Modifying the consistency of food and fluids for swallowing difficulties in dementia (Protocol)

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[Intervention Protocol]

Modifying the consistency of food and fluids for swallowing difficulties in dementia

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

(1) To determine the effectiveness of modifying the consistency of food and fluids in improving oral intake and reducing laryngeal penetration and aspiration

(2) To evaluate the adverse effects of modifying the consistency of food and fluids in adults with oropharyngeal dysphagia and dementia

BACKGROUND

Description of the condition

Dementia is a progressive and largely irreversible clinical syndrome that is characterised by a widespread impairment of mental function. Although many people with dementia retain positive personality traits and personal attributes, as their condition progresses they can experience some or all of memory loss, language impairment, disorientation, changes in personality, difficulties with activities of daily living, self-neglect, psychiatric symptoms (for example, apathy, depression or psychosis) and out-of-character behaviour (National Institute for Health and Excellence 2006).
It is estimated that 24.3 million people are living with dementia worldwide, with 4.6 million new cases chronicled every year. The number of people affected is expected to double every 20 years to 81.1 million by 2040 (Ferri 2005) although the prevalence of dementia based on more recent research is anticipated to be lower than predicted due to limitations of earlier epidemiology studies (Matthews 2013). Types of dementia include vascular dementia, Lewy body dementia, fronto-temporal dementia, mixed type dementia and the most common form Alzheimer's disease. The various subtypes of dementia have characteristic clinical features and a different course of disease progression, although there is a high degree of overlap between them. The course of the illness may be gradual and insidious, as is classically the case in Alzheimer's disease (Cahill 2012). The disease has no single cause or cure, however increasing age remains by far the single strongest risk factor for dementia (Daviglus 2010; Ferri 2005).
Individuals with dementia often present with feeding difficulties or dysphagia, or both. Feeding difficulties can include difficulty self-feeding with problems initiating feeding tasks, transferring food into the mouth and maintaining attention to the feeding task (Chang 2011). Dysphagia is defined as a swallowing disorder that

involves any one or more of the oral, pharyngeal or oesophageal stages of swallowing. This review concerns dysphagia (swallowing disorder) rather than feeding problems per se.

Dysphagia is always a symptom of an underlying disease or difficulty and can have a multitude of causes, which may be neurological, surgical, mechanical or psychological (Easterling 2008). Individuals with dementia may also have other characteristics that can influence swallowing such as increased age, reduced physical mobility, poor dentition, dependent feeding and use of medications which can affect swallow function (Smith 2009). Dysphagia can manifest through clinical signs such as leakage of food or fluids on eating and drinking, drooling, coughing or choking during or after eating or drinking, food sticking in the oropharyngeal or oesophageal regions, regurgitation, gastroesophageal reflux and odynophagia (Groher 2010). The consequences of dysphagia for patients with dementia can include dehydration, malnutrition, weight loss, aspiration pneumonia and death (Gräsbeck 2003; Hudson 2000; Langmore 2002). All individuals with dementia can develop dysphagia, most often in the later stages of the illness (Suh 2009).

Description of the intervention

A range of interventions are used in the management of dysphagia in people with dementia. These can include behavioural strategies (Brush 1998), modification of food consistencies (Logemann 2008), postural manoeuvres (for example, chin tuck) (Robbins 2008), pharmaceutical interventions (Wada 2001), environmental modification (Koss 1998) or enteral feeding (Kuo 2009). The National Institute for Health and Excellence (NICE) guidelines on dementia advises that enteral feeding should only be considered where dysphagia is a transient phenomenon and that enteral feeding should not generally be used with individuals with severe dementia (National Institute for Health and Excellence 2006). Oral intake, modified as necessary, should be the main aim of treatment for individuals presenting with oral feeding difficulties (Royal College of Physicians 2010).

Modification of food and liquid is therefore an important management strategy for dysphagia in people with dementia. This coupled with the increase in research, awareness and prevalence of dysphagia in individuals with dementia means that modifying the consistency of food and fluids for swallowing difficulties has become topical for speech and language therapists (SLTs), medical physicians, nurses, members of multidisciplinary care teams, people with dementia themselves and also their families. This review is specifically concerned with modifying the consistency of food and fluids as an intervention strategy. For the purpose of this review, modification of food and fluids will include any intervention that involves alteration to the consistency of food or fluids given to people with dysphagia resulting from dementia.

