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Non-pharmacological therapies for dysphagia in Parkinson's disease (Review)



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[Intervention Review]

Non-pharmacological therapies for dysphagia in Parkinson's disease

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ABSTRACT

Background

Dysphagia occurs frequently in Parkinson's disease although patients themselves may be unaware of swallowing difficulties. Speech and language therapists in conjunction with nurses and dietitians use techniques that aim to improve swallowing and reduce the risk of choking, aspiration and chest infections.

Objectives

To compare the efficacy and effectiveness of non-pharmacological swallowing therapy for dysphagia versus placebo or no intervention in patients with Parkinson's disease.

To compare one form of non-pharmacological swallowing therapy for dysphagia with another in patients with Parkinson's disease.

Search methods

Relevant trials were identified by electronic searches of MEDLINE, EMBASE, CINAHL, ISI-SCI, AMED, MANTIS, REHABDATA, REHADAT, GEROLIT, Pascal, LILACS, MedCarib, JICST-EPlus, AIM, IMEMR, SIGLE, ISI-ISTP, DISSABS, Conference Papers Index, Aslib Index to Theses, the Cochrane Controlled Trials Register, the CentreWatch Clinical Trials listing service, the metaRegister of Controlled Trials, ClinicalTrials.gov, CRISP, PEDro, NIDRR and NRR; and examination of the reference lists of identified studies and other reviews.

Selection criteria

Only randomised controlled trials (RCT) were included. We did not examine any trials using drugs or surgery to treat the dysphagia. We did not examine any trials where part of the therapist's advice was to insert a nasogastric or percutaneous gastrostomy tube.

Data collection and analysis

Not applicable.

Main results

No randomised controlled trials or controlled trials were found that examined the efficacy of non-pharmacological swallowing therapy for the treatment of dysphagia in Parkinson's disease. However there is one large RCT currently recruiting patients that will compare 'chin down' posture with thickened liquids in the treatment of dysphagia. The main outcomes will be the rates of aspiration and pneumonia.



Authors' conclusions

There is currently no evidence to support or refute the efficacy of non-pharmacological swallowing therapy for dysphagia in Parkinson's disease. Large well designed placebo-controlled RCTs are required to assess the effectiveness of swallowing therapy for dysphagia in Parkinson's disease and reported according to CONSORT guidelines. Suitable outcome measures should be chosen so that the efficacy and effectiveness of non-pharmacological swallowing therapy can be assessed and an economic analysis performed. Outcomes which have meaning to patients and carers should be used wherever possible since they need to know the value of this therapy in practical terms. The patients should be followed for at least 6 months to determine the duration of any improvement.

PLAIN LANGUAGE SUMMARY

Dysphagia occurs frequently in Parkinson's disease although patients themselves may be unaware of swallowing difficulties. Speech and language therapists in conjunction with nurses and dietiticians use techniques that aim to improve swallowing and reduce the risk of choking and chest infections.

This review compared the benefits of swallowing therapy versus placebo (sham therapy) or no therapy for swallowing disorders in Parkinson's disease. Relevant trials were identified by electronic searches of 21 medical literature databases, various registers of clinical trials and an examination of the reference lists of identified studies and other reviews.

Only randomised controlled trials (RCT) were eligible for this review. In RCTs the patients are assigned to each of the groups in a random fashion so as to reduce the potential for bias. Either one group of patients had swallowing therapy, the other had a sham treatment or no treatment, or two forms of swallowing therapy were compared to each other.

There were no controlled trials, randomised or otherwise, in this field. Therefore there is no trial evidence to prove or disprove the benefit of swallowing therapy for the treatment of swallowing disorders in people with Parkinson's disease. It should be emphasised that this lack of evidence does not mean lack of effect.

There is one large RCT currently recruiting patients that will compare 'chin down' posture with thickened liquids in the treatment of dysphagia. The main outcomes in this study will be the rates of aspiration and pneumonia.

Large well designed placebo-controlled RCTs are needed to assess the effectiveness of swallowing therapy for swallowing disorders in Parkinson's disease. The design of the trials should minimise bias and be reported fully using CONSORT guidelines. Outcome measures with particular relevance to patients should be chosen and the patients followed for at least 6 months to determine the duration of any improvement.



