Interventions for improving oral health in people after stroke

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Interventions for improving oral health in people after stroke (Review)

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[Intervention Review]

Interventions for improving oral health in people after stroke

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ABSTRACT

Background

For people with physical, sensory and cognitive limitations due to stroke, the routine practice of oral health care (OHC) may become a challenge. Evidence-based supported oral care intervention is essential for this patient group.

Objectives

To compare the effectiveness of OHC interventions with usual care or other treatment options for ensuring oral health in people after a stroke.

Search methods

We searched the Cochrane Stroke Group and Cochrane Oral Health Group trials registers, CENTRAL, MEDLINE, Embase, and six other databases in February 2019. We scanned reference lists from relevant papers and contacted authors and researchers in the field. We handsearched the reference lists of relevant articles and contacted other researchers. There were no language restrictions.

Selection criteria

We included randomised controlled trials (RCTs) that evaluated one or more interventions designed to improve the cleanliness and health of the mouth, tongue and teeth in people with a stroke who received assisted OHC led by healthcare staff. We included trials with a mixed population provided we could extract the stroke-specific data. The primary outcomes were dental plaque or denture plaque. Secondary outcomes included presence of oral disease, presence of related infection and oral opportunistic pathogens related to OHC and pneumonia, stroke survivor and providers' knowledge and attitudes to OHC, and patient satisfaction and quality of life.

Data collection and analysis

Two review authors independently screened abstracts and full-text articles according to prespecified selection criteria, extracted data and assessed the methodological quality using the Cochrane 'Risk of bias' tool. We sought clarification from investigators when required. Where suitable statistical data were available, we combined the selected outcome data in pooled meta-analyses. We used GRADE to assess the quality of evidence for each outcome.

Main results

Fifteen RCTs (22 randomised comparisons) involving 3631 participants with data for 1546 people with stroke met the selection criteria.

OHC interventions compared with usual care

Seven trials (2865 participants, with data for 903 participants with stroke, 1028 healthcare providers, 94 informal carers) investigated OHC interventions compared with usual care.

Multi-component OHC interventions showed no evidence of a difference in the mean score (DMS) of dental plaque one month after the intervention was delivered (DMS -0.66, 95% CI -1.40 to 0.09; 2 trials, 83 participants; $I^2 = 83\%$; $P = 0.08$; very low-quality evidence).

Stroke survivors had less plaque on their dentures when staff had access to the multi-component OHC intervention (DMS -1.31, 95% CI -1.96 to -0.66; 1 trial, 38 participants; $P < 0.0001$; low-quality evidence).

There was no evidence of a difference in gingivitis (DMS -0.60, 95% CI -1.66 to 0.45; 2 trials, 83 participants; $I^2 = 93\%$; $P = 0.26$; very low-quality evidence) or denture-induced stomatitis (DMS -0.33, 95% CI -0.92 to 0.26; 1 trial, 38 participants; $P = 0.69$; low-quality evidence) among participants receiving the multi-component OHC protocol compared with usual care one month after the intervention. There was no difference in the incidence of pneumonia in participants receiving a multi-component OHC intervention (99 participants; 5 incidents of pneumonia) compared with those receiving usual care (105 participants; 1 incident of pneumonia) (OR 4.17, CI 95% 0.82 to 21.11; 1 trial, 204 participants; $P = 0.08$; low-quality evidence).

OHC training for stroke survivors and healthcare providers significantly improved their OHC knowledge at one month after training (SMD 0.70, 95% CI 0.06 to 1.35; 3 trials, 728 participants; $I^2 = 94\%$; $P = 0.03$; very low-quality evidence). Pooled data one month after training also showed evidence of a difference between stroke survivor and providers' oral health attitudes (SMD 0.28, 95% CI 0.01 to 0.54; 3 trials, 728 participants; $I^2 = 65\%$; $P = 0.06$; very low-quality evidence).

OHC interventions compared with placebo

Three trials (394 participants, with data for 271 participants with stroke) compared an OHC intervention with placebo. There were no data for primary outcomes. There was no evidence of a difference in the incidence of pneumonia in participants receiving an OHC intervention compared with placebo (OR 0.39, CI 95% 0.14 to 1.09; 2 trials, 242 participants; $I^2 = 42\%$; $P = 0.07$; low-quality evidence). However, decontamination gel reduced the incidence of pneumonia among the intervention group compared with placebo gel group (OR 0.20, 95% CI 0.05 to 0.84; 1 trial, 203 participants; $P = 0.028$). There was no difference in the incidence of pneumonia in participants treated with povidone-iodine compared with a placebo (OR 0.81, 95% CI 0.18 to 3.51; 1 trial, 39 participants; $P = 0.77$).

One OHC intervention compared with another OHC intervention

Twelve trials (372 participants with stroke) compared one OHC intervention with another OHC intervention. There was no difference in dental plaque scores between those participants that received an enhanced multi-component OHC intervention compared with conventional OHC interventions at three months (MD -0.04, 95% CI -0.33 to 0.25; 1 trial, 61 participants; $P = 0.78$; low-quality evidence). There were no data for denture plaque.

Authors' conclusions

We found low- to very low-quality evidence suggesting that OHC interventions can improve the cleanliness of patient's dentures and stroke survivor and providers' knowledge and attitudes. There is limited low-quality evidence that selective decontamination gel may be more beneficial than placebo at reducing the incidence of pneumonia. Improvements in the cleanliness of a patient's own teeth was limited. We judged the quality of the evidence included within meta-analyses to be low or very low quality, and this limits our confidence in the results. We still lack high-quality evidence of the optimal approach to providing OHC to people after stroke.

PLAIN LANGUAGE SUMMARY

Interventions for improving oral health in people after stroke

Review question

We wanted to know whether oral healthcare (OHC) interventions improve the oral health of people who have had a stroke, and if any one OHC intervention provided more benefit than another approach.

Background

Three quarters of people who have had a stroke experience physical problems, and the weakness, lack of co-ordination and cognitive (attention, memory, language and orientation) problems that may accompany a stroke can make it difficult for a person to maintain the health and cleanliness of their mouth, tongue and teeth on their own. A clean mouth feels good and the practice of OHC (removing dental plaque (a soft, sticky film that builds up on your teeth) and traces of food) is a crucial factor in maintaining the health of the mouth, teeth and gums. A clean and healthy mouth also prevents pain or discomfort and allows people to eat a range of nutritious foods. Maintaining good oral care may be difficult after a stroke and healthcare staff may have to assist in providing such care.

We wanted to see whether OHC interventions could improve the cleanliness of stroke survivors' teeth by reducing dental plaque or denture plaque (our primary outcomes). We were also interested in whether OHC interventions would improve other (secondary) outcomes including patient satisfaction and quality of life, presence of oral disease, presence of related infection, and stroke survivor and providers' knowledge and attitudes to OHC.

Search date

The evidence is current to February 2019.

Study characteristics

We included 15 studies (22 comparisons) involving 1546 people with stroke, 1028 staff and 94 carers in this updated review. Seven trials compared OHC with usual care; three trials compared OHC with placebo (pretend treatment or usual care), and 12 trials compared two different types of OHC.

Key results

We found little evidence to inform how OHC is best delivered. There was low-quality evidence from trials that compared OHC with standard care showing that OHC reduced denture plaque. There was no difference for studies that measured dental plaque. We found very low-quality evidence to show that training nursing staff and family carers improved their knowledge and attitudes to OHC. There was low-quality evidence that demonstrated the beneficial impact of a decontamination gel (to reduce the number of bacteria in the mouth) on the incidence of pneumonia compared with placebo gel among patients in a stroke ward. However, there was no other information on how best to provide OHC and more studies are urgently needed.

Quality of the evidence

Despite the inclusion of several new trials of OHC for people after stroke since our last review update there remains a lack of high-quality evidence to inform OHC in stroke care settings.

Conclusion

We judged the quality of the current evidence in this review to be low to very low. We lack high-quality evidence of the optimal approach to providing OHC to people after stroke. Additional well-conducted clinical trials are needed.

SUMMARY OF FINDINGS

Summary of findings 1. Oral health care interventions compared with usual care for people after stroke

Oral health interventions compared with usual care for people after stroke

Patient or population: adults with stroke

Settings: hospital, home or residential care

Intervention: oral health intervention

Comparison: usual care

Outcomes (assessed at up to 1 month postinter- vention)	Relative ef- fect (95% CI)	No of par- ticipants (studies)	Direction of effect	Quality of the evi- dence (GRADE)	Comments
Dental plaque (Analysis 1.1)	DMS -0.66 (-1.40 to 0.09)	83 partici- pants (2 trials; Frenkel 2001 ; Kim 2014a)	No evidence of benefit or harm	⊕⊕⊕⊕ ^{a,b,c} Very low	<ul style="list-style-type: none"> Frenkel 2001 assessed dental plaque using the simplified oral hygiene index (Greene 1964) (scale 0–3). Kim 2014a used the Silness and Loe Plaque Index (Silness 1964) to assess dental plaque (scale 0–3, where 0 = an absence of plaque and 3 = an abundance of plaque).
Denture plaque (Analysis 1.3)	DMS -1.31 (-1.96 to -0.66)	38 partici- pants (1 trial; Frenkel 2001)	Favoured OHC inter- vention	⊕⊕⊕⊕ ^{a,b} Low	<ul style="list-style-type: none"> Assessed with method described by Augsburger 1982 (scale 0–4)
Presence of oral disease: gingivitis (Analysis 1.4)	DMS -0.60 (-1.66 to 0.45)	83 partici- pants (2 trials; Frenkel 2001 ; Kim 2014a)	No evidence of benefit or harm	⊕⊕⊕⊕ ^{a,b,c} Very low	<ul style="list-style-type: none"> Frenkel 2001 used the method described by Suomi 1968 (scale 0–2 scale, where 0 = no inflammation, 1 = marginal gingivitis and 2 = severe gingivitis spreading to the attached gingiva). Kim 2014a used the Loe 1967 (scale 0–3, where 0 = no inflammation and 3 = severe gingivitis)

Presence of oral disease: denture-induced stomatitis (Analysis 1.6)	DMS -0.33 (-0.92 to 0.26)	38 participants (1 trial; Frenkel 2001)	No evidence of benefit or harm	⊕⊕⊕⊕ ^{a,b} Low	<ul style="list-style-type: none"> Assessed according to Budtz-Jorgensen 1978 classification (scale 0–3)
Presence of related infection: pneumonia (Analysis 1.7)	OR 4.17 (0.82 to 21.11) (intervention group: 5 incidents of pneumonia (99 participants); usual care group: 1 incident of pneumonia (105 participants))	204 participants (1 trial; SO-CLE II)	No evidence of benefit or harm	⊕⊕⊕⊕ ^{a,b} Low	<ul style="list-style-type: none"> Assessed using Mann criteria (Mann 1999)
Stroke survivor and providers' knowledge to OHC: knowledge (Analysis 1.8)	SMD 0.70 (0.06 to 1.35)	728 participants (3 trials; Ab Malik 2017 ; Frenkel 2001 ; Kuo 2016)	Favours OHC intervention	⊕⊕⊕⊕ ^{a,b,c,d} Very low	<p>Knowledge assessed with non-validated self-administered questionnaires.</p> <ul style="list-style-type: none"> Ab Malik 2017 assessed knowledge of OHC using 5 items (dental plaque, gum bleeding, consequences of dental plaque, how to prevent gingivitis and how oral health affects general health) based on a questionnaire from Al-Omiri 2006. Scores were 0–5, with higher scores indicating greater OHC knowledge. Frenkel 2001 measured knowledge using a true/false response to 26 statements, with each correct answer scoring one. The outcome was presented as a composite outcome score. Kuo 2016 developed and measured OHC knowledge using a 44-item Knowledge of Oral Care questionnaire; 26/44 items were based on Frenkel 2001 carers questionnaire. Items were scored using a true/false response, with each correct answer scoring 1. The outcome was presented as composite outcome score.
Stroke survivor and providers' attitudes to OHC: attitude (Analysis 1.11)	SMD 0.28 (0.01 to 0.54)	728 participants (3 trials; Ab Malik 2017 ; Frenkel 2001 ; Kuo 2016)	Favours OHC intervention	⊕⊕⊕⊕ ^{a,b,c,d} Very low	<p>Attitude assessed with non-validated self-administered questionnaires.</p> <ul style="list-style-type: none"> Ab Malik 2017 assessed attitude using items derived from the manual of "Constructing Questionnaires Based on the Theory of Planned Behavior" (Francis 2004) and modified to the oral health context. Higher scores reflect a more positive attitude to OHC.

- [Frenkel 2001](#) assessed attitude to oral health using a 5-point Likert scale to 25 statements on OHC (including 12 on carers' own oral health) tested attitudes. The outcome was presented as a composite outcome score.
- [Kuo 2016](#) developed and measured a 19-item Attitude to Oral Care questionnaire; 13/19 were based on [Frenkel 2001](#) carers questionnaire and scored using a 5-point Likert scale.

GRADE Working Group grades of evidence

High quality: further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

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 quality: we are very uncertain about the estimate.

CI: confidence interval; **DMS:** difference in mean score; **OHC:** oral health care; **OR:** odds ratio; **SMD:** standard mean difference.

^aDowngraded one level as there were serious limitations identified in the risk of bias.

^bDowngraded one level because of imprecision.

^cDowngraded one level because of inconsistency of results.

^dDowngraded one level because of indirectness of the evidence based on variations in outcome measures.

Summary of findings 2. Oral health care intervention compared with placebo for people after stroke

Oral health care intervention compared with placebo for stroke

Patient or population: adults with stroke

Settings: hospital based

Intervention: oral care intervention

Comparison: placebo

Outcomes	Relative effect (95% CI)	No of participants (trials)	Direction of effect	Quality of the evidence (GRADE)	Comments
Dental plaque	—	—	—	—	We found no studies.
Denture plaque	—	—	—	—	We found no studies.
Presence of oral disease	—	—	—	—	We found no studies.
Presence of related infection: pneumonia	OR 0.39 (0.14 to 1.09)	242 participants	No evidence of benefit or harm	$\oplus\oplus\oplus\oplus$ ^{a,b} Low	<ul style="list-style-type: none"> • Gosney 2006 – intervention was selective decontamination gel; evidence of benefit as compared to placebo (OR 0.20, 95% CI 0.05 to 0.84). Assessed im-

(Analysis 2.1)		(2 trials; Gosney 2006 ; Seguin 2014)			<p>mediately postintervention (3 weeks), based on clinical signs and symptoms of pneumonia as recorded in case notes.</p> <ul style="list-style-type: none"> Seguin 2014 – intervention was povidine-iodine; no evidence of benefit or harm (OR 0.81, 95% CI 0.18 to 3.51). Assessed immediately postintervention (30 days) using criteria outlined in American Thoracic Society 2005.
Stroke survivor and providers' knowledge and attitudes to oral health care	—	—	—	—	We found no studies.

GRADE Working Group grades of evidence

High quality: further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

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 quality: we are very uncertain about the estimate.

CI: confidence interval; OR: odds ratio; RR: risk ratio.

^aDowngraded one level as there were serious limitations identified in the risk of bias.

^bDowngraded one level because of indirectness.

Summary of findings 3. One oral healthcare intervention compared with another oral healthcare intervention for people after stroke

Oral health care intervention compared with another oral health care intervention for stroke

Patient or population: adults with stroke

Settings: hospital based

Intervention: oral care intervention

Comparison: another oral health care intervention

Outcomes	Relative effect (95% CI)	No of participants (trials)	Direction of effect	Quality of the evidence (GRADE)	Comments
Dental plaque (Analysis 3.1)	MD -0.04 (-0.33 to 0.25)	61 participants (1 trial; Ab Malik 2018)	No evidence of benefit or harm	^{a,b} Low	<ul style="list-style-type: none"> Assessed immediately postintervention (3 months). Measured using the Silness and Loe Plaque Index (Silness 1964) (scale 0–3, where 0 = absence of plaque and 3 = abundant presence of plaque).

Denture plaque	—	—	—	—	We found no studies.
Presence of oral disease	—	—	—	—	We found no studies.
Presence of related infection: pneumo- nia	—	—	—	—	We found no studies.
Stroke survivor and providers' knowl- edge and attitudes to oral health care	—	—	—	—	We found no studies.

GRADE Working Group grades of evidence

High quality: further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

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 quality: we are very uncertain about the estimate.

CI: confidence interval; **MD:** mean difference.

^aDowngraded one level as there were serious limitations identified in the risk of bias.

^bDowngraded one level because of imprecision.

BACKGROUND

Three quarters of stroke survivors experience physical deficits (Adamson 2004), and the weakness, lack of co-ordination and cognitive problems that may accompany a stroke can make it difficult for a person to maintain the health and cleanliness of their mouth, tongue and teeth on their own (RCP 2016). Facial muscle strength and tone and oral sensation may alter after stroke, resulting in poorly controlled dentures and altered chewing and oral clearance patterns. Together with swallowing impairment, all these factors impact on an individual's nutritional intake, which also has a negative impact on rehabilitation and other functional outcomes (Geeganage 2012; Nakazora 2017; RCP 2016).

Description of the condition

Dry mouth, oral ulcers and stomatitis are common side effects of medication (RCP 2016; Yuan 2015). Dysphagia and poor oral clearance of food and fluid residue further contribute to dental decay and microbial load observed among stroke survivors (Dai 2015; Kishore 2018; Zhu 2008). Some patients have pre-existing oral health problems – for example gum disease has been linked to the incidence of cardiovascular disease, diabetes and stroke (Michishige 1999). The more severe a stroke, the more dependent the stroke survivors are on others to support or facilitate their oral health care (OHC).

Pneumonia is a common complication after stroke and is associated with high mortality, long stays in hospital and a lower potential for function recovery (Hilker 2003; Katzan 2003; Langhorne 2000). While reports of the numbers affected vary, stroke-associated pneumonia has been reported to affect between 2% and 63% of stroke survivors (Hannawi 2013; Kishore 2018). The onset of stroke-associated pneumonia is thought to be related to the severity of patients' stroke, their functional impairment (both pre- and poststroke onset) and level of consciousness (Chumbler 2010). People with stroke who have swallowing problems (dysphagia) are more likely to develop pneumonia than people with stroke with normal swallowing function, but aspiration of food and fluid into the lungs alone does not fully account for the incidence of pneumonia (Chumbler 2010). The possibility of a relationship between stroke-associated pneumonia and patients' oral health has received increasing attention.

Description of the intervention

Providing OHC to people with different stroke and dental profiles (those with natural teeth, dentures, both or neither) within stroke care settings is a challenge (Brady 2011). OHC practice varies across wards, often delegated to junior nursing staff. Staff are inadequately supported to provide this care (Horne 2015; Talbot 2005). Current descriptions of OHC interventions incorporate staff knowledge, assessment, equipment, agents, planned intervention, monitored nutritional intake and specialist referral components (Brady 2011; Wagner 2016) (see [Types of interventions](#)).

How the intervention might work

If the mouth is not kept clean then the increasing buildup of debris contributes to plaque, tartar, dental decay and gum disease. If left untreated and in a state of continuing poor oral health this can develop into calcified plaque (tartar), tooth loss, stomatitis, gingivitis and periodontitis (Peres 2019; Watt 2019). The health benefits of high-quality care after stroke (Ingeman 2011), and

the complementary role that various members of the multi-disciplinary stroke team could play in the provision of OHC has been outlined, including dental health, dietetic and occupational therapy professionals (Bailey 2004; Bellomo 2005). As in other aspects of stroke care, rehabilitation goals that aim to maintain or regain independent OHC skills would be appropriate in the stroke care setting (Bellomo 2005).

Why it is important to do this review

Systematic review evidence indicates that enhanced OHC has a preventive effect on the incidence of pneumonia among nursing home residents (absolute risk reductions between 6.6% and 11.7%; numbers needed to treat for an additional beneficial outcome 9 to 15) (Sjögren 2008), and ventilated populations (Chan 2007). More recently one non-randomised study in a stroke care setting suggested benefits in the use of a coproduced OHC programme involving nursing staff education, access to OHC assessments, protocols and OHC equipment (odds ratio (OR) for pneumonia in the OHC group was 0.71, 95% confidence interval (CI) 0.51 to 0.98; $P = 0.041$) (Wagner 2016). The dearth of evidence underpinning staff-led oral care practice in healthcare settings has been highlighted (Lyons 2018; RCP 2016). It is crucial to undertake a rigorous systematic review and meta-analyses of the available evidence relating to the effectiveness of oral care interventions for people after stroke in order to inform evidence-based care and rehabilitation of people after stroke.

OBJECTIVES

To compare the effectiveness of OHC interventions with usual care, or other treatment options for ensuring oral health in people after a stroke.

METHODS

Criteria for considering studies for this review

Types of studies

We identified randomised controlled trials (RCTs) that evaluated one or more interventions designed to improve oral health. We included trials that recruited from a healthcare setting with a mixed population provided it was possible to extract the data specific to the individuals poststroke.

Types of participants

We included adults (aged 18 years or greater) with a diagnosis of stroke who received assisted OHC led by healthcare staff.

Types of interventions

We included trials that evaluated an intervention designed to improve routine-assisted OHC in a stroke care setting.

The interventions fell into the following broad categories:

- assessment tool;
- equipment (e.g. toothbrush);
- agent (e.g. mouthwash);
- staff, volunteer or family carer training;
- OHC promotion.

Types of outcome measures

A comprehensive, valid and reliable measurement tool for assessing oral health and cleanliness is currently lacking. We recorded a range of outcomes that correspond to different aspects of oral health and cleanliness and OHC delivery.

Primary outcomes

- Dental plaque.
- Denture plaque.

Secondary outcomes

- Presence of oral disease: gingivitis, denture-induced stomatitis, periodontal disease.
- Presence of related infection and primary oral opportunistic pathogens related to OHC and pneumonia: pneumonia, anaerobic Gram-negative bacillus (AGNB), *Candida* and *Staphylococcus aureus*.
- Oral health knowledge and attitudes.
- Patient satisfaction and quality of life: care received, oral comfort and appearance, quality of life.

We recorded outcome measurements taken up to 12 months postintervention. We took dental data of included studies at the patient level.

