Interventions for dysphagia in acute stroke (Review)

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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 (Axelsson 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 enterally, 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

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 -4.3 to +12.5), 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 non-dysphagic 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.

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Internal sources of support

- King's College Hospital Audit Committee UK

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** Indicates the major publication for the study*

TABLES

Characteristics of included studies

Study	Bath 1997
Methods	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.
Participants	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.
Interventions	Factorial trial: PEG versus NGT; intensive versus conservative swallowing therapyPEG:NGT: up to 3 NG tubes.Intensive swallowing therapy: as for conservative, plus voluntary control (tongue-holding), sensory

Characteristics of included studies (*Continued*)

	stimulation (tactile, oromotor exercises, swallow practice).Conservative swallowing therapy: review, advice regarding feeding route, postural/dietary modification, safe swallowing methods.
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, oropharngeal delay time (by videofluroscopy) at 4 weeks.
Notes	Exclusions: orogastrointestinal disease, concurrent severe illness, coagulopathy, pre-morbid dependency, sever dementia, psychiatric illness.Follow-up: 3 months.
Allocation concealment	A – Adequate

Study	**Gariballa 1998**
Methods	Method of randomisation unclear. Blinding of outcomes unclear. Analysis by ITT unclear. Crossovers unclear. Baseline factors balanced.
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**
Methods	Computer-generated randomisation. Blinded outcome assessments by SALT. Analysis by ITT unclear. Balancing of baseline prognostic factors between treatment groups unclear.
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-recumberant position for 6 weeks.
Outcomes	Case fatality at 6 weeks. Amount of feed administered. Change in nutritional status. Treatment failure. Length of hospital stay. Number of times tube inserted.
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.
Interventions	Rx: nifedipine (LA 30 mg orally daily, Bayer UK).Pl: matching tablet.Treatment for 4 weeks.
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 questionaire relating to speech and swallowing problems in 162 admissions;Group 2: 2 wards who did not fill in a questionaire in 233 admissions.Study excluded because:(i) not randomised;(ii) most patients not stroke.

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

Characteristics of ongoing studies

Study	**FOOD**
Trial name or title	FOOD (Feed or ordinary Diet). Part of the International Stroke Trials Collaboration
Participants	Acute stroke < 1 week Size: 9000 (a) 6000 (b) 2000 (c) 1000
Interventions	(a) oral supplemental feeding (b) early versus late tube feeding (c) PEG tube versus NG tube feeding
Outcomes	Primary: (a) dependence (modified Rankin score >=3) (b,c) severe dependence (modified Rankin score >=4) Secondary outcomes: 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
Starting date	1996
Contact information	Dr M Dennis 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: msd@skull.dcn.ed.ac.uk
Notes	Funding:

Characteristics of ongoing studies (*Continued*)

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

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

ANALYSES

Comparison 01. Feeding route

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

Comparison 02. Swallowing therapy

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

Comparison 03. Fluid supplementation

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Time to resolution of dysphagia (days)	1	20	Weighted Mean Difference (Fixed) 95% CI	-8.10 [-20.84, 4.64]

Comparison 04. Food supplementation

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

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

Date authors' conclusions section amended	Information not supplied by author
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DOI	10.1002/14651858.CD000323
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GRAPHS AND OTHER TABLES

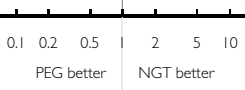
Analysis 01.01. Comparison 01 Feeding route, Outcome 01 Case fatality at end of trial

Review: Interventions for dysphagia in acute stroke

Comparison: 01 Feeding route

Outcome: 01 Case fatality at end of trial

Study	Treatment n/N	Control n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
01 PEG versus NGT					
Norton 1996	2/16	8/14		59.6	0.14 [0.03, 0.64]
Bath 1997	6/10	6/9		40.4	0.76 [0.12, 4.69]
Total (95% CI)	**26**	**23**		**100.0**	**0.28 [0.09, 0.89]**
Total events: 8 (Treatment), 14 (Control)					
Test for heterogeneity chi-square=1.94 df=1 p=0.16 I^2 =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

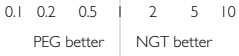
Outcome: 02 Death or disabled at end of trial

Study	Treatment n/N	Control n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
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

Study	Treatment n/N	Control n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
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

