Effectiveness of interventions to improve, maintain or facilitate oral food and/or drink intake in people with dementia: a systematic review

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Background:

There are over 0.8 million people living with dementia in the UK (1), and 163,000 cases of dementia are diagnosed in England and Wales each year (2) - the number of people with dementia is increasing. The needs of people with dementia are increasingly complex as the illness progresses.

Eating and drinking difficulties are a major source of ill health and stress across the stages of dementia in multiple settings. People with dementia are more likely to drink insufficient fluid, be malnourished, and the risk of malnutrition increases as dementia progresses (3-5). This may be for many reasons, including poor appetite and decreased sense of thirst, forgetting to eat and drink, days becoming less structured around food and drink, reduced social contact, changes in food preferences, problems with physical coordination, chewing and swallowing (6;7). People with dementia have ten times the risk of hospital admission for dehydration (3% of admissions) and anorexia (1% of admissions) as primary diagnoses than age-matched controls (0.3% of admissions for dehydration, 0.1% for anorexia), and admissions for abdominal pain, constipation, nausea and vomiting and bronchopneumonia are all higher for those with dementia (8). In addition, the high levels of comorbidity, need for medication and its metabolism can all be affected by fluid and nutritional status.

When the Alzheimer's Society, through the James Lind Alliance, brought together health and social care practitioners and people with dementia and their carers, to identify priorities for research, one of the top ten priorities was "What are the most effective ways to encourage people with dementia to eat, drink and maintain nutritional intake?" (9) Clearly there is a need for accessible information on eating, drinking and swallowing for those with dementia and their carers.

While systematic reviews have been carried out to assess the potential nutritional causes of dementia, the literature examining the effectiveness of interventions to support people with dementia to eat and drink well is more limited. An early systematic review carried out with the Joanna Briggs Institute (JBI) explored factors related to poor hydration, and how best to maintain adequate hydration in older people (10;11), and a recent JBI review considered the effectiveness of mealtime interventions to improve nutritional intake of adults in acute care settings (12), but neither addressed specific issues for those with dementia. Similarly a Cochrane review assessed effectiveness of protein and energy supplementation in older people at risk of malnutrition, but did not specifically address issues for people with dementia (13). JBI systematic reviews have explored effectiveness of interventions to reduce undernutrition and promote eating in people with

dementia (14), effectiveness of oral liquid nutritional supplements (15) and thickened fluids (16) for people with dementia living in residential care. Independently produced systematic reviews have also been published, but had limited or ill-described search strategies (limiting their ability to identify the relevant studies) (17;18), addressed a limited though useful subgroup of interventions (19-21) or were in need of updating (22). While these reviews provide a good background they also leave some gaps. Synthesis of the evidence around drinking and hydration needs to be updated and made specific to those with dementia. The full set of possibly useful interventions needs to be assessed. These include educational interventions with people with dementia and with carers, modification of foods (such as provision of finger foods, or liquidising of foods), stimulating appetite (such as wine before a meal, exercise or priming by having good food smells around immediately before meals), equipment (including using contrasting colour, and cups to allow those with physical disabilities to drink independently), staffing (changing staff numbers or roles), environment (such as making dining rooms more homely), dealing with problems such as oral care and continence, and assessment and intervention for swallowing difficulties.

To make the review findings more accessible, we need to clearly address the questions of people with dementia and their carers around eating and drinking. The evidence needs to be summarised in light of the settings in which they have been tested, and the degree of dementia of the targeted participants. This will help to ensure that people with dementia and their carers have access to the best current evidence to help them continue to eat and drink well.

Aim: To systematically review the literature to assess the effectiveness of interventions to improve, maintain or facilitate oral food and drink intake, nutrition and hydration status, in people with dementia (in any setting, living independently in the community or with varying levels of care and support, and with different types and degrees of dementia).