Search methods for identification of studies

See the 'Specialized register' section at the Cochrane Stroke Group website (www.dcn.ed.ac.uk/csrg/entity/searchmethods.pdf). We searched for trials in all languages and planned to arrange translation of relevant papers published in languages other than English.

Electronic searches

We searched the trials registers of the Cochrane Stroke Group (last searched 18 February 2019) and the Cochrane Oral Health Group (last searched 20 February 2018) ([Appendix 1](#)).

In addition, we searched the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL; 2019, Issue 2) in the Cochrane Library (searched 18 February 2019) ([Appendix 2](#));
- MEDLINE Ovid (1946 to 15 February 2019) ([Appendix 3](#));
- Embase Ovid (1974 to 18 February 2019) ([Appendix 4](#)); and
- CINAHL EBSCO (Cumulative Index to Nursing and Allied Health Literature; 1982 to 18 February 2019) ([Appendix 5](#)).

We also searched the following resources for ongoing trials:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (<http://www.clinicaltrials.gov>; searched 18 February 2019) ([Appendix 6](#));
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; searched 18 February 2019) ([Appendix 6](#)).

For the previous version of this review, we searched the Research Findings Electronic Register (to February 2006), and the National Research Register (Issue 1, 2006). These sources are no longer

available and so our search update did not include them. The earlier search strategies are shown in [Appendix 7](#).

Searching other resources

In an effort to identify further published, unpublished and ongoing studies, we searched Web of Science Conference Proceedings Citation Index-Science (last searched 25 February 2019), Zetoc (last search 25 February 2019) and Proquest Dissertations and Theses (last search 25 February 2019) using key terms shown in [Appendix 8](#).

We scanned reference lists from relevant papers and contacted authors and researchers in the field. We did not handsearch any journals or conference proceedings in addition to those already searched on behalf of Cochrane UK and the Cochrane Stroke Group.

Data collection and analysis

Selection of studies

We considered RCTs that addressed OHC interventions for inclusion on the basis of study design, interventions and outcome measures used. All RCTs that examined OHC interventions for older populations (which had the potential to have included individuals post stroke) were eligible for inclusion. One review author (MB, BB or PC) screened titles of the records identified through the electronic searches described above and excluded any obviously irrelevant studies. Two members of the review team (MB, and BB, PC or DF) independently reviewed the abstracts of potentially relevant studies to determine if they met the selection criteria.

We obtained full-text papers of the remaining studies that fulfilled the listed inclusion criteria and these were independently assessed by two members of the review team (MB, BB, PC, DF). In some cases, we contacted the trial authors to retrieve additional information before we could make a final decision. We resolved conflicting decisions through discussion. Studies judged as ineligible for inclusion, together with reasons for their exclusion, are listed in the [Characteristics of excluded studies](#) table.

Data extraction and management

Two members of the review team (MB, BB, PC, DF) independently performed data extraction, and we contacted study authors to request missing data (or data in a suitable format) for inclusion in the review. For trials based on a mixed population, we contacted the study authors to establish whether the details relating to stroke survivors were available. All data provided were at participant level, rather than tooth level.

We developed and piloted a standardised data extraction sheet. We extracted the following information: study design, recruitment and setting, participants' demographics, inclusion and exclusion criteria, outcome measures used and time points, duration of follow-up and summary outcome data.

We profiled specific intervention details using the template for intervention description and replication (TIDieR) checklist ([Hoffmann 2014](#)). This included details of the intervention (intervention rationale, materials, procedures, provider, delivery mode, dose, tailoring, modification, adherence and related aspects of fidelity).

We also used the TIDieR checklist to extract relevant data for each control group to document what intervention was delivered

(i.e. we made every effort to profile all interventions, including those in the comparison role of 'usual care' by their constituent components). Where trialists used the term 'usual care' in the absence of any additional details such as profiling was not possible. Usual care is highly variable (e.g. [Talbot 2005](#)), and thus we profiled the intervention by that general term only.

Assessment of risk of bias in included studies

Two review authors (MB, BB PC, DF) independently documented the methodological quality of the included studies using items specified by the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2019](#)). They judged each study as potentially 'high risk', 'low risk' or 'unclear' risk of bias, against the following nine quality criteria.

- Random sequence generation (selection bias).
- Allocation concealment (selection bias).
- Blinding of participants and personnel (performance bias).
- Blinding of outcome assessment (detection bias).
- Incomplete outcome data (attrition bias).
- Selective reporting (reporting bias).
- Baseline comparability of groups.
- Whether an a priori power calculation had been conducted.
- Other potential confounders.

We sought clarification from study authors if details were unavailable from the text. We resolved disagreements by consensus between the review authors.

Measures of treatment effect

We grouped studies together in terms of their interventions and outcomes. Where suitable statistical summary data were available, we combined the selected outcome data in pooled meta-analyses. For dichotomous outcomes, we calculated the effect measure as the risk ratio (RR) with 95% confidence intervals (CI). For dichotomous outcomes with rare events (i.e. an event rate of less than 10%), we calculated Peto odds ratios (OR) with 95% CI.

For ordinal scales (10 or more categories) and for continuous data, and where the same measurement tool was used across trials, we calculated the treatment effect using mean differences (MD) and 95% CI. If different scales were used in different trials, we planned to use standardised mean differences (SMD) and 95% CI. For non-normal data and ordinal scales with fewer than 10 categories, we planned to use a defined cut-off and to treat the data as a dichotomous outcome.

An earlier version of the review, [Brady 2006](#), used Proc Mixed in the statistical package SAS (www.sas.com/) to analyse the individual patient data for poststroke participants to take account of the clustering in the [Frenkel 2001](#) study, and used the generic inverse variance section of Review Manager 5 for presentation purposes ([Review Manager 2014](#)). Consequently, we calculated the estimates and standard errors of the same effect measure for all the other studies in the same meta-analysis using the methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2019](#)).

Unit of analysis issues

The unit of analysis was per participant randomised, rather than tooth level. Where a trial included three or more arms, we split the number of participants in the control group across the two interventions. In the case of continuous data, the means and standard deviations (SD) remained the same. In the case of dichotomous data, both the number of events and total number of participants were split across the relevant number of arms. Where we identified a cluster RCT, we planned to identify the unit of randomisation, the unit of analysis and, wherever possible, the intraclass correlation coefficient to adjust results to account for cluster effect.

Dealing with missing data

In cases where only partial summary data were reported, for example mean final value scores were available but SDs were unavailable, we calculated these values from available information using methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2019](#)). In cases where data needed to be transformed (e.g. from median and interquartile range (IQR) scores to mean and SD), we used methods described in [Weir 2018](#). We also contacted trialists to request missing data.

Assessment of heterogeneity

We assessed statistical heterogeneity between trials using the I^2 statistic available in the Review Manager 5 ([Review Manager 2014](#)). If statistical heterogeneity existed (in the absence of co-existing clinical or methodological heterogeneity), we planned to use a random-effects model to pool the trials. We used a fixed-effect model if there was no evidence of clinical, methodological or statistical heterogeneity.

We interpreted the results using the I^2 statistic thresholds recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2019](#)):

- 0 to 40% – potentially unimportant;
- 30% to 60% – may represent moderate heterogeneity;
- 50% to 90% – may represent substantial heterogeneity;
- 75% to 100% – considerable heterogeneity.

Data synthesis

We analysed data using Review Manager 5 ([Review Manager 2014](#)). We combined data from individual trials for meta-analysis if the interventions and outcomes were sufficiently similar (determined by consensus).

We created 'Summary of findings' tables for the three comparisons identified. We presented the key findings of the review, including a summary of the quantity of data, the magnitude of effect size, and the overall quality of evidence. We summarised the short-term findings for our primary outcomes including dental plaque and denture plaque. We also presented data for the presence of oral disease (i.e. gingivitis, denture-induced stomatitis), presence of related infection (i.e. for pneumonia only), and stroke survivor and providers' oral health knowledge and attitude.

We used the GRADE approach ([Guyatt 2008](#); [Guyatt 2011a](#)), as described in the *Cochrane Handbook for Systematic Reviews of*

Interventions, to present the evidence quality for each combination of intervention and outcome (Higgins 2019).

The quality of a body of evidence for a specific outcome was graded against the following factors:

- limitations of study (e.g. risk of bias due to poor study design or conduct (Guyatt 2011b);
- publication bias (Guyatt 2011c);
- imprecision of results (e.g. wide CIs for treatment effect) (Guyatt 2011d);
- inconsistency of results (e.g. large I^2 statistic) (Guyatt 2011e);
- indirectness of evidence (e.g. variations in participants, interventions, comparisons and outcomes) (Guyatt 2011f).

The GRADE approach specifies four levels of quality, that is, high-, moderate-, low- and very low-quality evidence, based on the following definitions:

- high quality: it is unlikely that further research will change our confidence in the estimate of effect;
- moderate quality: further research is likely to have an impact and may change our confidence in the estimates of effect;
- low quality: further research is very likely to have an important impact on our confidence in the estimate of effect;
- very low quality: any estimate of effect is very uncertain.

Sensitivity analysis

We planned to conduct sensitivity analyses for primary outcomes to explore the effect of the following methodological features:

- method of randomisation (high risk of bias, low risk of bias and unclear risk of bias);
- extent of allocation concealment at randomisation (high risk of bias, low risk of bias and unclear risk of bias);
- presence of assessor blinding (high risk of bias, low risk of bias and unclear risk of bias).

We planned to carry out these planned sensitivity analyses when there were six or more studies included in a single analysis.

RESULTS

Description of studies

Results of the search

Our updated search strategy identified 19,525 records from electronic databases (Appendix 1; Appendix 2; Appendix 3; Appendix 4; Appendix 5; Appendix 6). The flow of literature through the searching and screening is shown in the PRISMA flow diagram (Figure 1). Following the updated search, we identified 12 new studies (19 randomised comparisons for inclusion in this 2019 update) (Ab Malik 2017; Ab Malik 2018; Chipps 2014; Dai 2017; Juthani-Mehta 2015; Kim 2014a; Kobayashi 2017i/Kobayashi 2017ii/Kobayashi 2017iii/Kobayashi 2017iv/Kobayashi 2017v/Kobayashi 2017vi; Kuo 2016; Lam 2013i/Lam 2013ii/Lam 2013iii; Lee 2011; Seguin 2014; SOCLE II). These new trials were synthesised with the three trials (Fields 2008; Frenkel 2001; Gosney 2006) included in earlier versions of this review (Brady 2006).

Figure 1. Study flow diagram. RCT: randomised controlled trial.

We also identified three ongoing trials (ChiCTR-IPR-17013403; Hollaar 2015; MAPS-2) (see [Characteristics of ongoing studies table](#)). Our searches identified nine trials which may be eligible for inclusion, but we were unable to retrieve stroke-specific data from them for the purposes of this review (Cabov 2010; IRCT2017012232101N1; IRCT2017091636194N1; Jin 2018; Marchini 2018; Mori 2012; NCT00610324; NCT03219346; Yakiwchuk 2013). These studies are detailed in the [Characteristics of studies awaiting classification table](#).

Included studies

In this update of our review, we included 15 trials (22 randomised controlled comparisons) (Ab Malik 2017; Ab Malik 2018; Chipps 2014; Dai 2017; Fields 2008; Frenkel 2001; Gosney 2006; Juthani-Mehta 2015; Kim 2014; Kobayashi 2017i/Kobayashi 2017ii/Kobayashi 2017iii/Kobayashi 2017iv/Kobayashi 2017v/Kobayashi 2017vi; Kuo 2016; Lam 2013i/Lam 2013ii/Lam 2013iii; Lee 2011; Seguin 2014; SOCLE II).

Seven trials were registered on clinical trials databases (Ab Malik 2017; Ab Malik 2018; Dai 2017; Juthani-Mehta 2015; Lam 2013i/Lam 2013ii/Lam 2013iii; Seguin 2014; SOCLE II); the remaining eight trials were not registered (Chipps 2014; Fields 2008; Frenkel 2001; Gosney 2006; Kim 2014; Kobayashi 2017i/Kobayashi 2017ii/Kobayashi 2017iii/Kobayashi 2017iv/Kobayashi 2017v/Kobayashi 2017vi; Kuo 2016; Lee 2011) (Table 1).

Nine studies employed a parallel RCT design (Ab Malik 2018; Chipps 2014; Dai 2017; Fields 2008; Gosney 2006; Kim 2014; Kuo 2016; Lee 2011; Seguin 2014); three conducted a cluster RCT design (Ab Malik 2017; Frenkel 2001; Juthani-Mehta 2015); and one used a stepped-wedge cluster RCT design (SOCLE II). Two trials randomised participants across three or more trial arms (Kobayashi 2017i/Kobayashi 2017ii/Kobayashi 2017iii/Kobayashi 2017iv/Kobayashi 2017v/Kobayashi 2017vi; Lam 2013i/Lam 2013ii/Lam 2013iii). For the purposes of this review, we have presented these data separately within randomised paired comparisons (indicated using roman numerals i, ii, iii, etc. as appropriate) and these paired comparisons will be referred to as 'trials,' from this point onwards.

Four trials recruited a mixed participant population (Frenkel 2001; Juthani-Mehta 2015; Seguin 2014; SOCLE II), but some of the trialists shared the stroke-specific dataset with the authors for the purposes of this review (Frenkel 2001; Seguin 2014; SOCLE II).

We present a summary of the key features of the studies in the following sections, and have provided a more indepth description in the [Characteristics of included studies table](#).

Location and recruitment setting

Most trials recruited from single sites (14/22) (Chipps 2014; Dai 2017; Fields 2008; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Lam 2013i; Lam 2013ii; Lam 2013iii; Lee 2011); the remaining trials recruited participants from multiple centres, ranging from three sites (Gosney 2006; Kuo 2016) to 36 sites (Juthani-Mehta 2015).

Studies were carried out in France (Seguin 2014), Hong Kong, People's Republic of China (Dai 2017; Lam 2013i; Lam 2013ii;

Lam 2013iii), Japan (Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi), Malaysia (Ab Malik 2017; Ab Malik 2018), South Korea (Kim 2014a; Lee 2011), Taiwan (Kuo 2016), the UK (Frenkel 2001; Gosney 2006; SOCLE II), and the USA (Chipps 2014; Fields 2008; Juthani-Mehta 2015).

The setting varied across trials, including intensive care units (Fields 2008; Kim 2014a; Seguin 2014), acute rehabilitation unit (Chipps 2014), stroke rehabilitation units (Gosney 2006; Lam 2013i; Lam 2013ii; Lam 2013iii; SOCLE II), hospital (no details) (Ab Malik 2017; Ab Malik 2018; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi), outpatient (Dai 2017), nursing homes (Frenkel 2001; Juthani-Mehta 2015), and hospital-outreach home care (Kuo 2016). Setting details were unavailable for one trial (Lee 2011).

Details of recruitment strategies, settings, geographical location and trial registration details are summarised in [Table 1](#).

Type of participants

Of the 3631 participants involved in the 22 trials, 1028 were staff (registered nurses, care assistants and nursing home carers) (Ab Malik 2017; Frenkel 2001; SOCLE II); 94 family carers (Kuo 2016), and 1546 people with stroke (Ab Malik 2018; Chipps 2014; Dai 2017; Fields 2008; Frenkel 2001; Gosney 2006; Juthani-Mehta 2015; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Lam 2013i; Lam 2013ii; Lam 2013iii; Lee 2011; Seguin 2014; SOCLE II) (see [Table 2](#)).

The number of participants randomised ranged from 24 (Lee 2011), to 834 (Juthani-Mehta 2015), with six trials randomising more than 100 participants (Ab Malik 2017; Frenkel 2001; Gosney 2006; Juthani-Mehta 2015; Seguin 2014; SOCLE II). The age of participants ranged from 20 to 96 years, but was not reported in three trials (Ab Malik 2017; Fields 2008; Lee 2011).

Most trials included stroke-only populations (Ab Malik 2017; Ab Malik 2018; Chipps 2014; Dai 2017; Fields 2008; Gosney 2006; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Lee 2011); four trials recruited participants from mixed populations (Frenkel 2001; Juthani-Mehta 2015; Seguin 2014; SOCLE II). Further details of the type of stroke and onset and other details of the participants included are summarised in [Table 2](#).

Participants were randomised at the hospital level in two trials (Ab Malik 2017; SOCLE II), nursing home in two trials (Frenkel 2001; Juthani-Mehta 2015), or at the individual level in 18 trials (Ab Malik 2018; Chipps 2014; Dai 2017; Fields 2008; Gosney 2006; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Lee 2011; Seguin 2014).

Type of interventions

In the following section, we present a narrative synthesis of the different interventions that were delivered within the three comparisons groups: OHC versus no treatment/usual care, OHC versus placebo and one OHC intervention versus another OHC

intervention. Details of the different intervention components are summarised in [Table 3](#).

Oral healthcare interventions versus no treatment or usual care

In this comparison we considered the benefits of OHC interventions compared to no treatment or usual care, where usual care lacked description of the nature and content of that intervention.

Of the 22 randomised trials, seven investigated OHC interventions compared with usual care. Three of these trials were educational interventions ([Ab Malik 2017](#); [Frenkel 2001](#); [Kuo 2016](#)), and the remaining four trials delivered a multi-component OHC protocol ([Fields 2008](#); [Juthani-Mehta 2015](#); [Kim 2014a](#); [SOCLE II](#)).

Four trials involved the delivery of multi-component OHC protocol compared to usual care, involving the provision of various combinations of education and training, materials (e.g. toothbrush, toothpaste, mouth gel, mouthwash, tongue cleaners, lip balm, care protocols) and assessment tools ([Table 3](#); [Fields 2008](#); [Juthani-Mehta 2015](#); [Kim 2014a](#); [SOCLE II](#)). The intervention was delivered once a day ([Kim 2014a](#)), twice a day ([Juthani-Mehta 2015](#); [SOCLE II](#)), or three times a day ([Fields 2008](#)), by a dentist ([Kim 2014a](#)), nursing aides ([Juthani-Mehta 2015](#)), or nursing staff (registered nurses, nursing assistants, nursing students) ([Fields 2008](#); [SOCLE II](#)).

Trials which delivered specific educational training interventions were diverse, and aimed at registered nurses ([Ab Malik 2017](#)), care assistants ([Frenkel 2001](#)), or informal carers ([Kuo 2016](#)). Educational interventions for staff included an online continuing professional development programme for registered nurses ([Ab Malik 2017](#)), while [Frenkel 2001](#) described face-to-face standardised OHC education training in combination with practical demonstrations for care assistants working in nursing homes. [Kuo 2016](#) delivered home-based OHC training using multiple teaching strategies

The control group was offered general stroke care training ([Ab Malik 2017](#)), delayed OHC training ([Frenkel 2001](#); [Kuo 2016](#)), usual oral care provided by nursing staff ([Fields 2008](#); [SOCLE II](#)), or standard care ([Juthani-Mehta 2015](#)). It was not clear what the control group received in [Kim 2014a](#) ([Table 3](#)).

Oral healthcare interventions versus placebo

Three trials compared an OHC intervention with placebo ([Gosney 2006](#); [Lee 2011](#); [Seguin 2014](#)) ([Table 3](#)). The interventions included selective decontamination of the digestive tract using an Orabase gel ([Gosney 2006](#)), a povidone-iodine rinse ([Seguin 2014](#)), and Saengmaeg-san extract ([Lee 2011](#)). The interventions in this comparison were delivered by a nurse or the patient (or both) in the [Gosney 2006](#) trial. The regimens for each intervention varied: interventions were delivered three times a day ([Lee 2011](#)), four times a day ([Gosney 2006](#)), or six times per day ([Seguin 2014](#)). The duration of the intervention also varied across these trials from seven days ([Lee 2011](#)), three weeks ([Gosney 2006](#)), and up to 30 days ([Gosney 2006](#)).

One oral healthcare interventions versus another oral healthcare intervention

Twelve trials compared one OHC intervention with another OHC intervention ([Ab Malik 2018](#); [Chipps 2014](#); [Dai 2017](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#);

[Kobayashi 2017v](#); [Kobayashi 2017vi](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)).

Multi-component OHC interventions involved the provision of various combinations (see [Table 3](#)):

- training: tooth models ([Ab Malik 2018](#); [Dai 2017](#)), provision of educational leaflets ([Ab Malik 2018](#); [Dai 2017](#)), manufacturers' instructions ([Dai 2017](#));
- toothbrush: powered toothbrush ([Ab Malik 2018](#); [Chipps 2014](#); [Dai 2017](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)), or manual toothbrush ([Ab Malik 2018](#); [Chipps 2014](#); [Dai 2017](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#));
- toothpaste: commercial and generic brands ([Ab Malik 2018](#); [Chipps 2014](#); [Dai 2017](#));
- mouth gel ([Ab Malik 2018](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017vi](#));
- mouthwash: various commercial and generic brands ([Chipps 2014](#); [Dai 2017](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#));
- tongue cleaners ([Chipps 2014](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#));
- lip balm ([Chipps 2014](#));
- care protocols: for example assisted brushing ([Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#));
- other: for example floss picks ([Chipps 2014](#)); mouthpaste ([Chipps 2014](#)); water ([Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#)).

The intervention was delivered by dental assistants ([Ab Malik 2018](#); [Dai 2017](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)), registered nurses ([Chipps 2014](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#)), nurse aides ([Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)), and dentists ([Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)).

The mode of delivery was typically individual and face-to-face, but the regimen varied across trials in this comparison including OHC 'daily' ([Ab Malik 2018](#)), once a day ([Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#)), or twice daily ([Chipps 2014](#); [Dai 2017](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)).

Outcomes

In the absence of any core outcome measurement set, we collected a broad range of outcome data reflecting data from patient, staff and service levels of care. [Table 4](#) summarises the outcome measures reported across the included trials.

Primary outcomes

- Dental plaque: eight trials measured dental plaque. Six used the Silness and Loe Plaque Index described by [Silness 1964](#) ([Ab Malik 2018](#); [Dai 2017](#); [Kim 2014a](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)), and two used the simplified Oral Hygiene Method described by [Greene 1964](#) ([Frenkel 2001](#); [SOCLE II](#)).

