducted in the USA ($n = 6$), Brazil ($n = 4$), Korea ($n = 3$) and the Netherlands ($n = 3$). One or two studies each originated from the other nine countries. In terms of geographic location on continents, North and South America accounted for 38.46% ($n = 10$) of the studies, Asia, and Europe for almost 27% ($n = 7$) each and Africa and Oceania for 3.85% respectively, both including only one study on the continent (supplemental material 5).

4.4. Age

In all but one study (Bajjens et al., 2013) the mean or individual age of participants was reported. The overall mean age of the participants included in the 25 studies was 68 years. The lowest mean age was 58.3 years (El Sharkawi et al., 2002) and the highest mean age was 70.5 years (Nagaya et al., 2000). Bajjens et al. (2013) only provided the median age of the included participants which was 68 years. The youngest participant was 42 years (Heijnen et al., 2012) and the oldest participant was 84 years (Athukorala et al., 2014) based on information provided in 16

of the studies.

The individual ages of 92 participants were reported in eleven studies. The most common age group was 70–79 years with 38 participants (41.3%) followed by the age group 60–69 years with 30 participants (32.61%). Fig. 1 depicts the number of participants in each age group.

Four studies specified the age of participants in their inclusion and exclusion criteria. The first study (Baijens et al., 2013) excluded participants > 80 years due to presbyphagia. The second study (Heijnen et al., 2012) only included participants between the ages of 40–80 and therefore excluded participants younger than 40 or older than 80. No justification for this exclusion was provided in the study. Ortega and colleagues (2019) specified in their inclusion criteria that participants had to be over 18 years. Lastly, in one study (Troche et al., 2010) the authors only included participants aged between 55 and 85 years, hence excluding participants younger than 55 and older than 85 years. No explanation was given for this inclusion criterion.

4.5. Sex

Two studies did not report the sex of the included participants (Khedr et al., 2019; Park et al., 2022). Therefore, the sex of 39 of the 849 included participants remains unknown. In the remaining 24 studies, 567 male (70%) and 243 female (30%) participants were included.

Of the studies that included at least three participants and provided information on the participants' sex ($n = 21$), two studies (Pitts et al., 2009; Silva-Arone et al., 2021) included male participants only without providing a rationale for this. One study (Regan et al., 2010) included more women than men. All other 18 studies included more male than female participants. Despite the sex imbalance in most studies, no study explicitly excluded participants based on their sex.

4.6. PD duration

The participants' PD duration was not reported in nine (Baijens et al., 2012; Byeon, 2016; El Sharkawi et al., 2002; Heijnen et al., 2012; Ortega et al., 2020; Pitts et al., 2009; Regan et al., 2010; Silva-Arone et al., 2021; Troche et al., 2010) of the 26 studies. One study (Baijens et al., 2013) reported that the participants' disease duration was at least 5 years. The overall mean disease duration of the other 16 studies was 7.26 years, with the shortest being one year and the longest being 20 years. The participants' individual disease duration was provided in seven studies including 51 participants. Of these, 23 participants (45.1%) had a disease duration of 1–5 years, 22 participants (43.14%) lived for 6–10 years with PD, 5 participants (9.8%) for 11–15 years and one participant (1.96%) for 16–20 years (see Fig. 2). Overall, 88.24% of included participants were diagnosed with PD 1–10 years prior to being enrolled in the according study.

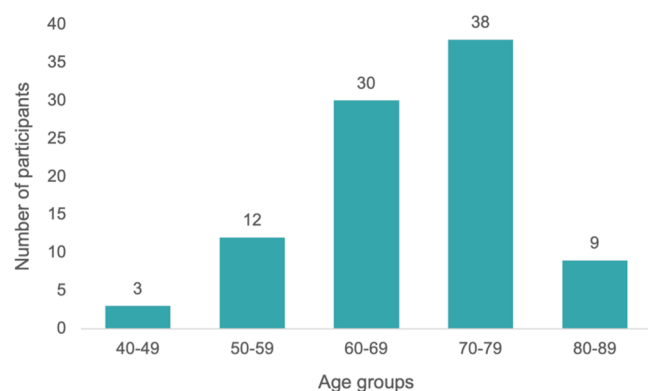


Fig. 1. Number of participants in each age group based on individual ages from eleven studies with 92 participants.

