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Biofeedback to improve the safety and efficiency of the swallow function in people with Parkinson's disease and dysphagia

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Review question(s)

What is the effectiveness of interventions using biofeedback to improve swallow function in adults with Parkinson's disease?

What is the safety of interventions using biofeedback to improve swallow function in adults with Parkinson's disease?

Searches

We will conduct the following searches:

Electronic bibliographic databases:

1. EMBASE (inception – January 2017),

2. PubMed (inception - January 2017),

3. CINAHL (inception - January 2017)

4. Web of Science (inception - January 2017),

5. Elsevier Scopus (inception - January 2017),

6. ScienceDirect (inception - January 2017),

7. AMED (inception - January 2017),

8. The Cochrane Database of Systematic Reviews (inception - January 2017),

9. ProQuest Dissertations and Theses A & I (inception - January 2017), and

10. Google Scholar (inception - January 2017).

Relevant conference proceedings: Conference proceedings of the annual congresses of Dysphagia Research Society, European Society Swallowing Disorders, International congress of Parkinson's disease and Movement Disorders, World Congresses for Neurorehabilitation will be hand-searched by Irene Battel (IB) and Irene Calvo (IC).

Reference lists: IB will search the reference lists of included studies to screen for the presence of any novel citations, which were not identified during the initial systematic search.

Authors will not apply any language or date restrictions within searches.

Types of study to be included

We will include randomised control studies (RCTs) and non-randomised studies. We define 'non-randomised studies' as any studies estimating the effectiveness of a recruitment intervention that does not use randomisation in order to allocate participants to the intervention or comparison groups. These types of studies are referred to by multiple names in the literature including, but not limited to: observational studies, cohort studies, and case-control studies. We will also include case series with either post-test or pre-test/post-test concrete outcomes. There are no restrictions on the language of publication. The methodological quality of included studies will be graded using "Checklists of methodological issues for review authors to consider when including non-randomized studies in systematic review" (Wells et al. 2013).

Condition or domain being studied

Swallowing disorders (dysphagia) occur frequently in Parkinson's disease (PD) patients. Several studies confirm that the vast majority of people with PD will develop dysphagia during the course of the disease (Miller et al. 2009). A meta-analysis based on studies using objective instrumental evaluation suggests that the prevalence of dysphagia in PD is as high as 87% (Kalf et al. 2012).

The nature of swallowing impairment is characterized by drooling, poor bolus formation, a deficiency of tongue movements and prolonged oral transit which results in a delay in the triggering of the pharyngeal swallow reflex (Miller et al. 2009), vallecula and pyriform sinus pooling, somatosensory deficiencies and a high risk of penetration and/or aspiration (Troche et al. 2014). In PD patients, dysphagia is characterized not only by weakness and tremor, but also by a deficit in motor planning and coordination. Many studies have suggested that the neural impairments in PD are manifested as a reduced ability to plan motor acts based on internal cues, and that these could be the causes of the freezing and coordination deficit during swallowing (Suttrup et al. 2016, Athukorala et al.2014).

Participants/ population

Participants are male and female adults over 18 years of age with a clinical diagnosis of PD according to the United Kingdom Parkinson's Disease Society (UPDRS) Brain Bank diagnostic criteria (Hughes 1992), or other similar published clinical diagnostic criteria. We will include studies of people at all stages of the disease, at all disease severity levels presenting with all severities of dysphagia.

We will exclude participants with parkinsonian syndromes (multiple system atrophy, progressive supranuclear palsy, and dementia with Lewy bodies).

Intervention(s), exposure(s)

The intervention of interest is biofeedback. We will include studies that provide swallowing treatment using biofeedback. The biofeedback will involve any external visual, auditory, or tactile cue or combination of cues delivered using any type of device or equipment, which gives information to the individual with PD on their swallow function.

Comparator(s)/ control

The comparator interventions will be:

(1) No intervention;

(2) Usual care that does not involve biofeedback (e.g diet modification, postural changes, safe swallowing strategies);

(3) Sham interventions;

(4) Other swallowing interventions that do not include biofeedback.

Outcome(s)

Primary outcomes

(1) Change in timing and efficiency of swallowing assessed by instrumental evaluation (videofluoroscopy or FEES or manometry) using valid reliable outcome measurement scales (e.g penetration-aspiration scale; residue scales etc.).

(2) Change in frequency and amount of aspiration (food/fluid entering lungs) and safety of swallowing as assessed by instrumental evaluation.

Secondary outcomes
(1) Change in oral intake status as measured by validated scales (e.g. functional oral intake scale, Crary et al. 2005);

(2) Change in nutritional status as measured using a validated scale (e.g. malnutrition universal screening tool, Stratton et al. 2004);

(3) Change in health-related quality of life as measured by quality of life measures and swallowing quality of life measures by participant and/or caregiver report;

(4) Compliance with intervention;

(5) Adverse events attributable to the intervention (e.g increased dysphagia, fatigue etc.).