Modification of fluids can include changing the consistency to different degrees by adding a thickening agent to the liquid. The consistencies of fluids can range from 'water like' fluids to 'pudding like' fluids. The consistency of foods can also be altered from a regular texture to 'extensively modified texture food'. The terminology and definitions of different food and fluid consistencies vary both within and between countries. Table 1 and Table 2 provide published national descriptors and unpublished information regarding the terminology and definitions for modified food and fluids used in Australia, Ireland, Japan, New Zealand, Sweden, the United Kingdom, the United States of America, and Denmark, Canada, Spain, the Netherlands and Brazil (Cichero 2013).

The rationale for altering the consistency of food and fluids is that this can compensate for a swallowing deficit or change the swallow pattern toward the goal of improved swallow function (Groher 2010). Modifying the consistency of food and drinks is one of the most common strategies used in diet modification by SLTs, based on the assumption that in doing so it can prevent aspiration (food or fluid entering the lungs). There is currently no international consensus regarding the terminology that should be used for different consistencies of food and fluid. However, the International Dysphagia Diet Standardisation Initiative (IDDSI 2012) aims to develop global standardised terminology and definitions for texture modified foods and thickened liquids for individuals of all ages with dysphagia, in all care settings and for all cultures, by December 2014.

For the purposes of this review, modifying food and fluid consistency as an intervention can be provided in any setting and can be delivered by a trained person or a team. Diet can be given orally with the person with dementia self-feeding or the person can be assisted with his or her eating and drinking by trained carers. Food or fluid consistencies should be delivered by carers trained to modify the diet specifically according to instructions given by a SLT or other appropriately trained healthcare professional following assessment.

How the intervention might work

Modifications to food and fluid consistencies are hypothesized to lead to physiological changes in swallowing including changes in lingual, submental and hyolaryngeal activity and duration of hyolaryngeal closure (Robbins 2008). Increasing the viscosity of a fluid can lead to a reduced rate of liquid bolus transit and increased sensory awareness (Dantas 1990; Troche 2008). It can also influence opening of the upper oesophageal sphincter (Bisch 1994). This reduced rate of bolus movement and increase in sensory awareness may enhance the safety and efficiency of swallowing, thus reducing the risk of aspiration or penetration of fluid into the airway. It is believed that increasing the viscosity of the fluid bolus by altering its consistency allows individuals a better opportunity to swallow with a reduced risk of airway compromise. Similarly, altering the consistency of food is thought to lead to physiological changes which can reduce an individual's risk of aspiration. Food is often modified according to a patient's oral motor

control (Garcia 2010). It is believed that by modifying the consistency of food, oral preparation of the bolus is more efficient. This is thought to improve an individual's ability to swallow the food bolus safely.

Why it is important to do this review

The management options for people with dementia and dysphagia are limited. It is recommended that artificial feeding should only be considered if dysphagia is thought to be a transient phenomenon and should not generally be used in people with severe dementia for whom dysphagia or disinclination to eat is a manifestation of disease severity (National Institute for Health and Excellence 2006; Royal College of Physicians 2010). As a result of these guidelines, modified consistency food and fluids are used increasingly with people presenting with dysphagia as a result of dementia.

The belief that altering the consistency of food and fluids can help individuals with dementia and dysphagia swallow more safely and more efficiently is widely held. However, there is evidence that it can have significant psychological and social consequences and can affect quality of life. It may also lead to dehydration and malnutrition as thickened fluids can be unpalatable and the choice of food that is recommended may be limited (Easterling 2008; Ekberg 2002). Other studies suggest that drinking very thick liquids (those with the consistency of honey) may in fact be harmful for older adults with swallowing problems (Robbins 2008).

Other management strategies include behavioural interventions and, although research has investigated their effectiveness for dysphagia in acute and subacute stroke (Geeganage 2012), the evidence to support this intervention for individuals with dementia and dysphagia is scant. Postural changes have some benefit and some studies suggest that a simple chin tuck posture is as effective as diet modification (Logemann 2008).

Evidence on the benefits and risks of modifying the consistency of food and fluids as well as directions for research is mandatory to improve the care of people with dementia and dysphagia. This information is required to inform decision making by clinicians, multidisciplinary teams, people with dementia, their families and other key stakeholders.