Objectives:

- To summarise the evidence of effectiveness of interventions in a rigorous way that minimises bias
- To address the specific questions raised by our stakeholders
- To highlight research priorities in this area

Specific questions to be addressed by the review were formulated by the research team following consultations with members of two patient and public involvement groups (the Public & Patient Involvement in Research, PPIRes, from Norfolk and Suffolk and the Public Involvement in Research Group, PIRG, from Hertfordshire). The groups, and their members, were asked to comment on the protocol and let us know what questions they would like the review to address. The questions to be addressed by the review include:

1. What are the most effective ways to encourage people with dementia to eat, drink and maintain nutritional intake?
2. For people with mild dementia, what interventions can help to maintain or improve food intake or nutritional status?
3. For people with mild dementia, what interventions can help to maintain or improve fluid intake or hydration status?
    - (repeat questions 2 & 3 for mild cognitive impairment, moderate dementia and severe dementia)
4. For people with dementia living in their own homes with a carer, what interventions can help to maintain or improve food intake or nutritional status?
5. For people with dementia living in their own homes with a carer, what interventions can help to maintain or improve fluid intake or hydration status?
    - (repeat questions 4 and 5 for those living at home with a part time or no carer, for those living in residential care, for those in hospital)
6. For people with Alzheimer's dementia, what interventions can help to maintain or improve food intake or nutritional status?
7. For people with Alzheimer's dementia, what interventions can help to maintain or improve fluid intake or hydration status?
    - (repeat questions 6 and 7 for those with vascular dementia, Dementia with Lewy bodies, mild cognitive impairment, other types of dementia, and mixed populations)
8. For people with dementia, what interventions aimed at improving or maintaining food and/or fluid intake, nutrition or hydration status, support meaningful activity (activity around food or drink that is personally fulfilling, that people enjoy, look forward to or find important)?
9. For people with dementia, are there any interventions that; worsen food or fluid intake, worsen enjoyment or quality of life, or worsen meaningful activity or social inclusion?
10. Do individualised interventions appear more effective than those that are not individualised, in helping people with dementia to maintain or improve food and/or drink intake, nutrition or hydration status (or related outcomes)?
11. Do interventions to assess swallowing (and where necessary treat swallowing problems) have any effect on food or drink intake, nutrition or hydration status (or related outcomes)?
12. Do interventions to improve oral hygiene have any effect on food or drink intake, nutrition or hydration status (or related outcomes)?"
13. For people with dementia living in the community, does type of carer providing the intervention affect the outcomes (e.g. close relative vs paid carer, full time vs occasional carer)?
14. For people with dementia, does emotional closeness of the carer (e.g. close relative vs paid carer) affect the outcomes?
15. Are there any interventions that are particularly effective in helping people with dementia to maintain or improve food and/or drink intake, nutrition or hydration status (or related outcomes) during periods of acute illness?

Criteria for inclusion:

Types of study:

We will consider all intervention or action research studies with a control group including: randomised control trials, cluster randomised trials, quasi-experimental studies, before-after studies. Included studies will have an intervention of at least 5 consecutive days duration (or follow up of at least 5 days for educational interventions). Cross-over studies will also be included, but will only contribute to short term outcomes such as food or drink intake.

Participants:

We will consider all studies involving a minimum of 3 adult humans with any type of dementia (Alzheimer's, vascular dementia, dementia with Lewy bodies or other rarer types) or any stage of dementia (mild to severe) or mild cognitive impairment, in any setting (community dwelling, hospital or residential care, using formal (including day care and peripatetic services) or informal care). We will exclude those at the end of life or requiring palliative care. Criteria or method of diagnosis of dementia and mild cognitive impairment is not an inclusion criterion, but will be assessed as part of study validity. Studies that include dementia patients among other groups will be considered if results for dementia patients can be separated or if they constitute 75% or more of the participants.

Interventions:

Any intervention (including educational interventions with people with dementia and with carers, modification of foods (such as provision of finger foods, or liquidising of foods), stimulating appetite (such as wine, good food smells or exercise), equipment (including using contrasting colour, and cups to allow those with physical disabilities to drink independently), staffing (changing staff numbers or roles), environment (such as making dining rooms more homely), dealing with problems such as oral care and continence, and assessment and intervention for swallowing difficulties) aiming to increase or facilitate oral food and/or drink intake (in those who are experiencing difficulty) or maintain oral food and/or drink intake (in those with no apparent difficulty), or improve, facilitate or maintain nutrition or hydration status.

Enteral tube feeding will not be considered for this review as a Cochrane review already exists in this area (23). We will include studies only where it is possible to separate out the effects of an intervention on oral food or drink from effects of enteral tube feeds or intravenous fluids or nutrients. Pharmacological interventions (for example, pharmacological appetite stimulants, non-food supplements including vitamin, mineral or other capsules, tablets or injections) will be excluded.

Comparator:

Usual food and/or drink provision.

