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Interventions for dysphagia in acute stroke (Review)

Bath PMW, Bath-Hextall FJ, Smithard DG

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2008, Issue 3

http://www.thecochranelibrary.com
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Interventions for dysphagia in acute stroke (Review)

Bath PMW, Bath-Hextall FJ, Smithard DG

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ABSTRACT

Background
It is unclear how dysphagic patients should be fed and treated after acute stroke.

Objectives
The objective of this review was to assess the effect of different management strategies for dysphagic stroke patients, in particular how and when to feed, whether to supplement nutritional intake, and how and whether to treat dysphagia.

Search strategy
We searched the Cochrane Stroke Group trials register, Medline, Embase, ISI, and existing review articles. We contacted researchers in the field and equipment manufacturers. Date of the most recent searches: March 1999.

Selection criteria
Unconfounded truly or quasi randomised controlled trials in dysphagic patients with acute/subacute (within 3 months) stroke.

Data collection and analysis
Three reviewers independently applied the trial inclusion criteria. Two reviewers assessed trial quality and extracted the data.

Main results
Percutaneous endoscopic gastrostomy (PEG) versus nasogastric tube (NGT) feeding: two trials (49 patients) suggest that PEG reduces end-of-trial case fatality (Peto Odds Ratio, OR 0.28, 95% CI 0.09 to 0.89) and treatment failures (OR 0.10, 95% CI 0.02 to 0.52), and improves nutritional status, assessed as weight (Weighted Men Difference, WMD +4.1 kg, 95% CI -4.3 to +12.5), mid-arm circumference (WMD +2.2 cm, 95% CI -0.5 to +4.9) or serum albumin (WMD + 7.0 g/l, 95% CI +4.9 to +9.1) as compared with NGT feeding; two larger studies are ongoing. Timing of feeding: no completed trials; one large study is ongoing. Swallowing therapy for dysphagia: two trials (85 patients) suggest that formal swallowing therapy does not significantly reduce end-of-trial dysphagia rates (OR 0.55, 95% CI 0.18 to 1.66). Drug therapy for dysphagia: one trial (17 patients); nifedipine did not alter end-of-trial case fatality or the frequency of dysphagia. Nutritional supplementation: one trial (42 patients) found a non-significant trend to a lower case fatality, and significantly increased energy and protein intake; one large trial is ongoing and data is awaited from two other studies. Fluid supplementation: one trial (20 patients) found that supplementation did not alter the time to resolution of dysphagia.

Authors' conclusions
Too few studies have been performed, and these have involved too few patients. PEG feeding may improve outcome and nutrition as compared with NGT feeding. Further research is required to assess how and when patients are fed, and the effect of swallowing or drug therapy on dysphagia.

PLAIN LANGUAGE SUMMARY

Strategies to feed and treat people with swallowing difficulties after a stroke (dysphagia)
Difficulties in swallowing occur in up to half of people experiencing a non-fatal stroke. Although some spontaneously recover this function in the first two weeks, many continue to have problems that interfere with physical function, nutrition, recovery and quality of life. Because of the inability to swallow safely, fluid can also get into the airways causing chest infections and pneumonia. People can be fed through a tube, inserted either up the nose and into the stomach (nasogastric tube) or through the skin of the abdomen into the stomach (percutaneous endoscopic gastrostomy). Nasogastric tubes are easy to insert but many people find them uncomfortable and pull them out. Two controlled trials (49 patients) looked at the effectiveness of the two types of feeding tubes. The tube through the abdomen was associated with fewer deaths and treatment failures. This tube does require an operation and may be associated with chest infections and infection around the insertion site but does not irritate the patient. From two trials (85 patients), formal swallowing therapy did not significantly reduce dysphagia compared with standard treatment and in 17 patients the drug nifedipine was ineffective.

**BACKGROUND**

Dysphagia is common after stroke involving between 27% and 50% of patients (Gordon 1987; Wolfe 1993; Odderson 1995). About one half of dysphagic patients either die or recover spontaneously within the first 14 days of stroke onset leaving half with swallowing deficits that can significantly impair function, recovery and quality of life (Barer 1989). Complications of dysphagia include aspiration leading to chest infection and pneumonia (Brin 1988; Smithard 1996; Teasell 1996; Daniels 1998), malnutrition, increased length of hospital stay and re-admission to hospital (Smithard 1993; Odderson 1995; Smithard 1996). As a result, dysphagia is associated with an increased risk of death (Smithard 1996). Nutritional deficits are known to be prevalent in stroke patients at the time of admission and during their hospital stay (Axlsson 1989; Gariballa 1998a). Malnutrition is associated with an increased mortality and may impair recovery and increase length of hospital stay thereby increasing costs (Smithard 1993; Gariballa 1998a). Thus, both dysphagia and malnutrition are risk factors for poor outcome after stroke. Techniques for treating dysphagia, generally administered by Speech and Language Therapists (SLT), have been described involving either ‘direct’ or ‘indirect’ strategies (Logemann 1993). Direct techniques include modification of food consistency (Logemann 1991). Indirect strategies include stimulation of oral and pharyngeal structures (Lazarra 1986). However, it remains unclear whether patients managed using such techniques fare better than those receiving no specific dysphagia therapy. Dysphagic stroke patients may be fed intravenously (parenteral nutrition) or enteral feeding, the latter via either a nasogastric tube (NGT) or percutaneous endoscopic gastrostomy (PEG) feeding tube. Insertion of a NGT is easy, quick, relatively non-invasive, requires little training, and has a negligible mortality (O’Mahony 1995); however, many patients find NGTs uncomfortable and repeatedly pull the tube out resulting in interrupted feeding and the potential for malnutrition. In contrast, PEG requires an invasive procedure with insertion of the feeding tube through the anterior abdominal wall, an operation which can be complicated by bleeding, peritonitis or perforation of other abdominal organs. PEG may be associated with chest infections, local infection around the insertion site, and tubes being pulled out (Wanklyn 1995).

However, PEG is less irritating and more cosmetically acceptable to patients; PEG also appears to lead to superior feeding in respect of weight maintenance and nutritional status, at least in patients with long-term neurogenic dysphagia, e.g. persistent vegetative state and traumatic brain damage (Wicks 1992). The relative merits of PEG and NGT, and when to commence feeding, have been assessed in a qualitative review (O’Mahony 1995). However, it remains unclear whether, firstly, PEG is superior to NGT feeding in patients with dysphagia secondary to stroke, and secondly, when feeding should be commenced following stroke onset. Intravenously feeding of dysphagic patients is generally unnecessary in view of its cost, invasive nature and risk of infection, except in patients with enteral dysfunction. This Cochrane systematic review assessed randomised controlled trials, in acute stroke, of i) therapy for dysphagia, and ii) feeding strategies including NGT and PEG, and timing.