- Denture plaque: two trials measured denture plaque using a method described by [Augsburger 1982](#) ([Frenkel 2001](#); [SOCLE II](#)).

Registered dentists assessed plaque (dental and denture) in [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#), and dentist and dental hygienist assessed plaque in [Kim 2014a](#). In [SOCLE II](#), the [SOCLE](#) research assistant and one research nurse measured plaque. Both were trained in the procedure. A dental specialist trained the research assistant over two half-day sessions, and performed inter-rater reliability checks. The research assistant then trained the nurse and performed checks to ensure consistency in scoring. Assessor details were unclear in two trials ([Ab Malik 2018](#); [Dai 2017](#)); however, [Ab Malik 2018](#) reported that the assessor was trained by the head of the research team.

Secondary outcomes

- Presence of oral disease. Six trials measured gingival bleeding using the Gingival Bleeding Index ([Dai 2017](#); [Frenkel 2001](#); [Kim 2014a](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)). Other measures at patient level included denture-induced stomatitis ([Frenkel 2001](#)), Tooth Mobility Index ([Frenkel 2001](#); [Kim 2014a](#)), Decayed, Missing and Filled Teeth Index ([Dai 2017](#); [Kim 2014a](#)), Clinical Attachment Loss ([Kim 2014a](#)), calculus (buccal and lingual surfaces) ([Frenkel 2001](#)), and root caries ([Frenkel 2001](#)).
- Presence of related infection and oral opportunistic pathogens related to OHC and pneumonia. Eight trials collected information on pneumonia events ([Fields 2008](#); [Gosney 2006](#); [Juthani-Mehta 2015](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#); [Seguin 2014](#); [SOCLE II](#)), although diagnostic criteria varied across studies (see [Table 5](#)). Fourteen trials measured the prevalence of different opportunistic pathogens ([Ab Malik 2018](#); [Chippes 2014](#); [Dai 2017](#); [Gosney 2006](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#); [Seguin 2014](#)) ([Table 4](#)).
- Oral health knowledge and attitudes. Four trials used self-administered questionnaires to capture attitudes towards and knowledge of OHC provision ([Ab Malik 2017](#); [Frenkel 2001](#); [Kuo 2016](#); [SOCLE II](#)).
- Patient satisfaction and quality of life. Six trials included a measure of patient satisfaction or quality of life. [SOCLE II](#) reported the Oral Health Impact Profile (O-HIP), [Seguin 2014](#) reported the tolerance of the oral procedure and [Lee 2011](#) used a visual analogue scale to evaluate oral dryness. Patient satisfaction with the intervention and the condition of their mouth was assessed using a 5-point rating scale ([Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)).

Adverse events

One trial reported data relating to any intervention adverse event (e.g. broken or missing dentures) ([SOCLE II](#)).

Other

We noted measures of length of hospital stay ([Seguin 2014](#); [SOCLE II](#)), death ([Seguin 2014](#); [SOCLE II](#)), use of antibiotics ([Gosney 2006](#); [SOCLE II](#)), nutritional intake ([Chippes 2014](#)), swallowing assessments ([Chippes 2014](#)), and stroke severity ([Ab Malik 2018](#); [Gosney 2006](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)), but these were not extracted for the purposes of this review (see [Table 4](#)).

Most trials collected short-term data (less than one month). Follow-up data collection ranged from day five ([Chippes 2014](#)), day 10 ([Chippes 2014](#); [Fields 2008](#)); one week ([Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#); [Lee 2011](#)), two weeks ([Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#)), 2.2 weeks (ranged from one to five weeks) ([Kim 2014a](#)), three weeks ([Gosney 2006](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#)), to one month ([Ab Malik 2017](#); [Frenkel 2001](#); [Kuo 2016](#); [Seguin 2014](#)).

Longer-term follow-up ranged from two months ([Kuo 2016](#)), three months ([Ab Malik 2018](#); [Dai 2017](#)), six months ([Ab Malik 2017](#); [Ab Malik 2018](#); [Dai 2017](#); [Frenkel 2001](#)), to 2.5 years ([Juthani-Mehta 2015](#)). One trial captured participant data throughout the duration of their hospital ward stay and used national health record linkage to follow-up participants three months after discharge ([SOCLE II](#)).

Funding sources

Funding details are summarised in the [Characteristics of included studies](#) table. Twenty trials provided funding statements ([Ab Malik 2017](#); [Ab Malik 2018](#); [Chippes 2014](#); [Dai 2017](#); [Frenkel 2001](#); [Gosney 2006](#); [Juthani-Mehta 2015](#); [Kim 2014a](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#); [Kuo 2016](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#); [Seguin 2014](#); [SOCLE II](#)); one trials provided no funding details ([Fields 2008](#)).

Sixteen trials reported no conflict of interest ([Ab Malik 2017](#); [Ab Malik 2018](#); [Dai 2017](#); [Juthani-Mehta 2015](#); [Kim 2014a](#); [Kobayashi 2017i](#); [Kobayashi 2017ii](#); [Kobayashi 2017iii](#); [Kobayashi 2017iv](#); [Kobayashi 2017v](#); [Kobayashi 2017vi](#); [Kuo 2016](#); [Lam 2013i](#); [Lam 2013ii](#); [Lam 2013iii](#); [SOCLE II](#)); three trials did not report a conflict of interest statement ([Chippes 2014](#); [Fields 2008](#); [Frenkel 2001](#)); and two trials reported a potential conflict of interest ([Gosney 2006](#); [Seguin 2014](#)) (see [Characteristics of included studies](#) table).

We were unable to determine whether [Lee 2011](#) had published a funding statement or reported a conflict of interest because of a lack of translation.

Excluded studies

We excluded 20 trials. We were unable to obtain information specific to participants who had experienced a stroke from eight potentially eligible trials ([Brailsford 2002](#); [Hajizamani 2006](#); [Mojon 1998](#); [Quagliarello 2009](#); [Redwood 2001](#); [Schou 1989](#); [Simons 1997](#); [Simons 2002](#)). We excluded one trial as it did not target OHC in people after stroke ([Kim 2014b](#)). We excluded four trials as they were not OHC interventions ([Duck-Won 2013](#); [Forster 2013](#); [Hägglund 2017](#); [NCT01777672](#)). We excluded three trials evaluating specialist dental interventions (e.g. periodontal therapy), which were not 'routine assisted OHC' ([Jones 2007](#); [Kikutani 2006](#); [NCT02541032](#)). Two trials had an OHC components but one did not report relevant outcome measures ([Murray 2016](#)), and the other provided matched OHC interventions across both participant groups ([NCT02379182](#)). We excluded the remaining trials because they reported no patient involvement ([Lee 2017](#)), or targeted secondary stroke prevention ([Boden-Albala 2016](#)). Details for exclusion can be found in the [Characteristics of excluded studies](#) table.

Risk of bias in included studies

Details of the methodological quality can be found in the 'Risk of bias' tables for each of the included trials within the [Characteristics of included studies](#) table (see [Figure 2](#) and [Figure 3](#)).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Figure 3. (Continued)

SOCLE II

Half of the randomised trials (11/22) explicitly reported both inclusion and exclusion criteria (Chippes 2014; Fields 2008; Frenkel 2001; Gosney 2006; Juthani-Mehta 2015; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Seguin 2014; SOCLE II). Four trials did not provide details of the exclusion criteria (Ab Malik 2017; Ab Malik 2018; Dai 2017; Kim 2014a). Six trials reported the exclusion criteria only (Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi), and we were unable to extract inclusion and exclusion criteria details in Lee 2011.

Nine trials provided statistical data for the meta-analyses (Ab Malik 2017; Ab Malik 2018; Frenkel 2001; Gosney 2006; Kim 2014a; Kuo 2016; Lee 2011; Seguin 2014; SOCLE II). Suitable statistical summary data were unavailable or could not be extracted for inclusion within the meta-analysis in 13 trials (Chippes 2014; Dai 2017; Fields 2008; Juthani-Mehta 2015; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Lam 2013i; Lam 2013ii; Lam 2013iii).

Allocation

Eleven trials reported the randomisation sequence. Methods to generate the sequence included block randomisation (Dai 2017; Lam 2013i; Lam 2013ii; Lam 2013iii), computer generated (Ab Malik 2017; Ab Malik 2018; Chippes 2014; Gosney 2006; Seguin 2014; SOCLE II), and a random number table (Frenkel 2001). We judged the remaining trials as having an unclear risk of bias because the method of randomisation sequence generation was not reported (Fields 2008; Juthani-Mehta 2015; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016), or we were unable to translate the full text (Lee 2011).

We judged allocation concealment as adequate in six trials (Ab Malik 2017; Chippes 2014; Dai 2017; Frenkel 2001; Gosney 2006; SOCLE II); we judged the remaining 16 trials as unclear risk of bias as they did not report allocation concealment in sufficient detail (Ab Malik 2018; Fields 2008; Juthani-Mehta 2015; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Lee 2011; Seguin 2014).

Blinding

Four trials reported blinding participants who were involved in the trial (Ab Malik 2017; Gosney 2006; Lee 2011; Seguin 2014); of these, three trials compared OHC intervention with a placebo (Gosney 2006; Lee 2011; Seguin 2014). We judged five trials as potentially high risk for blinding participants and personnel (Ab Malik 2018; Dai 2017; Fields 2008; Frenkel 2001; SOCLE II). There was insufficient information available to judge risk of bias in the remaining 13 trials (Chippes 2014; Juthani-Mehta 2015; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii).

While it is frequently challenging to blind participants or clinicians because of the nature of the intervention, it is possible to blind the outcome assessor. However, only nine trials reported blinding the outcome assessors to group allocation (Ab Malik 2017; Ab Malik 2018; Chippes 2014; Dai 2017; Gosney 2006; Juthani-Mehta 2015; Lee 2011; Seguin 2014; SOCLE II). Blinding to outcome measures was unclear in 13 trials (Fields 2008; Frenkel 2001; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii).

Incomplete outcome data

Thirteen trials reported dropout and withdrawals adequately (Chippes 2014; Dai 2017; Frenkel 2001; Juthani-Mehta 2015; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Seguin 2014; SOCLE II). We judged eight trials at high risk of bias because of high attrition rates and a lack of explanation for dropouts (Ab Malik 2017; Ab Malik 2018; Fields 2008; Gosney 2006; Kim 2014a; Lam 2013i; Lam 2013ii; Lam 2013iii). We were unable to judge attrition bias in one trial because we were unable to obtain a translation (Lee 2011). Where available, we present details of dropouts in Table 6.

Three trials used an intention-to-treat (ITT) analysis (Chippes 2014; Juthani-Mehta 2015; SOCLE II), and one trial conducted a partial ITT analysis (Frenkel 2001). One trial reported that they employed ITT analysis although not all participants were included in the final analysis (Ab Malik 2017). Sixteen trials did not use an ITT analysis (Ab Malik 2018; Dai 2017; Fields 2008; Gosney 2006; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Seguin 2014). We were unable to judge whether ITT was employed in Lee 2011 because of a lack of translation.

Selective reporting

We considered nine trials at low risk of reporting bias (Ab Malik 2017; Ab Malik 2018; Chippes 2014; Dai 2017; Juthani-Mehta 2015; Kim 2014a; Kuo 2016; Seguin 2014; SOCLE II) (Figure 2; Figure 3). We judged eight trials at high risk (Fields 2008; Gosney 2006; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi). We judged five trials as unclear because of insufficient detail (Frenkel 2001), due to a lack of translation (Lee 2011), or statistical information was presented in such a way that further clarification was required from the authors (Lam 2013i; Lam 2013ii; Lam 2013iii).

Other potential sources of bias

Baseline demographics were comparable and judged at low risk in 12 trials (Ab Malik 2018; Dai 2017; Frenkel 2001; Gosney 2006; Juthani-Mehta 2015; Kim 2014a; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Seguin 2014; SOCLE II). We judged one trial at high risk as the intervention group had a higher baseline incidence of positive *S aureus* cultures (Chippes 2014). The remaining trials did not present participants' baseline demographic details so we were unable to draw any conclusions about comparability in these trials.

(Ab Malik 2017; Fields 2008; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi). We were unable to obtain baseline demographics in Lee 2011 because of a lack of translation.

Sample size calculations were conducted a priori in 13 trials (Ab Malik 2017; Ab Malik 2018; Chipps 2014; Dai 2017; Fields 2008; Frenkel 2001; Juthani-Mehta 2015; Kuo 2016; Lam 2013i; Lam 2013ii; Lam 2013iii; Seguin 2014; SOCLE II). As a pilot trial, SOCLE II described plans for sample size calculations based on the trial findings but described an a priori sample target for the patient and healthcare staff participant population within the pilot. Sample size calculations were not reported in the remaining nine comparisons (Gosney 2006; Kim 2014a; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Lee 2011).

We judged several trials to have an unclear risk of bias due to limited data (Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi), or partial reporting of trial methodology (Ab Malik 2017; Kim 2014a; Seguin 2014). For example, Kim 2014a reported that complete randomisation was not performed through the entire process of the trial, but there is little information about what issues may have led to incomplete randomisation. We were unable to obtain a complete translation of one paper and were unable to judge whether there were other bias reported (Lee 2011).

Two trials were terminated early for futility (Fields 2008; Juthani-Mehta 2015). The quality of the Fields 2008 trial was difficult to judge because there were very little information or summary data in the published report. In contrast, Juthani-Mehta 2015 was stopped as the conditional power under observed treatment difference was nearly zero.

Effects of interventions

See: **Summary of findings 1** Oral health care interventions compared with usual care for people after stroke; **Summary of findings 2** Oral health care intervention compared with placebo for people after stroke; **Summary of findings 3** One oral healthcare intervention compared with another oral healthcare intervention for people after stroke

The results of this review are presented below within the three comparisons: OHC versus usual care or no treatment, OHC versus placebo, and OHC intervention versus another OHC intervention.

Comparison 1: oral health care versus usual care

See **Summary of findings 1**.

Seven trials investigated the effectiveness of an OHC intervention compared with usual care (Ab Malik 2017; Fields 2008; Frenkel 2001; Juthani-Mehta 2015; Kim 2014a; Kuo 2016; SOCLE II).

Primary outcomes

1.1 Dental plaque

We present the data from two trials that reported dental plaque (Frenkel 2001; Kim 2014a). Multi-component OHC interventions showed no evidence of a difference in the mean score (DMS) for dental plaque at one month post-intervention (DMS -0.66, 95% CI

-1.40 to 0.09; 2 trials, 83 participants; $I^2 = 83\%$; $P = 0.08$: very low-quality evidence; **Analysis 1.1**).

Six months after the multi-component OHC intervention, dental plaque scores in Frenkel 2001 were similar for the residents in both groups of residential homes (DMS -0.43, 95% CI -0.98 to 0.13; $P = 0.13$) (**Analysis 1.2**).

1.2 Denture plaque

Residents in the homes where staff had access to the multi-component OHC intervention had less plaque on their dentures than those residents in homes that continued to provide usual care (DMS -1.31, 95% CI -1.96 to -0.66; 1 trial, 38 participants; $P < 0.0001$; low-quality evidence) (Frenkel 2001). This difference was still observed six months after the training intervention (DMS -1.57, 95% CI -2.23 to -0.92; $P < 0.00001$) (Frenkel 2001) (**Analysis 1.3**).

Secondary outcomes

1.3 Presence of oral disease

1.3.1 Gingivitis

There was no evidence of a difference in gingivitis among participants receiving the multi-component OHC protocol compared with usual care one month after the intervention (DMS -0.60, 95% CI -1.66 to 0.45; 2 trials, 83 participants; $I^2 = 93\%$; $P = 0.26$; very low-quality evidence) (Frenkel 2001; Kim 2014a) (**Analysis 1.4**).

Six months after training, there was no evidence of a significant difference in gingivitis between the intervention and usual care groups in the Frenkel 2001 trial (DMS -0.25, 95% CI -0.61 to 0.10) (**Analysis 1.5**).

1.3.2 Denture-induced stomatitis

Residents' denture-induced stomatitis showed no evidence of a difference between the groups one or six months after the multi-component OHC intervention (1 month: DMS -0.33, 95% CI -0.92 to 0.26; 38 participants; 1 trial; $P = 0.28$; low-quality evidence; 6 months: DMS -0.10, 95% CI -0.61 to 0.40; 1 trial; $P = 0.69$) (Frenkel 2001) (**Analysis 1.6**).

1.4 Presence of related infection or oral opportunistic pathogens

1.4.1 Pneumonia

There was no evidence of a difference in the incidence of pneumonia among participants in wards with access to a multi-component OHC intervention (99 participants; 5 incidents of pneumonia) compared with those receiving usual care (105 participants; 1 incident of pneumonia) (OR 4.17, CI 95% 0.82 to 21.11; 1 trial; $P = 0.08$; low-quality evidence) (SOCLE II) (**Analysis 1.7**).

1.5 Stroke survivor and providers' knowledge of and attitudes to oral health care

1.5.1 Knowledge

We pooled the data from three trials that targeted change in OHC knowledge among stroke survivors and OHC providers' including registered nurses (Ab Malik 2017), nursing home care assistants (Frenkel 2001), and family carers (Kuo 2016). One month after training, stroke survivors and OHC providers demonstrated higher knowledge scores than providers who had no access to training

(SMD 0.70, 95% CI 0.06 to 1.35; 3 trials, 728 participants; $I^2 = 94\%$; $P = 0.03$; very low-quality evidence) (Analysis 1.8).

Trained family carers continued to demonstrate higher knowledge two months after training (MD 11.30, CI 95% 8.78 to 13.82; 1 trial, 94 participants; $P < 0.00001$) (Analysis 1.9), as did trained staff six months after training compared with usual care (SMD 0.34, 95% CI 0.18 to 0.50; 2 trials, 596 participants; $I^2 = 7\%$; $P < 0.0001$) (Analysis 1.10).

1.5.2 Attitude

We pooled the data from three trials which targeted change in stroke survivor and providers' oral health attitudes. Trials rated staff attitudes (Ab Malik 2017; Frenkel 2001), and family carers attitudes (Kuo 2016), to OHC using a Likert scale. Pooled data one month after training showed evidence of a difference between stroke survivor and OHC providers who had received OHC-specific training compared to those who received generic Internet-based professional development training (Ab Malik 2017), or delayed training (Frenkel 2001; Kuo 2016) (SMD 0.28, 95% CI 0.01 to 0.54; 3 trials, 728 participants; $I^2 = 65\%$; $P = 0.04$; very low-quality evidence) (Analysis 1.11).

Family carers' improved attitudes was not sustained two months after training (MD 2.00, CI 95% -0.12 to 4.12; 1 trial, 94 participants; $P = 0.06$) (Analysis 1.12). Similarly, there was no evidence of a difference six months after training in staff attitude (SMD 0.36, 95% CI -0.01 to 0.74; 2 trials, 596 participants; $I^2 = 80\%$, $P = 0.06$) (Ab Malik 2017; Frenkel 2001) (Analysis 1.13).

Comparison 2: oral healthcare intervention versus placebo

See Summary of findings 2.

Primary outcomes

2.1 Dental plaque

None of the trials in this comparison group reported dental plaque.

2.2 Denture plaque

None of the trials in this comparison group reported denture plaque.

Secondary outcomes

2.3 Presence of related infection or oral opportunistic pathogens

2.3.1 Pneumonia

Two trials reported the incidence of pneumonia (Gosney 2006; Seguin 2014). Data from all 203 randomised participants were available from the Gosney 2006 trial, although full follow-up data were only available for 164 individuals. The trialists provided stroke-specific data (39 participants) from Seguin 2014 for the purposes of this review.

Decontamination gel reduced the incidence of pneumonia among the intervention group compared with participants receiving placebo gel (OR 0.20, 95% CI 0.05 to 0.84; 203 participants; 1 trial; $P = 0.028$) (Gosney 2006). There was no difference in the incidence of pneumonia in participants treated with povidone-iodine compared with a placebo (OR 0.81, 95% CI 0.18 to 3.51; 39 participants; 1 trial; $P = 0.77$) (Seguin 2014). Pooling these data found no evidence of a difference in the incidence of pneumonia in participants receiving

an OHC intervention compared with placebo (OR 0.39, CI 95% 0.14 to 1.09; 2 trials, 242 participants; $I^2 = 42\%$; $P = 0.07$; low-quality evidence) (Analysis 2.1).

2.3.2 Aerobic Gram-negative bacilli

2.3.2.1 Acquired AGNB

Two trials reported the incidence of acquired AGNB following admission with stroke (Gosney 2006; Seguin 2014). There was no evidence of a difference between participants who were using the OHC intervention and those in the placebo group (RR 0.56, 95% CI 0.32 to 1.01; 2 trials, 242 participants; $I^2 = 0\%$; $P = 0.05$) (Analysis 2.2).

2.3.2.2 Carriage of AGNB

There was no evidence of a difference between the groups in relation to carriage of AGNB (RR 0.91, CI 95% 0.48 to 1.74) (Gosney 2006) (Analysis 2.3).

2.4 Patient satisfaction

2.4.1 Patient-reported oral dryness

One trial examined the effectiveness of Saengmaeg-san extract (11 participants) compared with placebo (10 participants) on xerostomia using a patient-reported questionnaire (Lee 2011). There was no evidence of a difference between groups after one week of treatment for: oral dryness (day and night) (MD -0.13, CI 95% -1.81 to 1.55; $P = 0.88$); oral dryness (daytime only) (MD -0.64, CI 95% -2.43 to 1.15; $P = 0.48$); oral dryness while eating a meal (MD 0.66, CI 95% -1.61 to 2.93; $P = 0.57$) or while swallowing food (MD -0.62, CI 95% -2.53 to 1.29; $P = 0.53$); lack of saliva (MD 1.12, CI 95% -0.28 to 2.52; $P = 0.12$) or general discomfort (MD 0.45, CI 95% -0.91 to 1.81; $P = 0.52$) (Analysis 2.4).

Comparison 3: oral health care versus another oral health care intervention

Twelve trials investigated the effectiveness of one enhanced multi-component OHC intervention compared with another OHC intervention (Ab Malik 2018; Chipps 2014; Dai 2017; Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi; Lam 2013i; Lam 2013ii; Lam 2013iii).