Three timeframes will be examined (1) immediate change in outcome measures; (2) short-term change in outcome measures (1-12 weeks); and long-term change (12 weeks +).

Data extraction, (selection and coding)

Studies will be selected following a database search. Isolde Harpur (IH) will design and pilot a systematic search strategy to apply across all electronic databases identified in the protocol as relevant to the subject. Searches of electronic databases using this search strategy will subsequently be conducted by two other authors (IB and IC). These authors will also hand-search the annual scientific meetings identified as relevant in this protocol. A reference manager software (Zetero www.zetero.org) will be used to manage references.

Screening of titles will be conducted using Covidence by three authors (Irene Battel-IB; Irene Calvo-IC and Margaret Walshe-MW). Following duplicate deletion, double screening of titles and abstracts will be conducted by IB and IC, to exclude obviously ineligible results. Following this, articles identified as potentially relevant will be subsequently screened for eligibility by IB and IC. IB will scan the reference lists of included studies to identify further relevant articles. A third author (MW) will act as an independent reviewer and any discrepancies will be resolved through discussion.

The following data will be extracted:

Study design, setting, type of intervention, comparison intervention if relevant, population characteristics (severity of PD; severity of dysphagia; gender, number of participants, outcome, differences in outcome measures pre- and post-intervention, and compliance with the intervention), adverse effects, and the methodological quality of the studies.

This will be done using a specifically devised data extraction form.

Data will be extracted regarding: study design, setting, participant demographics, outcome measurement, prevalence figures and statistical robustness.

Descriptive analysis will initially be accomplished using Excel (Microsoft Corporation) spreadsheets, with subsequent exportation to statistical software, as appropriate. Statistical advice will be given by Margaret Lawler (ML).

IB will address missing/unclear data by contacting authors for studies published within the last ten years. Studies will be excluded if no response is received following two contact attempts.

Risk of bias (quality) assessment

Two review authors (IB, IC) will independently assess risk of bias in all included studies. The Cochrane Collaboration's Risk of Bias tool for assessing risk of bias will be used for randomised controlled trials, and will address such issues as sequence generation, allocation sequence concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, other potential threats to validity, and other biases such as differences in baseline characteristics between the experimental groups, sources of funding, e.g. the pharmaceutical industry, and conflicts of interest (Higgins 2011).

The Risk Of Bias In Non-randomized Studies - of Interventions (ROBINS-I; https://sites.google.com/site/riskofbiastool/) tool will be used to assess the risk of bias due to confounding, and will consider aspects of methodological quality such as participant selection, measurements of interventions, departures from intended interventions, missing data, measurements of outcomes and selection of the reported results. Each study will be rated as having a critical, serious, moderate or low risk of bias based on a judgement on the gathered information. Reporting of information on the flow of participants through the trial (e.g. from a CONSORT diagram) will also be recorded.

We will resolve any disagreements by discussion and consensus agreement within the review team.

Strategy for data synthesis

We anticipate there will be limited scope for meta-analysis due to the range of outcomes and the small number of RCTs that exist in the area. Trials will be analysed according to the type of intervention used in the study. Interventions will be grouped when their form or content is deemed to be sufficiently similar.

The analysis will be narrative description of the data, and we intend to present the data in tables, grouped by intervention type. Where population, intervention and outcome are sufficiently similar to allow pooling of data in a meta-analysis, we will look for both visual evidence of heterogeneity in forest plots and statistical evidence of heterogeneity using the chi-square test for heterogeneity (Gardner et al. 2016).

Analysis of subgroups or subsets

If sufficient data are available, we will perform a subgroup analysis, in which the following intervention characteristics will be considered:

(1) Type of biofeedback (e.g visual /auditory /verbal);

(2) Intensity of swallowing interventions;

(3) Stage of the disease and severity of dysphagia.

Dissemination plans

The authors intend to submit this study in its completed form for publication in an appropriate peer-reviewed international journal. Also, the primary author intends to present the results at the annual congress of the European Society for Swallowing Disorders.

Contact details for further information

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01 June 2017

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This project is unfunded

Conflicts of interest
None known

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Subject indexing assigned by CRD

Subject index terms
Deglutition; Deglutition Disorders; Humans; Neurofeedback; Neurological Rehabilitation; Parkinson Disease; Patient Safety; Safety; Treatment Outcome

Stage of review
Ongoing

Date of registration in PROSPERO
24 January 2017

Date of publication of this revision
24 January 2017

Stage of review at time of this submission	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No