**OBJECTIVES**

To determine, separately in dysphagic and non-dysphagic stroke patients: i) how and when to feed; ii) what, and how much, food and fluids to administer; iii) whether therapy improves swallowing and clinical outcome.

**CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW**

Types of studies

All unconfounded truly or quasi randomised controlled trials involving patients with acute stroke and comparing:

In dysphagic patients:

- i) formal swallowing assessment versus no (or limited) assessment, or
- ii) formal swallowing treatment versus no (or limited) treatment (just assessment), or
- iii) early feeding versus late feeding, or
- iv) parenteral versus enteral feeding, or
- v) PEG versus NGT feeding, or

- e) therapy for dysphagia, and
- f) feeding strategies including NGT and PEG, and timing.

**Types of outcome measures**

- Patient-derived measures of swallowing function and feeding.
- Clinical outcome.

**Types of studies**

- Randomised controlled trials of dysphagia therapy, or
- Randomised controlled trials of feeding strategies, or
- Randomised controlled trials of swallowing assessment, or
- Randomised controlled trials of treatment versus no (or limited) treatment (just assessment).

**Types of participants**

- Stroke population.
- Non-dysphagic stroke population.
- Dysphagic stroke population.

**Types of intervention**

- Dysphagia therapy.
- Feeding strategies.
- Swallowing assessment.
- Treatment versus no (or limited) treatment (just assessment).

**Types of control**

- No intervention.
- Limited intervention.
- Standard intervention.

**Types of comparisons**

- Therapy versus control.
- Dysphagia therapy versus dysphagia therapy.
- Parenteral feeding versus enteral feeding.
- Early feeding versus late feeding.
- Therapy versus no (or limited) therapy.
- Assessment versus no (or limited) assessment.

**Types of inclusion**

- Randomised controlled trials of single feeding tube type versus another feeding tube type.
- Randomised controlled trials of single swallowing assessment method versus another swallowing assessment method.
- Randomised controlled trials of single treatment versus another treatment.

**Types of exclusion**

- Observational studies.
- Case studies.
- Case series.
- Uncontrolled trials.
- Non-randomised trials.
- Single case studies.
- Conference proceedings.

**Types of language**

- English.
- All languages.

**Types of additional search**

- Electronic databases.
- Handsearching.
- Reviewers' personal files.
vi) types of fluids.

In non-dysphagic subjects:

i) nutritional supplementation versus no supplementation.

Trials were excluded if they recruited patients after three months of stroke onset or if they involved a large proportion of patients with non-stroke causes of dysphagia.

Types of participants

Patients with acute stroke whether of ischaemic or haemorrhagic type. Dysphagia had to be diagnosed either clinically or using videofluoroscopy. Trials assessing nutritional supplementation could include dysphagic or non-dysphagic patients.

Types of intervention

Four main types of intervention were analysed:

i) the effect of feeding route, including PEG, NGT, intravenous and subcutaneous; or

ii) the timing of feeding; or

iii) the effect of nutritional and fluid supplementation; or

iv) the effect of formal swallowing therapy.

Types of outcome measures

Information on the following outcome measures was obtained for each trial, where available:

i) case fatality at end of trial;

ii) deterioration (within 4 weeks) - judged using a stroke neurological impairment scale;

iii) late disability - assessed using an ADL scale;

iv) resumption of normal feeding - judged as oral intake of normal quality food;

v) length of hospital stay;

vi) discharge destination;

vii) quality of life;

viii) frequency of aspiration;

ix) nutritional measures, e.g. weight, arm circumference, serum albumin;

x) pneumonia - determined clinically or radiographically;

xi) feeding tube failures;

xii) resolution of dysphagia, i.e. resumption of normal feeding.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Stroke Group methods used in reviews.

This review has drawn on the search strategy developed for the Stroke Group as a whole. All possible relevant trials were identified in the Specialised Register of Controlled Trials (see review group details for more information). The register was last searched by the Stroke Group Co-ordinator for this review in March 1999 using a search strategy designed to identify all relevant trials. We also contacted the Special Interest Group in Adult Acquired Dysphagia of the Royal College of Speech and Language Therapists, and companies who manufacture PEG/NGT related equipment to see if they had information on ongoing trials of dysphagia treatment or feeding route.

METHODS OF THE REVIEW

Three of us independently selected trials for inclusion in the review and extracted data from the trial reports. We then sought additional information from the principal investigators of the trials that appeared to meet the inclusion criteria. We noted information on randomisation, blinding, analysis, the number of patients randomised, time of treatment from stroke, type of dysphagia therapy, patient withdrawals and losses to follow-up, and relevant outcomes (defined above). We tested for heterogeneity and calculated a weighted estimate of the typical treatment effect across trials using the odds ratio (OR) for binary data and weighted mean difference (WMD) for continuous data using the Cochrane statistical package, “Review Manager” (Revman 3.1 for Mac). We performed sensitivity analyses relating to method of randomisation (true versus quasi), outcome blinding, stroke type (infarct versus haemorrhage), and time to treatment.

DESCRIPTION OF STUDIES

PEG versus NGT feeding

Four trials comparing PEG and NGT feeding were identified (Baeten 1992; Park 1992; Norton 1996; Bath 1997) of which two were excluded because most patients did not have dysphagia secondary to stroke (Baeten 1992; Park 1992). Norton and colleagues studied 30 patients at 2 centres (Norton 1996). The unpublished study of Bath et al was a factorial trial of PEG versus NGT and formal swallowing therapy versus conservative swallowing management (Bath 1997). This trial planned to enrol 160 patients but ceased early because of the high study case fatality rate (58%). The studies of Norton et al and Bath et al recruited a total of 49 patients (Norton 1996; Bath 1997). Two other trials are ongoing: FOOD and PEGASUS (FOOD; PEGASUS).

Timing of feeding

No completed RCTs assessing this question were found. One trial is ongoing (FOOD). A study assessing the effect of early versus later enteral feeding on hospital length of stay was excluded because it was not randomised (Nyswonger 1992).

Swallowing therapy for dysphagia

Four trials assessing the effect of swallowing therapy were found (Rosenbek 1991; DePippo 1994; Sukthankar 1994; Mann 1997). Three of these were excluded for reasons of (i) crossover design (Rosenbek 1991), (ii) no control group (DePippo 1994), and (iii) mixed aetiology of dysphagia (Sukthankar 1994). The study of
Mann is assessing the effect of graded amounts of swallowing therapy in 300 patients; interim results were published on 99 patients (Mann 1997).