See Summary of findings 3.

Primary outcomes

3.1 Dental plaque

Five RCTs reported dental plaque index scores (Ab Malik 2018; Dai 2017; Lam 2013i; Lam 2013ii; Lam 2013iii); however, we were only able to extract dental plaque scores from one trial for inclusion in this comparison (Ab Malik 2018). There was no evidence of a difference in dental plaque between those participants who received an enhanced multi-component OHC intervention compared with conventional OHC group at three or six months (3 months: MD -0.04, CI 95% -0.33 to 0.25; 1 trial, 61 participants; $P = 0.78$; Analysis 3.1; 6 months: MD -0.15, CI 95% -0.46 to 0.16; 1 trial, 54 participants; $P = 0.34$; Analysis 3.2).

3.2 Denture plaque

None of the trials in this comparison group reported denture plaque.

Secondary outcomes

3.3 Presence of related infection or oral opportunistic pathogens

3.3.1 Aerobic Gram-negative bacilli

Two trials reported the prevalence of AGNB at three months ([Ab Malik 2018](#); [Dai 2017](#)). There was no evidence of a difference between participants who received the enhanced OHC intervention and those who received routine OHC (RR 1.00, CI 95% 0.71 to 1.42; 126 participants; $P = 1.00$) ([Analysis 3.3](#)).

Similarly, there was no evidence of a difference in the prevalence of AGNB at six months in one trial (RR 0.80, CI 95% 0.47 to 1.38; 52 participants; $P = 0.42$) ([Analysis 3.4](#)).

3.3.2 Candida

One trial reported the prevalence of oral candida ([Ab Malik 2018](#)). There was no evidence of a difference in the total number of participants with oral candida among participants who received enhanced OHC intervention or routine OHC at three or six months' follow-up (3 months: RR 1.08, CI 95% 0.61 to 1.89; 52 participants; $P = 0.80$; [Analysis 3.5](#); 6 months: RR 1.17, CI 95% 0.62 to 2.20; 52 participants; $P = 0.63$; [Analysis 3.6](#)).

3.3.3 Staphylococcus aureus

Two trials reported the prevalence of *S aureus* in stroke survivors measured at day 10 ([Chipps 2014](#)), and at three months ([Dai 2017](#)). There was no evidence of a difference between the groups receiving enhanced OHC or routine OHC interventions (OR 1.29, CI 95% 0.57 to 2.91; 119 participants; $P = 0.55$) ([Analysis 3.7](#)).

Sensitivity analysis

As such disparate trials were included in the review, we had no opportunity to conduct the sensitivity analyses planned at the protocol stage.

DISCUSSION

Summary of main results

In this third update of this review we included 15 trials (22 randomised comparisons, which we referred to as 22 trials) involving 3631 participants with data for 1546 people with stroke, 1028 healthcare providers and 94 informal carers that compared the effects of OHC interventions with usual care, placebo or another OHC intervention (see [Summary of findings 1](#); [Summary of findings 2](#); [Summary of findings 3](#)).

Comparison 1: oral healthcare interventions versus usual care

See [Summary of findings 1](#).

- No moderate or high-quality evidence for improving oral health in people after stroke.
- Low and very low-quality evidence showed that:
 - * OHC interventions could improve denture plaque one month after training which was maintained six months after the intervention was delivered;
 - * OHC interventions could improve stroke survivor and providers' knowledge one month after training. The

improvement in knowledge was sustained six months after the intervention was delivered;

- * OHC interventions could improve stroke survivor and providers' attitudes to OHC one month after training, but this improvement was not sustained longer term (greater than one month).

Comparison 2: oral healthcare intervention versus placebo

See [Summary of findings 2](#).

- No moderate- or high-grade evidence for improving oral health in people after stroke.
- Low-quality evidence showed no benefit or harm for OHC interventions compared with placebo on the incidence of pneumonia; however, people with stroke treated with gel for selective decontamination of the digestive tract had a lower incidence of pneumonia compared with placebo gel.

Comparison 3: one oral healthcare intervention versus another oral healthcare intervention

See [Summary of findings 3](#).

- No moderate- or high-quality evidence for improving oral health in people after stroke.
- Low-quality evidence showed no benefit or harm for enhanced multi-component OHC interventions compared with other OHC interventions for dental plaque.

Overall completeness and applicability of evidence

Despite the inclusion of several new trials of OHC for people after stroke since our last review update ([Brady 2006](#)), there remains a lack of high-quality evidence to inform OHC in stroke care settings. Trials have evaluated three broad groups of OHC interventions: specialist OHC training compared to usual care (which was often no training), a specific OHC product compared to a placebo or enhanced multi-component OHC intervention compared to usual OHC interventions.

OHC interventions were shown to have a positive benefit on denture plaque at one month ([Frenkel 2001](#)), which was still evident at six months ([Frenkel 2001](#)). OHC interventions provided to healthcare staff had a positive impact on staff knowledge in two trials ([Ab Malik 2017](#); [Frenkel 2001](#)), as did training for informal carers (i.e. family carers) who were caring for stroke survivors at home in a third trial ([Kuo 2016](#)). These benefits persisted two months ([Kuo 2016](#)), and six months in a residential care setting after the training ([Frenkel 2001](#)). Staff attitudes towards OHC showed no evidence of training benefit, but improved attitudes were evident among family carers attitudes after OHC training ([Kuo 2016](#)).

Our review identified one trial that evaluated the effectiveness of a highly specific OHC intervention across a wide stroke population, including participants who were unable to provide informed consent (but proxy consent was provided instead). There was evidence of a beneficial effect of the decontamination gel compared with placebo gel ([Gosney 2006](#)).

This was a highly complex review which incorporated many multi-component interventions. Additional description of the specific participants included within each of the trials would be relevant, but we did not plan to profile participants based on their level

of dependency for personal self-care, presence of dysphagia, cognitive status or the chronicity of the stroke.

A wide range of complex, multi-component OHC interventions were developed, delivered and evaluated compared to usual care or another OHC treatment, involving the provision of various combinations of training, toothbrush, toothpaste, mouth gel, mouthwash, tongue cleaners, lip balm, care protocols and assessment tools. Comparisons also involved differences in the quality of the equipment such as powered toothbrushes versus manual, or different types of lip balm.

However, there was limited overlap in the outcomes captured across these trials which included dental plaque, denture plaque, stomatitis, oral pharyngeal cultures, gingival bleeding, pneumonia, antibiotic use, dryness and quality of life. Carers' OHC knowledge and attitudes were measured as was the documentation of OHC assessments and care plans, specialist dental referrals and economic outcomes. Similarly, many trialists used questionnaires to capture outcome data that were not validated (Ab Malik 2017; Frenkel 2001; Kuo 2016; Lee 2011), or captured using different diagnostic criteria which for pneumonia was reported using clinical signs and symptoms (Gosney 2006), Mann chest criteria (SOCLE II), or reported as a radiographically documented event (Juthani-Mehta 2015).

Quality of the evidence

It was often difficult to judge the quality of the evidence as a result of incomplete reporting. Randomisation was adequately reported in half of the trials, but allocation concealment was only clearly reported in six trials, and the remainder were judged as unclear. Blinding to avoid performance bias was possible and adequately reported in four trials with the majority of trials being judged as unclear or at high risk of bias. While it is not always possible to blind the participants or clinicians because of the nature of the intervention, it should be possible to blind the outcome assessor. While blinding outcome assessors is always desirable, it is not possible when it is a self-report measure, and the patients are not blinded. However, whether blinding outcome assessors to outcome measures was attempted was judged as low risk of bias in eight randomised trials.

Finally, we noted that over a third of the included trials were also judged as having a high risk of attrition bias and selective reporting. These judgments contributed to the downgrading of the quality of the evidence from high to moderate for all outcomes. We also downgraded the quality of evidence for all outcomes, other than staff knowledge, for imprecision as the results were often derived from a single trial. There were too few trials to assess inconsistency of results or publication bias. In summary, we judged the quality of the evidence synthesised within the meta-analyses to be low to very low quality, and this limits our confidence in the results.

Potential biases in the review process

We conducted a comprehensive search for high-quality trials that evaluated the effectiveness of OHC in people after stroke. We are confident we have identified most published trials of relevance to the review, but it is possible that despite our efforts, we may be unaware of additional unpublished work. Our search strategy and study selection criteria were agreed in advance and applied to all identified trials.

Our data extraction processes were completed independently and then compared. Whenever possible, we extracted all relevant data and sought missing data directly from the trialists for inclusion within the review. However, there remains a number of other relevant trials that could not be fully included. Of the trials eligible for inclusion in this review, eight were unable to provide stroke-specific data. Of these, five investigated OHC programme interventions (Hajizamani 2006; Mojon 1998; Quagliarello 2009; Redwood 2001; Schou 1989), two examined the use of medicated gum (Simons 1997; Simons 2002), and one a varnish (Brailsford 2002). Our searches also identified a further nine trials which may be eligible for inclusion in updates of this review, but it is unclear at this time whether stroke-specific data are available (Cabov 2010; IRCT2017012232101N1; IRCT2017091636194N1; Jin 2018; Marchini 2018; Mori 2012; NCT00610324; NCT03219346; Yakiwchuk 2013).

Agreements and disagreements with other studies or reviews

The maintenance of oral health after stroke should be a priority (in research and clinical settings) given the wide-reaching implications of poor oral health. One recent systematic review found that periodontal problems, dental caries and tooth loss were greater among stroke survivors than controls (Dai 2017). They were also less likely to seek specialist dental support after their stroke than non-stroke peers. We also have national-based audit data to support the premise that poor oral health may be closely linked to stroke survivors' ability to care for their own mouth and teeth, seek specialist support when required, and their stroke-related functional abilities and mobility (Kim 2018). Efforts continue to be made to improve the quality of OHC in stroke care settings and a range of possible approaches to enhance the provision of OHC after stroke were considered in this review. We continue to lack moderate- or high-quality evidence of whether high-quality OHC interventions reduce the number of people experiencing pneumonia after stroke (Lyons 2018).

AUTHORS' CONCLUSIONS

Implications for practice

There is a paucity of moderate- or high-quality evidence relating to oral care interventions for people after a stroke. What little evidence is available suggests that a specialist training session can improve healthcare staff's and family carers' knowledge of oral health care (OHC), and this is maintained over time. It may also have a positive impact on family carers' attitudes towards OHC. Our review also found limited low-quality evidence to show a beneficial effect of training and multi-component OHC intervention on patient's oral health.

Good oral health is vital to an individual's ability to speak, eat, stay healthy and recover well after their stroke. Although we lack clear evidence of the optimal approach to providing OHC to people after stroke, it appears important that staff are supported (training in particular) to deliver such care. Our findings support the recommendations within several international clinical guidelines that oral care intervention of some type is better than nothing. Further clarity about the specific type, frequency and regimen of oral care that results in superior outcomes for people after stroke is still required.

Implications for research

The evidence presented within this review indicates the potential benefits of specialist OHC on nursing staff and family members' knowledge and attitudes, and the benefits of decontamination gel on the incidence of pneumonia. Further trials are needed to identify the optimal approach to OHC after stroke. Some efforts need to be made to increase the co-ordination of research on this topic given the wide range of outcome measures and even wider range of measurement tools seen in this review. Consistent use of the recent consensus terminology and diagnostic criteria for pneumonia after stroke (Smith 2015), and consensus on core outcome set for trials of OHC interventions after stroke would greatly improve the strength of future meta-analyses on this topic. We welcome the recently funded work on a core outcome set relevant to this review (COMET Initiative; www.comet-initiative.org/studies/details/1081?result=true).

Inclusion of a clinically representative stroke population is important for the clinical relevance of future research. Of the trials included in this review, only four reported including people with incapacity or severe stroke impairments. We know that severity of stroke is linked to pneumonia incidence and that people who are most severely impaired are those who are also most reliant on others to support their OHC (Kim 2018). While recruitment of these subgroups of stroke survivors may be a challenge, it is important

to capture a clinically relevant trial population so that we can develop and evaluate effective interventions that will benefit these subgroups in practice.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ab Malik 2017

Study characteristics	
Methods	Cluster RCT randomised at hospital level, Malaysia Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: all registered nurses caring for people with stroke were invited to take part; informed written consent Exclusion criteria: not reported OHC training group: 277 registered nurses General stroke care training group: 270 registered nurses Details of participants are shown in Table 2

Interventions for improving oral health in people after stroke (Review)

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Ab Malik 2017 (Continued)

Interventions

OHC training

- Intervention: Internet-based continuing professional development programme
- Materials: secure internet portal, computer
- Agent: none
- Procedures: online training programme was specific to provision of oral hygiene care in stroke patients. Programme covered oral health knowledge, attitudes, subjective norms, means of behavioural control and intention. Contents included information on good oral condition and importance of having good oral health, consequences of poor oral hygiene and importance of nurses' roles and care of people with stroke. Provided by: stroke physicians (rehabilitation medicine) and dentists, and followed good practices of computer-aided learning for oral health. Development of contents was guided by the definition of the theory of planned behaviour domains and scope of the study.
- Training: as described above
- Delivery: online; 1-to-1
- Location: unclear
- Regimen: participants were reminded and encouraged to complete the Internet-based continuing professional development programme every 6 weeks; no details about length of programme
- Tailoring: not reported
- Modification: not reported
- Adherence: not reported

General stroke care training

- Intervention: Internet-based generic continuing professional development programme not specific to OHC
- Materials: secure internet portal, computer
- Procedures: programme related to 'bundles of care' for people with stroke that included some details on oral hygiene care but not specific to theory of planned behaviour.
- Provided by: stroke physicians and physicians
- Training: as described above
- Delivery: online; 1-to-1
- Location: unclear
- Regimen: participants were reminded and encouraged to complete the Internet-based continuing professional development programme every 6 weeks; no details about length of programme
- Tailoring: not reported
- Modification: not reported
- Adherence: not reported

Outcomes

Outcomes: questionnaire on practice of providing oral hygiene care to people with stroke (contained 12 items specific to attitudes, subjective norm, perceived behaviour control and general intention to providing oral hygiene care related to Theory of Planned Behaviour), knowledge of OHC (assessed using 5 items related to dental plaque, gum bleeding, consequences of dental plaque, how to prevent gingivitis and how oral health affects general health)

Data collection: baseline, 1 and 6 months postintervention

Funding

Authors declared no conflicts of interest. Study funded by The University of Hong Kong

Notes

Dropouts are detailed in [Table 6](#)

Statistical data included within the review meta-analyses

Risk of bias
Bias
Authors' judgement
Support for judgement

Ab Malik 2017 (Continued)

Random sequence generation (selection bias)	Low risk	Quote: "Hospitals were first stratified by size into either large, medium, or small in terms of number of health care providers. From each stratified group, hospitals were block-randomized in groups of 4 ('ABBA') by a computer-generated randomization method."
Allocation concealment (selection bias)	Low risk	Quote: "5 hospitals were assigned to the test group (277 registered nurses) and 5 hospitals were assigned to the control group (270 registered nurses). The allocation sequence was concealed from the investigator coordinating the trial (who had contact with the centers)."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Participants were also blind as to what groups they were assigned to, as both received a form of Web-based CPD."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "the assessor was 'blind' as to what group participants had been assigned."
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment; high attrition rate (82/277 in OHC training group and 92/270 in general stroke care training group). Total dropouts accounted for (quote: "loss to follow-up was because nurses were transferred to other wards or hospitals"). However, dropouts were only reported in CONSORT diagram as loss to follow-up, so unclear when participants dropped out (month 1 or 6). Study authors reported that ITT analysis employed but not all participants appeared to be included in the final analyses.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Unclear risk	Comment: insufficient information. Unable to compare baseline demographics for healthcare provider and environmental characteristics as data were combined. Quote: "no significant difference between the response rate among those in the test and control groups."
A priori power calculation	Low risk	Comment: yes Quote: "With the assumption that this practice is at 50% and that it will not change without education intervention, whereas there will be a 25% improvement in practices following CAL intervention (i.e. 63% of nurses will practice oral care in rehabilitation). Then a proposed sample size of 247 in each group is required with sample power at 80%. Allowing for nonparticipation and a dropout rate of ~20%, thus it was prudent to attempt to recruit over 600 nurses (300 per group) in total to test the hypothesis."
Other bias	Unclear risk	Comment: limited information supplied about how long each group were exposed to the intervention (i.e. how frequently they used the programme and total duration).

Ab Malik 2018
Study characteristics

Methods Parallel RCT randomised at individual level, Malaysia

Ab Malik 2018 (Continued)

Study recruitment and setting details: see [Table 1](#)

Participants	<p>Inclusion criteria: hospitalised people with stroke managed by a stroke rehabilitation team (mBI < 70), able to follow instructions, medically stable, not receiving antibiotics or antimicrobial agents and were not edentulous</p> <p>Exclusion criteria: not reported</p> <p>Intense method group: 38 participants</p> <p>Conventional method group: 48 participants</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: intense method for plaque control • Materials: powered tooth-brush (Oral B Pro-Health DB4010), gel (Hexigel chlorhexidine gluconate gel) • Agent: 1% chlorhexidine gel (Hexigel chlorhexidine gluconate gel) • Procedures: daily tooth brushing with powered toothbrush and gel. Individual oral hygiene instruction given by dental assistant, using a plastic tooth model and a pamphlet on tooth brushing techniques • Provided by: dental assistant • Training: not reported • Delivery: face-to-face, 1:1, ward • Regimen: "daily"; no other details reported • Tailoring: not reported • Modification: not reported • Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: conventional method for plaque control • Materials: manual Oral-B-super thin and extra soft bristles toothbrush, standard commercial tooth-paste (Colgate Maximum Cavity Protection) • Procedures: daily manual tooth brushing. Individual oral hygiene instruction given by dental assistant, using a plastic tooth model and a pamphlet on tooth brushing techniques • Provided by: dental assistant • Training: not reported • Delivery: face-to-face, 1:1, ward • Regimen: "daily"; no other details reported • Tailoring: not reported • Modification: not reported • Adherence: not reported
Outcomes	<p>Primary outcomes: Dental Plaque Index assessed using Silness and Loe Plaque Index (Silness 1964)</p> <p>Secondary outcomes: presence and type of dental prosthesis, mBI</p> <p>Data collection: baseline, 3 and 6 months postintervention</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by The University of Hong Kong</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Ab Malik 2018 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: participants were block randomised into 2 groups, in a group size of 2 (ABBA) Quote: "Computer-generated randomisation sequences were used for the random allocation of the patients, and this was performed by the head of the research team."
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: reported as a "single-blinded study." Oral hygiene kits were prepared by a dental assistant who was not involved in oral health assessments and sample collections. Each oral hygiene kit was placed in the same type of packaging, colour coded and was not transparent. However, participants must have been aware of difference in toothbrushes (manual vs powered), and the application of gel (or not).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Patient's allocation was kept anonymous from the examiner." "One examiner was involved in the assessment of all patients at the three-time points. The examiner was trained on the oral assessment by the head of the research team and functional assessments (mBI) by a rehabilitation physician before commencing with the study."
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: dropouts accounted for but high attrition rate (37%) across the trial (13/38 in intensive group; 19/48 in conventional group) at 6 months. ITT not employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "No significant differences between test and control groups."
A priori power calculation	Low risk	Yes. Quote: "The primary outcome was the changes in the dental plaque score [PI scores]. A sample size of 23 subjects per group was calculated based on the detection of a clinically meaningful PI change score of 0.55 an anticipated SD of 0.642 and 80% power. To allow for potential dropout rates of 40%; at least 38 patients per group were required."
Other bias	Low risk	None identified.

Ab Malik 2018
Study characteristics

Methods	Parallel RCT randomised at individual level, Malaysia Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: hospitalised people with stroke managed by a stroke rehabilitation team (mBI < 70), able to follow instructions, medically stable, not receiving antibiotics or antimicrobial agents and were not edentulous

Ab Malik 2018 (Continued)

Exclusion criteria: not reported

Intense method group: 38 participants

Conventional method group: 48 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: intense method for plaque control Materials: powered tooth-brush (Oral B Pro-Health DB4010), gel (Hexigel chlorhexidine gluconate gel) Agent: 1% chlorhexidine gel (Hexigel chlorhexidine gluconate gel) Procedures: daily tooth brushing with powered toothbrush and gel. Individual oral hygiene instruction given by dental assistant, using a plastic tooth model and a pamphlet on tooth brushing techniques Provided by: dental assistant Training: not reported Delivery: face-to-face, 1:1, ward Regimen: "daily"; no other details reported Tailoring: not reported Modification: not reported Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: conventional method for plaque control Materials: manual Oral-B-super thin and extra soft bristles toothbrush, standard commercial tooth-paste (Colgate Maximum Cavity Protection) Procedures: daily manual tooth brushing. Individual oral hygiene instruction given by dental assistant, using a plastic tooth model and a pamphlet on tooth brushing techniques Provided by: dental assistant Training: not reported Delivery: face-to-face, 1:1, ward Regimen: "daily"; no other details reported Tailoring: not reported Modification: not reported Adherence: not reported
Outcomes	<p>Primary outcomes: Dental Plaque Index assessed using Silness and Loe Plaque Index (Silness 1964)</p> <p>Secondary outcomes: presence and type of dental prosthesis, mBI</p> <p>Data collection: baseline, 3 and 6 months postintervention</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by The University of Hong Kong</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: participants were block randomised into 2 groups, in a group size of 2 (ABBA)

Ab Malik 2018 (Continued)

		Quote: "Computer-generated randomisation sequences were used for the random allocation of the patients, and this was performed by the head of the research team."
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: reported as a "single-blinded study." Oral hygiene kits were prepared by a dental assistant who was not involved in oral health assessments and sample collections. Each oral hygiene kit was placed in the same type of packaging, colour coded and was not transparent. However, participants must have been aware of difference in toothbrushes (manual vs powered), and the application of gel (or not).
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Patient's allocation was kept anonymous from the examiner." "One examiner was involved in the assessment of all patients at the three-time points. The examiner was trained on the oral assessment by the head of the research team and functional assessments (mBI) by a rehabilitation physician before commencing with the study."
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: dropouts accounted for but high attrition rate (37%) across the trial (13/38 in intensive group; 19/48 in conventional group) at 6 months. ITT not employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "No significant differences between test and control groups."
A priori power calculation	Low risk	Yes. Quote: "The primary outcome was the changes in the dental plaque score [PI scores]. A sample size of 23 subjects per group was calculated based on the detection of a clinically meaningful PI change score of 0.55 an anticipated SD of 0.642 and 80% power. To allow for potential dropout rates of 40%; at least 38 patients per group were required."
Other bias	Low risk	None identified.