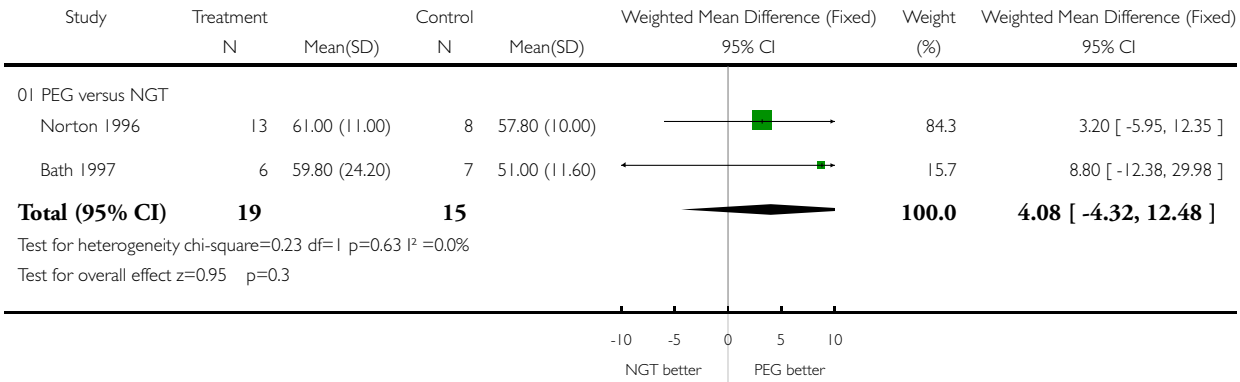
Test for overall effect z=0.87 p=0.4

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)

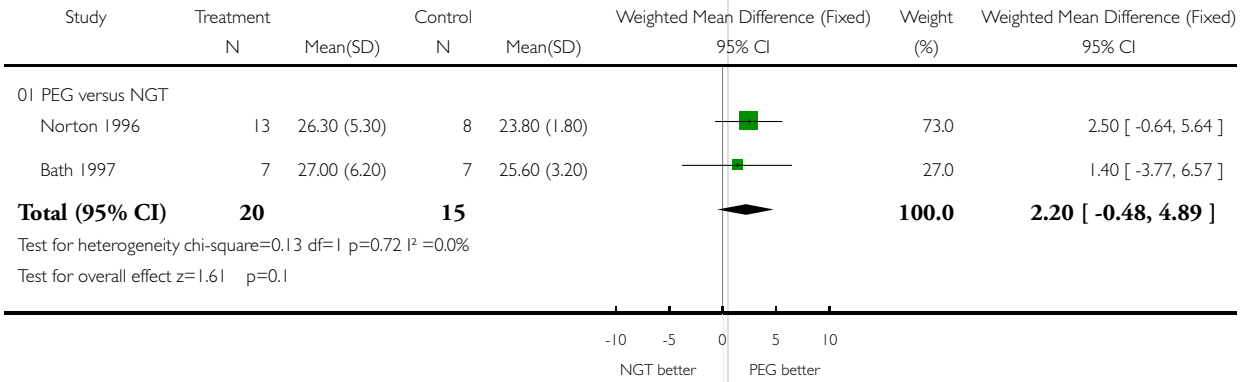


Analysis 01.05. Comparison 01 Feeding route, Outcome 05 Mid-arm circumference (LVCF)

Review: Interventions for dysphagia in acute stroke

Comparison: 01 Feeding route

Outcome: 05 Mid-arm circumference (LVCF)



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)

Study	Treatment N	Mean(SD)	Control N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 PEG versus NGT							
Norton 1996	15	30.10 (3.60)	10	22.30 (2.20)		88.4	7.80 [5.52, 10.08]
Bath 1997	7	27.90 (6.10)	8	27.00 (6.30)		11.6	0.90 [-5.38, 7.18]
Total (95% CI)	**22**		**18**			**100.0**	**7.00 [4.86, 9.14]**

Test for heterogeneity chi-square=4.10 df=1 p=0.04 I^2 =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

Study	Treatment n/N	Control n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
01 PEG versus NGT					
Norton 1996	0/16	3/14		51.1	0.10 [0.01, 1.05]
Bath 1997	0/10	3/9		48.9	0.09 [0.01, 1.03]
Total (95% CI)	**26**	**23**		**100.0**	**0.10 [0.02, 0.52]**

Total events: 0 (Treatment), 6 (Control)

Test for heterogeneity chi-square=0.00 df=1 p=0.97 I^2 =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)