Drug therapy for dysphagia
Only one study was identified which involved administration of nifedipine (a dihydropyridine calcium channel blocker) to 17 patients (Perez 1997).

Nutritional supplementation
Four studies were found which assessed the effect of calorie supplementation. One study assessed non-dysphagic patients with impaired nutritional status (Gariballa 1998). Correspondence is awaited from two sets of authors (Honda 1990; Davalos 1994) while one trial is ongoing (FOOD).

Fluid supplementation
One study was found which compared administering free water and thickened fluids with thickened fluids alone in patients known to aspirate thin fluids (Garon 1997).

Miscellaneous studies
Three other studies were identified. The first, a trial comparing hydration routes (intravenous versus subcutaneous) (Challiner 1994), was excluded because no outcome measures relevant to this review were recorded. A second study, assessing the effect of referral to speech & language therapy (SALT), was excluded because it was not randomised (Wimbury 1990). The third study assessed palatal electrical stimulation and was non-randomised (Park 1997).

Definition of patients
Five studies involving “dysphagic” patients gave definitions of dysphagia (expanded definitions are present in the relevant publications):

- “... assessment includes cranial nerve and orofacial examinations and swallow trials on specified consistencies with special reference to those structures, functions and features significant in swallowing, e.g. voice quality.” (Bath 1997);
- “... documented aspiration of thin liquids only, as verified by barium videofluoroscopic swallow evaluation.” (Garon 1997);
- “... clinical and videofluoroscopic evidence of dysphagia...” (Mann 1997);
- “... the absence of a normal gag reflex or the inability to swallow 50 ml of sterile water easily without choking, or both.” (Norton 1996);
- “... who required compensatory techniques and a modified diet to maintain nutrition.” (Perez 1997).

The study of food supplementation did not define impaired nutritional status (Gariballa 1998).

**Methodological Quality**

Four trials involved randomisation by computer thereby ensuring concealment of allocation (Bath 1997; Garon 1997; Mann 1997; Perez 1997). Randomisation procedures were unclear in two studies (Norton 1996; Gariballa 1998). Baseline prognostic factors were similar in three trials (Garon 1997; Perez 1997; Gariballa 1998); matching in the other three studies was unclear (Norton 1996; Bath 1997; Mann 1997). Outcomes were assessed in a blinded fashion in two trials (Mann 1997; Perez 1997) and unblinded in the other two studies (Norton 1996; Bath 1997); outcome blinding was unclear in two trials (Garon 1997; Gariballa 1998).

**Results**

No sensitivity analyses were performed.

PEG versus NGT feeding
PEG was associated with significantly lower end-of-trial case fatality rates (odds ratio, OR 0.28, 95% CI 0.09 to 0.89) and treatment failures (OR 0.10, 95% CI 0.02 to 0.52) than NGT feeding in the two trials comparing these (Norton 1996; Bath 1997). PEG feeding was also associated with improved measures of nutrition, including higher weight (weighted mean difference, WMD +4.1 kg, 95% CI -3.0 to +11.2), mid-arm circumference (WMD +2.2 cm, 95% CI -0.5 to +4.9) and serum albumin concentration (WMD +7.0 g/l, 95% CI +4.9 to +9.1) although only the last was significant. However, the confidence intervals were wide for all measures due to the small number of subjects (49) studied.

Timing of feeding
No data available.

Nutritional supplementation
Data only available from one small trial (Gariballa 1998). Nutritional supplementation was associated with a non-significant trend to a lower case fatality, and significantly increased energy and protein intake.

Fluid supplementation
Data only available from one small trial (Garon 1997). Fluid supplementation did not alter the time to resolution of dysphagia.

Swallowing therapy for dysphagia
Formal swallowing therapy was associated with a non-significant reduction in end-of-trial dysphagia (OR 0.55, 95% CI 0.18 to 1.66) as compared with standard care in the two trials comparing these (Bath 1997; Mann 1997).

Drug therapy for dysphagia
Data only available from one small trial (Perez 1997). Drug therapy with nifedipine did not alter end-of-trial case fatality or the frequency of dysphagia.
DISCUSSION

Only six studies, all small, were identified which assessed feeding and swallowing treatment strategies in stroke patients. Five of these studies involved patients with dysphagia; one trial studied nondysphagic patients. It has been proposed that other RCTs may have been performed but never published with the results now lost in “file drawers” (Koretz 1996).

Limited evidence from two trials suggests that PEG feeding may be associated with a better outcome and nutrition than NGT feeding (Kearns 1996). However, no data are available on when feeding should be commenced or whether nutritional intake should be supplemented.

The large ongoing FOOD trial should add considerably to knowledge on the timing and route of feeding in dysphagic stroke patients. This study is also addressing whether oral supplemental feeding benefits non-dysphagic stroke patients, a question addressed in one existing small trial. One small trial assessed the effect of giving water to patients who aspirate thin fluid.

Only two trials have assessed the effect of formal swallowing therapy on resolution of dysphagia and no reliable conclusions can be drawn.

AUTHORS’ CONCLUSIONS

Implications for practice

Too few studies have been performed and patients included to allow definitive statements to be made on management and feeding strategies for dysphagic stroke patients.

Implications for research

It is evident that very few RCTs have examined the management of feeding in stroke patients and the treatment of dysphagia. The questions of (i) whether PEG is superior to NGT feeding, (ii) whether supplemental feeding is beneficial, and (iii) when feeding should commence, are now being tested in two trials (FOOD, PEGASUS). However, whether swallowing or drug therapy improve dysphagia remains unclear and further research needs to be initiated.

FEEDBACK

Length of stay

Summary

The graph in Metaview for ‘length of stay in hospital’ in the comparison of feeding routes does not have any data in it.

Author’s reply

‘Length of stay in hospital’ was a pre-planned outcome measure. Unfortunately, no data was available from any of the included trials. Hence, this comparison should have been removed from Metaview, and will be in the next version of the review unless new data become available.

Contributors

Mark Fenton

POTENTIAL CONFLICT OF INTEREST

Professor Bath and Dr Smithard have been involved in trials included in this review (Bath 1997; Perez 1997). No pharmaceutical companies, manufacturers of feeding equipment, or other commercial concerns, were involved in the data analysis or its interpretation.