Chipps 2014
Study characteristics

Methods	RCT randomised at individual level, USA Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 18 years, able to communicate in English and give informed consent, primary diagnosis of a stroke within 30 days of admission to the rehabilitation unit, admitted directly from an acute care facility, oral or pharyngeal dysphasia identified by a bedside swallow examination by speech and language therapist, modified barium swallow or fibreoptic endoscopic evaluation of swallowing Exclusion criteria: current comorbid diagnoses of pneumonia, known infection of oral cavity or receiving therapy for infection of oral cavity (or both), documented history of a haematological disorder, medically restricted fluid intake, allergy to Listerine or other study products, currently wearing dentures, pregnant or nursing mothers, history of MRSA infection or colonisation

Chipps 2014 (Continued)

Enhanced oral care group: 29 participants

Routine oral care group: 22 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: enhanced oral care • Materials: oral care box which contained supplies (battery-operated toothbrush, toothpaste, Listerine, floss picks, tongue cleaner, lip balm) • Agent: Braun Oral B with timer, Crest-Pro-Health Toothpaste, Listerine, Glide disposable Floss Picks, Sunstar Dual Action tongue Cleaner, Carmex Lip Balm • Procedures: twice daily OHC, 5 elements – timed toothbrushing with battery powered toothbrush twice a day for 30 seconds in each quadrant, tongue brushing, flossing, mouthrinse and lip care provided by trained registered nurse interventionists • Provided by: registered nurses • Training: all staff – in-service training which included details of study, and importance of blinded assessments. Subgroup of Royal College of Nurses selected as study interventionists had training sessions on the new protocol. Dentist and dental hygienist provided training in use of equipment and approach • Delivery: face-to-face, 1:1, ward • Regimen: twice daily at predetermined time points for 10 days, mouthrinse once per day. Timed toothbrushing 30 seconds in each quadrant for 10 days • Tailoring: none • Modification: none • Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: routine oral care • Materials: standard stock hospital care products • Agent: hospital toothbrush (Sage), Oral Care Sodium Bicarbonate Mouthpaste (Sage), Careline alcohol-free mouthwash, Regular Chaplet lip balm • Procedures: OHC as per hospital policy • Training: inservice describing the study protocol, included details of study and importance of blinded oral assessments • Provided by: all nursing staff and patient care assistants • Delivery: face-to-face, 1:1, ward • Regimen: OHC as per hospital policy which includes toothbrushing, mouthrinse and lip balm with standard stock hospital OHC products. Once or twice daily as clinically appropriate • Tailoring: none • Modification: none • Adherence: not reported
Outcomes	<p>Outcomes: nasal and oropharyngeal cultures; R-THROAT assessment; MASA; FOIS</p> <p>Data collection: baseline (time 1), study day 5 (time 2), and following completion of 10-day protocol (time 3). FOIS assessed on days 2 and 10</p>
Funding	<p>Conflicts of interest: not reported. Study funded by Sigma Theta Tau International and the Rehabilitation Nurses Foundation</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Suitable statistical data permitting inclusion within the review meta-analyses unavailable</p>

Chipps 2014 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer-generated randomised table.
Allocation concealment (selection bias)	Low risk	Comment: sealed envelope determining study group.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "subjects in the intervention group received an 'oral care box' which contained supplies required for the intervention oral care intervention. This box was placed out of view of the speech and language therapists. All staff members were made aware of the patient's inclusion in the study with a sign over the bed." Comment: the initial training provided to all nursing staff and patient care assistants who worked on the unit provided details of the study and included the importance of the blinded oral assessments done by the speech and language therapists
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: oral cavity assessments (R-THROAT) and MASA were obtained by 2 blinded speech and language therapists
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for. High attrition rate for the enhanced group (8 participants) compared with routine group (1 participant). ITT analysis employed.
Selective reporting (reporting bias)	Low risk	Comment; all prespecified outcomes reported.
Baseline data comparable?	High risk	Quote: "No significant in patient characteristics (age, gender and race) or swallowing ability. However the control group had a significantly higher baseline R-THROAT score and the intervention group had a higher baseline incidence of positive <i>S. aureus</i> cultures."
A priori power calculation	Low risk	Yes. Quote: "Sample size based on a 22 point difference in MASA test. To obtain 70% power for a 2-sample t-test, 21 subjects were needed for each group."
Other bias	Low risk	Comment: none identified.

Chipps 2014

Study characteristics

Methods	RCT randomised at individual level, USA Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 18 years, able to communicate in English and give informed consent, primary diagnosis of a stroke within 30 days of admission to the rehabilitation unit, admitted directly from an acute care facility, oral or pharyngeal dysphasia identified by a bedside swallow examination by speech and language therapist, modified barium swallow or fiberoptic endoscopic evaluation of swallowing

Chipps 2014 (Continued)

Exclusion criteria: current comorbid diagnoses of pneumonia, known infection of oral cavity or receiving therapy for infection of oral cavity (or both), documented history of a haematological disorder, medically restricted fluid intake, allergy to Listerine or other study products, currently wearing dentures, pregnant or nursing mothers, history of MRSA infection or colonisation

Enhanced oral care group: 29 participants

Routine oral care group: 22 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: enhanced oral care Materials: oral care box which contained supplies (battery-operated toothbrush, toothpaste, Listerine, floss picks, tongue cleaner, lip balm) Agent: Braun Oral B with timer, Crest-Pro-Health Toothpaste, Listerine, Glide disposable Floss Picks, Sunstar Dual Action tongue Cleaner, Carmex Lip Balm Procedures: twice daily OHC, 5 elements – timed toothbrushing with battery powered toothbrush twice a day for 30 seconds in each quadrant, tongue brushing, flossing, mouthrinse and lip care provided by trained registered nurse interventionists Provided by: registered nurses Training: all staff – in-service training which included details of study, and importance of blinded assessments. Subgroup of Royal College of Nurses selected as study interventionists had training sessions on the new protocol. Dentist and dental hygienist provided training in use of equipment and approach Delivery: face-to-face, 1:1, ward Regimen: twice daily at predetermined time points for 10 days, mouthrinse once per day. Timed toothbrushing 30 seconds in each quadrant for 10 days Tailoring: none Modification: none Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: routine oral care Materials: standard stock hospital care products Agent: hospital toothbrush (Sage), Oral Care Sodium Bicarbonate Mouthpaste (Sage), Careline alcohol-free mouthwash, Regular Chaplet lip balm Procedures: OHC as per hospital policy Training: inservice describing the study protocol, included details of study and importance of blinded oral assessments Provided by: all nursing staff and patient care assistants Delivery: face-to-face, 1:1, ward Regimen: OHC as per hospital policy which includes toothbrushing, mouthrinse and lip balm with standard stock hospital OHC products. Once or twice daily as clinically appropriate Tailoring: none Modification: none Adherence: not reported
Outcomes	<p>Outcomes: nasal and oropharyngeal cultures; R-THROAT assessment; MASA; FOIS</p> <p>Data collection: baseline (time 1), study day 5 (time 2), and following completion of 10-day protocol (time 3). FOIS assessed on days 2 and 10</p>
Funding	<p>Conflicts of interest: not reported. Study funded by Sigma Theta Tau International and the Rehabilitation Nurses Foundation</p>

Chipps 2014 (Continued)

Notes

Dropouts are detailed in [Table 6](#)

Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer-generated randomised table.
Allocation concealment (selection bias)	Low risk	Comment: sealed envelope determining study group.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote: "subjects in the intervention group received an 'oral care box' which contained supplies required for the intervention oral care intervention. This box was placed out of view of the speech and language therapists. All staff members were made aware of the patient's inclusion in the study with a sign over the bed." Comment: the initial training provided to all nursing staff and patient care assistants who worked on the unit provided details of the study and included the importance of the blinded oral assessments done by the speech and language therapists
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: oral cavity assessments (R-THROAT) and MASA were obtained by 2 blinded speech and language therapists
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for. High attrition rate for the enhanced group (8 participants) compared with routine group (1 participant). ITT analysis employed.
Selective reporting (reporting bias)	Low risk	Comment; all prespecified outcomes reported.
Baseline data comparable?	High risk	Quote: "No significant in patient characteristics (age, gender and race) or swallowing ability. However the control group had a significantly higher baseline R-THROAT score and the intervention group had a higher baseline incidence of positive <i>S. aureus</i> cultures."
A priori power calculation	Low risk	Yes. Quote: "Sample size based on a 22 point difference in MASA test. To obtain 70% power for a 2-sample t-test, 21 subjects were needed for each group."
Other bias	Low risk	Comment: none identified.

Dai 2017

Study characteristics

Methods	RCT randomised at individual level, Hong Kong Special Administrative Region of the People's Republic of China Study recruitment and setting details: see Table 1
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Interventions for improving oral health in people after stroke (Review)

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Dai 2017 (Continued)

Participants

Inclusion criteria: admitted to outpatient rehabilitation programme within 6 months; had moderate-to-severe functional disability – BI scores < 70; not edentulous; no more than mild cognitive impairment (i.e.) Mini Mental Status Examination > 18; able to follow a 1-step command (as an assessment of communication); no indwelling nasogastric feeding tubes

Exclusion criteria: none reported

Advanced oral hygiene care group: 47 participants

Conventional oral hygiene care group: 47 participants

Details of participants are shown in [Table 2](#)

Interventions

Multi-component OHC intervention

- Intervention: advanced oral hygiene care programme
- Materials: powered toothbrush (Oral-B AdvancePower™ 400 series), 0.2% chlorhexidine gluconate mouthrinse (Corsodyl), a standard toothpaste (Colgate Maximum Cavity Protection), oral hygiene pamphlet
- Agent: 0.2% chlorhexidine gluconate mouthrinse (Corsodyl), standardised toothpaste (Colgate Maximum Cavity Protection)
- Procedures: supply of a powered toothbrush, mouthrinse, toothpaste and oral hygiene training. All participants attended a 1-to-1 oral hygiene training conducted by a dental surgery assistant. Participants were provided with specific manufacturer's instructions regarding the use of powered toothbrush. In addition, they were provided with a 3 months' supply of mouthrinse and were instructed to rinse twice daily with 10 mL of the mouthrinse (at least 30 minutes after brushing)
- Provided by: dental surgery assistant
- Training: all participants were given a standardised OHC pamphlet. OHC practice was demonstrated on tooth block models. Participants were asked to adhere to OHC protocol and brush their teeth in a systematic way. Training sessions lasted approximately 30 minutes
- Delivery: face-to-face, 1:1
- Location: non-clinical room
- Regimen: toothbrushing and mouthrinse twice daily for 6 months
- Tailoring: none
- Modification: none
- Adherence: none

Multi-component OHC Intervention

- Intervention: conventional oral hygiene care programme
- Materials: standard stock hospital care products
- Agent: manual toothbrush (Oral-B Pro-Health All-In-One), standard toothpaste (Colgate Maximum Cavity Protection)
- Procedures: supplied manual toothbrush and toothpaste plus oral hygiene training
- Provided by: dental surgery assistant
- Training: all participants attended a 1-to-1 OHC training conducted by a dental surgery assistant. All participants were given a standardised OHC pamphlet. OHC practice was demonstrated on tooth block models. Participants were asked to adhere to OHC protocol and brush their teeth in a systematic way. Training sessions lasted approximately 30 minutes
- Delivery: face-to-face, 1:1
- Location: non-clinical room
- Regimen: twice daily for 6 months
- Tailoring: none
- Modification: none
- Adherence: none

Dai 2017 (Continued)

Outcomes	<p>Primary outcomes: oral hygiene status as assessed by Dental Plaque Index (Silness 1964), and Gingival Bleeding Index (Ainamo 1975)</p> <p>Secondary outcomes: oral hygiene status and gingival bleeding at 6 months, dental caries experience, periodontal health, oral mucosa conditions, dental prosthesis status, adverse effects of chlorhexidine</p> <p>Data collection: baseline, 3- and 6-month follow-up</p>
Funding	Study authors declared no conflicts of interest. Study funded by General Research Fund, Hong Kong (Project no. 774012)
Notes	<p>Dropouts are detailed in Table 6</p> <p>Suitable statistical data permitting inclusion within the review meta-analyses were not available</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: computer generated "block randomized with a group size of 4 (ABBA)."
Allocation concealment (selection bias)	Low risk	Quote: "The randomized sequence was computer generated by the project supervisor. The allocation sequence number of each subject was concealed in an opaque envelope and provided to a nurse at the rehabilitation centre who was independent of the research team."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: single-blind study. Participants were aware of their treatment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessors were blind to which group subjects were assigned to."
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>Comment: dropouts accounted for. High attrition rate for the conventional care group.</p> <p>Quote: "no significant difference in the profile and oral health status of participants with respect to participation and drop-out at 3-month assessment were apparent (Table A and B in Appendix II [of the publication]). No significant difference in the profile and oral health status of participants with respect to participation and drop-out at 6-month assessment were apparent except reported dental attendance pattern and brushing habits ($p < 0.01$) (Table C and D in Appendix II [of the publication]). ITT not employed but it was reported that when conducting regression analysis, the method Last Observation Carried Forward (LOCF) was employed to deal with missing outcomes at follow-up reviews."</p>
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "At baseline there was no significant difference in the profile of subjects" [between the enhanced and conventional care groups (Table E in Appendix II in the publication)]
A priori power calculation	Low risk	Yes.

Dai 2017 (Continued)

Quote: "Sample size was calculated based on intended ability to detect a significant difference in the primary outcome variable – the level of dental plaque between two groups at three-month review ... the number of study subjects would require 38 per group, based on 80% power and the statistical significance level set at 0.05. Anticipating a 20% dropout rate over the course of the clinical trial, the initial sample size for each treatment group was proposed as 47 patients per group (94 subjects in total)."

Other bias	Low risk	None identified.
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Dai 2017

Study characteristics

Methods	<p>RCT randomised at individual level, Hong Kong Special Administrative Region of the People's Republic of China</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: admitted to outpatient rehabilitation programme within 6 months; had moderate-to-severe functional disability – BI scores < 70; not edentulous; no more than mild cognitive impairment (i.e.) Mini Mental Status Examination > 18; able to follow a 1-step command (as an assessment of communication); no indwelling nasogastric feeding tubes</p> <p>Exclusion criteria: none reported</p> <p>Advanced oral hygiene care group: 47 participants</p> <p>Conventional oral hygiene care group: 47 participants</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: advanced oral hygiene care programme Materials: powered toothbrush (Oral-B AdvancePower™ 400 series), 0.2% chlorhexidine gluconate mouthrinse (Corsodyl), a standard toothpaste (Colgate Maximum Cavity Protection), oral hygiene pamphlet Agent: 0.2% chlorhexidine gluconate mouthrinse (Corsodyl), standardised toothpaste (Colgate Maximum Cavity Protection) Procedures: supply of a powered toothbrush, mouthrinse, toothpaste and oral hygiene training. All participants attended a 1-to-1 oral hygiene training conducted by a dental surgery assistant. Participants were provided with specific manufacturer's instructions regarding the use of powered toothbrush. In addition, they were provided with a 3 months' supply of mouthrinse and were instructed to rinse twice daily with 10 mL of the mouthrinse (at least 30 minutes after brushing) Provided by: dental surgery assistant Training: all participants were given a standardised OHC pamphlet. OHC practice was demonstrated on tooth block models. Participants were asked to adhere to OHC protocol and brush their teeth in a systematic way. Training sessions lasted approximately 30 minutes Delivery: face-to-face, 1:1 Location: non-clinical room Regimen: toothbrushing and mouthrinse twice daily for 6 months Tailoring: none Modification: none Adherence: none <p>Multi-component OHC Intervention</p>

Dai 2017 (Continued)

- Intervention: conventional oral hygiene care programme
- Materials: standard stock hospital care products
- Agent: manual toothbrush (Oral-B Pro-Health All-In-One), standard toothpaste (Colgate Maximum Cavity Protection)
- Procedures: supplied manual toothbrush and toothpaste plus oral hygiene training
- Provided by: dental surgery assistant
- Training: all participants attended a 1-to-1 OHC training conducted by a dental surgery assistant. All participants were given a standardised OHC pamphlet. OHC practice was demonstrated on tooth block models. Participants were asked to adhere to OHC protocol and brush their teeth in a systematic way. Training sessions lasted approximately 30 minutes
- Delivery: face-to-face, 1:1
- Location: non-clinical room
- Regimen: twice daily for 6 months
- Tailoring: none
- Modification: none
- Adherence: none

Outcomes	<p>Primary outcomes: oral hygiene status as assessed by Dental Plaque Index (Silness 1964), and Gingival Bleeding Index (Ainamo 1975)</p> <p>Secondary outcomes: oral hygiene status and gingival bleeding at 6 months, dental caries experience, periodontal health, oral mucosa conditions, dental prosthesis status, adverse effects of chlorhexidine</p> <p>Data collection: baseline, 3- and 6-month follow-up</p>
Funding	Study authors declared no conflicts of interest. Study funded by General Research Fund, Hong Kong (Project no. 774012)
Notes	<p>Dropouts are detailed in Table 6</p> <p>Suitable statistical data permitting inclusion within the review meta-analyses were not available</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: computer generated "block randomized with a group size of 4 (ABBA)."
Allocation concealment (selection bias)	Low risk	Quote: "The randomized sequence was computer generated by the project supervisor. The allocation sequence number of each subject was concealed in an opaque envelope and provided to a nurse at the rehabilitation centre who was independent of the research team."
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: single-blind study. Participants were aware of their treatment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Assessors were blind to which group subjects were assigned to."
Incomplete outcome data (attrition bias) All outcomes	Low risk	<p>Comment: dropouts accounted for. High attrition rate for the conventional care group.</p> <p>Quote: "no significant difference in the profile and oral health status of participants with respect to participation and drop-out at 3-month assessment were</p>

Dai 2017 (Continued)

		apparent (Table A and B in Appendix II [of the publication]). No significant difference in the profile and oral health status of participants with respect to participation and drop-out at 6-month assessment were apparent except reported dental attendance pattern and brushing habits ($p < 0.01$) (Table C and D in Appendix II [of the publication]). ITT not employed but it was reported that when conducting regression analysis, the method Last Observation Carried Forward (LOCF) was employed to deal with missing outcomes at follow-up reviews."
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "At baseline there was no significant difference in the profile of subjects" [between the enhanced and conventional care groups (Table E in Appendix II in the publication)]
A priori power calculation	Low risk	Yes. Quote: "Sample size was calculated based on intended ability to detect a significant difference in the primary outcome variable – the level of dental plaque between two groups at three-month review ... the number of study subjects would require 38 per group, based on 80% power and the statistical significance level set at 0.05. Anticipating a 20% dropout rate over the course of the clinical trial, the initial sample size for each treatment group was proposed as 47 patients per group (94 subjects in total)."
Other bias	Low risk	None identified.

Fields 2008

Study characteristics

Methods	RCT randomised at individual level, USA Study recruitment and setting details: see Table 1
Participants	345 (but completed data only available on 200) Inclusion criteria: admissions to intensive care unit, mechanically ventilated, intubated in hospital for < 24 hours, no previous diagnosis of pneumonia Exclusion criteria: people with prior tracheostomies, aged < 18 years, people with AIDS secondary to immunocompromised systems, people who were edentulous OHC group: number of participants not reported Usual care group: number of participants not reported Details of participants are shown in Table 2
Interventions	Multi-component OHC Intervention <ul style="list-style-type: none"> Intervention: OHC and timed toothbrushing in care bundle (nurse education; protocol; OHC assessment every 12 hours; OHC kit) Materials: OHC kit containing – new toothbrush for every OHC session; toothpaste; Toothette (foam swab), lip moisturiser Procedures: teeth were brushed with a suction toothbrush every 8 hours; suction as required Provided by: nursing staff

Fields 2008 (Continued)

- Training: nursing staff instruction on OHC. Laminated care with basic instructions
- Delivery: face-to-face, 1:1
- Location: 24-bed intensive care unit
- Regimen: protocol: brushing of teeth, tongue and hard palate every 8 hours (3 times daily) for ≥ 1 minute, Toothette on teeth, tongue and hard palate for ≥ 1 minute; application of moisturiser as required; oral/pharyngeal suction as required. OHC assessment every 12 hours
- Tailoring: none
- Modification: none
- Adherence: not reported

Control

- Intervention: usual oral care
- Materials: toothbrush (kit had 2 toothbrushes); Toothette (foam swab), lip moisturiser
- Procedures: received "usual care" which could include daily toothbrushing along with Toothette mouth care as needed
- Provided by: nursing staff
- Training: none
- Delivery: face-to-face, 1:1
- Location: 24-bed intensive care unit
- Regimen: "as required"
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	<p>Primary outcome: VAP (Table 5 for diagnostic criteria)</p> <p>Secondary outcome: nurse-completed patient worksheets</p> <p>Data collection: worksheets documented after each oral care session</p>
Funding	Conflicts of interest: not reported. Funding: not reported
Notes	<p>Unable to obtain additional unpublished information from authors. RCT terminated early when the OHC group had a VAP rate of 0% over 1000 ventilator days, which was sustained for 6-months (while there were 4 VAPs over 6 months in usual care group)</p> <p>Outcome measures reported prevent inclusion within a meta-analysis</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation assisted by the clinical nursing research programme of Summa Health Systems and the Biostatistics Department of North Eastern Ohio Universities Colleges of Medicine and Pharmacy.
Allocation concealment (selection bias)	Unclear risk	Comment: sequentially numbered envelopes (unclear whether they were opaque) containing the randomised worksheets. Envelopes were taken in sequence.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: nurses carrying out the OHC interventions were not blinded.
Blinding of outcome assessment (detection bias)	Unclear risk	Comment: VAP was collected by infection control nurse who may have been blinded.