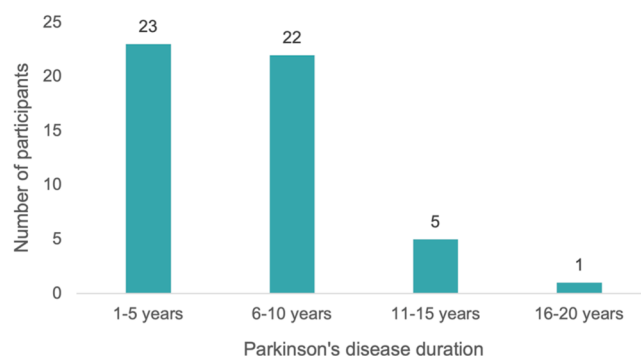


Fig. 2. Parkinson's disease duration and number of participants in each group based on data from seven studies with 51 participants.

One study (Sasegbon et al., 2021) excluded participants that were diagnosed < 2 years prior to the beginning of the study. Another study (Silva-Arone et al., 2021) excluded participants that were diagnosed < 6 months beforehand without a regular follow-up by a neurologist. Additionally, it is unclear whether for example a PD duration of at least 5 years was an inclusion criterion and therefore, people that had received their PD diagnosis less than 5 years ago were excluded.

4.7. PD severity

Of the 26 studies, five studies (Feng et al., 2019; Ortega et al., 2019; Wei et al., 2017; Xie et al., 2018; Yeo et al., 2021) did not provide any information on the participants' disease severity. In all other 21 studies the severity of PD was rated using the H&Y scale (Hoehn and Yahr, 1967). A modified version adding stages 1.5 and 2.5 (Goetz et al., 2004) was used by some but not all studies.

The median PD severity measured on the H&Y scale was 2.5 based on information of 15 studies with 392 participants. Three studies (Ayres et al., 2017; Khedr et al., 2019; Manor et al., 2013) reported only the median H&Y stage (3.3, 2.6 and 2.2 respectively) without providing individual data of participants. One study (Byeon, 2016) reported that 26 participants were staged ≤ 3 and also reported that seven participants were staged > 4.

Fig. 3 depicts the number of participants categorised to each H&Y stage based on individual data provided in 14 studies with 213 participants. Of these, stages 2–3 make up 85% of all participants.

In total, seven studies excluded participants with specific H&Y stages. Of these, four studies (Claus et al., 2021; Pitts et al., 2009; Sasegbon et al., 2021; Troche et al., 2010) excluded participants staged 1 and 5 without any explanation. Pitts et al. (2009) additionally excluded participants who were staged 4. Argolo et al. (2013) excluded

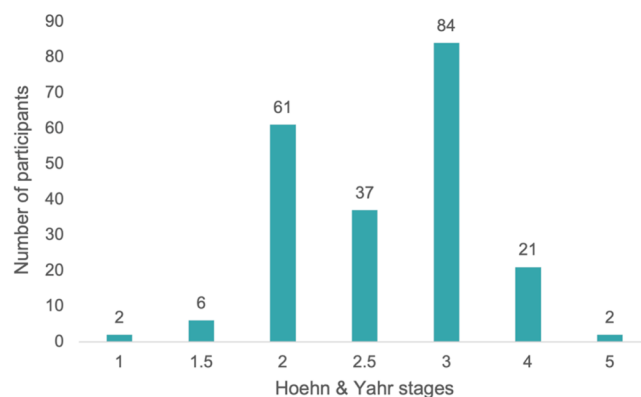


Fig. 3. Parkinson's disease severity and number of participants in each Hoehn and Yahr stage based on data from 14 studies with 213 participants.

participants with H&Y stage 5 with the rationale that they are unable to come to the hospital. Nagaya et al. (2000) excluded stages 1 and 2 justifying that these participants do not have dysphagia and stage 5 due to an inability to comply with the swallow intervention. Finally, Heijnen and colleagues (2012) state in their discussion section that only a few participants with H&Y stages 4 and 5 were included primarily for practical purposes. Overall, five studies each excluded participants with stage 1 and 5, and one study each excluded stage 2 and 4. No study excluded participants with H&Y stage 3.