Outcomes:

Primary outcomes

- ❖ Nutritional status (e.g. body mass index, weight, or any recognised nutrition marker)
- ❖ Hydration status (e.g. plasma osmolality, tonicity or osmolarity, urine volume, osmolality or specific gravity, admission to hospital with acute dehydration or acute kidney injury, or provision of intravenous or subcutaneous fluids)
- ❖ Meaningful activity and/or enjoyment of food and/or drink (activity around food or drink that is personally fulfilling, that people enjoy, look forward to or find important)?
- Measures of quality of life

Secondary outcomes

- ❖ Quantity of food intake (e.g. proportion of food provided that is eaten, energy intake)
- ❖ Quantity of fluid intake (e.g. volume of drinks imbibed daily)
- ❖ Quality or adequacy of food and/or drink intake (including ability to eat independently, and ability to swallow without aspirating)
- Measures of functional status (e.g. Barthel Index, Activities of Daily Living, mobility)
- Measures of cognitive status (eg mini-mental state exam)
- Views or attitudes of participants, carers and staff
- Cost effectiveness measures, or measures related to resource use (such as unscheduled hospital admissions)

Tertiary outcomes

- Mortality
- Health outcomes such as urinary tract infections, kidney stones, constipation, measures of continence, wound healing, respiratory infection, aspiration pneumonia, other infections (that may be related to nutrition or hydration status)

Studies will be included where they collect and report at least one of the (specifically food or fluid based) categories of outcomes indicated by a diamond in the list above.

Search strategy:

We will search the following databases for relevant studies; MEDLINE, EMBASE, CINAHL, PsychInfo, the Cochrane library (including Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment, NHS Economic Evaluation Database), the meta-register of controlled trials (a trial register that includes the International Standard Randomised Controlled Trial Number Register, ISRCTN, and the NIH Clinical Trials Register), ALOIS (Cochrane Dementia and Cognitive Improvement Group comprehensive register of dementia trials) and Dissertation and Thesis abstracts, the International Alzheimer's Disease Research Portfolio (IADRP). Bibliographies of included studies as well as list of included and excluded studies from relevant existing systematic reviews will be checked for other relevant studies. The search will not by limited by language or time period.

The search strategy developed for Medline will be a complex strategy combining text and indexing terms, truncation and Boolean operators. It will be tested against a set of studies known to fit the

inclusion criteria, to ensure the search strategy is working well. This electronic strategy will be adapted to the other databases.

Methods:

Data collection

Initial screening of titles and abstracts against the inclusion criteria will be done by two reviewers independently. Full text of any papers identified by any of the reviewers will be collected for assessment.

An inclusion form will be used to assess studies for inclusion/ exclusion (see appendix 1). The form will be completed for each study independently by two reviewers. Differences will be resolved by discussion and when necessary will be arbitrated by a third reviewer. Multiple publications from the same study will be grouped together.

Data will be extracted from included studies using a form designed for this purpose, and quality characteristics will be extracted onto the same form. Data will be extracted in duplicate and include; bibliographic information (study authors, year and country of publication, details of multiple publications), study design, details of study participants (inclusion criteria, number, age, sex, type of dementia, diagnostic criteria, stage of dementia, setting), interventions (description of intervention, duration, details of comparator), and outcomes. For each study we will extract numbers of events and numbers of participants in each arm (which will allow us to calculate the relative risk and 95% confidence interval) for categorical data. For continuous data we will extract change data (change from baseline to the end of study) and the standard deviation of the change, and number of participants for each arm, to allow us to calculate the mean difference or standardised mean difference and the 95% CI. Where change data are not provided then we will use end data (outcome data at the end of the intervention).

Differences between reviewers will be resolved through discussion and if needed a third reviewer will arbitrate. We will attempt to contact researchers to clarify data on validity, participant characteristics, intervention or control characteristics or outcomes as needed.

Quality assessment

The methodological quality of each of the included studies and its risk of bias will be assessed using Cochrane risk of bias tool (24;25). In addition to the generic criteria we will assess the validity of methods of diagnosis of dementia, of outcome measures and baseline comparability between groups.

The quality assessment will be carried out independently by two reviewers.

Data synthesis

Results of searches and process of including studies will be described as well as presented using a flow chart. Characteristics and quality of included studies, and details of studies assessed in full

text but excluded, will be tabulated and discussed in narrative form. A summary of findings table will be presented including number of participants, main outcomes, magnitude of effects on main outcomes and strength of evidence.