ACKNOWLEDGEMENTS

We thank Ms Jean Kerr and Ms Morwenna Collins, both Speech & Language Therapists, for their help with the early stages of the project. We also thank the Cochrane Stroke Review Group for helping identify trials, and their editors and external assessor for comments on the review. Several trialists and other interested healthcare staff reviewed the draft manuscript and made comments - we thank each of them: CGMI Baeten (Netherlands), MS Dennis (UK), BR Garon (USA), GJ Hankey (Australia), GKT Holmes (UK), PR Mills (UK), B Norton (UK), C Ormiston (USA), J Rosenbek (USA), G Vanhooren (Belgium). Finally, we are grateful to the funding bodies who supported this research. Naturally any mistakes are our own. We would be very grateful to be informed of any other related completed or ongoing trials.

SOURCES OF SUPPORT

External sources of support

- South Thames NHS Executive UK
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- Wolfson Foundation UK
- Stroke Association UK

Internal sources of support

- King’s College Hospital Audit Committee UK
References to studies included in this review

Bath 1997 [unpublished data only]

Gariballa 1998 [published data only]

Garon 1997 [published and unpublished data]

Mann 1997 [published and unpublished data]

Norton 1996 [published data only]

Perez 1997 [published and unpublished data]

Rosenbek 1991

Sukthankar 1994

Wimbury 1990

References to studies awaiting assessment

Davalos 1994

Honda 1990

References to ongoing studies

**FOOD**

Dennis M. FOOD trial (Feed Or Ordinary Diet): a multicentre trial to evaluate various feeding policies in patients admitted to hospital with a recent stroke. *Stroke* 1998; 29:551.

The International Stroke Trials Collaboration. FOOD Trial (Feed Or Ordinary Diet). Protocol.

**PEGASUS**

Additional references

Axelsson 1989

Barer 1989

Brin 1988

Daniels 1988

Gariballa 1998a

Gordon 1987

Kearns 1996

Koretz 1996

Lazarra 1986

Logemann 1991

Logemann 1993

O’Mahony 1995

Odderson 1995

Smithard 1993

Smithard 1996

Teasell 1996

Wanklyn 1995

Wicks 1992

Wolfe 1993

* Indicates the major publication for the study

TABLES

Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Bath 1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>Computer-generated randomisation by minimisation (Medistat software). Outcomes assessed unblinded. Analysis by ITT. Crossovers: 3 NGT to PEG, 0 PEG to NGT. Balancing of baseline prognostic factors between treatment groups unclear.</td>
</tr>
<tr>
<td>Participants</td>
<td>1 centre in UK. 19 patients: 8 male, 11 female; mean age 77 (SD 11) years, 13 ischaemic stroke, 6 haemorrhagic stroke; 100% CT. Enrollment within 2 weeks of stroke onset.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Factorial trial: PEG versus NGT; intensive versus conservative swallowing therapy PEG:NGT: up to 3 NG tubes. Intensive swallowing therapy: as for conservative, plus voluntary control (tongue-holding), sensory</td>
</tr>
</tbody>
</table>
Characteristics of included studies (Continued)


| Outcomes | Primary outcomes: Resumption of safe feeding at 12 weeks, weight loss < 5% at 6 weeks, discharge by 6 weeks. Secondary outcomes: impairment, disability, handicap, quality of life, tube failures, chest infection, oropharyngeal delay time (by videofluoroscopy) at 4 weeks. |
| Notes | Exclusions: orogastrointestinal disease, concurrent severe illness, coagulopathy, pre-morbid dependency, severe dementia, psychiatric illness. Follow-up: 3 months. |

Allocation concealment A – Adequate

| Study | Gariballa 1998 |
| Participants | 1 centre in UK. 42 non-dysphagic patients with impaired nutritional status: gender ratio and mean age unclear. All ischaemic stroke. Enrollment within 1 week of stroke onset. |
| Interventions | Rx: daily enteral sip feeding and usual hospital food. C: usual hospital food. Treatment for 4 weeks. |
| Outcomes | Primary outcomes: energy intake and nutritional status. Secondary outcomes: 3 month case fatality. |
| Notes | Exclusions: dysphagia, normal nutritional status, haemorrhagic stroke. Follow-up: 3 months. |

Allocation concealment B – Unclear

| Study | Garon 1997 |
| Methods | Computer-generated randomisation. Outcomes assessed unblinded. Analysis by ITT. No crossovers, exclusions post-randomisation, or losses to follow-up. Baseline prognostic factors balanced between treatment groups. |
| Participants | 1 centre in USA. 20 patients with documented aspiration of thin fluids only: 14 male, 6 female; mean age 76.8 years. Stroke types unclear. Enrollment within 3 weeks of stroke onset: mean 12.8 days, range 4-19 days. |
| Interventions | Rx: thickened fluids and free water. C: thickened fluids only. Treatment until aspiration resolved (7-64 days). |
| Outcomes | Outcomes: development of pneumonia, dehydration, and satisfaction. Time to resolution of aspiration to thin fluids. |
| Notes | Exclusions: aspiration to thickened fluids. Follow-up: 30 days beyond resolution of aspiration. |

Allocation concealment A – Adequate

| Study | Mann 1997 |
| Participants | 1 centre in Australia. 99 patients, gender ratio unclear, mean age 73 years. Stroke types unclear. Enrollment within 2 weeks of stroke onset: mean 2 days, range 0-12 days. |
| Interventions | Rx 1: standardised high intensity swallowing therapy; Rx 2: standardised low intensity swallowing therapy; C: usual care. Treatment for up to 1 month. |
| Outcomes | Outcomes: time to return to normal diet; aspiration pneumonia. |
| Notes | Trial continues to 300 patients. Interim results published at 99 patients. Follow-up: 6 months. |

Allocation concealment A – Adequate
Study Norton 1996

Methods Method of randomisation unclear, code in sealed envelopes. Outcome assessments unblinded. Analysis by ITT. No crossovers, exclusions post-randomisation, or losses to follow-up. Balancing of baseline prognostic factors for treatment groups unclear.

Participants 2 centres in UK. 30 subjects: 11 male, 19 female; mean age 77. Stroke types not given; CT performed in 25 patients. Enrollment 14 (+/- 3) days post-admission. All patients were unconscious at admission with a dense hemiplegia. Dysphagia assessed by absence of normal gag reflex or inability to swallow 50 ml of sterile water without choking.

Interventions PEG tube (12 French gauge Fresenius or 24 French gauge Wilson Cook) inserted using percutaneous approach with pull-through. Antibiotic (cefuroxine 750mg iv) given prophylactically; sedation with 5-10mg diazepam. NGT (Flocare 500). All patients got standard enteral feed (Nutrison). Feed delivered via Flowcare 500 at 50ml/h for first 24 hours increased to 100ml/hour. Patients fed in a semi-recumbent position for 6 weeks.