4.8. OD severity

OD severity was not reported in twelve of the included studies (Argolo et al., 2013; Athukorala et al., 2014; Ayres et al., 2016, 2017; El Sharkawi et al., 2002; Feng et al., 2019; Nagaya et al., 2000; Ortega et al., 2020; Pitts et al., 2009; Sasegbon et al., 2021; Xie et al., 2018; Yeo et al., 2021). Across the remaining 14 studies, there was a wide heterogeneity in how OD severity was measured. Overall, five studies applied an instrumental assessment, three studies assessed patient reported outcome measures and one study conducted a clinical swallow evaluation to determine OD severity (Table 1). Four studies qualitatively described OD severity, “mild to severe dysphagic complaints” (Baijens et al., 2012, 2013), “severe dysphagia” (Curtis et al., 2020) and “mild to moderate dysphagia” (Troche et al., 2010), without any quantification. One study (Wei et al., 2017) used an unspecified 6-point scale without providing information on how it was measured and interpreted.

No studies reported any exclusion criteria regarding a specific OD severity. On average, participants with mild to moderate OD severities were included in the 13 studies and one participant with severe dysphagia in the single case study by Curtis et al. (2020).

4.9. Recruitment setting

Six studies (Curtis et al., 2020; Nagaya et al., 2000; Park et al., 2022; Pitts et al., 2009; Silva-Arone et al., 2021; Yeo et al., 2021) with a total of 34 participants did not report where participants were recruited from. The majority of participants ($n = 378$, 46.38%) were recruited from movement disorders clinics in seven studies (Argolo et al., 2013; Athukorala et al., 2014; Ayres et al., 2016, 2017; Manor et al., 2013; Troche et al., 2010; Wei et al., 2017). Four studies (Baijens et al., 2012; Claus et al., 2021; Khedr et al., 2019; Regan et al., 2010) recruited 103 participants (12.64%) from neurology departments. Two studies each

recruited 93 participants (11.41%) from rehabilitation departments (Byeon, 2016; Feng et al., 2019) and 178 participants (21.84%) from hospitals (Baijens et al., 2013; Heijnen et al., 2012) with no further specification regarding the department(s). All other studies recruited overall 63 participants (7.73%) from various different settings: an outpatient neurologist (El Sharkawi et al., 2002), local support groups (Jenks and Pitts, 2019), gastrointestinal physiology unit (Ortega et al., 2019), a mix of neurology and PD clinics and a PD UK branch meeting (Sasegbon et al., 2021) and a mix of participants from university and from a previous study (Xie et al., 2018). Supplemental material 6 provides an overview of the number of participants recruited from each setting. No study explicitly excluded participants from a specific setting.

4.10. Other neurological conditions

Only one study (Jenks and Pitts, 2019) explicitly included participants that had another neurological condition in addition to idiopathic PD. Therein, two participants with PD were included of which one had undergone deep brain stimulation (DBS) three years pre study enrolment, a history of smoking and sleep apnoea and the second had undergone removal of an intracranial tumour with no residual signs of dysphagia two years pre study enrolment (Jenks and Pitts, 2019).

Of the 26 studies, twelve studies (Argolo et al., 2013; Ayres et al., 2017; Baijens et al., 2012, 2013; Claus et al., 2021; El Sharkawi et al., 2002; Heijnen et al., 2012; Manor et al., 2013; Nagaya et al., 2000; Park et al., 2022; Silva-Arone et al., 2021; Troche et al., 2010) excluded any other neurological condition in general. Five of these studies specified a neurological condition that may affect swallowing or cause dysphagia, and one study additionally specified that it may affect pulmonary function. Seven studies (Athukorala et al., 2014; Feng et al., 2019; Khedr et al., 2019; Park et al., 2022; Regan et al., 2010; Sasegbon et al., 2021; Xie et al., 2018) excluded any other Parkinsonian Syndrome or specified some of these. Five studies (Athukorala et al., 2014; Feng et al., 2019; Khedr et al., 2019; Pitts et al., 2009; Regan et al., 2010) specifically excluded people post stroke. Three studies (Baijens et al., 2012, 2013; Heijnen et al., 2012) excluded people with DBS. Two studies (Khedr et al., 2019; Nagaya et al., 2000) also excluded people with encephalitis and two further studies (Heijnen et al., 2012; Sasegbon et al., 2021) also excluded people with epilepsy. Sasegbon et al. (2021) justified this due to epilepsy being a contraindication for receiving repetitive transcranial magnetic stimulation (rTMS). In the study by Khedr et al. (2019) the intervention was rTMS as well and multiple specific neurological

Table 1

Overview of way of measurement of oropharyngeal dysphagia severity with results of nine studies with a total of 270 participants.

