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Anne Marie Beck, Annette Kjaersgaard, Tina Hansen, Ingrid Poulsen

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Systematic review and evidence based recommendations on texture modified foods and thickened liquids for adults (above 17 years) with oropharyngeal dysphagia – an updated clinical guideline

Anne Marie Beck[1)], Annette Kjaersgaard[2)], Tina Hansen[3)], Ingrid Poulsen[4)]
1) Division of Nutrition and Health, , Faculty of Health and Technology, Metropolitan University College, and Research Unit for Nutrition, Herlev and Gentofte Hospital, Copenhagen, Denmark
2) Hammel Neurorehabilitation Centre and University Research Clinic, Aarhus University, Denmark
3) Division of Physical and Occupational Therapy, Faculty of Health and Technology, Metropolitan University College, Copenhagen, Denmark
4) RUBRIC (Research Unit on Brain Injury Rehabilitation Copenhagen), Department of Neurorehabilitation, TBI Unit, Copenhagen University Hospital, Denmark and Health, Arhus University, Denmark

Corresponding author: Anne Marie Beck ambe@phmetropol.dk

Abstract

Background & Aims
Oropharyngeal dysphagia (OD) has significant consequences for both the person with dysphagia and the society. An often-used treatment for OD is the recommendation of the texture of food and liquids. This recommendation seems to be based more on best practice than on evidence from a systematic review of existing scientific evidence. The aim of this paper was to report the result of an up-date of an original national guideline focussing on whether thickened liquids (review question 1) and modified foods (review question 2) are beneficial for adults above 17 years with OD in relation to three critical outcomes (aspiration, pneumonia and death) and seven important outcomes (dehydration, weight loss, mealtime performance, patient preferences, intervention adherence and quality of life).
Methods
Three steps were used. First: An updated systematic literature search. Second: An assessment of the quality of the evidence for each review question by means of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. , Third: Development of clinical recommendations based on the evidence, assessment of the risk benefit ratio, and perceived patient preferences.
Results
The body of evidence consisted of two RCTs for review question 1 both using nectar thickened liquids or honey-thickened liquids. No evidence was found for two important outcomes, mealtime performance and quality of life. With regard to risk of pneumonia, death, aspiration, dehydration, weight loss and intervention adherence no significant differences were found. The outcome addressing patient preferences, found a non-significant increased dissatisfaction with nectar thickened liquids (RR 1.11; 95% CI 0.95-1.30) and a significant increased dissatisfaction with honey thickened liquids compared to thin liquids/chin down (RR 1.18; 95% CI 1.01-1.37). No evidence was identified for review question 2.
Conclusions
Based on the quality of the evidence, assessment of the risk benefit ratio, and perceived patient preferences a weak recommendation against the use of texture modified liquids and good clinical practice pointing for the use of texture modified foods in patients with OD were made.

Introduction

Oropharyngeal dysphagia (OD) has a lot of significant consequences for both the person with dysphagia and the society depending. The safety and efficacy of the swallowing function is the one primarily affected by OD (1). Safety relates to the risk of aspiration due to food and liquid in the airways and efficacy relates to how effectively and fast the patient swallow food and liquid. This results in an increased risk of; aspiration and/or aspiration pneumonia, reduced oral intake, malnutrition, dehydration, morbidity and mortality (1, 2), social isolation. Besides a reduced quality of life this leads to an increased risk of hospitalization, increased length of stay and increased health care costs.(1, 2)

In an attempt to reduce risk of penetration to the airway it is often recommended to modify liquid viscosity to different levels, by means of a thickening agent. This recommendation is primarily based on accepted best practice, and not on a systematic review of the existing body of evidence (1). Another recommendation for OD is the use of texture-modified foods (3). Recently the 'International Dysphagia Diet Standardisation Initiative' (IDDSI) has suggested a continuum of 8 levels of textures , for different dysphagia severity levels consisting of (2). The background for the IDSSI is the great variation within and across countries with regard to nomenclature, levels of modification and characteristics (4). As an example, in Denmark, four different consistencies are defined, for both modified food and liquids (5).

In order to have some more evidence-based practice recommendations, the 'Danish Centre for Clinical Guidelines – Danish National Clearinghouse' (CFKR) in 2012 published ''The national clinical guideline on texture modified foods and thickened liquids for adults with OD''(3). A national clinical guideline is a set of systematically prepared, evidence-based scientific recommendations describing specific features of the diagnostic evaluation, the treatment, the care, and or the rehabilitation for specific patient groups. A systematic review (SR) formed the body of evidence for the national clinical guideline and the conclusion were that , the evidence in favour of texture modified foods and thickened liquids in OD were limited, since there were only a few, high quality studies was not strong (3). The recommendations were:

1) 'Special made and nutritionally enriched texture modified food (pureed and minced) and thickened liquid (nectar, honey and pudding consistency) and option courses are recommended for elderly persons with chronic OD' (B* = downgraded evidence level due to low quality studies)(3).
2) 'Chin down procedure and thin liquid should be first choice rather than thickened liquid in cases of chronic OD (A = highest evidence level)' (3).
3) 'In the acute phase individual counselling with a follow up and adjustment of the consistency of texture modified food and thickened liquid should be given (A)' (3).

National guidelines published by CFKR ought to be updated every fourth year (6). In addition, the methods used in formulating the guidelines, have been revised according to the required methodology for development of National clinical guidelines defined by the Danish Health and Medicines Authority (DHMA)(7). The aim of this paper was to report the result of an up-date of the original national guideline focussing on whether thickened liquids (review question 1) and modified foods (review question 2) are beneficial for adults above 17 years with OD in relation to three critical outcomes (aspiration, pneumonia and death) and seven important outcomes (dehydration, weight loss, mealtime performance, patient preferences, intervention adherence and quality of life), using the approach recommended by DHMA.

Materials and methods

The steps follow the methodology for National clinical guideline development from DHMA. First step: An updated systematic literature search (7) of relevant guidelines, systematic reviews/meta-analyses, and randomized controlled trials. Second step: Assessment of, the quality of the body of evidence for each review question by means of the 'Grading of Recommendations Assessment, Development and Evaluation' (GRADE) system (8). Third step: Development of clinical recommendations based on the evidence, assessment of the risk benefit ratio, and perceived patient preferences (7). The protocol was registered at PROSPERO (CRD42016047336).