Interventions for improving oral health in people after stroke (Review)

Fields 2008 (Continued)

All outcomes

Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: 345 participants but completed data only available for 200. ITT analysis not performed.
Selective reporting (reporting bias)	High risk	Comment: > 4000 ventilator days but authors reported only adequate documentation for 1850 days. Few details reported in publication (e.g. information on baseline groups, numbers randomised to each intervention, other outcome measures collected were unreported).
Baseline data comparable?	Unclear risk	Comment: no information given to judge comparability of groups.
A priori power calculation	Low risk	Comment: yes, sample size calculation was performed requiring a sample of 200 ventilator-dependent participants or 2000 ventilator days.
Other bias	High risk	Comment: trial terminated early.

Fields 2008

Study characteristics

Methods	RCT randomised at individual level, USA Study recruitment and setting details: see Table 1
Participants	345 (but completed data only available on 200) Inclusion criteria: admissions to intensive care unit, mechanically ventilated, intubated in hospital for < 24 hours, no previous diagnosis of pneumonia Exclusion criteria: people with prior tracheostomies, aged < 18 years, people with AIDS secondary to immunocompromised systems, people who were edentulous OHC group: number of participants not reported Usual care group: number of participants not reported Details of participants are shown in Table 2
Interventions	Multi-component OHC Intervention <ul style="list-style-type: none"> Intervention: OHC and timed toothbrushing in care bundle (nurse education; protocol; OHC assessment every 12 hours; OHC kit) Materials: OHC kit containing – new toothbrush for every OHC session; toothpaste; Toothette (foam swab), lip moisturiser Procedures: teeth were brushed with a suction toothbrush every 8 hours; suction as required Provided by: nursing staff Training: nursing staff instruction on OHC. Laminated care with basic instructions Delivery: face-to-face, 1:1 Location: 24-bed intensive care unit Regimen: protocol: brushing of teeth, tongue and hard palate every 8 hours (3 times daily) for ≥ 1 minute, Toothette on teeth, tongue and hard palate for ≥ 1 minute; application of moisturiser as required; oral/pharyngeal suction as required. OHC assessment every 12 hours Tailoring: none Modification: none

Fields 2008 (Continued)

- Adherence: not reported

Control

- Intervention: usual oral care
- Materials: toothbrush (kit had 2 toothbrushes); Toothette (foam swab), lip moisturiser
- Procedures: received "usual care" which could include daily toothbrushing along with Toothette mouth care as needed
- Provided by: nursing staff
- Training: none
- Delivery: face-to-face, 1:1
- Location: 24-bed intensive care unit
- Regimen: "as required"
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	<p>Primary outcome: VAP (Table 5 for diagnostic criteria)</p> <p>Secondary outcome: nurse-completed patient worksheets</p> <p>Data collection: worksheets documented after each oral care session</p>
Funding	Conflicts of interest: not reported. Funding: not reported
Notes	<p>Unable to obtain additional unpublished information from authors. RCT terminated early when the OHC group had a VAP rate of 0% over 1000 ventilator days, which was sustained for 6-months (while there were 4 VAPs over 6 months in usual care group)</p> <p>Outcome measures reported prevent inclusion within a meta-analysis</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: randomisation assisted by the clinical nursing research programme of Summa Health Systems and the Biostatistics Department of North Eastern Ohio Universities Colleges of Medicine and Pharmacy.
Allocation concealment (selection bias)	Unclear risk	Comment: sequentially numbered envelopes (unclear whether they were opaque) containing the randomised worksheets. Envelopes were taken in sequence.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: nurses carrying out the OHC interventions were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: VAP was collected by infection control nurse who may have been blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: 345 participants but completed data only available for 200. ITT analysis not performed.
Selective reporting (reporting bias)	High risk	Comment: > 4000 ventilator days but authors reported only adequate documentation for 1850 days. Few details reported in publication (e.g. information

Fields 2008 (Continued)

		on baseline groups, numbers randomised to each intervention, other outcome measures collected were unreported).
Baseline data comparable?	Unclear risk	Comment: no information given to judge comparability of groups.
A priori power calculation	Low risk	Comment: yes, sample size calculation was performed requiring a sample of 200 ventilator-dependent participants or 2000 ventilator days.
Other bias	High risk	Comment: trial terminated early.

Frenkel 2001

Study characteristics

Methods	Cluster RCT randomised at nursing home level, UK Study recruitment and setting details: see Table 1
Participants	22 nursing homes (with 20–40 beds), 369 carers employed in the nursing homes Inclusion criteria: residents who wore dentures or had ≥ 1 natural teeth or both, and whose general health permitted oral examination Exclusion criteria: significant cognitive impairment Workplace OHC training session group: 9 nursing homes; 72 residents (from 151 non-stroke specific residents) Usual care group: 11 nursing homes; 40 residents (from 144 non-stroke specific residents) Details of participants are shown in Table 2
Interventions	Multi-component OHC Intervention <ul style="list-style-type: none"> Intervention: workplace OHC training session Materials: booklet, teaching aids and models (including a dentate manikin head), toothbrushes Agent: none Procedures: educational session involved opportunity for carers to discuss feelings about oral health, role of plaque in oral disease, demonstrations of brushing techniques for dentures and natural teeth; practice on teaching aids and models (e.g. dentate manikin head). Participants given booklet on oral health and course attendance certificate. Toothbrushes were distributed to all participants to encourage oral hygiene activity Provided by: health promotor – dental hygienist who had a Further Adult Education certificate, a certificate in Health Education, Diploma in Dental health Delivery, 20 years' teaching experience Training: as described above Delivery: face-to-face; group; nursing homes Regimen: 60-minute session delivered 2 months postbaseline Tailoring: none Modification: none Adherence: not reported Usual care <ul style="list-style-type: none"> Intervention: usual care Materials: none Agent: none

Frenkel 2001 (Continued)

- Procedures: none reported (quote: "health education programme was delivered to control homes after all data collection was complete")
- Provided by: none
- Delivery: none
- Regimen: none
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	<p>Primary outcomes: dental plaque (Simplified Oral Hygiene Index), denture plaque (0–4 scale), denture-induced stomatitis (0–3 scale), dental plaque (0–3 scale), gingivitis (0–2 scale), carers' oral health knowledge (26 questions), carers' attitudes (25 statements rated on 0- to 5-point scale)</p> <p>Secondary outcomes: calculus on buccal and lingual surfaces (present/absent), root caries (present/absent), tooth mobility (present/absent)</p> <p>Data collection: questionnaires were administered at baseline, 1 and 6 months</p>
Funding	Conflicts of interest: not reported. Study funded by the NHS Executive South West, Research and Development Directorate
Notes	<p>Dropouts are detailed in Table 6</p> <p>Note: availability of residents varied over the duration of the trial (baseline: 55 residents; 1 month after training: 57 residents; 6 months after training: 53 residents)</p> <p>Data included in the review reflected the knowledge and attitude of all care assistants employed within the nursing homes at the data collection points including those that started their employment after the training intervention. Thus, the impact of a training intervention delivered in a care setting with a characteristically high rate of staff turnover was reflected in the results. Not all available care assistants chose to participate in the training or to return a completed questionnaire (baseline = 80.5%; 1 month after training = 81.1%; 6 months after training = 77.2%). The number of care assistants employed varied (baseline: 369 assistants; 1 month after training: 322 assistants; 6 months after training: 289 assistants)</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: 1 researcher was not involved in the intervention or data collection allocated the 22 nursing homes using block randomisation (block size 4) to either a workplace OHC training session group or a usual care group using a table of random numbers.
Allocation concealment (selection bias)	Low risk	Comment: allocation codes were passed directly to the health promoter delivering the training programme and the participating homes were asked to conceal their allocation from the data collector.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: self-administered questionnaires so carers were aware of allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Health promoter visited control and intervention group homes at the outset of the trial to explain when the training sessions would take place, and to ask staff to conceal their group allocation from the investigator conducting follow-up assessments."

Frenkel 2001 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: partial, ITT analysis – analysis of carer measures was repeated on data from all carers working at each measurement time point. This allowed assessment of whether including carers that had not been present at the time of the initial intervention impacted upon the findings. Analysis of patient data was based only on individuals who were resident within the nursing homes at both baseline and follow-up time point.
Selective reporting (reporting bias)	Unclear risk	Comment: some indication of completeness of follow-up except for the dental plaque measure where some teeth could not be scored.
Baseline data comparable?	Low risk	Comment: baseline groups comparable (age, dental status, oral health status); some differences (gender, mobility, last seen by dentist).
A priori power calculation	Low risk	Comment: yes; sample size calculations were conducted a priori for both carers and patients.
Other bias	Unclear risk	Comment: details of inter- or intrarater reliability were not reported.

Frenkel 2001
Study characteristics

Methods	Cluster RCT randomised at nursing home level, UK Study recruitment and setting details: see Table 1
Participants	22 nursing homes (with 20–40 beds), 369 carers employed in the nursing homes Inclusion criteria: residents who wore dentures or had ≥ 1 natural teeth or both, and whose general health permitted oral examination Exclusion criteria: significant cognitive impairment Workplace OHC training session group: 9 nursing homes; 72 residents (from 151 non-stroke specific residents) Usual care group: 11 nursing homes; 40 residents (from 144 non-stroke specific residents) Details of participants are shown in Table 2
Interventions	Multi-component OHC Intervention <ul style="list-style-type: none">• Intervention: workplace OHC training session• Materials: booklet, teaching aids and models (including a dentate manikin head), toothbrushes• Agent: none• Procedures: educational session involved opportunity for carers to discuss feelings about oral health, role of plaque in oral disease, demonstrations of brushing techniques for dentures and natural teeth; practice on teaching aids and models (e.g. dentate manikin head). Participants given booklet on oral health and course attendance certificate. Toothbrushes were distributed to all participants to encourage oral hygiene activity• Provided by: health promotor – dental hygienist who had a Further Adult Education certificate, a certificate in Health Education, Diploma in Dental health Delivery, 20 years' teaching experience• Training: as described above• Delivery: face-to-face; group; nursing homes• Regimen: 60-minute session delivered 2 months postbaseline• Tailoring: none• Modification: none

Interventions for improving oral health in people after stroke (Review)

Frenkel 2001 (Continued)

- Adherence: not reported

Usual care

- Intervention: usual care
- Materials: none
- Agent: none
- Procedures: none reported (quote: "health education programme was delivered to control homes after all data collection was complete")
- Provided by: none
- Delivery: none
- Regimen: none
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	<p>Primary outcomes: dental plaque (Simplified Oral Hygiene Index), denture plaque (0–4 scale), denture-induced stomatitis (0–3 scale), dental plaque (0–3 scale), gingivitis (0–2 scale), carers' oral health knowledge (26 questions), carers' attitudes (25 statements rated on 0- to 5-point scale)</p> <p>Secondary outcomes: calculus on buccal and lingual surfaces (present/absent), root caries (present/absent), tooth mobility (present/absent)</p> <p>Data collection: questionnaires were administered at baseline, 1 and 6 months</p>
Funding	Conflicts of interest: not reported. Study funded by the NHS Executive South West, Research and Development Directorate
Notes	<p>Dropouts are detailed in Table 6</p> <p>Note: availability of residents varied over the duration of the trial (baseline: 55 residents; 1 month after training: 57 residents; 6 months after training: 53 residents)</p> <p>Data included in the review reflected the knowledge and attitude of all care assistants employed within the nursing homes at the data collection points including those that started their employment after the training intervention. Thus, the impact of a training intervention delivered in a care setting with a characteristically high rate of staff turnover was reflected in the results. Not all available care assistants chose to participate in the training or to return a completed questionnaire (baseline = 80.5%; 1 month after training = 81.1%; 6 months after training = 77.2%). The number of care assistants employed varied (baseline: 369 assistants; 1 month after training: 322 assistants; 6 months after training: 289 assistants)</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: 1 researcher was not involved in the intervention or data collection allocated the 22 nursing homes using block randomisation (block size 4) to either a workplace OHC training session group or a usual care group using a table of random numbers.
Allocation concealment (selection bias)	Low risk	Comment: allocation codes were passed directly to the health promoter delivering the training programme and the participating homes were asked to conceal their allocation from the data collector.
Blinding of participants and personnel (performance bias)	High risk	Comment: self-administered questionnaires so carers were aware of allocation.

Frenkel 2001 (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Health promoter visited control and intervention group homes at the outset of the trial to explain when the training sessions would take place, and to ask staff to conceal their group allocation from the investigator conducting follow-up assessments."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: partial, ITT analysis – analysis of carer measures was repeated on data from all carers working at each measurement time point. This allowed assessment of whether including carers that had not been present at the time of the initial intervention impacted upon the findings. Analysis of patient data was based only on individuals who were resident within the nursing homes at both baseline and follow-up time point.
Selective reporting (reporting bias)	Unclear risk	Comment: some indication of completeness of follow-up except for the dental plaque measure where some teeth could not be scored.
Baseline data comparable?	Low risk	Comment: baseline groups comparable (age, dental status, oral health status); some differences (gender, mobility, last seen by dentist).
A priori power calculation	Low risk	Comment: yes; sample size calculations were conducted a priori for both carers and patients.
Other bias	Unclear risk	Comment: details of inter- or intrarater reliability were not reported.

Gosney 2006
Study characteristics

Methods	RCT randomised at individual level, UK Study recruitment and setting details: see Table 1
Participants	Inclusions: within 24 hours of admission, first acute stroke Exclusions: receiving antibiotic or steroid medication (including inhaled steroids), prior stroke OHC gel group: 103 participants Placebo gel group: 100 participants Details of participants are shown in Table 2
Interventions	OHC gel (colistin, polymyxin, amphotericin B) <ul style="list-style-type: none">• Intervention: selective decontamination of digestive tract oral gel• Materials: Orabase gel, gloves, spatula• Agent: Orabase 500 mg gel (containing 2% (w/v) colistin, 2% (w/v) polymyxin E, 2% (w/v) amphotericin B)• Training: not reported• Procedures: gel was applied by a nurse (gloved finger or spatula) or by the patient (clean finger) to the mucous membranes of the mouth• Provided by: nurse or patient• Delivery: face-to-face; 1:1; acute stroke assessment units, hospital• Regimen: 4 times daily. Treatment duration for participants with 'unsafe swallow' was 3 weeks; for participants with a 'safe swallow' was 2 weeks• Tailoring: none

Gosney 2006 (Continued)

- Modification: none
- Adherence: not reported

Placebo gel

- Intervention: placebo
- Materials: placebo gel 500 mg
- Procedures: gel was applied by a nurse (gloved finger or spatula) or by the patient (clean finger) to the mucous membranes of the mouth
- Provided by: nurse or patient
- Delivery: face-to-face; 1:1; acute stroke assessment units, hospital
- Regimen: 4 times daily. Treatment duration for participants with 'unsafe swallow' was 3 weeks; for participants with a 'safe swallow' was 2 weeks
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	<p>Outcomes: colonisation by AGNB; carriage of AGNB on ≥ 2 consecutive samples; septicaemia or respiratory tract infections (or both) during hospital stay; pneumonia; BI; Scandinavian Stroke Scale; administration of antibiotics</p> <p>Data collection: oral swabs obtained at baseline, and 3 days/week for 3 weeks; BI and Scandinavian Stroke Scale measured at baseline, days 8 and 15 of hospital stay; clinical signs and symptoms of pneumonia and antibiotics prescribed were obtained from case notes</p>
Funding	1 study author (AEW) was employed as a research nurse by the funding body. Authors declared that they had no conflicts of interest. Study funded by Northwest Zonal Research and Development
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer-generated random numbers.
Allocation concealment (selection bias)	Low risk	Comment: research pharmacist conducted randomisation remotely.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: double-blind study.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: double-blind study.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: dropouts not fully accounted for. 20 participants died, but 19 participants withdrew. No explanation for the 19 withdrawals. ITT analysis not employed.
Selective reporting (reporting bias)	High risk	Comment: of 203 participants included at baseline, data only on 164 remaining in study at follow-up. BI (on days 8 and 15 of hospital stay) and Scandinavian Stroke Scale (on days 8 and 15 of hospital stay) unreported.

Gosney 2006 (Continued)

Baseline data comparable?	Low risk	Comment: groups comparable (gender, age, discharge destination).
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Low risk	Comment: none identified.

Gosney 2006
Study characteristics

Methods	<p>RCT randomised at individual level, UK</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusions: within 24 hours of admission, first acute stroke</p> <p>Exclusions: receiving antibiotic or steroid medication (including inhaled steroids), prior stroke</p> <p>OHC gel group: 103 participants</p> <p>Placebo gel group: 100 participants</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>OHC gel (colistin, polymyxin, amphotericin B)</p> <ul style="list-style-type: none"> Intervention: selective decontamination of digestive tract oral gel Materials: Orabase gel, gloves, spatula Agent: Orabase 500 mg gel (containing 2% (w/v) colistin, 2% (w/v) polymyxin E, 2% (w/v) amphotericin B) Training: not reported Procedures: gel was applied by a nurse (gloved finger or spatula) or by the patient (clean finger) to the mucous membranes of the mouth Provided by: nurse or patient Delivery: face-to-face; 1:1; acute stroke assessment units, hospital Regimen: 4 times daily. Treatment duration for participants with 'unsafe swallow' was 3 weeks; for participants with a 'safe swallow' was 2 weeks Tailoring: none Modification: none Adherence: not reported <p>Placebo gel</p> <ul style="list-style-type: none"> Intervention: placebo Materials: placebo gel 500 mg Procedures: gel was applied by a nurse (gloved finger or spatula) or by the patient (clean finger) to the mucous membranes of the mouth Provided by: nurse or patient Delivery: face-to-face; 1:1; acute stroke assessment units, hospital Regimen: 4 times daily. Treatment duration for participants with 'unsafe swallow' was 3 weeks; for participants with a 'safe swallow' was 2 weeks Tailoring: none Modification: none Adherence: not reported

Gosney 2006 (Continued)

Outcomes	<p>Outcomes: colonisation by AGNB; carriage of AGNB on ≥ 2 consecutive samples; septicaemia or respiratory tract infections (or both) during hospital stay; pneumonia; BI; Scandinavian Stroke Scale; administration of antibiotics</p> <p>Data collection: oral swabs obtained at baseline, and 3 days/week for 3 weeks; BI and Scandinavian Stroke Scale measured at baseline, days 8 and 15 of hospital stay; clinical signs and symptoms of pneumonia and antibiotics prescribed were obtained from case notes</p>
Funding	1 study author (AEW) was employed as a research nurse by the funding body. Authors declared that they had no conflicts of interest. Study funded by Northwest Zonal Research and Development
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: computer-generated random numbers.
Allocation concealment (selection bias)	Low risk	Comment: research pharmacist conducted randomisation remotely.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: double-blind study.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: double-blind study.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: dropouts not fully accounted for. 20 participants died, but 19 participants withdrew. No explanation for the 19 withdrawals. ITT analysis not employed.
Selective reporting (reporting bias)	High risk	Comment: of 203 participants included at baseline, data only on 164 remaining in study at follow-up. BI (on days 8 and 15 of hospital stay) and Scandinavian Stroke Scale (on days 8 and 15 of hospital stay) unreported.
Baseline data comparable?	Low risk	Comment: groups comparable (gender, age, discharge destination).
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Low risk	Comment: none identified.

Juthani-Mehta 2015
Study characteristics

Methods	<p>Cluster-RCT randomised at nursing home level, USA</p> <p>Study recruitment and setting details: see Table 1</p>
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Juthani-Mehta 2015 (Continued)

Participants	<p>Inclusion criteria: long-term care residents aged > 65 years, resided at the nursing home for ≥ 1 month, at least 1 of 2 modifiable risk factors for pneumonia (impaired oral hygiene, swallowing difficulty)</p> <p>Exclusion criteria: housing for short-term rehabilitation, presence of a gastric or jejunostomy tube, presence of a tracheostomy, life expectancy < 3 months, current use of chlorhexidine, pneumonia within the previous 6 weeks, previous enrolment in the study, unwillingness to give informed consent, non-English speaking, inappropriateness for the study in opinion of nursing home administration</p> <p>Multi-component OHC group: 18 homes allocated (434 participants; of whom 100 had a stroke)</p> <p>Usual care group: 18 homes allocated (400 participants; of whom 92 had a stroke)</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: multi-component OHC intervention • Materials: oral chlorhexidine • Agent: 0.12% chlorhexidine oral rinse • Training: study personnel trained nursing home staff about intervention procedures • Procedures: manual tooth and gum brushing plus chlorhexidine oral rinse, plus upright positioning during feeding. Tailored to participants who could either perform self-care or required assistance • Provided by: nursing aides • Training provider: not reported • Delivery: face-to-face; 1:1; nursing home • Regimen: twice per day • Duration: unclear but study participants were followed up for 2.5 years • Tailoring: intervention protocol was tailored to participants who could either perform self-care or required assistance (detailed in Supplementary Appendix of paper) • Modification: none • Adherence: adherence to chlorhexidine and toothpaste usage were measured by comparing expected vs actual volumes (Table 4). No dropouts reported <p>Usual care</p> <ul style="list-style-type: none"> • Intervention: standard care • Materials: not reported • Procedures: not reported • Provided by: not reported • Delivery: not reported • Regimen: not reported • Tailoring: not reported • Modification: none • Adherence: no dropouts reported
Outcomes	<p>Primary outcomes: radiographically documented pneumonia (Table 5)</p> <p>Secondary outcomes: development of a first lower respiratory tract infection; adherence to chlorhexidine (compared expected vs actual chlorhexidine volume expenditure), oral brushing adherence (compared expected vs actual residual toothpaste tube weight), upright feeding positioning adherence was evaluated qualitatively once per month</p> <p>Data collection: baseline and participants were followed for up to 2.5 years for development of primary outcome</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the National Institutes of Health, the National Institute on Aging (NIA) (K23AG028691, R01AG030093 and P30AG021342)</p>

Juthani-Mehta 2015 (Continued)

Notes	Dropouts are detailed in Table 6
	Statistical data not included within the review meta-analyses
	Note: the number of stroke participants were reported but we were unable to access the outcome data specific to participants who had a stroke and so they were not included in the meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: nursing homes were stratified into 2 groups by number of minutes that nursing aides spent with residents per day, > 140 aide minutes were high stratum, < 140 minutes per day were low stratum. Homes were randomised within stratum using a permuted block design.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: insufficient information.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: 2 investigators adjudicated all the outcomes, blinded to the randomisation status of the participants and the cumulative incidence during the trial.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for. Missing outcome data balanced, with no significance differences for either outcome between the 2 groups. ITT employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes were reported.
Baseline data comparable?	Low risk	Comment: no difference in age, sex, race or ethnicity, comorbidities, mental status, functional status except for 1 measure of behaviour (resists care).
A priori power calculation	Low risk	Comment: yes; target of 828 participants to detect a 25% reduction in pneumonia rate.
Other bias	Unclear risk	Comment; the study was terminated for futility as the conditional power under observed treatment difference was nearly 0.