OBJECTIVES

(1) To determine the effectiveness of modifying the consistency of food and fluids in improving oral intake and reducing laryngeal penetration and aspiration

(2) To evaluate the adverse effects of modifying the consistency of food and fluids in adults with oropharyngeal dysphagia and dementia

METHODS

Criteria for considering studies for this review

Types of studies

We will include all published and unpublished randomised controlled trials (RCTs), quasi-randomised controlled clinical trials and cluster-randomised controlled trials published in any language. Relevant RCTs are classified as all trials that involve at least one group receiving modified food or fluid consistency, or both, aimed at improving or eliminating dysphagia and one group receiving a control treatment or no treatment, with concurrent enrolment and follow-up of the test- and control-treated groups, and where treatments to be administered are allocated by a random process, such as the use of a random-number table (Lefebvre 2011).

We will classify as quasi-randomised controlled clinical trials all trials of similar design where the method of allocation to the treatment group is known but is not considered strictly random for example, alternate allocation by day or date of birth or medical record number. Control measures will include for example, placebos, active treatment, no-treatment, dosage forms and regimens (Lefebvre 2011). As dementia and dysphagia are both progressive we will only include cross-over trials in the review if the data from the first intervention period were reported, and we will only use this trial data.

Types of participants

Adults with a clinical diagnosis of dementia who have symptoms and signs of difficulty swallowing and in whom aspiration or penetration has been confirmed by a full clinical bedside evaluation, videofluoroscopy or fibreoptic examination of swallowing (FEES) using valid reliable measures, where available, such as the Penetration Aspiration Scale (Rosenbek 1996). We will include trials with participants who suffer any type and severity of dementia. We will impose no limitations regarding the stage of dementia.

Types of interventions

Interventions

- Diet modification involving any alteration to the consistency of food or fluids, or both, given to people with dementia

Comparisons

- Intervention versus no intervention (i.e. modified consistency food and/or fluids versus a normal diet that is not modified in either consistency, volume, taste or temperature or alternative non-feeding)

- Intervention versus other intervention that does not involve diet modification (i.e. modified consistency food and/or fluids versus any other intervention that does not involve modification of food or fluids such as compensatory strategies e.g. chin tuck, head turn)

- Intervention versus other intervention that involves modification to sensory properties of food or fluid only (i.e. modified consistency food and/or fluids versus a diet that does not modify consistency but involves modification to sensory properties of food and/or fluids such as carbonation, temperature etc.)

Types of outcome measures

Primary outcomes

1. Aspiration or laryngeal penetration of food or fluids, or both, as rated on objective assessment (videofluoroscopy, fibreoptic examination of swallowing safety (FEES)
2. Nutritional status as measured by increase in weight, prevention of weight loss, increase in grip strength, increase in calorific intake, change in standardized and validated screening tool such as the Mini Nutritional Screening Tool (Guigoz 1996) or the Malnutrition Universal Screening Tool (Stratton 2004), reduction in number of hospitalisations for rehydration
3. Respiratory status defined by clinical assessment that may include a chest x-ray, decreased incidence of aspiration related pneumonia
4. Adverse events associated with diet modification including hospitalisation, psychological effects, aspiration pneumonia, malnutrition, dehydration and death

Secondary outcomes

1. Non-compliance with dietary modifications
2. Quality of life as measured by patient or carer report, validated quality of life measures, validated psychosocial impact measures

Search methods for identification of studies

Electronic searches

We will search ALOIS (www.medicine.ox.ac.uk/alois), the Cochrane Dementia and Cognitive Improvement Group Specialized Register. The search terms used will be: diet*, food*, liquid*, fluid*, solid*, feed*, eat*, meal*, swallow*.
ALOIS is maintained by the Trials Search Co-ordinator and contains dementia and cognitive improvement studies identified as follows.

1. Monthly searches of a number of major healthcare databases: MEDLINE, EMBASE, CINAHL, PsycINFO and LILACS.
2. Monthly searches of a number of trial registers: metaRegister of Controlled Trials; Umin Japan Trial Register; World Health Organization Clinical Trials Registry Platform portal (which covers ClinicalTrials.gov; ISRCTN; Chinese Clinical Trials Register; German clinical trials register; Iranian Registry of Clinical Trials and the Netherlands National Trials Register, plus others).
3. Quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library*.
4. Monthly searches of a number of grey literature sources: ISI Web of Knowledge Conference Proceedings; Index to Theses; Australasian Digital Theses.