<u>First step: systematic literature search</u>

The standard elements of the review questions provided the basis for defining the eligibility criteria. The review questions were organized according to Patient - Intervention - Comparison – Outcome (PICO) were 1) what is the effect of modification of liquid viscosity in adults with OD? And 2) what is the effect of texture modified food in adults with OD?
With regard to the intervention, the levels of modification and characteristics were not specifically specified, but based on the levels in the included papers.
According to GRADE outcomes were defined as either 'critical' or 'important' (8) (see Table 1).

Inclusion criteria

- Studies and clinical guidelines, which primary focused on texture modified food and liquid (including oral nutritional supplements from the industry), and performed among adults with OD, where texture modification of food and thickened liquid have an impact.
- The time restriction was from 2010 and to May 2016 onwards, since the systematic review was an update of the former SR (3).

Exclusion criteria

- Studies and clinical guidelines where the participants' sole source of nutrition was enteral nutrition.
- Non-English and non-Nordic language literature.
- Studies were the topic was a review of screening and assessment methods for OD or malnutrition.

Identification of evidence

A systematic search in relevant databases was performed by a research librarian (ACMM) and two of the authors (IP, AB).
The databases included: 'Trip database', 'NICE', 'Scottish Intercollegiate Guidelines Network' (SIGN), 'National Guideline Clearinghouse' (USA), 'The Joanna Briggs Institute Library', 'HTA Database' (CRD database), 'SBU' (Sweden), 'The National Social Board' (Sweden), 'The Norwegian Directorate of Health', 'The Norwegian Knowledge Centre for the Health Services', 'The Cochrane Library', 'PubMed', and 'CINAHL'.
The search strategy included terms relating to dysphagia; swallowing disorders; swallowing disorder; swallowing difficulty; swallowing difficult; disorders deglutition; deglutition disorders; deglutition disorder; can't get food down; cannot get food down; difficulty swallowing; difficulty in swallowing; texture; texture modification; nutrition. Detailed search strategies for each database are available from the authors on request. Further searches were conducted by screening the list of references in all selected publications

The search was planned in three steps and performed in November 2015 and in May 2016:
First, existing international guidelines should be retrieved and scrutinized for any relevant content according to the two defined review questions.
The next step should involve a follow-up literature search for SR's and meta-analyses
During the final step, follow-up literature searches for relevant primary literature (randomized controlled trials) should be performed.

The titles of the studies generated from the searches were reviewed for inclusion by two authors (IP, AB). Titles which possibly fitted the inclusion criteria were examined in more detail by the same two authors who reviewed the abstract, and selected possible eligible studies based on the in- and exclusion criteria for the SR. Based on this, full-text papers were retrieved and read by all authors and final decision for inclusion made if all agreed. The study selection process from identification to exclusion in all three steps was documented using the PRISMA flow chart (9).

<u>Second step: Quality assessment of evidence and analysis</u>

Guidelines

The 'Appraisal of Guidelines for Research & Evaluation' (AGREE II) Instrument (10) was used by two of the authors (AB, IP) to assess the quality of the clinical guidelines identified in step 1. Any disagreements were solved through discussions. A total of 23 key items is organized within six domains followed by two global rating items ('Overall Assessment' including the rating of the overall quality of the clinical guideline and whether the clinical guideline would be recommended for use in practice) is included AGREE II (10). The six domains are: '1) Scope and Purpose; 2) Stakeholder Involvement; 3) Rigour of Development; 4) Clarity of Presentation; 5) Applicability and 6) Editorial Independence' (10). In order to assess whether the quality of a clinical guideline is high enough to be included in the updated version of the guideline, the criteria defined by DHMA was applied and the focus was on domain 3) This domain has a focus on the Rigour of development of the guideline. This is judged by considering whether a 'systematic method has been used to search for evidence; whether the following is clearly described; The inclusion criteria for selecting the evidence, The strengths and limitations of the body of evidence; The methods for formulating the recommendations; whether the health benefits, side effects, and risks have been considered in formulating the recommendations; whether there is an explicit link between the recommendations and the supporting evidence; whether the clinical guideline has been externally reviewed by experts prior to its publication; and whether a procedure for updating the clinical guideline is provided' (7, 10).

Systematic reviews

To assess the methodological quality of the SRs identified in step 2, a measurement tool to assess SRs (AMSTAR) (11) was used independently by two of the authors (AB, IP). Any disagreements were solved through discussions. AMSTAR assess the following topics (11): '1) was an 'a priori' design provided? 2) Was there duplicate study selection and data extraction? 3) Was a comprehensive literature search performed? 4) Was the status of publication (i.e. grey literature) used as an inclusion criterion? 5) Was a list of studies (included and excluded) provided? 6) Were the characteristics of the included studies provided? 7) Was the scientific quality of the included studies assessed and documented? 8) Was the scientific quality of the included studies used appropriately in formulating conclusions? 9) Were the methods used to combine the findings of studies appropriate? 10) Was the likelihood of publication bias assessed? 11) Was the conflict of interest included? Four answers are possible; Yes; No; can't answer; not applicable and a maximum score of 11 can be obtained (11). According to the required methodology for development of National clinical guidelines in Denmark, the inclusion of SRs should be based on AMSTAR topic 3 and 7 (7). If Meta-analysis was performed, inclusion is also based on AMSTAR topic 9.)(7).

Primary literature (randomized controlled trials)

The Cochrane Collaboration's Risk of Bias tool (12) was used to critically appraise and assess each included RCT in step 3 .(12) The tool includes six domains: 'random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and selective reporting' (12). As recommended biases not addressed in these six domains were evaluated in the last domain; other bias. Each domain was assessed to be at 'Low risk', 'High risk' or at 'Unclear risk' of bias (12). The assessment was performed by two of the authors (AK, TH) and presented in a Cochrane Risk of bias table using RevMan (version 5.3) (12) Any disagreements were solved through discussions.

Data extraction, synthesis of data and statistical analysis

If clinical guidelines or SRs identified and assessed in step 1 and 2 were of high quality and up-to date, the intention was to use the results directly. If relevant RCTs were published after the guidelines or SRs, the plan was to assess their quality, extract their data and include these in new meta-analyses using the principles from The Cochrane Handbook for Systematic Review of Interventions (12), also by means of RevMan (version 5.3)(13). If the composition of elements in the intervention and criteria for patient inclusion varied, random effects meta-analyses were planned. If not fixed effect meta-analysis would be undertaken. Relative risk (RR) would be calculated for dichotomous outcomes. Heterogeneity among studies would be assessed using I^2 statistics.