Juthani-Mehta 2015

Study characteristics

Methods	Cluster-RCT randomised at nursing home level, USA Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: long-term care residents aged > 65 years, resided at the nursing home for ≥ 1 month, at least 1 of 2 modifiable risk factors for pneumonia (impaired oral hygiene, swallowing difficulty) Exclusion criteria: housing for short-term rehabilitation, presence of a gastric or jejunostomy tube, presence of a tracheostomy, life expectancy < 3 months, current use of chlorhexidine, pneumonia

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Juthani-Mehta 2015 (Continued)

within the previous 6 weeks, previous enrolment in the study, unwillingness to give informed consent, non-English speaking, inappropriateness for the study in opinion of nursing home administration

Multi-component OHC group: 18 homes allocated (434 participants; of whom 100 had a stroke)

Usual care group: 18 homes allocated (400 participants; of whom 92 had a stroke)

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: multi-component OHC intervention Materials: oral chlorhexidine Agent: 0.12% chlorhexidine oral rinse Training: study personnel trained nursing home staff about intervention procedures Procedures: manual tooth and gum brushing plus chlorhexidine oral rinse, plus upright positioning during feeding. Tailored to participants who could either perform self-care or required assistance Provided by: nursing aides Training provider: not reported Delivery: face-to-face; 1:1; nursing home Regimen: twice per day Duration: unclear but study participants were followed up for 2.5 years Tailoring: intervention protocol was tailored to participants who could either perform self-care or required assistance (detailed in Supplementary Appendix of paper) Modification: none Adherence: adherence to chlorhexidine and toothpaste usage were measured by comparing expected vs actual volumes (Table 4). No dropouts reported <p>Usual care</p> <ul style="list-style-type: none"> Intervention: standard care Materials: not reported Procedures: not reported Provided by: not reported Delivery: not reported Regimen: not reported Tailoring: not reported Modification: none Adherence: no dropouts reported
Outcomes	<p>Primary outcomes: radiographically documented pneumonia (Table 5)</p> <p>Secondary outcomes: development of a first lower respiratory tract infection; adherence to chlorhexidine (compared expected vs actual chlorhexidine volume expenditure), oral brushing adherence (compared expected vs actual residual toothpaste tube weight), upright feeding positioning adherence was evaluated qualitatively once per month</p> <p>Data collection: baseline and participants were followed for up to 2.5 years for development of primary outcome</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the National Institutes of Health, the National Institute on Aging (NIA) (K23AG028691, R01AG030093 and P30AG021342)</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data not included within the review meta-analyses</p>

Juthani-Mehta 2015 (Continued)

Note: the number of stroke participants were reported but we were unable to access the outcome data specific to participants who had a stroke and so they were not included in the meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: nursing homes were stratified into 2 groups by number of minutes that nursing aides spent with residents per day, > 140 aide minutes were high stratum, < 140 minutes per day were low stratum. Homes were randomised within stratum using a permuted block design.
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: insufficient information.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: 2 investigators adjudicated all the outcomes, blinded to the randomisation status of the participants and the cumulative incidence during the trial.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for. Missing outcome data balanced, with no significance differences for either outcome between the 2 groups. ITT employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes were reported.
Baseline data comparable?	Low risk	Comment: no difference in age, sex, race or ethnicity, comorbidities, mental status, functional status except for 1 measure of behaviour (resists care).
A priori power calculation	Low risk	Comment: yes; target of 828 participants to detect a 25% reduction in pneumonia rate.
Other bias	Unclear risk	Comment; the study was terminated for futility as the conditional power under observed treatment difference was nearly 0.

Kim 2014a
Study characteristics

Methods	RCT randomised at individual level, South Korea Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: first-ever stroke, had ≥ 6 teeth and no sign of infection with any contagious pathogen Exclusion criteria: not reported OHC group: 29 participants Usual care group: 27 participants Details of participants are shown in Table 2

Interventions for improving oral health in people after stroke (Review)

Kim 2014a (Continued)

Interventions

Multi-component OHC intervention

- Intervention: OHC programme
- Materials: childrens toothbrush, interdental toothbrush, mouth gag (for unconscious patients), vacuum suction
- Agent: chlorhexidine
- Procedures: toothbrushes were used to remove tooth plaque, and tongue cleaner to remove tongue plaque. Gauze soaked in 0.5% chlorhexidine used to clean oral mucosa and tooth surface, vacuum suction performed to clean mouth
- Provided by: dentist
- Training: not reported
- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: once a day delivered over a mean period of dental intervention: 15.69 (SD 10.02) days
- Tailoring: none
- Modification: none
- Adherence: not reported

Usual care

- Intervention: no details; just referred to as a control group
- Materials: not reported
- Procedures: not reported
- Provided by: not reported
- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: mean period of dental intervention: 18.15 (SD 8.07) days
- Tailoring: not reported
- Modification: none
- Adherence: not reported

Outcomes

Outcomes: decayed missing and filled teeth index; Tooth Mobility Index; Loe and Silness Dental Plaque Index ([Loe 1967](#)); Gingival Index; clinical attachment loss; colonisation degree of Candida (under artificial lighting)

Data collection: baseline (after stabilisation of vital signs following intensive care unit admission) and post-treatment (before discharge: mean 2.2 weeks; range 1–5 weeks)

Funding

Study authors declared no financial conflicts of interest. Study funded by research grants from Yeungnam University (2010)

Notes

Dropouts are detailed in [Table 6](#)

Statistical data included within the review meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were assigned randomly to two groups (intervention or control) matched with sex and age by a nurse who managed the Intensive Care Unit and was independently involved in this research."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.

Kim 2014a (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: dropouts accounted for but high attrition rate for both groups (34 participants) reported in the first week after first oral examination.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Comment: groups were comparable for demographic and disease characteristics. More participants in the multi-component OHC intervention 45- to 54-year age group compared with usual care group. This was not significant across the entire age range.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	High risk	Quote: "Complete randomisation was not performed throughout the entire process of the research." Comment: no other details reported.

Kim 2014a

Study characteristics

Methods	RCT randomised at individual level, South Korea Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: first-ever stroke, had ≥ 6 teeth and no sign of infection with any contagious pathogen Exclusion criteria: not reported OHC group: 29 participants Usual care group: 27 participants Details of participants are shown in Table 2
Interventions	Multi-component OHC intervention <ul style="list-style-type: none"> Intervention: OHC programme Materials: childrens toothbrush, interdental toothbrush, mouth gag (for unconscious patients), vacuum suction Agent: chlorhexidine Procedures: toothbrushes were used to remove tooth plaque, and tongue cleaner to remove tongue plaque. Gauze soaked in 0.5% chlorhexidine used to clean oral mucosa and tooth surface, vacuum suction performed to clean mouth Provided by: dentist Training: not reported

Kim 2014a (Continued)

- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: once a day delivered over a mean period of dental intervention: 15.69 (SD 10.02) days
- Tailoring: none
- Modification: none
- Adherence: not reported

Usual care

- Intervention: no details; just referred to as a control group
- Materials: not reported
- Procedures: not reported
- Provided by: not reported
- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: mean period of dental intervention: 18.15 (SD 8.07) days
- Tailoring: not reported
- Modification: none
- Adherence: not reported

Outcomes	<p>Outcomes: decayed missing and filled teeth index; Tooth Mobility Index; Loe and Silness Dental Plaque Index (Loe 1967); Gingival Index; clinical attachment loss; colonisation degree of Candida (under artificial lighting)</p> <p>Data collection: baseline (after stabilisation of vital signs following intensive care unit admission) and post-treatment (before discharge: mean 2.2 weeks; range 1–5 weeks)</p>
Funding	Study authors declared no financial conflicts of interest. Study funded by research grants from Yeungnam University (2010)
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were assigned randomly to two groups (intervention or control) matched with sex and age by a nurse who managed the Intensive Care Unit and was independently involved in this research."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: not reported.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: dropouts accounted for but high attrition rate for both groups (34 participants) reported in the first week after first oral examination.

Kim 2014a (Continued)

Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Comment: groups were comparable for demographic and disease characteristics. More participants in the multi-component OHC intervention 45- to 54-year age group compared with usual care group. This was not significant across the entire age range.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	High risk	Quote: "Complete randomisation was not performed throughout the entire process of the research." Comment: no other details reported.

Kobayashi 2017i

Study characteristics

Methods	RCT randomised at individual level, Japan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: not reported Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study Sample size: quote: "60 participants randomly divided" Details of participants are shown in Table 2
Interventions	Multi-component OHC intervention <ul style="list-style-type: none"> Intervention: mouthwash and moisturising gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein; ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein; ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of OHC by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: not reported

Kobayashi 2017i (Continued)

Multi-component OHC intervention

- Intervention: mouthwash
- Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan)
- Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan)
- Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side
- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of OHC by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, weeks 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.

Kobayashi 2017i (Continued)

Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017i
Study characteristics

Methods	<p>RCT randomised at individual level, Japan</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: not reported</p> <p>Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study</p> <p>Sample size: quote: "60 participants randomly divided"</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: mouthwash and moisturising gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein; ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein; ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of OHC by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: mouthwash Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan)

Kobayashi 2017i (Continued)

- Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side
- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of OHC by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, weeks 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.

Kobayashi 2017i (Continued)

Other bias	Unclear risk	Comment: limited data reported in the study.
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Kobayashi 2017ii
Study characteristics

Methods	<p>RCT randomised at individual level, Japan</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: not reported</p> <p>Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study</p> <p>Sample size: quote: "60 participants randomly divided."</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: mouthwash and gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of OHC by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: no dropouts reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: water and moisturising gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side.

Kobayashi 2017ii (Continued)

After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper

- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of oral cleaning by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: no dropouts reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017ii

Study characteristics

Methods	<p>RCT randomised at individual level, Japan</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: not reported</p> <p>Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study</p> <p>Sample size: quote: "60 participants randomly divided."</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: mouthwash and gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of OHC by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: no dropouts reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: water and moisturising gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of oral cleaning by the dentist Delivery: face-to-face; 1-to-1

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- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: no dropouts reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017iii
Study characteristics
Interventions for improving oral health in people after stroke (Review)

Kobayashi 2017iii (Continued)

Methods	<p>RCT randomised at individual level, Japan</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: not reported</p> <p>Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study</p> <p>Sample size: not reported for each group (quote: "60 participants randomly divided")</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: mouthwash and gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of OHC by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: no dropouts reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: water alone Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan) Agent: none Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of OHC by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: no dropouts reported

Kobayashi 2017iii (Continued)

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017iii
Study characteristics

Methods	RCT randomised at individual level, Japan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: not reported

Kobayashi 2017iii (Continued)

Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study

Sample size: not reported for each group (quote: "60 participants randomly divided")

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: mouthwash and gel • Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) • Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan) • Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper • Provided by: a dentist or 1 of 5 nurses • Training: instructed on the method of OHC by the dentist • Delivery: face-to-face; 1-to-1 • Location: hospital • Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks • Tailoring: none • Modification: none • Adherence: no dropouts reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: water alone • Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), tongue brush (Tongue-Mate Kamemizu Chem, Osaka, Japan) • Agent: none • Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side • Provided by: a dentist or 1 of 5 nurses • Training: instructed on the method of OHC by the dentist • Delivery: face-to-face; 1-to-1 • Location: hospital • Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks • Tailoring: none • Modification: none • Adherence: no dropouts reported
Outcomes	<p>Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface</p> <p>Data collection: baseline, week 1 and 2</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan</p>

Kobayashi 2017iii (Continued)

Notes

Dropouts are detailed in [Table 6](#)

Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017iv
Study characteristics

Methods	RCT randomised at individual level, Japan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: not reported Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study Sample size: quote: "60 participants randomly divided." Details of participants are shown in Table 2
Interventions	Multi-component OHC intervention

Kobayashi 2017iv (Continued)

- Intervention: mouthwash
- Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan)
- Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan)
- Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side
- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of oral cleaning by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: no dropouts reported

Multi-component OHC Intervention

- Intervention: water and moisturising gel
- Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan)
- Agent: mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan)
- Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper
- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of oral cleaning by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: no dropouts reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable
Risk of bias	
Bias	Authors' judgement Support for judgement

Kobayashi 2017iv (Continued)

Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017iv
Study characteristics

Methods	RCT randomised at individual level, Japan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: not reported Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study Sample size: quote: "60 participants randomly divided." Details of participants are shown in Table 2
Interventions	Multi-component OHC intervention <ul style="list-style-type: none"> Intervention: mouthwash Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side

Interventions for improving oral health in people after stroke (Review)

Kobayashi 2017iv (Continued)

- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of oral cleaning by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: no dropouts reported

Multi-component OHC Intervention

- Intervention: water and moisturising gel
- Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan)
- Agent: mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan)
- Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper
- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of oral cleaning by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: no dropouts reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias)	Unclear risk	Comment: not reported.

Interventions for improving oral health in people after stroke (Review)

Kobayashi 2017iv (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017v
Study characteristics

Methods	RCT randomised at individual level, Japan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: not reported Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study Sample size: quote: "60 participants randomly divided." Details of participants are shown in Table 2
Interventions	Multi-component OHC intervention <ul style="list-style-type: none"> Intervention: mouthwash Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of oral cleaning by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: not reported

Kobayashi 2017v (Continued)

Multi-component OHC intervention

- Intervention: water alone
- Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), tongue brush (Tongue-Mate Kamemizu Chem, Osaka, Japan)
- Agent: none
- Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side
- Provided by: a dentist or 1 of 5 nurses
- Training: instructed on the method of oral cleaning by the dentist
- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1, and week 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.

Kobayashi 2017v (Continued)

Baseline data comparable?	Unclear risk	Comment: authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017v
Study characteristics

Methods	<p>RCT randomised at individual level, Japan</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: not reported</p> <p>Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study</p> <p>Sample size: quote: "60 participants randomly divided."</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: mouthwash Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouthwash (ConCool Mouth Rinse; Weltec, Osaka, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan) Agent: mouthwash contained cetylpyridinium chloride (ConCool Mouth Rinse; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in mouthwash. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in mouthwash was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of oral cleaning by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: water alone Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), tongue brush (TongueMate Kamemizu Chem, Osaka, Japan) Agent: none Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of oral cleaning by the dentist

Kobayashi 2017v (Continued)

- Delivery: face-to-face; 1-to-1
- Location: hospital
- Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks
- Tailoring: none
- Modification: none
- Adherence: not reported

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1, and week 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017vi

Study characteristics

Methods	<p>RCT randomised at individual level, Japan</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: not reported</p> <p>Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study</p> <p>Sample size: quote: "60 participants randomly divided."</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: water and moisturising gel Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) Agent: mouth gel (1 g containing glycerine, lactoferrin and whey protein (ConCool Mouth Gel; Weltec, Osaka, Japan) Procedures: tooth and tongue cleaning once each day while the participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of oral cleaning by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: no dropouts reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: water alone Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), tongue brush (Tongue-Mate Kamemizu Chem, Osaka, Japan) Agent: none Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side Provided by: a dentist or 1 of 5 nurses Training: instructed on the method of oral cleaning by the dentist Delivery: face-to-face; 1-to-1 Location: hospital Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks Tailoring: none Modification: none Adherence: no dropouts reported

Kobayashi 2017vi (Continued)

Outcomes	Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface Data collection: baseline, week 1 and 2
Funding	Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kobayashi 2017vi
Study characteristics

Methods	RCT randomised at individual level, Japan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: not reported

Kobayashi 2017vi (Continued)

Exclusion criteria: receiving antibiotic or steroid therapy within 1 month before start of study

Sample size: quote: "60 participants randomly divided."

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: water and moisturising gel • Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), mouth gel (1 g containing glycerine, lactoferrin and whey protein: ConCool Mouth Gel; Weltec, Osaka, Japan), tongue scraper (Tongood; Molten, Hiroshima, Japan) • Agent: mouth gel (1 g containing glycerine, lactoferrin and whey protein (ConCool Mouth Gel; Weltec, Osaka, Japan) • Procedures: tooth and tongue cleaning once each day while the participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side. After wiping intraoral residues, the moisturising gel was applied to the surface of the tongue using an elastomeric tongue scraper • Provided by: a dentist or 1 of 5 nurses • Training: instructed on the method of oral cleaning by the dentist • Delivery: face-to-face; 1-to-1 • Location: hospital • Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks • Tailoring: none • Modification: none • Adherence: no dropouts reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: water alone • Materials: toothbrush (Dent EX; Lion Dental Products Company, Tokyo, Japan), tongue brush (Tongue-Mate Kamemizu Chem, Osaka, Japan) • Agent: none • Procedures: tooth and tongue cleaning once each day while participant was in a lying position. Teeth were cleaned for 3 minutes using a toothbrush immersed in water. Toothpaste was not applied. To clean the tongue, a tongue brush that was immersed in water was applied in 1 direction from the back to the tip of the tongue with a cleaning pressure of 100 gf applied 5 times on each side • Provided by: a dentist or 1 of 5 nurses • Training: instructed on the method of oral cleaning by the dentist • Delivery: face-to-face; 1-to-1 • Location: hospital • Regimen: specified oral cleaning (3 minutes) once each day for 2 weeks • Tailoring: none • Modification: none • Adherence: no dropouts reported
Outcomes	<p>Outcomes: total number of anaerobic bacteria on the tongue surface, tongue coating index, moisture level of the tongue surface</p> <p>Data collection: baseline, week 1 and 2</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by Research Funding for Longevity Sciences (25-7) from the National Center for Geriatrics and Gerontology, Japan</p>
Notes	<p>Dropouts are detailed in Table 6</p>

Kobayashi 2017vi (Continued)

Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly divided into four groups according to the methods used to clean the teeth and tongue."
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "measurements were carried out by one dentist who was excluded from carrying out the oral cleaning." Comment: insufficient information.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: no CONSORT diagram, no dropouts reported.
Selective reporting (reporting bias)	High risk	Comment: sample size for each group not reported and limited statistical information presented for each outcome measure.
Baseline data comparable?	Unclear risk	Comment: study authors reported no significant difference between groups on outcome measures at baseline; however, no baseline demographics reported so unable to judge whether the groups were comparable.
A priori power calculation	Unclear risk	Comment: not reported.
Other bias	Unclear risk	Comment: limited data reported in the study.

Kuo 2016
Study characteristics

Methods	RCT randomised at individual level, Taiwan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: carers were eligible if their family member had experienced a stroke (ICD-9 430–438), BI < 60, not able to 'intake oral,' actively caring for their stroke survivor (for ≥ 8 hours per day), able to communicate in Mandarin or Taiwanese Exclusion criteria: carers were excluded if their family member who had experienced stroke also had a confirmed diagnosis of pulmonary infection or a diagnosis of oral or tongue pathology, or if they were unable to open their mouth OHC group: 50 participants Usual care group: 50 participants

Kuo 2016 (Continued)

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC Intervention</p> <ul style="list-style-type: none"> Intervention: homebased OHC training. Theoretically guided by the PRECEDE-PROCEED model Materials: educational pamphlets, daily reminder sheets, dual action tongue cleaner (Sunstar American, Inc.), finger toothbrush Procedures: oral care overview (educational pamphlets), 20-minute verbal presentation discussing basic oral care procedures and risks, oral care products were provided (tongue cleaner and finger tooth brush), training, demonstrations, daily reminder (record) sheets, telephone follow-up at 1 month. Multiple teaching strategies including 1. brushing twice (after breakfast and before sleep) a day; 2. 2 minutes per time; 3. learning brushing sequence (from teeth to tongue); 4. learning tongue cleaning (distinguishing 6 regions, from left–middle–right of the anterior tongue to left–middle–right of the posterior tongue); 5. learning how to use the equipment (tongue cleaner and finger toothbrush); 6. checking the dental cavities; 7. confirming the method of toothbrush; 8. using the technique of bass brushing and oral mucosa cleaning. Programme detailed in Table 1. Provided by: the researchers Intervention and delivery of the training were conducted by a trained home healthcare nurse Training: qualified home healthcare nurse with 10 years of experience who had received training from a dental specialist Delivery: face-to-face; 1-to-1 Location: home Regimen: protocolised; oral cleaning (2 minutes twice daily for 2 months) Tailoring: none Modification: none Adherence: not reported <p>Usual care</p> <ul style="list-style-type: none"> Intervention: standard care Materials: not reported Procedures: encouraged to maintain routine OHC practices (including oral cleaning with cotton swabs) Provided by: not reported Delivery: not reported Regimen: not reported Tailoring: not reported Modification: not reported Adherence: no dropouts reported
Outcomes	<p>Outcomes: Knowledge of Oral Care questionnaire, Attitudes towards oral care questionnaire, Family caregiver self-efficacy of Oral care questionnaire, Behaviour of Oral Care questionnaire</p> <p>Data collection: baseline, month 1 and 2 of the intervention period</p>
Funding	<p>Study authors declared no conflicts of interest. There was no external funding for this study</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p> <p>Family carers in the control group were given the home-based OHC protocol after the 2-month intervention period</p>
Risk of bias	
Bias	<p>Authors' judgement Support for judgement</p>

Kuo 2016 (Continued)

Random sequence generation (selection bias)	Unclear risk	Comment: computer-generated random number table.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported although outcomes were self-reported questionnaires.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for; ITT not employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "Baseline characteristics (gender, education, family relationship, daily care time and age) were similar between the two groups."
A priori power calculation	Low risk	Yes. Quote: "Sample estimates were based on Cohen's (31) suggested criteria for comparing the means of two groups. With a power of 0.8 and $\alpha = 0.05$, a sample size of 26 family caregivers was required. Applying an estimated dropout rate of 25%, each group required 33 family caregivers. Further, the mortality rate for severe stroke survivors with home health care was also considered. Finally, the sample size was estimated based on three data collection times, and thus, we estimated the sample size as 50."
Other bias	Low risk	Comment: none identified.