To view a list of all sources searched for ALOIS see About ALOIS on the ALOIS website.
We will run additional separate searches in many of the above sources to ensure that the most up-to-date results are retrieved. The search strategy that will be used for the retrieval of reports of trials from MEDLINE (via the OvidSP platform) can be seen in Appendix 1.

Searching other resources

We will review reference lists from all included studies to identify other relevant trials. We will handsearch published abstracts of conference proceedings from both the Dysphagia Research Society and the European Society of Swallowing Disorders (both published in Dysphagia). ProQuest Dissertations & Theses will also be reviewed for relevant dissertation abstracts and authors will be contacted for data on trials as relevant.

Data collection and analysis

Selection of studies

We will merge the search results using reference management software and remove duplicate records of the same report. Two review authors (EF and MW) will independently read through titles, abstracts and key words identified from the literature search. Results from this search will be categorised as either 'relevant', 'potentially relevant' or 'not relevant'. If it is unclear from titles and abstracts whether a study should be included, copies of these trial reports

will be obtained for further analysis. We will resolve any disagreement on selection of studies by consensus discussion.
EF will retrieve full texts of relevant and potentially relevant reports and link multiple reports of the same study. Three authors (EF, MW and CS) will examine all full final texts of relevant reports for compliance with eligibility criteria. When the eligibility of the study is in question, we will contact the authors of the report for additional information. The review team will not be blinded to information about study authors, institutions, journal of publication or results. We will resolve any disagreements through discussion. We will calculate the inter-rater reliability for rating the eligibility of studies using a simple kappa statistic (Higgins 2011).

Data extraction and management

We will use a specifically designed form (Appendix 2) to extract data. For eligible studies two review authors (EF and MW) will extract the data using the agreed form. Any discrepancies will be resolved by discussion or by involving a third author. We will enter the data in Review Manager software (Revman 2012); the data will be checked for accuracy by a second author. When information regarding any of the data is unclear we will attempt to contact the authors for further information.

Assessment of risk of bias in included studies

Two authors (EF and MW) will assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreements by discussion or by involving a third assessor (CS or CW).

Measures of treatment effect

If sufficient trials are available and their populations are clinically similar, we will carry out meta-analyses of primary and secondary endpoints. We will use risk ratio (RR) and 95% confidence interval (CI) for the analysis of dichotomous outcomes, and mean difference (MD) or standardized mean difference (SMD) and 95% CI for continuous outcomes.

Unit of analysis issues

The unit of analysis is the individual with dementia. We will examine whether the number of measurements in the analysis match the number of individuals that were randomised to the intervention. Where the design of the trial requires it (for example, in the case of cluster-randomised trials or cross-over trials) the analysis will take account of the design. See Section 9.3 in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Dealing with missing data

Where possible, the authors will contact trial authors for them to supply missing data from included studies. For all outcomes, as far as possible, we will undertake analyses on an intention-to-treat basis. We will attempt to include in the analyses all participants randomised to each group and analyse all participants in the group to which they were allocated. The denominator for each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

Heterogeneity tests will be performed using a standard Chi^2 test (significance at $P < 0.1$) or an I^2 statistic (> 75%). If statistical heterogeneity is identified a number of options can be used to address this. Data can be checked again to ensure they are correct, heterogeneity can be explored, heterogeneity can be ignored, a random-effects meta-analysis can be performed, the effect measured can be changed, studies can be excluded or a meta-analysis may not be carried out. If there is evidence of heterogeneity, we will explore which factor causes it and will perform sensitivity analysis based on the possible reasons.

Assessment of reporting biases

We will identify reporting biases (publication bias, time lag bias, duplicate publication bias, location bias, citation bias, language bias or outcome-reporting bias) and minimise reporting biases through a comprehensive search for studies, inclusion of unpublished studies and use of trial registries. If 10 or more studies are identified we will construct a funnel plot.

Data synthesis

We will undertake statistical analysis using Review Manager 5.2 (Revman 2012). We will perform a meta-analysis for all randomised trials included in the review. We will consider all the outcomes listed for data synthesis and choose a random-effects model for the primary analysis in the case of heterogeneity (as measured by I^2). Where there is no statistical heterogeneity a fixed-effect model will be used.

Subgroup analysis and investigation of heterogeneity

The following subgroup analyses may be carried out, if sufficient data are available.