As a next step the results of the descriptive analysis and the meta-analysis was planned to be exported to the (GRADEpro) software (version 3.6)(14) in order to produce the GRADE Evidence Profiles and the Summary of Findings Tables. These tables were produced by two authors (TH and AB) and were used to summarize the evidence for each outcome in addition to the quality of the evidence, which is evaluated according to the presence and severity of methodological limitations, inconsistency, indirectness, imprecision and publication bias (8). The quality of the evidence is graded according to the GRADE system as high (⊕⊕⊕⊕), moderate (⊕⊕⊕◯), low (⊕⊕◯◯), or very low (⊕◯◯◯). (see Appendix A, table 1A) The definitions of each grading level is as follows: 'further research is very unlikely to change our confidence in the estimate of effect (= high quality); further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate (= moderate 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 (= low quality); we are very uncertain about the estimate (= very low quality)' (8).

Third step: Clinical recommendations

Categorizing, labelling and wording of the recommendations

The GRADE approach was used to derive the final recommendations in the up-dated clinical guideline. Using GRADE, the recommendations are expressed as either strong or weak, and either for or against an intervention. Further, the recommendations may be conditioned upon patient values and preferences, the resources available or the setting in which the intervention is intended to be implemented. The strength of the recommendation is determined by the extent to which one can be confident that the desirable consequences of an intervention outweigh its undesirable consequences. The desirable and undesirable consequences are classified as 'critical' and 'important but not critical' outcomes.

The lowest quality of evidence supporting any one critical outcome, determine the overall quality of the evidence (8). If no evidence is identified during the initial steps mentioned above, a consensus approach can be used to make a recommendation based on clinical experience and professional opinion among the working group (7). The categorizing, labelling and wording of the recommendations was performed by all authors collectively based on the descriptions in Appendix A (table 1B). When formulating the recommendations the description of the level of texture modifications, was based on the suggestions from IDDSI if no evidence was found (2). All recommendations were formulated by all authors.

Results

First step: systematic literature search

The study selection process from identification to exclusion in all three steps is presented in Appendix A (figure 1A-1C) using the PRISMA flow chart.

Second step: Quality assessment of evidence and analysis

Guidelines

During step 1) three guidelines were identified; Hookway et al. (15), SIGN (16) and The Management of Stroke Rehabilitation Working Group (17). After the assessment with AGREE II all guidelines were excluded, due to low quality in Domain 3) Rigour of development (see Appendix A, figure 1A).

Systematic reviews

During step 2) four SRs were identified (18-21) (see Appendix A figure 1B). These four where all included in our former clinical guideline (3). The assessment by means of AMSTAR resulted in a score of, respectively; 7 (Loeb et al. 2003) (18); 3 (Speyer et al. 2010)(19); 5 (Hines et al. 2010) (20)and 6 (Foley et al. 2008) (21) but for this update all four were excluded (see Appendix A, figure 1B).

Primary literature (RCTs)

The two RCTs: Robbins et al. 2008 (22) and Logemann et al. 2008 (23) identified through our systematic search in step 3 (see Appendix A, figure 1C) were already included in our former guideline. The details of the

two RCTs are presented in table 2. Risk of bias for the two RCTs is summarised in table 3 with the domains colour coded based on low (green), unclear (yellow) or high (red) risk.

Data extraction, synthesis of data and statistical analysis of the identified evidence

Only the two RCTs (22, 23) identified in the systematic search could directly answer our PICO (table 1). And this was only in relation to texture modified liquid. Since the study by Robbins et al. (22) had duration of three months while the study by Logemann et al. (23) assessed immediate elimination of aspiration, the included studies were judged not to be homogenous and therefore their results were not combined in meta-analysis. However, analysis was performed for each study in relation to the defined critical and important outcomes (table 1). The results of the descriptive analysis and the analysis were exported to the GRADEpro software (14) in order to produce the 'GRADE Evidence Profiles' (EP) and the 'Summary of Findings' (SoF) tables (see table 4a and 4b for the SoF tables). Specific results are presented below.

Texture modified liquids

The body of evidence consisted of the two RCTs identified during the literature search. Both studies used nectar thickened liquids or honey-thickened liquids as a compensatory strategy to facilitate safe and efficient intake of liquids amongst adults with OD compared to normal diet or usual care (22, 23). In both studies, the comparator addressed a restricted version of the review question 1, namely thin liquids and postural adjustment by means of chin down (thin liquids/chin down). In addition, the population in the identified studies was restricted to participants with dementia and/or Parkinson disease, and the age ranged from 50 to 95 years. Since the outcomes were measured at very different time points across the two included studies, meta-analysis was not performed.

With regard to the nectar-thickened liquids no evidence was found for two important outcomes, mealtime performance and quality of life. The current analysis of the critical outcomes at three month follow-up found a non-significant decreased risk of pneumonia (RR= 0.81; 95% CI 0.40-1.65) and death (RR= 0.91; 95% CI 0.51-1.62). For the important outcomes, the analysis found a non-significant reduction in aspiration during intervention (RR 0.93; 95%CI 0.80-1.07), and non-significant increased risk of dehydration (RR= 2.27; 95% CI 0.78-6.62) and weight loss (RR= 1.45; 95%CI 0.33-6.38) at three month follow-up. The outcome addressing patient preferences , found a non-significant increased dissatisfaction with nectar thickened liquids compared to thin liquids/chin down (RR= 1.11; 95% CI 0.95-1.30). No difference in the intervention adherence between nectar thickened liquids and thin liquids/chin down at three month follow up (RR= 1.01; 95% CI 0.79-1.28) was found. For all the identified outcomes, the quality of evidence was very low to low.

With regard to the honey-thickened liquids no evidence was found for two important outcomes, mealtime performance and quality of life. The current analysis of the critical outcomes at three month follow-up found a non-significant increased risk of pneumonia (RR= 1.58; 95% CI 0.89-2.80) and a decreased but non-significant risk of death (RR= 0.92; 95% CI 0.51-1.66). For the important outcomes, the analysis found a non-significant reduction in aspiration during intervention (RR 0.86; 95%CI 0.73-1.01), and a increased but non-significant risk of dehydration (RR= 2.81; 95% CI 1.00-7.92) and weight loss (RR= 1.58; 95%CI 0.36-6.95) at three month follow-up. The outcome addressing patient preferences , found a significant increased dissatisfaction with honey thickened liquids compared to thin liquids/chin down (RR= 1.18; 95% CI 1.01-1.37). There was a decrease (non-significant) in the intervention adherence to honey thickened liquids at three month follow up (RR= 1.13; 95% CI 0.90-1.41). For all the identified outcomes, the quality of the evidence was very low to low.