Study	Treatment n/N	Control n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
01 PEG versus NGT					
Norton 1996	0/16	10/14		100.0	0.04 [0.01, 0.20]
Total (95% CI)	**16**	**14**		**100.0**	**0.04 [0.01, 0.20]**
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

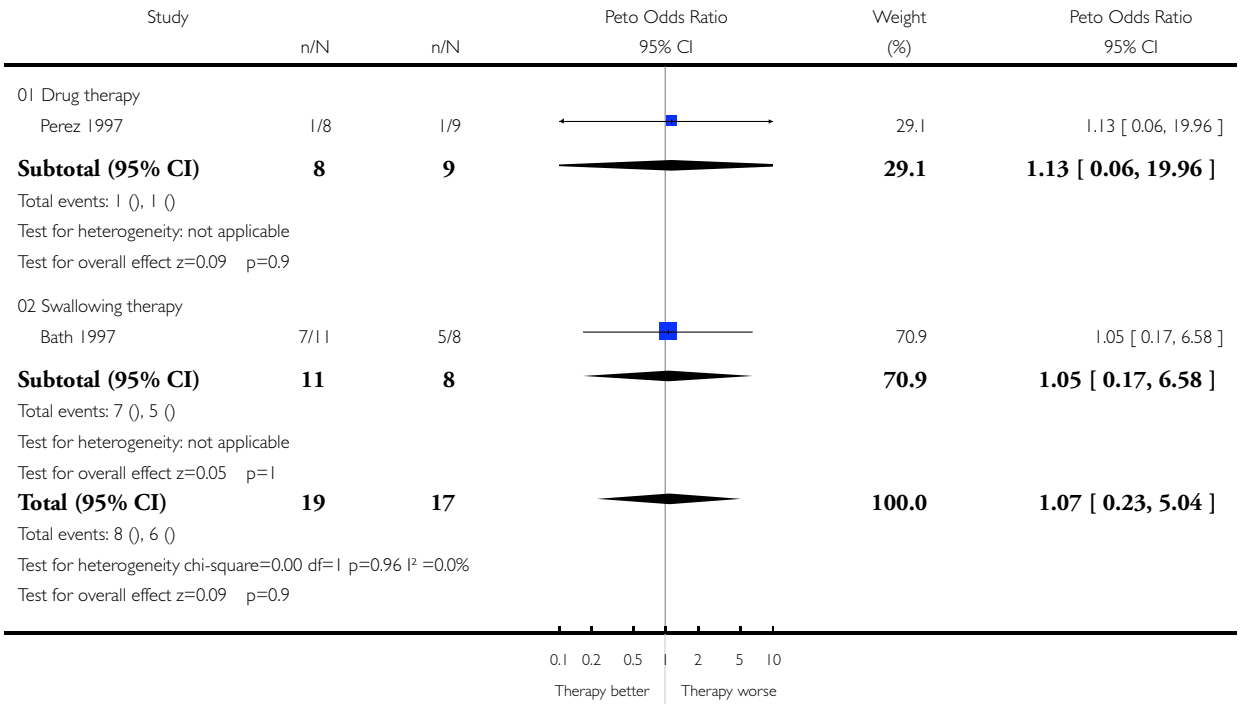
Study	Treatment N Mean(SD)	Control N Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 PEG versus NGT					
Total (95% CI)	**0**	**0**		**0.0**	**Not estimable**
Test for heterogeneity: not applicable					
Test for overall effect: not applicable					