1. Viscosity, grade of thickness (e.g. mildly thick versus moderately thick versus extremely thick).
2. Texture, type of texture (e.g. soft versus minced and moist versus smooth puree).
3. Type of thickener used (corn versus gum starch).
4. Severity of dementia as rated on a standardized scale, mild versus moderate versus severe dementia.

Sensitivity analysis

We will undertake sensitivity analysis to explore the potential influences on effect size. If heterogeneity results from low quality trials, we will exclude the lowest quality trials from this review.

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* *Indicates the major publication for the study*

ADDITIONAL TABLES

Table 1. Fluid consistencies (Cichero 2013)

Country < "Water like" ---------- "Pudding like">					
USA (NDD) National Dysphagia Diet Task Force 2002	Thin (1-50 cP)		Nectar-like (51-350 cP*)	Honey-like (351-1750 cP)	Spoon thick (>1750 cP)
United Kingdom National Patent Safety Agency 2011	Thin	Naturally thick fluid	Thickened fluid - Stage 1	Thickened fluid - Stage 2	Thickened fluid - Stage 3
Australia Atherton 2007	Regular	-	Level 150 - Mildly thick	Level 400 - Moderately thick	Level 900 - Extremely thick
Ireland IASLT & Irish Nutrition & Dietetic Institute 2009	Regular	Grade 1 - Very mildly thick	Grade 2 - Mildly thick	Grade 3 - Moderately thick	Grade 4 - Extremely thick
Japan Ministry of Health Labour and Welfare 2009	Less mildly thick (<50 mPa.s**)	Mildly thick (50-150 mPa.s)	Moderately thick (150-300 mPa.s)	Extremely thick (300-500 mPa.s)	Over extremely thick (>500 mPa.s)
Canada	Regular/thin/clear		Nectar/Stage1/ Level 1/>250cP/51-350 cP	Honey/Stage 2/ Level 2/>800cP/351c-1750cP/Default thick	Pudding/spoon thick/Stage 3/Level 3/>2000 cP/>1750 cP
Denmark Tolstrup Anderson 2013	Normal	Chocolate milk	Syrup	Jelly	

Table 1. Fluid consistencies (Cichero 2013) (*Continued*)

Spain	Thin			Medium	Full protection/ thick/pudding
Netherlands	Thin		'Thickened'		Pudding like
Brazil	Normal or thin	Thicker liquid	Nectar or honey		Paste or creamy (homogenous or heterogenous)
Sweden Wendin 2010	Liquids	Thickened liquids			

*cP = centipoise
**mPa.s = millipascal second
Both are units of viscosity. 1cP = 1mPsa

Table 2. Food consistencies (Cichero 2013)

Country < Regular food ---------- Extensively texture modified food >						
USA (NDD) National Dysphagia Diet Task Force 2002	Regular	Dysphagia advanced (bite sized, <2.5 cm)	Dysphagia mechanically altered (0.6cm)	Dysphagia pureed		
United Kingdom National Patent Safety Agency 2011		Texture E - Fork mashable dysphagia diet (1.5cm)	Texture D - Pre-mashed dysphagia diet (0.2cm)	Texture C - Thick puree dysphgia diet	Texture B - Thin puree dysphagia diet	
Australia Atherton 2007	Regular	Texture A - Soft (1.5cm)	Texture B - Minced + moist (0.5cm)	Texture C - Smooth pureed	Texture D - Liquidised	
Ireland IASLT & Irish Nutrition & Dietetic Institute 2009		Texture A - Soft	Texture B - Minced and moist	Texture C - Smooth pureed	Texture D - Liquidised	
Japan Ministry of Health Labour and Welfare 2009	Level 5 Normal diet	Level 4 Soft food	Level 3 (Dysphagia diet) Paste containing meat/fish	Level 2 (Dysphagia diet) Jelly food with protein (Rough jelly surface)	Level 1 (Dysphgaia diet) Smooth jelly food with protein, except	Level 0 (Test food) Smooth jelly food without protein

