PROSPERO International prospective register of systematic reviews

Effectiveness of interventions to improve, maintain or faciltate oral food and/or drink intake in people with dementia

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Review question(s)

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 question 1: What are the most effective ways to encourage people with dementia to eat, drink and maintain nutritional intake?

Specific question 2: For people with mild dementia, what interventions can help to maintain or improve food intake or nutritional status?

Specific question 3: For people with mild dementia, what interventions can help to maintain or improve fluid intake or hydration status?

o(repeat questions 2 & 3 for mild cognitive impairment, moderate dementia and severe dementia)

Specific question 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?

Specific question 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?

o (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)

Specific question 6: For people with Alzheimer's dementia, what interventions can help to maintain or improve food intake or nutritional status?

Specific question 7: For people with Alzheimer's dementia, what interventions can help to maintain or improve fluid intake or hydration status?

o(repeat questions 6 and 7 for those with vascular dementia, Dementia with Lewy bodies, mild cognitive impairment, other types of dementia, and mixed populations)

Specific question 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)?

Specific question 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?

Specific question 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)?

Specific question 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)?

Specific question 12:Do interventions to improve oral hygiene have any effect on food or drink intake, nutrition or hydration status (or related outcomes)?

Specific question 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)?

Specific question 14: For people with dementia, does emotional closeness of the carer (e.g. close relative vs paid carer) affect the outcomes?

Specific question 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?

Searches

We will search the following databases for relevant studies; MEDLINE, EMBASE, CINAHL, PsycINFO, the Cochrane library the Cochrane library (including Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment, NHS Economic Evaluation Database (NHS EED)), 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), the International Alzheimer's Disease Research Portfolio (IADRP) and Dissertation and Thesis abstracts.

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.

Link to search strategy

http://www.crd.york.ac.uk/PROSPEROFILES/7611_STRATEGY_20140118.pdf

Types of study to be included

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.

Condition or domain being studied

Eating and drinking in dementia.

Participants/ population

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.

Intervention(s), exposure(s)

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. 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(s)/ control

Usual food and/or drink provision.

Context

Studies from any setting will considered if they are intervention studies on patients with dementia who are able to eat and drink orally.

Outcome(s)

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

Studies will be included if they reported on at least one of the first three primary outcomes.

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 if they reported on at least one of the first three secondary outcomes

Data extraction, (selection and coding)

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. 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 will 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.

Risk of bias (quality) assessment

The methodological quality of each of the included studies and its risk of bias will be assessed using Cochrane guidelines. 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.

Strategy for data synthesis

Results of searches and process of including studies will be described as well as being 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-squared. The main analysis will include all included studies for each type of intervention with relevant outcomes.

Analysis of subgroups or subsets

Subgrouping will be used to explore the 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.

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 plans

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 with the 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.

Contact details for further information

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Conflicts of interest
None known

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Reference and/or URL for protocol
http://www.crd.york.ac.uk/PROSPEROFILES/7611_PROTOCOL_20140310.pdf

Stage of review
Ongoing

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24 February 2014

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11 April 2014

Stage of review at time of this submission	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	Yes	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No