Notes Exclusions: previous history of gastrointestinal disease, unfit for endoscopy or iv sedation. Follow-up: 6 weeks.

Allocation concealment B – Unclear

Study Perez 1997

Methods Computer-generated randomisation. Triple-blind trial; outcomes assessed by blinded therapist. Analysis by ITT. No crossovers or losses to follow-up. One subject withdrawn with heart failure (nifedipine group). Baseline prognostic factors balanced between treatment groups.

Participants 1 UK centre. 17 patients; nifedipine: 4 male, 4 female, mean age 77 (SD 7); placebo: 4 male, 5 female, mean age 77 (SD 6). All first ischaemic stroke, 100% CT. Enrollment 2 weeks after stroke.


Outcomes Primary outcome: clinical improvement in swallowing. Other outcomes: incidence of silent aspiration, pharyngeal transit time and response duration, swallowing delay (all assessed by videofluoroscopy), death.

Notes Exclusions: unable to sit, high clinical risk of aspiration, receptive dysphasia, cognitive impairment, pre-stroke dysphagia, existing neurological or psychiatric disease, current treatment with calcium channel blockers or aminophylline. Follow-up: 4 weeks. 1 patient withdrawn with heart failure.

Allocation concealment A – Adequate

C, control group; CT, computer tomography; ITT, intention to treat analysis; NGT, nasogastric tube; OR, odds ratio; PEG, percutaneous endoscopic gastrostomy tube; Pl, placebo group; Rx, treatment group; SALT, speech & language therapist (speech pathologist); SD, standard deviation; WMD, weighted mean difference.

Characteristics of excluded studies

Study Reason for exclusion

Baeten 1992 RCT comparing PEG and NGT feeding in 90 dysphagic patients with neurological problems (N=42, 47%), ear nose and throat disease (N=39, 43%) or post-surgery (N=9, 10%). Study excluded because most patients did not have stroke-related dysphagia.

Challiner 1994 RCT comparing hydration routes in 34 elderly acute stroke patients with either impaired consciousness or dysphagia. Group 1: subcutaneous hydration, N=17; Group 2: intravenous hydration, N=17. 2 litres of dextrose-saline/day given for 3 days. No difference in serum osmolality; subcutaneous hydration cheaper. Study excluded because outcome measures (plasma osmolality and sodium, and treatment cost) not relevant to this review.

DePippo 1994 RCT comparing three active interventions in 115 dysphagic stroke patients taught compensatory swallowing techniques. Group 1: patient/family choice of diet and food consistency, N=38; Group 2: therapist prescribed diet
Characteristics of excluded studies (Continued)

and food consistency, N=38; Group 3: therapist prescribed diet and food consistency, with daily reinforcement of compensatory swallowing techniques, N=39. Study excluded because no control group.

Nyswonger 1992 Retrospective case control study in 52 dysphagia stroke patients comparing those who were fed, or not, within 72 hours of admission. Length of stay was shorter in those fed early, 20.1 days versus 29.8 days. Study excluded because not RCT.

Park 1992 RCT comparing PEG and NGT feeding in 40 dysphagic patients. Study excluded because: (i) only 18 patients (45%) had cerebrovascular disease; (ii) only 5 of these were enrolled within 2 months of stroke onset; (iii) individual patient data unavailable so not possible to analyse subgroup of appropriate patients.

Park 1997 Single case study of oral (palatal) electrical stimulation in 4 stroke patients with chronic dysphagia. Study excluded because: (i) non RCT; (ii) non acute patients.

Rosenbek 1991 Crossover trial of thermal stimulation in 7 male dysphagic patients with multiple previous strokes. Study excluded because: (i) crossover trial; (ii) only 2 of 7 patients recruited within 3 months of stroke onset; (iii) randomisation status unclear.

Sukthankar 1994 RCT comparing swallowing therapy in 9 patients with dysphagia secondary to stroke or head injury: Group 1: regular therapy, N=4; Group 2: regular therapy and oral exercises, N=2; Group 3: regular therapy and oral exercises with visual and audio biofeedback, N=3. Study excluded because: (i) dysphagia of mixed aetiology; (ii) outcome measures (tongue and lip motor force) not relevant to this review.

Wimbury 1990 Non-randomised comparison of speech & language therapy (SALT) referrals for assessment of speech and swallowing in elderly patients, 40% of whom had had a stroke. Group 1: 2 wards who filled in a questionnaire relating to speech and swallowing problems in 162 admissions; Group 2: 2 wards who did not fill in a questionnaire in 233 admissions. Study excluded because: (i) non randomised; (ii) most patients not stroke.

NGT, nasogastric tube; PEG, percutaneous endoscopic gastrostomy; RCT, randomised controlled trial.

Characteristics of ongoing studies

<table>
<thead>
<tr>
<th>Study</th>
<th>FOOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial name or title</td>
<td>FOOD (Feed or ordinary Diet). Part of the International Stroke Trials Collaboration</td>
</tr>
<tr>
<td>Participants</td>
<td>Acute stroke &lt; 1 week</td>
</tr>
<tr>
<td>Size:</td>
<td>9000</td>
</tr>
<tr>
<td>(a)</td>
<td>6000</td>
</tr>
<tr>
<td>(b)</td>
<td>2000</td>
</tr>
<tr>
<td>(c)</td>
<td>1000</td>
</tr>
<tr>
<td>Interventions</td>
<td>(a) oral supplemental feeding</td>
</tr>
<tr>
<td></td>
<td>(b) early versus late tube feeding</td>
</tr>
<tr>
<td></td>
<td>(c) PEG tube versus NG tube feeding</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Primary:</td>
</tr>
<tr>
<td></td>
<td>(a) dependence (modified Rankin score &gt;=3)</td>
</tr>
<tr>
<td></td>
<td>(b,c) severe dependence (modified Rankin score &gt;=4)</td>
</tr>
<tr>
<td>Secondary outcomes:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>case fatality at 1 and 6 months, length of stay in hospital, number of days of tube feeding, adverse effects of feeding regimes, premature cessation of feeding regimes, quality of life</td>
</tr>
<tr>
<td>Starting date</td>
<td>1996</td>
</tr>
<tr>
<td>Contact information</td>
<td>Dr M Dennis</td>
</tr>
<tr>
<td>FOOD Trial Co-ordinating Centre, Neurosciences Trials Unit, Dept of Clinical Neurosciences, Western General Hospital, Edinburgh EH4 2XU. Tel: +44 131 537 3126; Fax: +44 131 332 5150; email: <a href="mailto:msd@skull.dcn.ed.ac.uk">msd@skull.dcn.ed.ac.uk</a></td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td>Funding:</td>
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Characteristics of ongoing studies (Continued)