Instrument	Scale	Description of scale/Cut-off score	Study's first author and year	Results	OD severity
VFS	DOSS (O'Neil et al., 1999)	Scale from 1 (severe dysphagia) to 6 (swallowing within normal limits)	Regan et al. (2010)	mean 4.4, range 1–6	mild to moderate
			Silva-Arone et al. (2021)	mean 4.6, range 4–5	mild to moderate
	FDS (Han et al., 1999)	Scale from 0 to 100, higher scores indicate more severe OD	Byeon (2016)	mean 34.3	Not stated; calculated using data as mild
	VDS (Kim et al., 2014)	Scale from 0 to 100, higher scores indicate more severe OD	Park et al. (2022)	mean 31.16	Reported as not high; calculated using data as mild
FEES	FEES-levodopa-test protocol (Warnecke et al., 2016)	Scale from 0 to 108, higher scores indicate more severe OD	Claus et al. (2021)	mean 13.5	Not stated; calculated using data as mild
CSE	MASA (Munn, 2002)	Scale from 0 to 200, score ≥ 178 indicates a swallow function within normal limits	Jenks and Pitts (2019)	mean 168.5	Not stated; calculated using data as mild
PROM	SDQ (Manor et al., 2007)	Scale from 0 to 42, score ≥ 14 indicates dysphagia	Khedr et al. (2019)	mean 16.8	Not stated; calculated using data as mild to moderate
			Manor et al. (2013)	mean 14.46	Not stated; calculated using data as mild to moderate
	DSS	Scale from 0 (cannot swallow at all) to 100 (normal swallow)	Heijnen et al. (2012)	median 67	Not stated; calculated using data as mild to moderate

CSE: clinical swallow evaluation, DOSS: Dysphagia Outcome and Severity Scale, DSS: Dysphagia Severity Scale, FDS: Functional Dysphagia Scale, FEES: Fiberoptic Endoscopic Evaluation of Swallowing, MASA: Mann Assessment of Swallowing Ability, OD: oropharyngeal dysphagia, PROM: Patient Reported Outcome Measure, SDQ: Swallowing Disturbance Questionnaire, VDS: Videofluoroscopic Dysphagia Scale, VFS: Videofluoroscopic Evaluation of Swallowing

conditions were excluded, such as intracranial metallic devices.

Six studies (Ayres et al., 2016; Byeon, 2016; Curtis et al., 2020; Jenks and Pitts, 2019; Ortega et al., 2019; Wei et al., 2017) did not specify if any other additional neurological conditions were excluded. Of these, three studies (Curtis et al., 2020; Jenks and Pitts, 2019; Yeo et al., 2021) were case studies with only one or two participants with PD. Curtis et al. (2020) included one participant who had no history of smoking or DBS. Yeo et al. (2021) included one participant with PD, one with multi system atrophy and two with head and neck cancer. One further study (Ortega et al., 2019) included participants post stroke as a control group.

Overall, the majority of studies excluded people with any other neurological condition, especially with PD Syndromes other than idiopathic PD and post stroke. None of these studies explicitly justified the exclusion criteria except for stating conditions that can cause dysphagia. Only one study included one participant with DBS where the primary swallowing intervention was not DBS.

4.11. Cognitive status

Two studies (Ayres et al., 2017; Curtis et al., 2020) stated to include participants with mild cognitive impairment according to the Montréal Cognitive Assessment (Nasreddine et al., 2005). However, the participants in the study by Ayres and colleagues (2017) showed no cognitive impairment according to the Mini Mental State Examination (MMSE) (Folstein et al., 1975) and participants with dementia were excluded.

Overall, five studies (El Sharkawi et al., 2002; Jenks and Pitts, 2019; Ortega et al., 2020; Xie et al., 2018; Yeo et al., 2021) did not report on the cognitive status of the included participants. Neither did they exclude cognitive disorders specifically. One study (Park et al., 2022) included participants with a mean MMSE score of 27, indicating normal cognition. However, it remains unclear if participants with impaired cognition were explicitly excluded. More than half of all included studies ($n = 15$) listed cognitive disorders and/or dementia as an exclusion criterion. Most often this was measured using the MMSE with cut-off scores varying from 23 to 25. Three studies (Khedr et al., 2019; Regan et al., 2010; Sasegbon et al., 2021) excluded people who lacked capacity or were unable to give informed consent.