Texture modified foods

No literature was identified that addressed the effects of using texture modified food consistencies as a compensatory strategy to facilitate safe and efficient intake of foods amongst adults with OD compared to normal diet (no food modification) or usual care.

Third step: Clinical recommendations

Categorizing, labelling and wording of the recommendations
The recommendations are presented in table 5 and described in details below.

Texture modified liquids
With regard to both nectar-thickened liquids and honey-thickened liquids the risk-benefit ratio was uncertain and it was therefore recommended that both levels for facilitating safe and efficient intake of liquids amongst adults with OD should only be used cautiously. The description of the levels was, respectively, slightly and mildly thick, taking the 'IDDSI Framework' (2) into consideration.
There were not identified any literature assessing the effect of moderate thick or extremely thick levels of liquids. Therefore, the authors took the results on review question 1 and 2 into consideration. Since the beneficial effect on the critical outcomes for nectar and honey thickened liquids are uncertain and there seems to be a tendency towards decreased patient preferences, weight loss and dehydration, it is highly likely that this might also relates to moderate and extremely thickened liquids. Consequently, it was concluded that it is not good clinical practice to offer moderate or extremely thick levels of liquids as a compensatory strategy to facilitate the intake of liquids amongst adults with OD.

Texture modified foods
No literature assessing the effect of texture modified food was identified. Therefore the working group took the IDDSI Framework (2) into consideration and concluded that it is 'good clinical practice' (8) to offer different levels adapted to the individual ingestive abilities of adults with OD (2).

Discussion

This paper reported the result of an update of an original national guideline focussing on whether thickened liquids (review question 1) and modified foods (review question 2) are beneficial for adults above 17 years with OD in relation to two critical outcomes (pneumonia and death) and eight important outcomes (aspiration, dehydration, weight loss, mealtime performance, patient preferences, intervention adherence and quality of life).

Based on the GRADE system, the final quality of evidence for the effect of modification of liquid viscosity in adults with OD was very low or low for all outcomes, and it was found that values and patient preferences were higher for thin than for modified liquids. In clinical guidelines it is very important to include the patient perspective (9). It is found that in general bolus modification is associated with decreased quality of life (24, 25). Within the GRADE system, evidence with ratings of 'low' and 'very low quality' indicates that there might be low confidence in the resulting effect estimates and that there are a need for additional evidence to draw conclusion (26). Based on this and balancing between desirable and undesirable consequences our findings permitted weak recommendations against routinely use of modified liquids in adults with OD. It has been speculated whether the application of the GRADE system in reviewing complex interventions such as OD management strategies (27), which are characterized by active engagement by participants and changes in behaviour in multiple settings, often leads to downgrading of evidence due to performance bias, imprecision and indirectness resulting in weak recommendations (28). However, the updated recommendations did not change the focus of the recommendations in the clinical guideline reported in Andersen et al (3). This conclusion is despite the fact, that the quality assessment methods used in the updating process by means of GRADE were different from Andersen et al (3), who used the evidence levels and grades of recommendations suggested by the 'Oxford Centre for Evidence-Based Medicine' (29) For this updated guideline, the influences of the GRADE system was related to the number of included studies. Andersen et al (3) included 16 papers, whereas this updated version only included two papers, of which both addressed modified liquids and were included in Andersen et al (3). This finding might reflect more rigor in

framing the review questions and the study selection process when following the new methodology for National clinical guideline development given by the DMHA (7) compared to the previous given by CFKR (6). One consequence was that our former recommendation to use 'Chin down' procedure and thin liquid as the 'first choice' rather than thickened liquid in chronic OD was not supported in the evidence in this updated version.

Texture modified liquid consistencies

Our recommendations against routinely use of modified liquid in adults with OD is somewhat stronger that the conclusion given by a recent systematic review and meta-analysis of thin liquids and safety protocols vs. thick liquids by Kaneoka et al. (30), even though they found no difference for risk of pneumonia. Our conclusion is also stronger than the one by Newman et al. (1) who conclude that in patients with OD liquids with increased viscosity is more beneficial in reducing risk of laryngeal penetration and/or aspiration. This is despite the fact that Newman et al. (1) found that although the increase of bolus viscosity immediately results in a more safe swallowing process, the amounts of oral and pharyngeal residue also increased, with risk of post swallowing airway invasion. Thus, in itself it is a risk and will vary depending of the nature and severity of the individual person with OD. Therefore it might be a weakness formulating broader recommendations when they are solely based on swallowing studies that assess the immediately effect of texture modifications.

Texture modified food consistencies

No literature was identified that addressed the effects of using texture modified food consistencies as a compensatory strategy to facilitate safe and efficient intake of foods amongst adults with OD compared to normal diet or usual care. However our clinical experiences from different rehabilitation settings justifies that different levels of texture modified food consistencies (5) are needed to assess a person with OD and to perform treatment in the process from enteral tube feeding to full oral intake by mouth. This is also supported by the systematic review done by the 'ISSDI framework' group (31) who describe that there are several characteristics of food texture, such as cohesiveness, hardness, and slipperiness that influences the swallowing mechanism.

Limitations

Our recommendations regarding the different texture modified levels of liquids (see table 5) are based on two studies, which specifically offered nectar and honey thickened liquids, which we assessed as being identical to slightly and mildly thick, respectively. Further, since the only RCTs involved subjects with Parkinson's disease or 'dementia', the results may or may not be applicable to subjects with oropharyngeal dysphagia as the result of other disorders.

We did not include a search in EMBASE and hence might have missed some important publications. On the other hand the searches performed were quite comprehensive so the risk of this is limited.

The patient perspective and acceptance is relevant aspects to include in a guideline of this kind as they have to life with the texture modified foods and thickened liquids maybe for rest of their lives and especially when the evidence of the recommendations are weak. Some evidence points out (24) that thickened liquids in general is not well accepted by users. When formulating the recommendations, we took the outcome addressing patient preferences, in one of the identified RCTs into consideration, but we could have focused more on patients/users perspectives

Perspective

As there was no sufficient evidence for giving new recommendations of texture modified food and thickened liquid to provide sufficient safe energy and protein intake in patients with OD more research is needed. A Cochrane review (32) on the way may help in shed more light on this. These findings and the results of

hopefully more research in this field may be included in an update of the present clinical guideline, expected to take place in 2020.

Conclusion

Based on the quality of the evidence, assessment of the risk benefit ratio, and perceived patient preferences a weak recommendation against the use of texture modified liquids and good clinical practice pointing for the use of texture modified foods in patients with OD were made.