NHS R&D HTA (UK); Stroke Association (UK); Chief Scientist Office, Scottish Executive; Chest Heart and Stroke Scotland (UK)

<table>
<thead>
<tr>
<th>Study</th>
<th>PEGASUS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial name or title</strong></td>
<td>Percutaneous Endoscopic Gastrostomy After Stroke</td>
</tr>
<tr>
<td><strong>Participants</strong></td>
<td>Dysphagia at 5-7 days post stroke</td>
</tr>
<tr>
<td><strong>Size</strong></td>
<td>400</td>
</tr>
<tr>
<td><strong>Interventions</strong></td>
<td>PEG versus conservative (limited oral, NGT, IV) feeding for 15 days, then best medical treatment</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td>Primary outcomes: Oxford Handicap Score at 6 months Secondary outcomes: mortality, chest infection, nutritional status, length of stay, discharge disposition</td>
</tr>
<tr>
<td><strong>Starting date</strong></td>
<td>1995</td>
</tr>
</tbody>
</table>

Notes

**ANALYSES**

Comparison 01. Feeding route

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Case fatality at end of trial</td>
<td>2</td>
<td>49</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.28 [0.09, 0.89]</td>
</tr>
<tr>
<td>02 Death or disabled at end of trial</td>
<td>1</td>
<td>19</td>
<td>Peto Odds Ratio 95% CI</td>
<td>Not estimable</td>
</tr>
<tr>
<td>03 Feeding tube in situ at end of trial</td>
<td>1</td>
<td>7</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.17 [0.00, 9.12]</td>
</tr>
<tr>
<td>04 Weight at end of trial (LVCF)</td>
<td>2</td>
<td>34</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>4.08 [-4.32, 12.48]</td>
</tr>
<tr>
<td>05 Mid-arm circumference (LVCF)</td>
<td>2</td>
<td>35</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>2.20 [-0.48, 4.89]</td>
</tr>
<tr>
<td>06 Albumin (LVCF)</td>
<td>2</td>
<td>40</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>7.00 [4.86, 9.14]</td>
</tr>
<tr>
<td>07 Treatment failure</td>
<td>2</td>
<td>49</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.10 [0.02, 0.52]</td>
</tr>
<tr>
<td>08 Missed feed (at least one day)</td>
<td>1</td>
<td>30</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.04 [0.01, 0.20]</td>
</tr>
<tr>
<td>09 Length of stay in hospital</td>
<td>0</td>
<td>0</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>Not estimable</td>
</tr>
</tbody>
</table>

Comparison 02. Swallowing therapy

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Case fatality at end of trial</td>
<td>2</td>
<td>36</td>
<td>Peto Odds Ratio 95% CI</td>
<td>1.07 [0.23, 5.04]</td>
</tr>
<tr>
<td>02 Dysphagia at end of trial</td>
<td>3</td>
<td>102</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.55 [0.18, 1.66]</td>
</tr>
<tr>
<td>03 Pharyngeal transit time (seconds)</td>
<td>0</td>
<td>0</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>Not estimable</td>
</tr>
</tbody>
</table>
Comparison 03. Fluid supplementation

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to resolution of dysphagia (days)</td>
<td>1</td>
<td>20</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>-8.10 [-20.84, 4.64]</td>
</tr>
</tbody>
</table>

Comparison 04. Food supplementation

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case fatality at end of trial</td>
<td>1</td>
<td>42</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.25 [0.06, 1.08]</td>
</tr>
<tr>
<td>Energy intake (kcal/day)</td>
<td>1</td>
<td>42</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>723.00 [522.95, 923.05]</td>
</tr>
<tr>
<td>Protein intake (g/day)</td>
<td>1</td>
<td>42</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>21.00 [12.95, 29.05]</td>
</tr>
</tbody>
</table>

INDEX TERMS

Medical Subject Headings (MeSH)
Deglutition Disorders [*etiology; *rehabilitation]; *Enteral Nutrition; Gastrostomy; Intubation, Gastrointestinal; Stroke [*complications; *rehabilitation]

MeSH check words
Humans

COVER SHEET

Title
Interventions for dysphagia in acute stroke

Authors
Bath PMW, Bath-Hextall FJ, Smithard DG

Contribution of author(s)
Philip Bath: conceived and designed the review; undertook searches, analysis of data, interpretation of data, and writing the review.
Fiona Bath: co-ordinated the review; entered data, collected data, and was responsible for data management.
David Smithard: undertook searches, interpretation of data, writing the review, and provided general advice.

Issue protocol first published
1997/1

Review first published
1999/4

Date of most recent amendment
17 August 2005

Date of most recent SUBSTANTIVE amendment
15 June 1999

What's New
Information not supplied by author

Date new studies sought but none found
Information not supplied by author

Date new studies found but not yet included/excluded
Information not supplied by author

Date new studies found and included/excluded
Information not supplied by author
Analysis 01.01. **Comparison 01 Feeding route, Outcome 01 Case fatality at end of trial**

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 01 Case fatality at end of trial

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI (%)</td>
<td>(%)</td>
<td>95% CI</td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norton 1996</td>
<td>2/16</td>
<td>8/14</td>
<td>0.14 [ 0.03, 0.64 ]</td>
<td>59.6</td>
<td></td>
</tr>
<tr>
<td>Bath 1997</td>
<td>6/10</td>
<td>6/9</td>
<td>0.76 [ 0.12, 4.69 ]</td>
<td>40.4</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>26</strong></td>
<td><strong>23</strong></td>
<td><strong>100.0</strong></td>
<td><strong>0.28 [ 0.09, 0.89 ]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 8 (Treatment), 14 (Control)  
Test for heterogeneity chi-square=1.94 df=1 p=0.16 I² =48.3%  
Test for overall effect z=2.15 p=0.03
**Analysis 01.02. Comparison 01 Feeding route, Outcome 02 Death or disabled at end of trial**

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 02 Death or disabled at end of trial

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI (%)</td>
<td></td>
<td>95% CI</td>
</tr>
</tbody>
</table>
| 01 PEG versus NGT  
Bath 1997 | 10/10     | 9/9     | 0.0             | Not estimable |                |

**Total (95% CI)**  
10 9 0.0 Not estimable

Total events: 10 (Treatment), 9 (Control)  
Test for heterogeneity: not applicable  
Test for overall effect: not applicable