BACKGROUND

Dysphagia occurs frequently in Parkinson's disease although patients themselves may be unaware of swallowing difficulties (Robbins 1986). Several abnormalities in the various phases of swallowing have been described and include abnormal bolus formation, transfer and oesophageal dysmotility (Bushmann 1989). Swallowing speed and bolus volume are significantly lower in patients when compared to age-matched controls, and decline significantly with increasing disease severity as measured by Hoehn and Yahr score (Clarke 1998). Dysphagia can lead to 'silent aspiration' and, although some authors have suggested that this leads to an increased risk of pneumonia which is a significant cause of mortality in patients with Parkinson's disease (Hoehn 1967; Robbins 1986), others have not found any association with dysphagia and chest infections requiring antibiotics (Clarke 1998).

Although levodopa improves swallowing speed (Clarke 1998), pharmacotherapy has only a limited amount to offer patients with more severe deficits. It has therefore been suggested that non-pharmacological swallowing therapy may improve the remaining dysphagia experienced by patients with Parkinson's disease. Therapists provide careful assessment and diagnosis of swallowing problems. They advise on swallowing technique, exercise and may offer dietary alternatives and advise on food consistency to reduce the risks of ill health and promote safety and comfort in swallowing.

Few studies have evaluated the role of non-pharmacological swallowing therapy for dysphagia (El-Sharkawi 98). As a result clinicians tend not to refer patients for such therapy. No survey has assessed the level of provision of non-pharmacological swallowing therapy, however the referral rate to speech and language therapists is low. A postal questionnaire of 261 Parkinson's patients in touch with the Parkinson's Disease Society in 1982 found that only 3% had seen a speech and language therapist (Oxtoby 1982). In Mutch et al's 1986 community-based study of 267 patients, 4% had seen a speech and language therapist (Mutch 1986). A survey of 72 Parkinson's patients attending a movement disorder clinic in 1995 found that 15% had seen a speech and language therapist (Clarke 1995). Finally, a members survey of the Parkinson's Disease Society of the United Kingdom with a total of 1,693 respondents found that 20% of respondents had been assessed or treated by a speech and language therapist (Yarrow 1999).

This systematic review aimed to compare the efficacy and effectiveness of non-pharmacological swallowing therapy for dysphagia versus placebo or no intervention in patients with Parkinson's disease. It also aimed to compare one form of swallowing therapy for dysphagia with another in patients with Parkinson's disease. We did not examine any trials using drugs, surgery or where part of the therapist's advice was to insert a nasogastric or percutaneous gastrostomy tube.

OBJECTIVES

- To compare the efficacy and effectiveness of nonpharmacological swallowing therapy for dysphagia versus placebo or no interventions in patients with Parkinson's disease.
- To compare one form of non-pharmacological swallowing therapy for dysphagia with another in patients with Parkinson's disease.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised trials comparing non-pharmacological swallowing therapy for dysphagia with placebo or no intervention were considered for inclusion in the study. All randomised trials comparing two forms of speech and language therapy for dysphagia were considered for inclusion in this study. Both random and quasi-random methods of allocation were allowed.

Types of participants

- Patients with a diagnosis of idiopathic Parkinson's disease (as defined by the authors of the studies).
- · Any duration of Parkinson's disease.
- All ages.
- · On any drug therapy.
- Any duration of treatment.

Types of interventions

Non-pharmacological swallowing therapy for dysphagia versus placebo intervention or no intervention. The aim of the therapy must be to make it safer and easier for the patient to swallow. We did not examine any trials using drugs, surgery or where part of the therapist's advice was to insert a nasogastric or percutaneous gastrostomy tube.

Types of outcome measures

- 1. Swallowing impairment;
- (a) Total scores of individual impairments (e.g. clinical rating of swallowing efficiency using videofluoroscopy)
- (b) Individual measures (e.g. bolus volume, swallowing speed, laryngeal, pharyngeal and oesophageal function etc.).
- 2. Frequency of chest infections.
- 3. Activities of daily living scores for eating and swallowing (e.g. Question 7 in United Parkinson's Disease Rating Scale, UPDRS).
- 4. Handicap and quality of life measures, both disease specific, (e.g. PDQ39), and generic, (e.g. SF36).
- 5. Depression rating scales (e.g. Hospital Anxiety and Depression Scale, HADS).
- 6. Adverse effects.
- 7. Carer outcomes (e.g. Carer strain index).
- 8. Economic analysis.