Contributions

All authors formulated the PICOs, i.e. participated in the conception and design of the update. AB and IP performed the systematic literature search and quality assessment. TH performed the data extraction, synthesis of data and data analysis. All authors contributed to the analysis and interpretation of data, and the categorizing, labelling and wording of the recommendations. AB drafted the article and AK, TH and IP revised it critically for important intellectual content. All authors approved the final version of the version to be submitted.

Conflict of interest statement

No conflict of interest

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519 Table 1. Eligibility criteria based on PICOS

Population	Patients above 17 years with oropharyngeal dysphagia in acute care (hospital) or chronic care (homecare home, nursing care facility)
Intervention	Texture modified food (any levels) Texture modified liquids (any levels)
Comparison	Usual care or normal diet (no food modification)
Outcome	Critical: Pneumonia and death Important: Aspiration, dehydration, nutritional status, mealtime performance, patient preferences, intervention adherence and quality of life
Type of studies	Randomised controlled trials, guidelines, systematic review incl. Cochrane reviews, qualitative studies

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522 Table 2. Included primary randomised controlled trials (RCTs)

	Method	Patient characteristic (age)	Interventions	Main results
Robbins et al. 2008 (22)	Multicenter RCT	515 patients Parkinson or dementia who aspirated thin liquids (age >50 years)	Drink all liquids in a chin-down posture. Control: Drink nectar-thick or honey-thick liquids in head-neutral position	The 3-month cumulative incidence of pneumonia was 0.098 and 0.116 in the chin-down posture and thickened-liquid groups. The 3-month cumulative incidence of pneumonia was 0.084 in the nectar-thick liquid group compared with 0.150 in the honey-thick liquid group.
Logemann et al. 2008 (23)	Multicenter RCT	711 patients with Parkinson and dementia (age range 50-95)	Thin liquid + "chin down" procedure, nectar thickened liquid and honey thickened liquid given in random order	Short term effect on aspiration: 39% (Parkinson) and 50% (dementia) aspirated on all interventions Aspiration of all pt. on thin liquid +"chin down" versus honey consistency (68% versus 53%, $p < 0.0001$) and aspiration at thin liquid + "chin down" versus nectar consistency (68% versus 63%, $p < 0.001$). Patients with most severe dementia exhibited least effectiveness on all interventions

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525 Table 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included
526 study (domains colour coded based on low (green) and unclear (yellow)).
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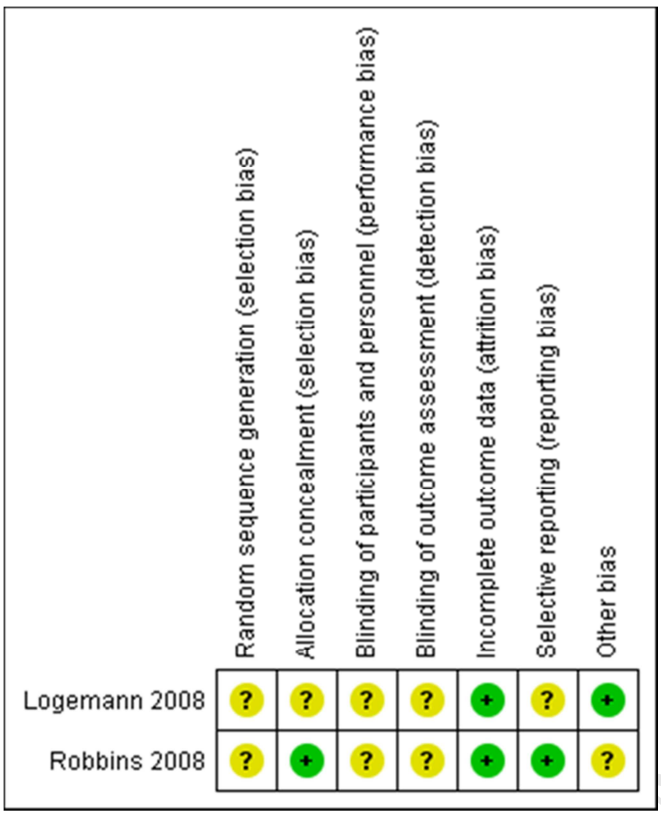

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533 Table 4a: Summary of findings: Nectar thickened liquids compared to normal diet or usual care in adults (>
534 18 years) with OD (ref. 22,23) (see separate file)
535
536 Table 4b: Summary of findings: Honey thickened liquids compared to normal diet or usual care in adults (>
537 18 years) with OD (ref. 22,23) (see separate file)

538

539 Tabel 5

Summary of the clinical guideline recommendations

Modified liquids		
	Slightly thick liquids	
↓		Use only nectar-thickened liquids after careful consideration as a compensatory strategy to facilitate the intake of liquids amongst adults with oropharyngeal dysphagia (OD), since the beneficial effect on the critical outcome is uncertain and there seems to be a tendency towards decreased patient preferences and dehydration.
	Mildly thick liquids	
↓		Use only honey-thickened liquids after careful consideration as a compensatory strategy to facilitate the intake of liquids amongst adults with oropharyngeal dysphagia, since the beneficial effect on the critical outcome is uncertain and there seems to be a tendency towards decreased patient preferences, weight loss and dehydration.
√	Moderately/extremely thick liquids	It is not good practice to offer honey thickened liquids ruinously as a compensatory strategy to facilitate the intake of liquids amongst adults with oropharyngeal dysphagia, since the beneficial effect on the critical outcome for other less thickened liquids is uncertain and there seems to be a tendency towards decreased patient preferences, weight loss and dehydration
Modified foods		
√		It is good practice to consider offering modified foods as a compensatory strategy to facilitate the intake of foods amongst adults with oropharyngeal dysphagia

Appendix A

Table 1A. Assessing quality of evidence by outcome (7)

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Assessing Quality of Evidence by Outcome

Table: GRADE's approach to rating quality of evidence (aka confidence in effect estimates)

For each outcome based on a systematic review and across outcomes (lowest quality across the outcomes critical for decision making)