Studies included in the review will initially be grouped by type of intervention (i.e. educational, environmental, food/ drink changes etc.) then by study design for tables and narrative synthesis (and for meta-analysis if studies are suitably comparable). The review will also carry out an overarching synthesis of interventions by setting, and separately by stage of dementia and by type of dementia, and further syntheses as required by the review questions. This will enable readers to gain an overview of useful interventions in dementia, and also to focus on the evidence for specific settings and/or specific groups of people with dementia.

If deemed appropriate with available data, results will be pooled in meta-analysis using Review Manager (RevMan) software. Heterogeneity will be quantified using I^2 (24). The main analysis will include all included studies for each type of intervention with relevant outcomes.

Subgrouping will be used to explore effectiveness of interventions based on the following categories:

Stage of dementia (mild/ moderate or severe): Clinical dementia stages will be grouped based on scales used in different studies. Below is a table for grouping by commonly used scales and their scores, including the Global Deterioration Scale (26), the Clinical Dementia Rating scale (27;28), the Montreal Cognitive Assessment (MoCA) (29) and the Mini Mental State Examination (30). Petersen's criteria, and a wide variety of other criteria and tests, are also used to define mild cognitive impairment (31;32). Any other scales used in included studies will be adapted to those groups:

Clinical stage	Scale & score
Mild Cognitive Impairment	Global Deterioration scale (GDS) = 3 Clinical Dementia Rating (CDR) = 0.5 Mini Mental State Examination (MMSE)= ≥24-≤ 26 The Montreal Cognitive Assessment (MoCA) =<26* Petersen's criteria
Mild Dementia	Global Deterioration scale (GDS) = 4 Clinical Dementia Rating (CDR) = 1 Mini Mental State Examination (MMSE)=20-26
Moderate dementia	Global Deterioration scale (GDS) = 5 Clinical Dementia Rating (CDR) = 2 Mini Mental State Examination (MMSE)=10-20
Severe dementia	Global Deterioration scale (GDS) = 6-7 Clinical Dementia Rating (CDR) = 3 Mini Mental State Examination (MMSE)= <10

Type of dementia, which will include vascular dementia, Alzheimer's, Dementia with Lewy bodies, mild cognitive impairment and other types of dementia, and mixed populations.

Different settings, Settings will include living at home without support, living at home with a resident carer, at home with an occasional carer (including housing with care), living in residential care, and medial settings such as a hospital.

Specific questions. Our service users have suggested specific questions to be addressed by the review. These are effectively subgroupings and will be addressed in the review synthesis.

We will conduct sensitivity analysis to assess the effects of interventions across studies at both high and low risk of bias.

Dissemination strategy

We plan to publish the systematic review (in an open access journal) so as to make the findings available to people with dementia and their carers. We will discuss wider dissemination of the findings within CLAHRC Eastern (our funders), with our stakeholder group and with groups with access to people with dementia, for example Age UK Norfolk, NorseCare and the Alzheimer's Society. By addressing questions within the review that are important to our stakeholders we aim to improve dissemination to those who need to use our results – the questions and their summary answers can be separated from the more scientific part of the review and used to inform best practice.

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Appendix 1

Interventions to improve oral food and/or drink intake in people with dementia (EDWINA) 2014

Study eligibility screening form

Study author: Year:

Reviewed by: Date:

1	Is it an intervention study?	**Yes / No / Unclear**
2	Was a control group used (or baseline data available for a pre-intervention period?)	**Yes / No / Unclear**
3	Did the control group have usual food/ drink provision?	**Yes / No / Unclear**
4	Does this study involve intervention or follow up for at least five consecutive days and at least three people?	**Yes / No / Unclear**
5	Are at least 75% of the study participants adult human with any type of dementia or mild cognitive impairment? Or if mixed groups, are the results for dementia/ MCI patients reported separately?	**Yes / No / Unclear**
6	Does the intervention aim to increase or maintain oral food and/or drink intake? Or improve/ maintain hydration/ nutritional status?	**Yes / No / Unclear**
7	Can we separate the effects of intervention from any pharmacological or tablet based interventions?	**Yes / No / Unclear**
8	Are there data available on any of the following: • hydration or nutritional status • Meaningful activity and/or enjoyment of food and/or drink • Quantity/ quality/ adequacy of food or drink intake (including ability to eat independently, and ability to swallow without aspirating)	**Yes / No / Unclear**

Please circle a decision below:

Include / Exclude/ Uncertain

"Include" = only if you answer 'yes' to all questions above.
"Exclude"= If you answer no to any of the questions above.
"Uncertain" = Please state what further action is required for clarification to enable final decision to be made.

Further action to be taken / specific questions for clarification

Reasons for exclusion