We will examine both short term and long term effects of the intervention.

Search methods for identification of studies

- 1. The review is based on the search strategy of the Movement Disorders Group and also the following more general search strategy:
- a. Dysphagia OR swallow OR rehabilitation OR speech OR voice OR language $\,$
- b. Parkinson OR Parkinson's disease OR Parkinsonism c. #a AND #b

Relevant trials were identified by electronic searches of general biomedical and science databases: MEDLINE (1966-2000),



EMBASE (1974-2000), CINAHL (1982-2000), ISI-SCI ((1981-2000); rehabilitation databases: AMED (1985-2000), MANTIS (1880-2000), REHABDATA (1956-2000), REHADAT, GEROLIT (1979-2000); English language databases of foreign language research and third world publications: Pascal (1984-2000), LILACS (1982-2000), MedCarib (17th Century-2000), JICST-EPlus (1985-2000), AIM (1993-2000), IMEMR (1984-2000) and hand searching of appropriate journals. Relevant trials were included on the Group's specialised register of randomised controlled trials.

- 2. The Cochrane Controlled Trials Register, the CentreWatch Clinical Trials listing service, the metaRegister of Controlled Trials, ClinicalTrials.gov, CRISP, PEDro, NIDRR and NRR, were also searched for relevant trials.
- 3. The reference lists of located trials and review articles were searched.
- 4. Grey literature (e.g. conference abstracts, theses and internal reports) were searched. This included The XIII International Congress on Parkinson's disease (1999), The International Congress of Parkinson's Disease and Movement Disorders (1990, 92, 94, 96, 97, 98), The American Academy of Neurology 51st annual meeting (1999). The following grey literature databases were searched: SIGLE (1980-2000), ISI-ISTP (1982-2000), DISSABS (1999-2000), Conference Papers Index (1982-2000) and Aslib Index to Theses (1970-2000).
- 5. National and regional professional associations were asked to search for relevant trials. Requests for help were placed on bulletin boards on their webpages.
- 6. Universities and colleges that carry out degree courses in speech and language therapy were asked to search for any relevant unpublished projects.
- 7. Patient support groups (e.g. The UK Parkinson's Disease Society and The World Parkinson's Disease Association) were asked if they had funded any relevant trials. Requests for help were placed on bulletin boards on their web pages.

Further details on this search strategy are available in the Group's module within the Cochrane library (www.cochrane.org). This includes explanations of the acronyms, sources and web sites.

Data collection and analysis

The authors independently assessed the studies identified by the search strategy. Disagreements about inclusions were resolved by discussion.

All authors of eligible studies were contacted for further unpublished details of their trials. The full papers were assessed for methodological quality by recording a number of items that could either introduce bias or could affect the assessment of the data presented in the study. This included the method of randomisation and blinding, whether an intention-to-treat analysis was used and the number of patients lost to follow up.

Eligible data was abstracted by two of the authors (KD and RW) onto standardised forms independently, checked for accuracy and amalgamated. Disagreements about inclusions were resolved by discussion.

RESULTS

Description of studies

No controlled trials, randomised or otherwise, were found that examined the effect of non-pharmacological swallowing therapy on dysphagia in Parkinson's disease.

Risk of bias in included studies

Not applicable.

Effects of interventions

Not applicable.

DISCUSSION

PRINCIPAL FINDINGS:

- No randomised controlled trials were found that examined the efficacy of non-pharmacological swallowing therapy for dysphagia in Parkinson's disease.
- We suggest that a survey needs to be carried out to determine
 what methods of non-pharmacological swallowing therapy
 are currently being used by therapists to treat Parkinsonian
 dysphagia, and whether there is a consensus as to 'bestpractice'.
- Large well designed RCTs are needed to demonstrate non-pharmacological swallowing therapy's efficacy and effectiveness in Parkinson's disease.

ONGOING TRIALS - THE SWALLOWING TRIAL (CSDRG Protocol 201) See Characteristics of Ongoing Trials Section for more details. This two part randomised clinical trial is designed to define the short-term (Part I) and long-term (Part II) effects of two commonly used interventions implemented to eliminate aspiration of thin liquids. These interventions are: (1) chin down posture and (2) liquid thickened to nectar or honey viscosity.