---

**Analysis 01.03. Comparison 01 Feeding route, Outcome 03 Feeding tube in situ at end of trial**

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 03 Feeding tube in situ at end of trial

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI (%)</td>
<td></td>
<td>95% CI</td>
</tr>
</tbody>
</table>
| 01 PEG versus NGT  
Bath 1997 | 3/4       | 3/3     | 100.0           | 0.17 [ 0.00, 9.12 ] |                |

**Total (95% CI)**  
4 3 100.0 0.17 [ 0.00, 9.12 ]

Total events: 3 (Treatment), 3 (Control)  
Test for heterogeneity: not applicable  
Test for overall effect z=0.87 p=0.4
### Analysis 01.04. Comparison 01 Feeding route, Outcome 04 Weight at end of trial (LVCF)

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 04 Weight at end of trial (LVCF)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>95% CI</th>
<th>95% CI</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>95% CI (%)</td>
<td></td>
<td>95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norton 1996</td>
<td>13 61.00 (11.00)</td>
<td>8 57.80 (10.00)</td>
<td>84.3</td>
<td>3.20</td>
<td>[ -5.95, 12.35 ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bath 1997</td>
<td>6 59.80 (24.20)</td>
<td>7 51.00 (11.60)</td>
<td>15.7</td>
<td>8.80</td>
<td>[ -12.38, 29.98 ]</td>
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<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>19</strong></td>
<td><strong>15</strong></td>
<td><strong>100.0</strong></td>
<td><strong>4.08</strong></td>
<td><strong>[-4.32, 12.48]</strong></td>
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</table>

Test for heterogeneity chi-square=0.23 df=1 p=0.63 I²=0.0%  
Test for overall effect z=0.95  p=0.3

### Analysis 01.05. Comparison 01 Feeding route, Outcome 05 Mid-arm circumference (LVCF)

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 05 Mid-arm circumference (LVCF)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>95% CI</th>
<th>95% CI</th>
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<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>95% CI (%)</td>
<td></td>
<td>95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norton 1996</td>
<td>13 26.30 (5.30)</td>
<td>8 23.80 (1.80)</td>
<td>73.0</td>
<td>2.50</td>
<td>[-0.64, 5.64 ]</td>
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</tr>
<tr>
<td>Bath 1997</td>
<td>7 27.00 (6.20)</td>
<td>7 25.60 (3.20)</td>
<td>27.0</td>
<td>1.40</td>
<td>[-3.77, 6.57 ]</td>
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</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>20</strong></td>
<td><strong>15</strong></td>
<td><strong>100.0</strong></td>
<td><strong>2.20</strong></td>
<td><strong>[-0.48, 4.89]</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity chi-square=0.13 df=1 p=0.72 I²=0.0%  
Test for overall effect z=1.61  p=0.1

Interventions for dysphagia in acute stroke (Review)  
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### Analysis 01.06. Comparison 01 Feeding route, Outcome 06 Albumin (LVCF)

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 06 Albumin (LVCF)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N</td>
<td>Mean(SD)</td>
<td>95% CI (%)</td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Norton 1996</td>
<td>15</td>
<td>30.10 (3.60)</td>
<td>10</td>
<td>22.30 (2.20)</td>
<td>-88.4</td>
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<tr>
<td>Bath 1997</td>
<td>7</td>
<td>27.90 (6.10)</td>
<td>8</td>
<td>27.00 (6.30)</td>
<td>11.6</td>
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<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>22</strong></td>
<td></td>
<td></td>
<td><strong>18</strong></td>
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</tr>
</tbody>
</table>

Test for heterogeneity chi-square=4.10 df=1 p=0.04 I² =75.6%
Test for overall effect z=6.41 p<0.00001

### Analysis 01.07. Comparison 01 Feeding route, Outcome 07 Treatment failure

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 07 Treatment failure

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI (%)</td>
<td>(%)</td>
<td>95% CI (%)</td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norton 1996</td>
<td>0/16</td>
<td>3/14</td>
<td>51.1</td>
<td>0.10</td>
<td>0.01, 1.05</td>
</tr>
<tr>
<td>Bath 1997</td>
<td>0/10</td>
<td>3/9</td>
<td>48.9</td>
<td>0.09</td>
<td>0.01, 1.03</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>26</strong></td>
<td><strong>23</strong></td>
<td>100.0</td>
<td>0.10</td>
<td>0.02, 0.52</td>
</tr>
</tbody>
</table>

Total events: 0 (Treatment), 6 (Control)
Test for heterogeneity chi-square=0.00 df=1 p=0.97 I² =0.0%
Test for overall effect z=2.73 p=0.006
### Analysis 01.08. Comparison 01 Feeding route, Outcome 08 Missed feed (at least one day)

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 08 Missed feed (at least one day)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/N</td>
<td>n/N</td>
<td>95% CI</td>
<td>(%)</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
<td>0/16</td>
<td>10/14</td>
<td>100.0</td>
<td>0.04 [ 0.01, 0.20 ]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>16</td>
<td>14</td>
<td>100.0</td>
<td>0.04 [ 0.01, 0.20 ]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 0 (Treatment), 10 (Control)  
Test for heterogeneity: not applicable  
Test for overall effect z=4.07  p=0.00005

### Analysis 01.09. Comparison 01 Feeding route, Outcome 09 Length of stay in hospital

**Review:** Interventions for dysphagia in acute stroke  
**Comparison:** 01 Feeding route  
**Outcome:** 09 Length of stay in hospital

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>95% CI</td>
<td>(%)</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>01 PEG versus NGT</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
<td>Not estimable</td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: not applicable  
Test for overall effect: not applicable
### Analysis 02.01. Comparison 02 Swallowing therapy, Outcome 01 Case fatality at end of trial

Review: Interventions for dysphagia in acute stroke
Comparison: 02 Swallowing therapy
Outcome: 01 Case fatality at end of trial