4.12. Psychological status

One study (Ayres et al., 2017) included participants with mild depression according to the Beck Depression Inventory (BDI) (Beck et al., 1996) with a mean score of 15.2. Most studies ($n = 16$) neither reported on the psychological status of the included participants nor did they specifically exclude people with e.g., depression. Six studies (Baijens et al., 2012, 2013; Claus et al., 2021; Heijnen et al., 2012; Khedr et al., 2019; Nagaya et al., 2000) excluded people with depression. However, only Claus et al. (2021) provided a cut-off score ($BDI > 19$ indicating severe depression). Two further studies (Argolo et al., 2013; Feng et al., 2019) excluded people with psychiatric disorders in general and one study (Troche et al., 2010) excluded people that had difficulties complying to the intervention due to neuropsychological difficulties such as severe depression or psychosis.

4.13. Additional participant characteristics

One study (Wei et al., 2017) included participants with comorbidities and reported on coronary heart disease, diabetes, high blood pressure and surgical history. Another study (Curtis et al., 2020) did not report on any exclusion criteria as this was a single case study. In all other 24 studies there was a high variety of exclusion criteria. Those that were applied in more than two studies are depicted in Fig. 4.

5. Discussion

This scoping review included 26 OD intervention studies in PD and

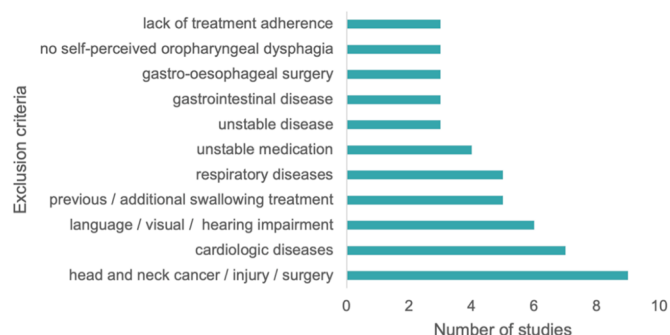


Fig. 4. Number of studies that applied each additional exclusion criterion.

has mapped the characteristics of included participants, along with underserved groups who are directly excluded from or failed to be included in these studies. Based on this, a typical participant with OD in PD can be depicted as a 68 year old man, recruited from a US movement disorders clinic, with a PD duration of 7 years, PD severity staged H&Y 2.5, mild OD, no history of head and neck cancer, cardiac disease, respiratory disease, depression, no DBS, no previous swallowing treatment, intact cognition, language, vision and hearing and both stable disease and medication intake. However, people with OD in PD in clinical practice oftentimes have a different appearance than the one reported here. We identified several underserved groups in OD intervention studies in PD.

5.1. Underserved groups in OD intervention studies in PD

Two largely underserved groups in OD intervention studies in PD are younger (< 50 years) as well as older (≥ 80 years) people. Participants in the included studies were on average 68 years. This is similar to other PD intervention trials, where participants are on average younger than in prevalence studies (Tosserams et al., 2018). However, only three studies applied explicit upper age limits (twice 80 years, once 85 years) and therefore intentionally excluded older participants and none applied lower age limits excluding people between 18 and 50 years. All other studies indirectly excluded younger and older people, most likely by applying other eligibility criteria that disproportionately affect younger and older people, such as PD duration, PD severity, OD severity, cognitive and psychological status, or simply failed to include these age groups.

The onset of PD symptoms before 50 years is considered as early-onset PD (EOPD) (Mehanna et al., 2022). None of the included OD intervention studies focused on EOPD specifically even though it is estimated that EOPD represents 3–7% of the PD population. It is argued that the needs of people with EOPD are different from those of people with PD, e.g., due to different clinical features and different impacts on employment and social perceptions (Mehanna et al., 2022).

As in other PD intervention trials, women represent an underserved group in OD intervention studies in PD as well. However, in other PD intervention trials women made up 41% of the participants (Tosserams et al., 2018) whereas in OD intervention trials in PD on average only 30% of participants were female. Despite this, no study explicitly excluded females. Yet there is emerging evidence of sex differences in both motor and non-motor symptoms and psychosocial issues (Subramanian et al., 2022). To improve the inclusion of women and other underserved gender groups in future OD intervention studies in PD, it is recommended to follow guidance by the Medical Science Sex and Gender Equity (MESSAGE) project, which is anticipated to be published in 2024 (Womersley and Norton, 2023). Furthermore, for authors and editors of scientific manuscripts it is suggested to adhere to the Sex and Gender Equity in Research (SAGER) guidelines for a consistent reporting of sex and gender information (Heidari et al., 2016).