Part I of the study will examine the effects of these interventions in the short-term i.e. during the oropharyngeal videofluorographic (VFG) study, also known as the modified barium swallow. Short term effects of these interventions will be assessed during the VFG study in participants with dementia or Parkinson's disease (with or without dementia) who are found to aspirate thin liquids during a set of qualifying swallows not using these interventions. The two interventions will then be introduced to all participants in a random order.The primary outcome measure will be the occurrence of aspiration on swallows using each of the two interventions.

Part II of the study examines the long-term (3 month) effect of the two interventions on pneumonia rates. Immediately after the VFG study, participants who are successful with both interventions (i.e. they do not aspirate when using any of the interventions) and participants who are unsuccessful with all interventions (i.e. they continue to aspirate), and whose family insist they continue to be fed orally will be randomised to one of the two interventions for use during liquid intake for three months. The primary outcome measure for part II of the study will be the incidence of pneumonia.

The study is aiming to recruit 987 patients, and the authors expect approximately 20% (197) of these will have Parkinson's disease. If recruitment is successful this will make this study the largest trial of



any paramedical therapy to treat Parkinson's disease in the world to date.

AUTHORS' CONCLUSIONS

Implications for practice

No controlled trials have evaluated the role of nonpharmacological swallowing therapy for dysphagia in Parkinson's disease. There is therefore no evidence to support or refute the efficacy of this therapy.

Implications for research

A Delphi-style survey is needed to develop a consensus as to what is 'standard' non-pharmacological swallowing therapy for dysphagia in Parkinson's disease. To obtain proof of the efficacy of non-pharmacological swallowing therapy for swallowing disorders in Parkinson's patients large randomised placebo-controlled trials are required.

Other reviews of rehabilitation therapies for Parkinson's disease have highlighted many methodological shortcomings. The issues arising from those reviews have a significant bearing on the conduct of future non-pharmacological swallowing therapy for dysphagia trials in Parkinson's disease and other conditions:-

- Firm diagnostic criteria should be used (e.g. UK Parkinson's Disease Brain Bank Criteria, Gibb 1988).
- Inclusion and exclusion criteria should be clear and trials should aim to enrol uniform cohorts of Parkinson disease patients.
- Investigators should clarify at what stage of the disease nonpharmacological swallowing therapy is being evaluated.

- A rigorous method of randomisation should be used and the allocation adequately concealed.
- Trials must have sufficient numbers of patients to avoid false negative conclusions.
- Trials must include an adequate placebo control intervention and a very clear description of the therapeutic intervention.
- The patients should be followed for at least 6 months after treatment to assess any long-term effects of the nonpharmacological swallowing therapy intervention.
- Regardless of the scale used, trials should report whether scores on impairment and disability refer to the 'on' or 'off' phase.
- Suitable outcome measures should be chosen so that the
 efficacy and effectiveness of non-pharmacological swallowing
 therapy can be assessed and an economic analysis performed.
 Outcomes which have meaning to patients and carers should be
 used wherever possible since they need to know the value of this
 therapy in practical terms.
- The data must be analysed on an intention-to-treat basis and the change in an outcome measure must be compared statistically across the two therapy groups.
- The trial should be reported according to the guidelines set out in the CONSORT statement (CONSORT 1996).

ACKNOWLEDGEMENTS

Many thanks to all of the authors of the swallowing study who assisted in providing details of their protocol. Also thanks to all of the people contacted whilst trying to locate any other unpublished randomised controlled trials.



REFERENCES

References to studies excluded from this review

El-Sharkawi 98 (published data only)

* El-Sharkawi, A, L. Ramig, J. Logeman, A. Pawlas, S. Baum, C. Werner. Voice treatment (LSVT) and swallowing in Parkinson's disease. *Movement Disorders* 1998;**13**(Supplement 2):121.

Patti 96 {published data only}

* Patti, F, A. Reggio, F. Nicoletti, T. Sellaroli, G. Deinite, Fr. Nicoletti. Effects of rehabilitation therapy on parkinsonians' disability and functional independence. *Journal of Neurologic Rehabilitation* 1996;**10**(4):223-231.