<table>
<thead>
<tr>
<th>Study</th>
<th>n/N</th>
<th>n/N</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>95% CI (%)</td>
<td></td>
<td>95% CI (%)</td>
</tr>
<tr>
<td><strong>01 Drug therapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perez 1997</td>
<td>1/8</td>
<td>1/9</td>
<td>29.1</td>
<td>1.13</td>
<td>[0.06, 19.96]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>8</td>
<td>9</td>
<td>29.1</td>
<td>1.13</td>
<td>[0.06, 19.96]</td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: ( z = 0.09 ) ( p = 0.9 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>02 Swallowing therapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bath 1997</td>
<td>7/11</td>
<td>5/8</td>
<td>70.9</td>
<td>1.05</td>
<td>[0.17, 6.58]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td>11</td>
<td>8</td>
<td>70.9</td>
<td>1.05</td>
<td>[0.17, 6.58]</td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: ( z = 0.05 ) ( p = 1 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>19</td>
<td>17</td>
<td>100.0</td>
<td>1.07</td>
<td>[0.23, 5.04]</td>
</tr>
<tr>
<td>Total events: 8 (); 6 ()</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity chi-square: ( df = 1 ) ( p = 0.96 ) ( \chi^2 = 0.00 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: ( z = 0.09 ) ( p = 0.9 )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Therapy better  Therapy worse
### Analysis 02.02. Comparison 02 Swallowing therapy, Outcome 02 Dysphagia at end of trial

**Review:** Interventions for dysphagia in acute stroke

**Comparison:** 02 Swallowing therapy

**Outcome:** 02 Dysphagia at end of trial

<table>
<thead>
<tr>
<th>Study</th>
<th>n/N</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>01 Drug therapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perez 1997</td>
<td>3/8</td>
<td>35.3</td>
<td>0.51 [0.08, 3.22]</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>35.3</td>
<td>0.51 [0.08, 3.22]</td>
<td></td>
</tr>
<tr>
<td><strong>Total events:</strong></td>
<td>3 (), 5 ()</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for heterogeneity:</strong></td>
<td>not applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong></td>
<td>z=0.72, p=0.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>02 Swallowing therapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bath 1997</td>
<td>3/4</td>
<td>7.7</td>
<td>0.17 [0.00, 9.12]</td>
<td></td>
</tr>
<tr>
<td>Mann 1997</td>
<td>51/63</td>
<td>57.0</td>
<td>0.68 [0.16, 2.93]</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>67</td>
<td>64.7</td>
<td>0.58 [0.15, 2.27]</td>
<td></td>
</tr>
<tr>
<td><strong>Total events:</strong></td>
<td>54 (), 16 ()</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for heterogeneity:</strong></td>
<td>chi-square=0.40, df=1, p=0.53, I²=0.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong></td>
<td>z=0.78, p=0.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>75</td>
<td>100.0</td>
<td>0.55 [0.18, 1.66]</td>
<td></td>
</tr>
<tr>
<td><strong>Total events:</strong></td>
<td>57 (), 21 ()</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for heterogeneity:</strong></td>
<td>chi-square=0.42, df=2, p=0.81, I²=0.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong></td>
<td>z=1.06, p=0.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Interventions for dysphagia in acute stroke (Review)

Copyright © 2008 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd
Analysis 02.03.  Comparison 02 Swallowing therapy, Outcome 03 Pharyngeal transit time (seconds)

Review: Interventions for dysphagia in acute stroke
Comparison: 02 Swallowing therapy
Outcome: 03 Pharyngeal transit time (seconds)

<table>
<thead>
<tr>
<th>Study</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>95% CI (%)</td>
</tr>
<tr>
<td>01 Drug therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subtotal (95% CI)</td>
<td>0 0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test for overall effect: not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02 Swallowing therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Subtotal (95% CI)</td>
<td>0 0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test for overall effect: not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total (95% CI)</td>
<td>0 0</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test for overall effect: not applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Analysis 03.01.  Comparison 03 Fluid supplementation, Outcome 01 Time to resolution of dysphagia (days)

Review: Interventions for dysphagia in acute stroke
Comparison: 03 Fluid supplementation
Outcome: 01 Time to resolution of dysphagia (days)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>95% CI (%)</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>01 Free thin fluids</td>
<td>10 19.10 (9.71)</td>
<td>10 27.20 (18.12)</td>
<td>-8.10 [-20.84, 4.64]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Garon 1997</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total (95% CI)</td>
<td>10 10</td>
<td>100.0 -8.10 [-20.84, 4.64]</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test for overall effect z=1.25  p=0.2</td>
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<td></td>
</tr>
</tbody>
</table>

Interventions for dysphagia in acute stroke (Review)  
Copyright © 2008 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd
### Analysis 04.01.  Comparison 04 Food supplementation, Outcome 01 Case fatality at end of trial

Review: Interventions for dysphagia in acute stroke  
Comparison: 04 Food supplementation  
Outcome: 01 Case fatality at end of trial

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI (%)</td>
<td>(%)</td>
<td>95% CI</td>
</tr>
<tr>
<td>Sip feeding</td>
<td>2/21</td>
<td>7/21</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gariballa 1998</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>21</td>
<td>21</td>
<td>100.0</td>
<td>0.25</td>
<td>[0.06, 1.08]</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>21</td>
<td></td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.25</td>
<td>[0.06, 1.08]</td>
</tr>
</tbody>
</table>

Total events: 2 (Treatment), 7 (Control)  
Test for heterogeneity: not applicable  
Test for overall effect $z=1.86$ $p=0.06$

### Analysis 04.02.  Comparison 04 Food supplementation, Outcome 02 Energy intake (kcal/day)

Review: Interventions for dysphagia in acute stroke  
Comparison: 04 Food supplementation  
Outcome: 02 Energy intake (kcal/day)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean(SD)</td>
<td>N Mean(SD)</td>
<td>(%)</td>
</tr>
<tr>
<td>Sip feeding</td>
<td>21</td>
<td>1807.00 (318.00)</td>
<td>21 1084.00 (343.00)</td>
<td></td>
</tr>
<tr>
<td>Gariballa 1998</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>21</td>
<td>100.0</td>
<td>723.00 [522.95, 923.05]</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Test for heterogeneity: not applicable  
Test for overall effect $z=7.08$ $p<0.00001$
### Analysis 04.03. Comparison 04 Food supplementation, Outcome 03 Protein intake (g/day)

Review: Interventions for dysphagia in acute stroke  
Comparison: 04 Food supplementation  
Outcome: 03 Protein intake (g/day)

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment</th>
<th>Control</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight</th>
<th>Weighted Mean Difference (Fixed)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N Mean(SD)</td>
<td>N Mean(SD)</td>
<td>95% CI (%)</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>01 Sip feeding</td>
<td>Gariballa 1998</td>
<td>21 65.10 (13.80)</td>
<td>21 44.10 (12.80)</td>
<td>* 100.0</td>
<td>21.00 [ 12.95, 29.05 ]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>21</td>
<td>21</td>
<td>100.0</td>
<td>21.00 [ 12.95, 29.05 ]</td>
<td></td>
</tr>
</tbody>
</table>

Test for heterogeneity: not applicable  
Test for overall effect $z=5.11$, $p<0.00001$