The underserving of women in these studies may be partly related to

the fact that women are underrepresented in recruitment settings, such as movement disorders clinics and are therefore less likely to be recruited into trials (Tosserams et al., 2018). In the included studies, almost half of the participants were recruited from movement disorders clinics and thus, limiting the opportunity for many underserved groups to be recruited into a trial.

This also affects non-white people with PD as they have been shown to be underserved in PD trials. The ethnicity of participants was not fully reported in any of the included studies, and thus it remains unknown whether specific ethnic groups are underserved in OD intervention studies in PD. One solution to improve the inclusion and report of underserved ethnicities in future OD intervention trials in PD is to incorporate the INCLUDE Ethnicity framework (NIHR, 2020) and follow the Trial Forge Guidance (Dawson et al., 2022) in the design, conduct and reporting of the study.

Considering the studies' country of origin, the majority originated from the USA. However, no study, e.g., originated from Canada or Australia, both countries with well-developed health services and research settings. As there is evidence that the characteristics of PD differ between geographical locations (Lim et al., 2019), the results of the studies are unlikely to be generalisable to all regions of the world.

Furthermore, people with longer PD duration and with very mild or very severe PD have been underserved in OD intervention trials in PD. On the one hand, longer PD duration and more severe PD are associated with older age and dementia. It is argued that as people get older, they are more likely to have lived with PD for longer, therefore their disease has progressed and become more severe, and they are at higher risk of developing dementia. Thus, some people with a longer PD duration may be indirectly excluded based on their age and cognitive status. On the other hand, people with milder PD may not have OD and therefore may not meet the study's eligibility criteria.

Another important underserved group in the included studies were people with more severe OD. Even though OD can be present regardless of the PD stage, mostly people with mild to moderate OD were included. None of the studies directly excluded a specific OD severity. Therefore, it is most likely that participants with severe OD were indirectly excluded by other exclusion criteria such as longer PD duration, more severe PD, higher age, or depression.

Lastly, the list of exclusion criteria based on non-motor symptoms and/or comorbidities in many included studies was long and in line with commonly used exclusion criteria in other PD intervention trials. However, applying these exclusion criteria may not only underserve one specific group, but also indirectly underserve other groups. Overall, to improve the inclusion of all important characteristics of people with OD in PD in future studies it is recommended to follow the INCLUDE guidance (NIHR, 2020).

5.2. Strengths and limitations

This scoping review included all types of intervention trials for OD in PD which prevented the study from becoming too restrictive in its analysis and helped to broaden its application and relevance. However, many studies failed to report important demographic data which consequently may affect the comprehensiveness of this review. More careful adherence to EQUATOR reporting guidelines (www.equator-network.org) is recommended to facilitate future scoping reviews. Furthermore, there were challenges associated with data analysis in the included studies due to lack of reporting on OD severity and how OD assessment scores were calculated. This meant that the authors had to individually determine OD severity based on limited data provided, which is a potential limitation of the study.

5.3. Conclusions

Overall, several underserved groups were identified in the included OD intervention studies in PD that match the most commonly identified

underserved groups in other PD intervention trials. Directly or indirectly excluding these groups poses a threat to the external validity of the studies as the included participants may not represent the general target population. It is therefore important to include all characteristics of people with OD in PD in future research studies on OD interventions in PD. By shifting participant recruitment to more diverse groups, pivotal results captured from intervention studies will be applicable and successful to a broader and more inclusive population and will ultimately strengthen the evidence base on OD interventions in PD. Despite this, it is not only important to include all characteristics of these participants but also to comprehensively report on them and provide a rationale for potential exclusions of specific characteristics.

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CRediT authorship contribution statement

JHirschwald: Investigation, Validation, Formal analysis, Data curation, Writing - original draft, Writing - review & editing, Visualisation; **LFinnegan**: Investigation, Writing - review & editing; **JHofacker**: Investigation, Writing - review & editing; **MWalshe**: Conceptualisation, Methodology, Investigation, Writing - review & editing, Supervision, Project administration.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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None.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.arr.2023.102150](https://doi.org/10.1016/j.arr.2023.102150).

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