Table 2. Food consistencies (Cichero 2013) (*Continued*)

					for meat and fish	
Canada	Easy to chew or regular/ general/ dysphagia general	Chopped or diced/sysphagia soft/sysphagia soft + minced/Stage 3/ Level 3/dental soft/ easy to chew with minced meat/cut up	Advanced minced/ minced with finger food/diced/ chopped/soft minced	Minced/ mashed/ modified minced/ dysphagia fully totally minced/Level 2 mechanical/ minced moist/ minced meat modified vegetables	Pureed/ thin pureed/dysphagia pureed/ Stage 1/Level 1/ semi-pureed	Blended/ liquidised
Denmark Tolstrup Anderson 2013	Normal	Soft		Puree		
Spain	Normal	Easy mastication		Puree		
Netherlands	Normal	Normal with soft meat/fish/ chicken - no particulates (e.g. peas, rice)	Mashed	Puree		
Brazil	Solid				Soft solid or puree	
Sweden Wendin 2010	Regular or cut	Coarse paté	Timbales	Jellied products	High viscosity fluids	Low viscosity fluids

APPENDICES

Appendix 1. MEDLINE search strategy

1. exp Dementia/
2. Delirium/
3. Wernicke Encephalopathy/
4. Delirium, Dementia, Amnestic, Cognitive Disorders/
5. dement*.mp.
6. alzheimer*.mp.
7. (lewy* adj2 bod*).mp.
8. deliri*.mp.
9. (chronic adj2 cerebrovascular).mp.
10. ("organic brain disease" or "organic brain syndrome").mp.
11. ("normal pressure hydrocephalus" and "shunt*").mp.
12. "benign senescent forgetfulness".mp.
13. (cerebr* adj2 deteriorat*).mp.
14. (cerebral* adj2 insufficient*).mp.
15. (pick* adj2 disease).mp.
16. (creutzfeldt or jcd or cjd).mp.
17. huntington*.mp.
18. binswanger*.mp.
19. korsako*.mp.
20. or/1-19
21. exp Deglutition Disorders/
22. dysphagia.ti,ab.
23. swallow*.ti,ab.
24. ((cough* or chok*) adj6 (eat* or food or meal* or drink*)).ti,ab.
25. "food sticking".ti,ab.
26. regurgitat*.ti,ab.
27. odynophagia.ti,ab.
28. drool*.ti,ab.
29. ("weight loss" or (los* adj3 weight)).ti,ab.
30. (nutri* adj3 deficien*).ti,ab.
31. oesophagitis.ti,ab.
32. "peptic stricture".ti,ab.
33. or/21-32
34. 20 and 33
35. Diet/
36. diet*.ti,ab.
37. (fluid* or liquid* or drink*).ti,ab.
38. (food* or solid* or meal* or consistency).ti,ab.
39. or/35-38
40. 34 and 39
41. randomized controlled trial.pt.
42. controlled clinical trial.pt.
43. randomized.ab.
44. placebo.ab.
45. randomly.ab.
46. trial.ab.
47. groups.ab.
48. or/41-47

49. 40 and 48

Appendix 2. Data Extraction Form

Modifying the consistency of food and fluids for swallowing difficulties in dementia

Study ID: _____ Lead Author: _____ Reviewer Initials: _____ Date of Review: _____

General Study Information

First Author	Year	Journal/Conference Proceeding etc	Country	Language	Single/Multicentre Trial	Study Duration

Study Eligibility

RCT/CCT	Relevant Participants	Relevant Interventions	Relevant Outcomes
Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear

Do not proceed if any of the above answers are "No" If study to be included in "Excluded Studies" section of the review, record below the information to be inserted into "Table of excluded studies"

Participant and trial characteristics

	Intervention Group	Comparison Group 1	Comparison Group 2
Participants	N=	N=	N=
Age (mean, median, range, SD) :	Mean: Median: Range: SD:	Mean: Median: Range: SD:	Mean: Median: Range: SD:
Gender of participants:	Male N= Female N= Both N= Not clear	Male N: Female N: Both N: Not clear	Male N: Female N: Both N: Not clear
Type of dementia within groups:	1. N= 2. N= 3. N= 4. N= 5. N=	1. N= 2. N= 3. N= 4. N= 5. N=	1. N= 2. N= 3. N= 4. N= 5. N=
Severity of dementia:	Mild N= Moderate N= Severe N=	Mild N= Moderate N= Severe N=	Mild N= Moderate N= Severe N=
Co-morbidities within exclusion criteria			

Trial characteristics

	Treatment Group	Comparison Group 1	Comparison Group 2
Interventions 1. Modified fluids 2. Modified food			
How was participant eligibility defined?			
Type of thickener used if relevant?			