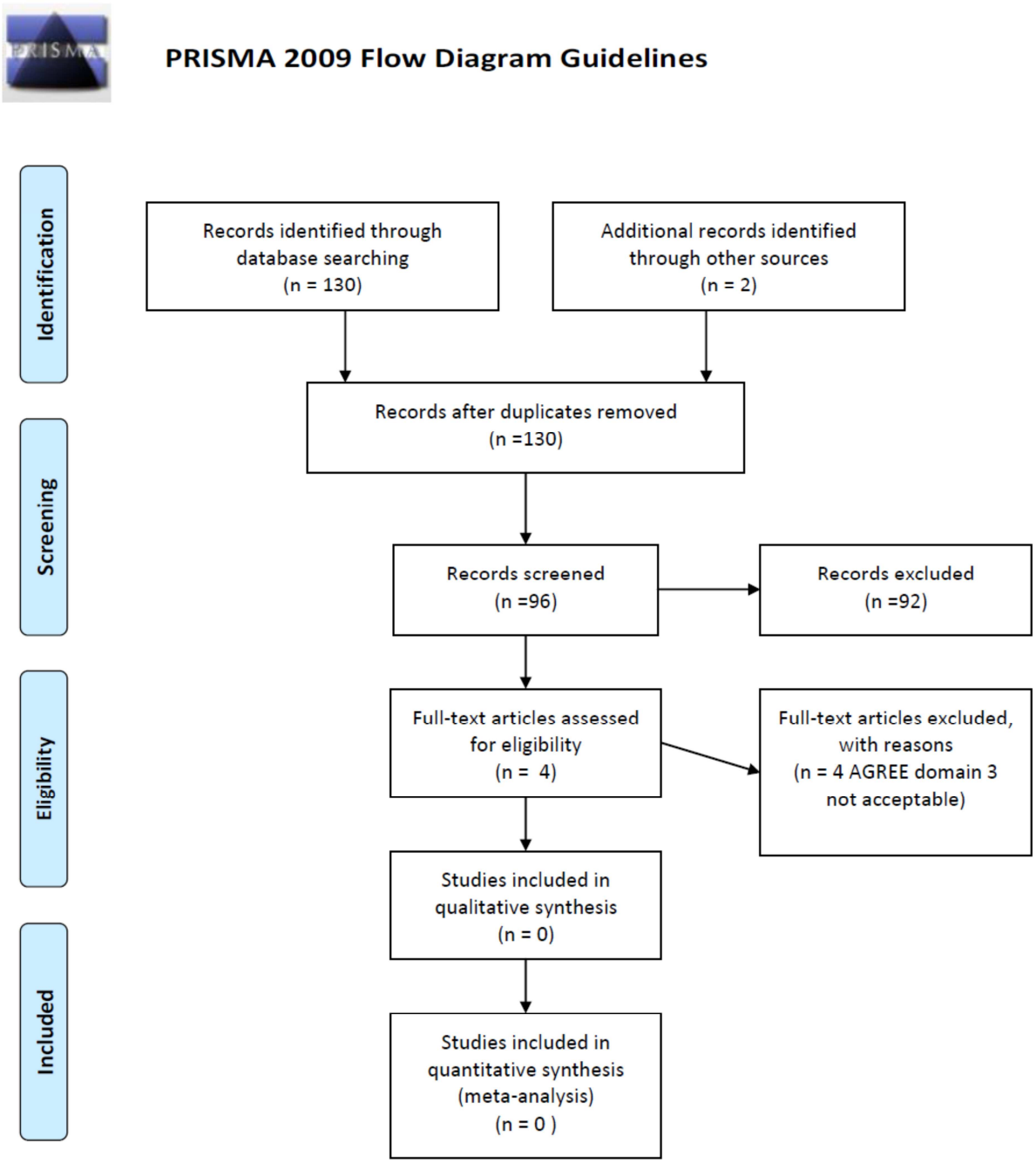
1. Establish initial level of confidence		2. Consider lowering or raising level of confidence		3. Final level of confidence rating
Study design	*Initial confidence in an estimate of effect*	*Reasons for considering lowering or raising confidence*		*Confidence in an estimate of effect across those considerations*
		↓ Lower if	↑ Higher if*	
Randomized trials →	High confidence	Risk of Bias Inconsistency Indirectness Imprecision Publication bias	Large effect Dose response All plausible confounding & bias • would reduce a demonstrated effect or • would suggest a spurious effect if no effect was observed	High ⊕⊕⊕⊕
				Moderate ⊕⊕⊕◯
Observational studies →	Low confidence			Low ⊕⊕◯◯
				Very low ⊕◯◯◯

*upgrading criteria are usually applicable to observational studies only.

Fig. 1. GRADE's approach to rating quality of evidence (aka confidence in effect estimates).

Table 1B. Grade of recommendations/descriptions

Grade of recommendations/descriptions	Benefits versus risk or burdens	Methodology quality of support evidence	Patient values and preferences	Implications
Strong recommendation for (↑↑) It is recommended that….	Benefits clearly outweigh risk or burden	Evidence without limitations	Patient values and preferences are well known and support the intervention	Can apply to most patients in most circumstances without reservation Most clinicians will prescribe the intervention
Strong recommendation against (↓↓) It *cannot* be recommended that….	Risk or burden clearly outweigh benefits,	Evidence without limitations Low or no benefit of the intervention Some or significant side-effects/complication to the intervention	Patient values and preferences are well known and *does not* support the intervention	Most patients do *not* want the intervention Most clinicians will *not* prescribe the intervention
Weak recommendation for (↑?) It may be considered to….	Benefits seems to outweigh risk and burdens	Evidence with important limitations The evidence seems to achieve some benefit No significant side-effects/complications	Patient values and preferences varies or are unknown	Most patients want the intervention but some will refuse Clinicians must assist the patients with their decision, according to the patients values and preferences
Weak recommendation against (↓?) It *cannot* be recommend to routinely use	Risk and burdens seems to outweigh the benefits	Evidence with important limitations Uncertainty about the benefits and side-effects/complications of the intervention Unwanted side-effects/complications might be marginal higher than the benefits	Patient values and preferences varies significantly or are unknown	Most patients do not want the intervention but some will say yes Clinicians must assist the patients with their decision, according to the patients values and preferences
Good Practice Point (√) *) The working group consider it as good clinical practice	Consensus	No evidence	Consensus	Consensus