References to ongoing studies

CSDRG Protocol 201 {unpublished data only}

THE SWALLOWING TRIAL.

Randomised study of two interventions for liquid aspiration: short-term and long-term effects.

CSDRG Protocol 201. Ongoing study Currently recruiting patients..

Additional references

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Clarke 1995

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Clarke 1998

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Begg, C, M. Cho, S. Eastwood, R. Horton, D. Moher, I. Olkin, R. Pitkin, D. Rennie, K. F. Schultz, D. Simel, D. F. Stroup. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *Journal of the American Medical Association* 1996;**276**(8):637-639.

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Oxtoby M. Parkinson's disease patients and their social needs. Parkinson's Disease Society 1982.

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Robbins JA, Logemann JA, Kirshner HS. Swallowing and speech production in Parkinson's disease. *Annals of Neurology* 1986;**19**:283-287. [MEDLINE: 86185374]

Yarrow 1999

Yarrow S. Members' 1998 survey of the Parkinson's Disease Society of the United Kingdom. In: Percival R, Hobson P editor(s). Parkinson's disease: Studies in psychological and social care. Leicester: BPS Books, 1999:79-92.

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion	
El-Sharkawi 98	This was an uncontrolled trial examining the efficacy of the Lee Silverman Voice Therapy (LS) method on 8 patients with idiopathic Parkinson's disease and a swallowing disorder. They re a positive effect for LSVT when compared to the untreated baseline levels. This study is mentas it is the only study found examining speech and language therapy's effect on swallowing oders.	
Patti 96	This RCT examined the efficacy of a program of rehabilitation therapy on inpatients. As part of the therapy patients had their swallowing assessed and if there were difficulties they were treated by a	

^{*} Indicates the major publication for the study



Study	Reason for exclusion
	speech and language therapist. It was not made clear how many of the patients in the trial received this swallowing therapy. Also all of the outcome measures were physiotherapeutic in nature so this trial is assessed in the 'Physiotherapy for patients with Parkinson's disease' Cochrane review.

Characteristics of ongoing studies [ordered by study ID]

CS	DKG	Pro	otoco	1201

Trial name or title	THE SWALLOWING TRIAL. Randomised study of two interventions for liquid aspiration: short-term and long-term effects. CSDRG Protocol 201	
Methods		
Participants	Aiming to recruit 987 patient for Part I of the trial and retain 740 for Part II. Expecting to recruit 80% demented and 20% Parkinsonian patients. Inclusion criteria: Patients with either dementia o Parkinson's disease, age 50-95, with suspected dysphagia with possible aspiration with liquids, living in a residential setting. Exclusion criteria: Smokers, drinkers, head or neck cancer or deformaties, >20 year history of ID-DM, other neurological diagnosis (except PD with multi-infarct dementia), had pneumonia within last 6 weeks, have a nasogasric tube or tracheotomy.	
Interventions	A. Chin down posture B. Liquid thickened to nectar or honey viscocity.	
Outcomes	Rate of aspiration Rate of pneumonia	
Starting date	Currently recruiting patients.	
Contact information	Jaqueline A. Hind, Regional Principal Investigator, Swallowing Clinical Trial, Department of Medicine, University of Wisconsin Medical School, VAMC-GRECC 11G, 2500 Overlook Terrace, Madison, WI 53705, USA. Tel: (608) 256 1901 ext. 1125 Fax: (608) 280 7023 E-mail: jahind@facstaff.wisc.edu	

WHAT'S NEW

Date	Event	Description
13 November 2008	Amended	Converted to new review format.



HISTORY

Protocol first published: Issue 4, 2000 Review first published: Issue 1, 2001

Date	Event	Description
22 November 2000	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

K H O Deane carried out the majority of the searching for eligible studies. All reviewers were involved in the determination of which studies were eligible for the review. All reviewers were involved in the writing of the review. K H O Deane was the primary author.

DECLARATIONS OF INTEREST

None.

SOURCES OF SUPPORT

Internal sources

• No sources of support supplied

External sources

• NHS Research and Development Programme for People with Physical and Complex Disabilities; Project PCD2/A1/250, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Deglutition; Deglutition Disorders [etiology] [*rehabilitation]; Parkinson Disease [*complications]; Physical Therapy Modalities; Randomized Controlled Trials as Topic

MeSH check words

Humans