(*Continued*)

Grade of viscosity			
Type of texture			
Time frames considered			
Trial design			

Methodological quality

Selection bias: · Sequence generation · Allocation concealment	Adequate/Inadequate/Unclear Adequate/Inadequate/Unclear	Adequate/Inadequate/Unclear Adequate/Inadequate/Unclear	Adequate/Inadequate/Unclear Adequate/Inadequate/Unclear
Performance Bias: · Blinding of participants · Blinding of other personnel	Yes/No/Unclear Yes/No/Unclear	Yes/No/Unclear Yes/No/Unclear	Yes/No/Unclear Yes/No/Unclear
Detection Bias: · Use of outcome measures apparent · Blinding of outcome assessors	Yes/No/Unclear Yes/No/Unclear	Yes/No/Unclear Yes/No/Unclear	Yes/No/Unclear Yes/No/Unclear
Reporting Bias · Time lag to publication · Language · Duplicate publication · Citation reporting	Yes/No/Unclear _____ Yes/No/Unclear Yes/No/Unclear Yes/No/Unclear	Yes/No/Unclear _____ Yes/No/Unclear Yes/No/Unclear Yes/No/Unclear	Yes/No/Unclear _____ Yes/No/Unclear Yes/No/Unclear Yes/No/Unclear

(*Continued*)

· Outcome reporting						
Attrition Bias: · Incomplete outcome data · Reasons specified	Yes/No/Unclear Yes/No/Unclear		Yes/No/Unclear Yes/No/Unclear		Yes/No/Unclear Yes/No/Unclear	
Intention to Treat	All participants entering trial	15% of fewer included	More than 15% included	Not analysed as "intention to treat"	Unclear	Withdrawals described Yes No

Data Extraction

	Treatment Group	**Comparison Group 1**	**Comparison Group 2**
Reduction or elimination of aspiration or laryngeal penetration on food and/or fluids as rated on objective assessment (videofluoroscopy, fibreoptic examination of swallowing safety (FEES) (Yes/No)	Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear
Change to nutritional status as measured by increase in weight, prevention of weight loss, increase in grip strength, increase in calorific intake, change in standardized and validated screening tool such as The Mini Nutritional Screening Tool (Guigoz 1996), the Malnutrition Universal Screening Tool (Stratton 2004), reduction in number of hospitalisations for rehydration (Yes/No)	Improved/ deteriorated/ unchanged/ not reported	Improved/ deteriorated/ unchanged/ not reported	Improved/ deteriorated/ unchanged/ not reported
Change to respiratory status defined by clinical assessment that may include a chest x-ray, decreased incidence of aspiration related pneumonia (Yes/No)	Reduction/No reduction/ Increase/ Not clear	Reduction/No reduction/ Increase/ Not clear	Reduction/No reduction/ Increase/ Not clear
Adverse events associated with diet modification including hospitalisation, psychologi-	Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear

(*Continued*)

cal effects, aspiration pneumonia, malnutrition, dehydration and death (Yes/No)			
Non compliance with dietary modifications.	Yes/No/Unclear	Yes/No/Unclear	Yes/No/Unclear
Change in quality of life as measured by patient/carer report, validated quality of life measures, validated psychosocial impact measures	Improved/ deteriorated/ unchanged/ not reported	Improved/ deteriorated/ unchanged/ not reported	Improved/ deteriorated/ unchanged/ not reported

Other information which you feel is relevant to the results

Overall Quality Score (GRADE rating)	
· High · Moderate · Low · Very Low	**High:** (Randomised trial/double ungraded Ix studies. Further research is very unlikely to change our confidence in the estimate of effect
	Moderate: Downgraded randomized trials / Upgraded observational studies. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
	Low: Double downgraded randomized trials/ observational studies. Low quality - further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
	Very Low: Triple downgraded randomized trials/downgraded observational studies/case series/case reports. Any estimate of effect is very uncertain

Review Author Comments:

Signed: .....

Date: .....

CONTRIBUTIONS OF AUTHORS

E Flynn drafted the protocol with support from M Walshe, C Smith and C Walsh. E Flynn developed the background section. M Walshe provided a methodological perspective and advice on writing the protocol. E Flynn, M Walshe and C Smith provided advice on content. C Walsh provided support for the data collection and analysis section. E Flynn secured funding for the review. All authors commented on all sections of the protocol and reviewed the final version prior to submission.

DECLARATIONS OF INTEREST

None known

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