Figur 1A. Flow-diagram for search of guidelines

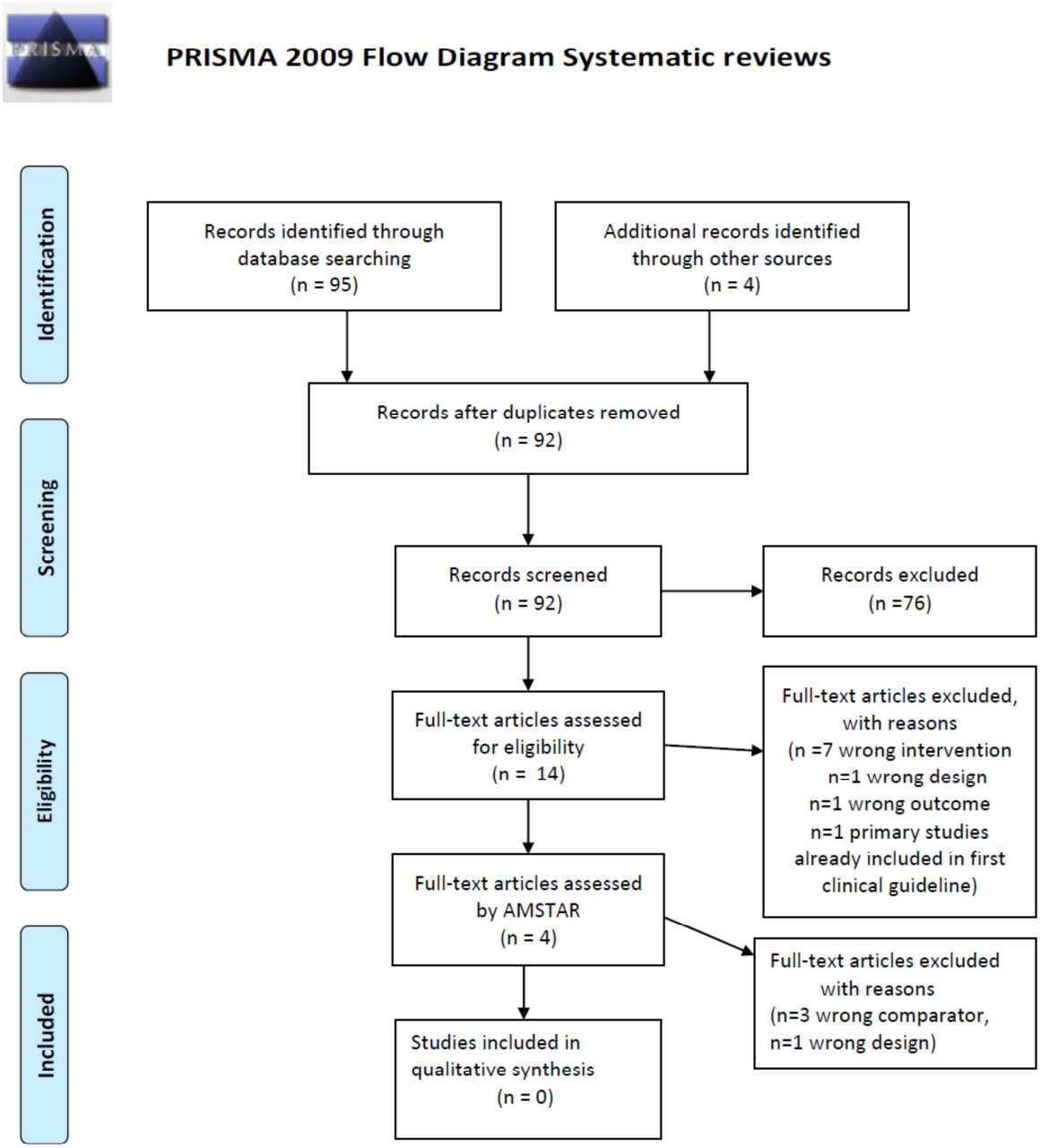


Figure 1B. Flow-diagram for search of systematic reviews

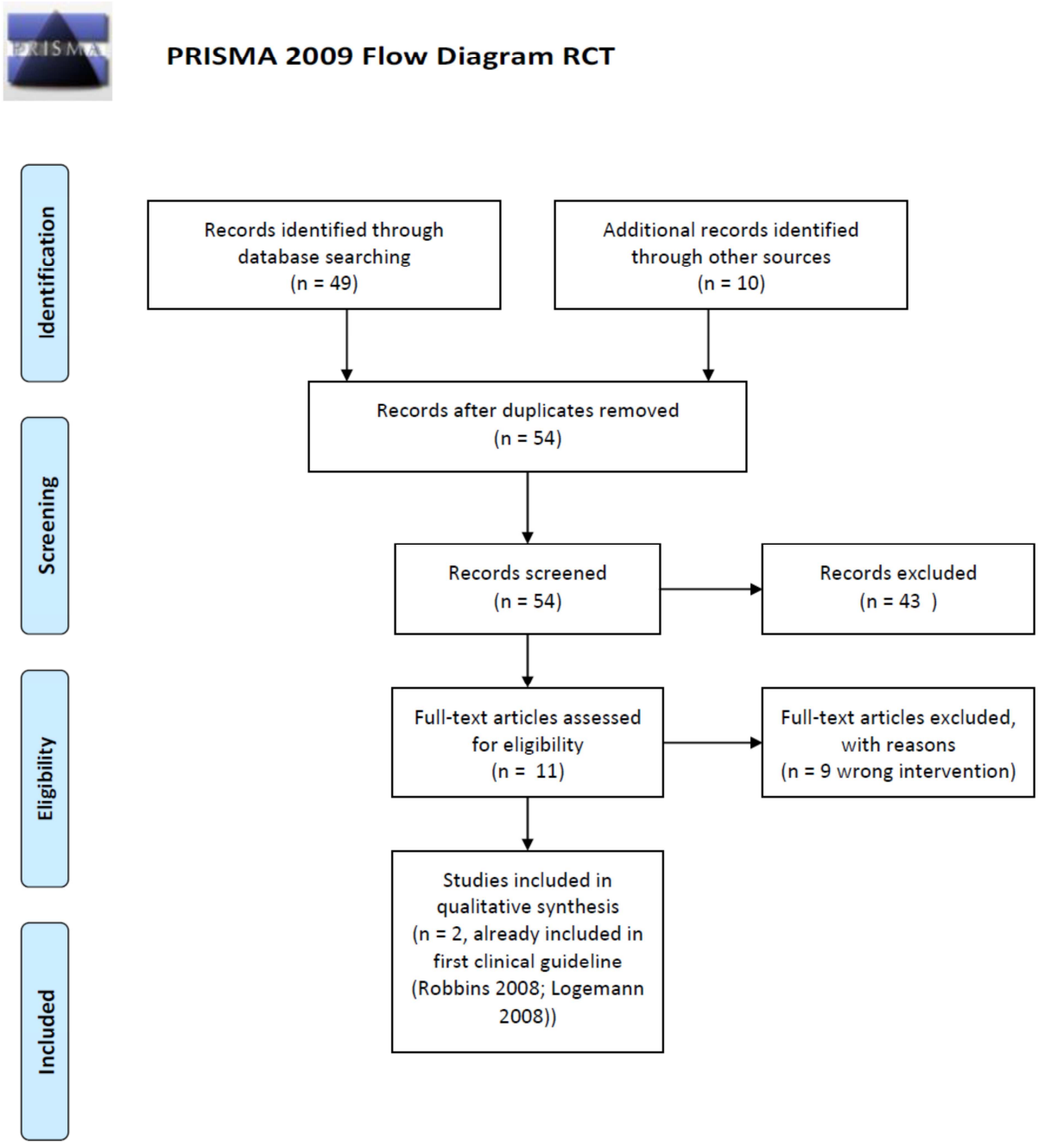


Figure 1C. Flow-diagram for search of Randomised controlled trials

Table 4a: Summary of findings: Nectar thickened liquids compared to normal diet or usual care in adults (> 18 years) with OD (22,23)