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

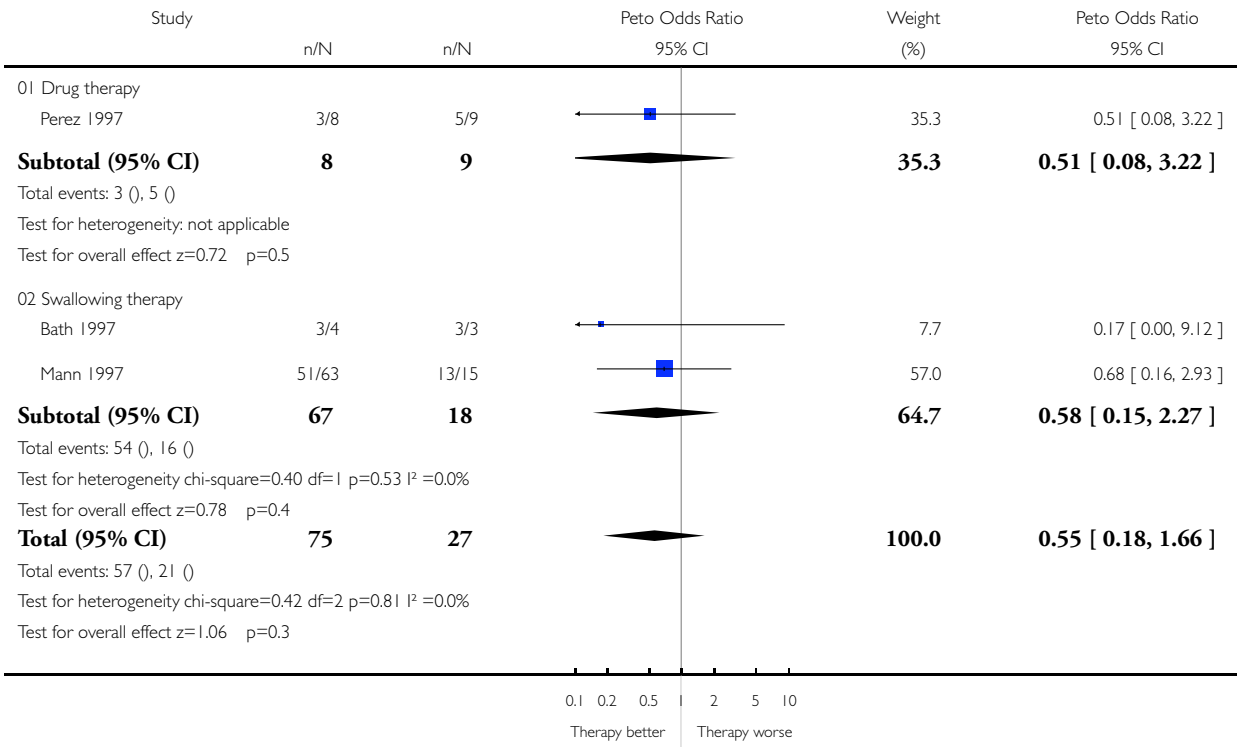


Analysis 02.02. Comparison 02 Swallowing therapy, Outcome 02 Dysphagia at end of trial

Review: Interventions for dysphagia in acute stroke

Comparison: 02 Swallowing therapy

Outcome: 02 Dysphagia at end of trial



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)

Study	N	Mean(SD)	N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 Drug therapy							
Subtotal (95% CI)	**0**		**0**			**0.0**	**Not estimable**
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
02 Swallowing therapy							
Subtotal (95% CI)	**0**		**0**			**0.0**	**Not estimable**
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							
Total (95% CI)	**0**		**0**			**0.0**	**Not estimable**
Test for heterogeneity: not applicable							
Test for overall effect: not applicable							

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)

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

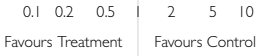
Analysis 04.01. Comparison 04 Food supplementation, Outcome 01 Case fatality at end of trial

Review: Interventions for dysphagia in acute stroke

Comparison: 04 Food supplementation

Outcome: 01 Case fatality at end of trial

Study	Treatment n/N	Control n/N	Peto Odds Ratio 95% CI	Weight (%)	Peto Odds Ratio 95% CI
01 Sip feeding					
Gariballa 1998	2/21	7/21		100.0	0.25 [0.06, 1.08]
Total (95% CI)	**21**	**21**		**100.0**	**0.25 [0.06, 1.08]**
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)

Study	Treatment N	Mean(SD)	Control N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 Sip feeding							
Gariballa 1998	21	1807.00 (318.00)	21	1084.00 (343.00)		100.0	723.00 [522.95, 923.05]
Total (95% CI)	**21**		**21**			**100.0**	**723.00 [522.95, 923.05]**
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)

Study	Treatment N	Mean(SD)	Control N	Mean(SD)	Weighted Mean Difference (Fixed) 95% CI	Weight (%)	Weighted Mean Difference (Fixed) 95% CI
01 Sip feeding							
Gariballa 1998	21	65.10 (13.80)	21	44.10 (12.80)		100.0	21.00 [12.95, 29.05]
Total (95% CI)	**21**		**21**			**100.0**	**21.00 [12.95, 29.05]**

Test for heterogeneity: not applicable

Test for overall effect z=5.11 p<0.00001