Patient or population: Adults (> 18 years) with OD; **Intervention**: Nectar thickened liquids; **Comparison**: Normal diet or usual care

Outcomes (time frame)	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)
	Risk with normal diet or usual care	**Risk with Modified textures**			
Fluid intake§	N/A	N/A	N/A	N/A	N/A
Aspiration (during intervention) §	707 per 1.000	**657 per 1.000** (565 to 756)	**RR 0.93** (0.80 to 1.07)	392 (1 RCT)[23]	⊕◯◯◯ VERY LOW [a-f]
Dehydration (3 months follow-up) §	23 per 1.000	**53 per 1.000** (18 to 153)	**RR 2.27** (0.78 to 6.62)	392 (1 RCT)[22]	⊕⊕◯◯ LOW [a,c,e,f]
Weight loss (3 month follow-up)	16 per 1.000	**23 per 1.000** (5 to 99)	**RR 1.45** (0.33 to 6.38)	390 (1 RCT)[22]	⊕◯◯◯ VERY LOW [a,c,e,f]
Pneumonia (3 month follow-up) #	93 per 1.000	**75 per 1.000** (37 to 153)	**RR 0.81** (0.40 to 1.65)	392 (1 RCT)[22]	⊕◯◯◯ VERY LOW [a,c,e,f]
Death (3 month follow-up) #	124 per 1.000	**112 per 1.000** (63 to 200)	**RR 0.91** (0.51 to 1.62)	392 (1 RCT)[22]	⊕◯◯◯ VERY LOW [a,c,e,f]
Dislike texture (during intervention) §	771 per 1.000	**856 per 1.000** (733 to 1.000)	**RR 1.11** (0.95 to 1.30)	140 (1 RCT)[23]	⊕◯◯◯ VERY LOW [a-f]
Adherence (3 month follow-up) §	702 per 1.000	**709 per 1.000** (554 to 898)	**RR 1.01** (0.79 to 1.28)	115 (1 RCT)[22]	⊕◯◯◯ VERY LOW [a,c,e,f]
Mealtime performance§	N/A	N/A	N/A	N/A	N/A
Health-related quality of life§	N/A	N/A	N/A	N/A	N/A

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
Critical outcome
§ **Important outcome**
Abbreviations: CI: Confidence interval; **RR:** Risk ratio; **N/A**: Not applicable due to no evidence found

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect; **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect; **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

a. Unclear random sequence generation (selection bias); **b**. Unclear allocation concealment (selection bias); **c.** Unclear blinding of participants and personal (performance bias)and outcome assessment (detection bias); **d**. Unclear selective reporting (reporting bias); **e.** Indirectness of evidence in terms of population and comparator; **f**. Imprecision of results since the CI is wide and includes RR=1

Table 4b: Summary of findings: Honey thickened liquids compared to normal diet or usual care in adults (> 18 years) with OD (22,23)

Patient or population: Adults (> 18 years) with OD; **Intervention**: Honey thickened liquids; **Comparison**: Normal diet or usual care

Outcomes (timeframe)	**Anticipated absolute effects*** (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)
	Risk with normal diet or usual care	**Risk with Modified textures**			
Fluid intake§	N/A	N/A	N/A	N/A	N/A
Aspiration (during intervention) §	707 per 1.000	**608 per 1.000** (516 to 714)	**RR 0.86** (0.73 to 1.01)	382 (1 RCT) [23]	⊕◯◯◯ VERY LOW [a-f]
Dehydration (3 month follow-up) §	23 per 1.000	**65 per 1.000** (23 to 183)	**RR 2.81** (1.00 to 7.92)	382 (1 RCT) [22]	⊕⊕◯◯ LOW [a,c,e,f]
Weight loss (3 month follow-up) §	15 per 1.000	**24 per 1.000** (6 to 107)	**RR 1.58** (0.36 to 6.95)	382 (1 RCT) [22]	⊕◯◯◯ VERY LOW
Pneumonia (3 month follow-up) #	93 per 1.000	**146 per 1.000** (82 to 259)	**RR 1.58** (0.89 to 2.80)	382 (1 RCT) [22]	⊕◯◯◯ VERY LOW
Death (3 month follow-up) #	124 per 1.000	**114 per 1.000** (63 to 205)	**RR 0.92** (0.51 to 1.66)	382 (1 RCT) [22]	⊕◯◯◯ VERY LOW
Dislike texture (during intervention) §	771 per 1.000	**910 per 1.000** (779 to 1.000)	**RR 1.18** (1.01 to 1.37)	125 (1 RCT) [23]	⊕⊕◯◯ LOW [a-f]
Adherence (3 month follow-up) §	702 per 1.000	**793 per 1.000** (632 to 989)	**RR 1.13** (0.90 to 1.41)	105 (1 RCT) [22]	⊕◯◯◯ VERY LOW
Mealtime performance§	N/A	N/A	N/A	N/A	N/A
Health-related quality of life§	N/A	N/A	N/A	N/A	N/A

*__The risk in the intervention group__ (and its 95% CI) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
[#] **Critical outcome**
[§] **Important outcome**
Abbreviations: CI: Confidence interval; **RR:** Risk ratio; **N/A**: Not applicable due to no evidence found

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect; **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect; **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

a. Unclear random sequence generation (selection bias); **b**. Unclear allocation concealment (selection bias); **c.** Unclear blinding of participants and personal (performance bias)and outcome assessment (detection bias); **d**. Unclear selective reporting (reporting bias); **e.** Indirectness of evidence in terms of population and comparator; **f**. Imprecision of results since the CI is wide and includes RR=1