Kuo 2016
Study characteristics

Methods	RCT randomised at individual level, Taiwan Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: carers were eligible if their family member had experienced a stroke (ICD-9 430–438), BI < 60, not able to 'intake oral,' actively caring for their stroke survivor (for ≥ 8 hours per day), able to communicate in Mandarin or Taiwanese Exclusion criteria: carers were excluded if their family member who had experienced stroke also had a confirmed diagnosis of pulmonary infection or a diagnosis of oral or tongue pathology, or if they were unable to open their mouth OHC group: 50 participants Usual care group: 50 participants

Kuo 2016 (Continued)

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC Intervention</p> <ul style="list-style-type: none"> • Intervention: homebased OHC training. Theoretically guided by the PRECEDE-PROCEED model • Materials: educational pamphlets, daily reminder sheets, dual action tongue cleaner (Sunstar American, Inc.), finger toothbrush • Procedures: oral care overview (educational pamphlets), 20-minute verbal presentation discussing basic oral care procedures and risks, oral care products were provided (tongue cleaner and finger tooth brush), training, demonstrations, daily reminder (record) sheets, telephone follow-up at 1 month. Multiple teaching strategies including 1. brushing twice (after breakfast and before sleep) a day; 2. 2 minutes per time; 3. learning brushing sequence (from teeth to tongue); 4. learning tongue cleaning (distinguishing 6 regions, from left–middle–right of the anterior tongue to left–middle–right of the posterior tongue); 5. learning how to use the equipment (tongue cleaner and finger toothbrush); 6. checking the dental cavities; 7. confirming the method of toothbrush; 8. using the technique of bass brushing and oral mucosa cleaning. Programme detailed in Table 1. • Provided by: the researchers • Intervention and delivery of the training were conducted by a trained home healthcare nurse • Training: qualified home healthcare nurse with 10 years of experience who had received training from a dental specialist • Delivery: face-to-face; 1-to-1 • Location: home • Regimen: protocolised; oral cleaning (2 minutes twice daily for 2 months) • Tailoring: none • Modification: none • Adherence: not reported <p>Usual care</p> <ul style="list-style-type: none"> • Intervention: standard care • Materials: not reported • Procedures: encouraged to maintain routine OHC practices (including oral cleaning with cotton swabs) • Provided by: not reported • Delivery: not reported • Regimen: not reported • Tailoring: not reported • Modification: not reported • Adherence: no dropouts reported
Outcomes	<p>Outcomes: Knowledge of Oral Care questionnaire, Attitudes towards oral care questionnaire, Family caregiver self-efficacy of Oral care questionnaire, Behaviour of Oral Care questionnaire</p> <p>Data collection: baseline, month 1 and 2 of the intervention period</p>
Funding	<p>Study authors declared no conflicts of interest. There was no external funding for this study</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p> <p>Family carers in the control group were given the home-based OHC protocol after the 2-month intervention period</p>
Risk of bias	
Bias	Authors' judgement Support for judgement

Kuo 2016 (Continued)

Random sequence generation (selection bias)	Unclear risk	Comment: computer-generated random number table.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported although outcomes were self-reported questionnaires.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for; ITT not employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "Baseline characteristics (gender, education, family relationship, daily care time and age) were similar between the two groups."
A priori power calculation	Low risk	Yes. Quote: "Sample estimates were based on Cohen's (31) suggested criteria for comparing the means of two groups. With a power of 0.8 and $\alpha = 0.05$, a sample size of 26 family caregivers was required. Applying an estimated dropout rate of 25%, each group required 33 family caregivers. Further, the mortality rate for severe stroke survivors with home health care was also considered. Finally, the sample size was estimated based on three data collection times, and thus, we estimated the sample size as 50."
Other bias	Low risk	Comment: none identified.

Lam 2013i
Study characteristics

Methods	RCT randomised at individual level, Hong Kong, People's Republic of China Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 50 years, stroke, BI < 70 , and admitted to rehabilitation unit within 7 days Exclusion criteria: edentulous, presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (Mini Mental Status Examination ≤ 9) or indwelling nasogastric feeding tube Oral hygiene instruction, mouthrinse and assisted brushing group: 25 participants Oral hygiene instruction and chlorhexidine mouthrinse group: 26 participants Details of participants are shown in Table 2
Interventions	Multi-component OHC intervention

Interventions for improving oral health in people after stroke (Review)

Lam 2013i (Continued)

- Intervention: oral hygiene instruction, mouthrinse and assisted brushing
- Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL)
- Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL)
- Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. Professional oral hygiene instruction provided by a dentist; quote: "nursing care aides administered mouthrinses and performed intermittent assisted brushing. Nursing care aides monitored participants for toothbrushing difficulties and ensured that tooth surfaces (buccal, occlusal, lingual) were cleaned in a systematic manner. Hand-over-hand guiding was provided if participants had difficulty handling and placing the toothbrush."
- Provided by: registered dentist, dental hygienists (certified), nurse aides
- Training: nursing care aides were provided with an oral health training session consisting of a 30-minute lecture comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Training sessions were carried out by certified dental hygienists
- Delivery: face-to-face, 1:1, rehabilitation ward
- Regimen: mouthrinse (spaced ≥ 2 hours apart from toothbrushing) and assistance with toothbrushing twice a day, delivered daily over a 3-week period
- Tailoring: none
- Modification: none
- Adherence: not reported

Multi-component OHC intervention

- Intervention: oral hygiene instruction and chlorhexidine mouthrinse
- Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL)
- Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL)
- Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. OHC training provided by a dentist; nursing care aides administered mouthrinses
- Provided by: registered dentist, dental hygienists (certified), nurse aides
- Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists."
- Delivery: face-to-face, 1:1, rehabilitation ward
- Regimen: mouthrinse twice daily, delivered daily over a 3-week period
- Tailoring: none
- Modification: none
- Adherence: reported 1 dropout because of non-compliance with mouthrinse

Outcomes	Outcomes: Dental Plaque Index, Gingival Bleeding Index, BI, swallowing disability (Royal Brisbane Hospital Outcome Measure for Swallowing), treatment satisfaction Data collection: baseline and 3 weeks (before hospital discharge)
Funding	Study authors declared no conflicts of interest. Study funded by the Committee of Research and Conference Grants of the University of Hong Kong
Notes	Dropouts are detailed in Table 6 Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
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Interventions for improving oral health in people after stroke (Review)

Lam 2013i (Continued)

Random sequence generation (selection bias)	Low risk	Comment: allocated randomly using block randomisation by a research assistant.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as 'single-blind' but insufficient information available to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment; high attrition rate (20.5%) but dropouts accounted for and balanced across groups. ITT not employed and unclear how missing data were dealt with in the analysis.
Selective reporting (reporting bias)	Unclear risk	Comment: although prespecified outcomes were reported, data were reported in Table 4 of the publication but it was unclear whether the data were mean/median (and IQR). Clarification required.
Baseline data comparable?	Low risk	Quote: "No significant differences between groups ($P > .05$) were noted at baseline with regards to demographic, oral health-related behaviours, or medications taken."
A priori power calculation	Low risk	Yes. Quote: "initial sample size was based on a Plaque index change score SD of 0.21 ± 0.40 , documented in a previous observational study and set at 40 patients per group in order to detect a difference of 0.3 in plaque change scores within and between groups, and account for (1) a 5% statistical significance level, (2) a power of 80%, and (3) an anticipated 10% dropout rate."
Other bias	High risk	Quote: "At the time of baseline assessment, over two-thirds (67.9%) of the patients reported not to have a regular daily brushing habit (i.e. at least once a day)." Comment: insufficient power – minimum sample size was not achieved.

Lam 2013i
Study characteristics

Methods	RCT randomised at individual level, Hong Kong, People's Republic of China Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 50 years, stroke, BI < 70 , and admitted to rehabilitation unit within 7 days Exclusion criteria: edentulous, presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (Mini Mental Status Examination ≤ 9) or indwelling nasogastric feeding tube Oral hygiene instruction, mouthrinse and assisted brushing group: 25 participants Oral hygiene instruction and chlorhexidine mouthrinse group: 26 participants

Interventions for improving oral health in people after stroke (Review)

Lam 2013i (Continued)

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction, mouthrinse and assisted brushing Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. Professional oral hygiene instruction provided by a dentist; quote: "nursing care aides administered mouthrinses and performed intermittent assisted brushing. Nursing care aides monitored participants for toothbrushing difficulties and ensured that tooth surfaces (buccal, occlusal, lingual) were cleaned in a systematic manner. Hand-over-hand guiding was provided if participants had difficulty handling and placing the toothbrush." Provided by: registered dentist, dental hygienists (certified), nurse aides Training: nursing care aides were provided with an oral health training session consisting of a 30-minute lecture comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Training sessions were carried out by certified dental hygienists Delivery: face-to-face, 1:1, rehabilitation ward Regimen: mouthrinse (spaced ≥ 2 hours apart from toothbrushing) and assistance with toothbrushing twice a day, delivered daily over a 3-week period Tailoring: none Modification: none Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction and chlorhexidine mouthrinse Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. OHC training provided by a dentist; nursing care aides administered mouthrinses Provided by: registered dentist, dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: mouthrinse twice daily, delivered daily over a 3-week period Tailoring: none Modification: none Adherence: reported 1 dropout because of non-compliance with mouthrinse
Outcomes	<p>Outcomes: Dental Plaque Index, Gingival Bleeding Index, BI, swallowing disability (Royal Brisbane Hospital Outcome Measure for Swallowing), treatment satisfaction</p> <p>Data collection: baseline and 3 weeks (before hospital discharge)</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the Committee of Research and Conference Grants of the University of Hong Kong</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Suitable statistical data permitting inclusion within the review meta-analyses unavailable</p>

Lam 2013i (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: allocated randomly using block randomisation by a research assistant.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as 'single-blind' but insufficient information available to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment; high attrition rate (20.5%) but dropouts accounted for and balanced across groups. ITT not employed and unclear how missing data were dealt with in the analysis.
Selective reporting (reporting bias)	Unclear risk	Comment: although prespecified outcomes were reported, data were reported in Table 4 of the publication but it was unclear whether the data were mean/median (and IQR). Clarification required.
Baseline data comparable?	Low risk	Quote: "No significant differences between groups ($P > .05$) were noted at baseline with regards to demographic, oral health-related behaviours, or medications taken."
A priori power calculation	Low risk	Yes. Quote: "initial sample size was based on a Plaque index change score SD of 0.21 ± 0.40 , documented in a previous observational study and set at 40 patients per group in order to detect a difference of 0.3 in plaque change scores within and between groups, and account for (1) a 5% statistical significance level, (2) a power of 80%, and (3) an anticipated 10% dropout rate."
Other bias	High risk	Quote: "At the time of baseline assessment, over two-thirds (67.9%) of the patients reported not to have a regular daily brushing habit (i.e. at least once a day)." Comment: insufficient power – minimum sample size was not achieved.

Lam 2013ii

Study characteristics

Methods	RCT randomised at individual level, Hong Kong, People's Republic of China Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 50 years, stroke, BI < 70 , and admitted to rehabilitation unit within 7 days Exclusion criteria: edentulous, presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (MMSE ≤ 9) or indwelling nasogastric feeding tube

Interventions for improving oral health in people after stroke (Review)

Lam 2013ii (Continued)

Oral hygiene instruction, mouthrinse and assisted brushing group: 25 participants

Oral hygiene instruction group: 30 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction, mouthrinse and assisted brushing Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. Professional oral hygiene instruction provided by a dentist; quote: "nursing care aides administered mouthrinses and performed intermittent assisted brushing. Nursing care aides monitored participants for toothbrushing difficulties and ensured that tooth surfaces (buccal, occlusal, lingual) were cleaned in a systematic manner. Hand-over-hand guiding was provided if participants had difficulty handling and placing the toothbrush." Provided by: registered dentist, dental hygienists (certified), nurse aides Training: nursing care aides were provided with an oral health training session consisting of a 30-minute lecture comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists Delivery: face-to-face, 1:1, rehabilitation ward Regimen: mouthrinse (spaced ≥ 2 hours apart from toothbrushing) and assistance with toothbrushing twice per day delivered over a 3-week period Tailoring: none Modification: none Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction Materials: electric toothbrush, a standard sodium fluoride toothpaste Agent: standard sodium fluoride toothpaste Procedures: all participants were provided with an electric toothbrush and toothpaste. Nurse care aides provided with oral care instruction Provided by: dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: none Tailoring: none Modification: none Adherence: not reported
Outcomes	<p>Outcomes: Dental Plaque Index, Gingival Bleeding Index, BI, swallowing disability (Royal Brisbane Hospital Outcome Measure for Swallowing), treatment satisfaction</p> <p>Data collection: baseline and 3 weeks (before hospital discharge)</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the Committee of Research and Conference Grants of the University of Hong Kong</p>
Notes	<p>Dropouts are detailed in Table 6</p>

Lam 2013ii (Continued)

Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: allocated randomly using block randomisation by a research assistant.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as 'single-blind' but insufficient information available to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: high attrition rate (20.5%) but dropouts accounted for and balanced across groups. ITT not employed and unclear how missing data were dealt with in the analysis.
Selective reporting (reporting bias)	Unclear risk	Comment: although prespecified outcomes were reported, data were reported in Table 4 of the publication but it was unclear whether the data were mean/median (and IQR). Clarification required.
Baseline data comparable?	Low risk	Quote: "No significant differences between groups ($P > .05$) were noted at baseline with regards to demographic, oral health-related behaviours, or medications taken."
A priori power calculation	Low risk	Yes. Quote: "initial sample size was based on a Plaque index change score SD of 0.21 ± 0.40 , documented in a previous observational study and set at 40 patients per group in order to detect a difference of 0.3 in plaque change scores within and between groups, and account for (1) a 5% statistical significance level, (2) a power of 80%, and (3) an anticipated 10% dropout rate."
Other bias	High risk	Comment: insufficient power – minimum sample size was not achieved. Quote: "At the time of baseline assessment, over two thirds (67.9%) of the patients reported not to have a regular daily brushing habit (i.e., at least once a day)."

Lam 2013ii

Study characteristics

Methods	RCT randomised at individual level, Hong Kong, People's Republic of China Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 50 years, stroke, BI < 70 , and admitted to rehabilitation unit within 7 days

Lam 2013ii (Continued)

Exclusion criteria: edentulous, presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (MMSE $\leq$ 9) or indwelling nasogastric feeding tube

Oral hygiene instruction, mouthrinse and assisted brushing group: 25 participants

Oral hygiene instruction group: 30 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction, mouthrinse and assisted brushing Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. Professional oral hygiene instruction provided by a dentist; quote: "nursing care aides administered mouthrinses and performed intermittent assisted brushing. Nursing care aides monitored participants for toothbrushing difficulties and ensured that tooth surfaces (buccal, occlusal, lingual) were cleaned in a systematic manner. Hand-over-hand guiding was provided if participants had difficulty handling and placing the toothbrush." Provided by: registered dentist, dental hygienists (certified), nurse aides Training: nursing care aides were provided with an oral health training session consisting of a 30-minute lecture comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists Delivery: face-to-face, 1:1, rehabilitation ward Regimen: mouthrinse (spaced $\geq$ 2 hours apart from toothbrushing) and assistance with toothbrushing twice per day delivered over a 3-week period Tailoring: none Modification: none Adherence: not reported <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction Materials: electric toothbrush, a standard sodium fluoride toothpaste Agent: standard sodium fluoride toothpaste Procedures: all participants were provided with an electric toothbrush and toothpaste. Nurse care aides provided with oral care instruction Provided by: dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: none Tailoring: none Modification: none Adherence: not reported
Outcomes	<p>Outcomes: Dental Plaque Index, Gingival Bleeding Index, BI, swallowing disability (Royal Brisbane Hospital Outcome Measure for Swallowing), treatment satisfaction</p> <p>Data collection: baseline and 3 weeks (before hospital discharge)</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the Committee of Research and Conference Grants of the University of Hong Kong</p>

Lam 2013ii (Continued)

Notes

Dropouts are detailed in [Table 6](#)

Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: allocated randomly using block randomisation by a research assistant.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as 'single-blind' but insufficient information available to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: high attrition rate (20.5%) but dropouts accounted for and balanced across groups. ITT not employed and unclear how missing data were dealt with in the analysis.
Selective reporting (reporting bias)	Unclear risk	Comment: although prespecified outcomes were reported, data were reported in Table 4 of the publication but it was unclear whether the data were mean/median (and IQR). Clarification required.
Baseline data comparable?	Low risk	Quote: "No significant differences between groups ($P > .05$) were noted at baseline with regards to demographic, oral health-related behaviours, or medications taken."
A priori power calculation	Low risk	Yes. Quote: "initial sample size was based on a Plaque index change score SD of 0.21 ± 0.40 , documented in a previous observational study and set at 40 patients per group in order to detect a difference of 0.3 in plaque change scores within and between groups, and account for (1) a 5% statistical significance level, (2) a power of 80%, and (3) an anticipated 10% dropout rate."
Other bias	High risk	Comment: insufficient power – minimum sample size was not achieved. Quote: "At the time of baseline assessment, over two thirds (67.9%) of the patients reported not to have a regular daily brushing habit (i.e., at least once a day)."

Lam 2013iii

Study characteristics

Methods	RCT randomised at individual level, Hong Kong, People's Republic of China Study recruitment and setting details: see Table 1
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Lam 2013iii (Continued)

Participants	<p>Inclusion criteria: aged ≥ 50 years, stroke, BI < 70, and admitted to rehabilitation unit with 7 days</p> <p>Exclusion criteria: edentulous, presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (MMSE ≤ 9) or indwelling nasogastric feeding tube</p> <p>Oral hygiene instruction and chlorhexidine mouthrinse group: 26 participants</p> <p>Oral hygiene instruction group: 30 participants</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction and chlorhexidine mouthrinse Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. Professional oral hygiene instruction provided by a dentist; nursing care aides administered mouthrinses Provided by: registered dentist, dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: mouthrinse twice per day delivered over a 3-week period Tailoring: none Modification: none Adherence: reported 1 dropout because of non-compliance with mouthrinse <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction Materials: electric toothbrush, a standard sodium fluoride toothpaste Agent: standard sodium fluoride toothpaste Procedures: all participants were provided with an electric toothbrush and toothpaste. Nurse care aides provided with oral care instruction Provided by: dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: none Tailoring: none Modification: none Adherence: not reported
Outcomes	<p>Outcomes: Dental Plaque Index, Gingival Bleeding Index, BI, swallowing disability (Royal Brisbane Hospital Outcome Measure for Swallowing), treatment satisfaction</p> <p>Data collection: baseline and 3 weeks (before hospital discharge)</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the Committee of Research and Conference Grants of the University of Hong Kong</p>
Notes	<p>Dropouts are detailed in Table 6</p>

Lam 2013iii (Continued)

Suitable statistical data permitting inclusion within the review meta-analyses unavailable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: allocated randomly using block randomisation by a research assistant.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as 'single-blind' but insufficient information available to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: high attrition rate (20.5%) but dropouts accounted for and balanced across groups. ITT not employed and not clear how missing data were dealt with in the analysis.
Selective reporting (reporting bias)	Unclear risk	Comment: although prespecified outcomes were reported, data were reported in Table 4 of the publication but it was unclear whether the data were mean/median (and IQR). Clarification required.
Baseline data comparable?	Low risk	Quote: "No significant differences between groups ($P > .05$) were noted at baseline with regards to demographic, oral health-related behaviours, or medications taken."
A priori power calculation	Low risk	Yes. Quote: "initial sample size was based on a Plaque index change score SD of 0.21 ± 0.40 , documented in a previous observational study and set at 40 patients per group in order to detect a difference of 0.3 in plaque change scores within and between groups, and account for (1) a 5% statistical significance level, (2) a power of 80%, and (3) an anticipated 10% dropout rate."
Other bias	High risk	Comment: insufficient power – minimum sample size was not achieved. Quote: "At the time of baseline assessment, over two thirds (67.9%) of the patients reported not to have a regular daily brushing habit (i.e., at least once a day)."

Lam 2013iii

Study characteristics

Methods	RCT randomised at individual level, Hong Kong, People's Republic of China Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 50 years, stroke, BI < 70 , and admitted to rehabilitation unit with 7 days

Lam 2013iii (Continued)

Exclusion criteria: edentulous, presented with communication difficulties (unable to follow a 1-step command) or severe cognitive impairment (MMSE $\leq$ 9) or indwelling nasogastric feeding tube

Oral hygiene instruction and chlorhexidine mouthrinse group: 26 participants

Oral hygiene instruction group: 30 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction and chlorhexidine mouthrinse Materials: electric toothbrush, a standard sodium fluoride toothpaste, chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Agent: chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL) Procedures: dentures were cleaned with a manual toothbrush. All participants were provided with an electric toothbrush and a standard sodium fluoride toothpaste. Professional oral hygiene instruction provided by a dentist; nursing care aides administered mouthrinses Provided by: registered dentist, dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: mouthrinse twice per day delivered over a 3-week period Tailoring: none Modification: none Adherence: reported 1 dropout because of non-compliance with mouthrinse <p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> Intervention: oral hygiene instruction Materials: electric toothbrush, a standard sodium fluoride toothpaste Agent: standard sodium fluoride toothpaste Procedures: all participants were provided with an electric toothbrush and toothpaste. Nurse care aides provided with oral care instruction Provided by: dental hygienists (certified), nurse aides Training: quote: "Nursing care aides were provided with an oral health training session consisting of a lecture (30 minutes) comprising basic concepts of oral health and disease, as well as a demonstration and practical exercise on the administration of mouthrinse and assisted brushing. Oral health training sessions were carried out by certified dental hygienists." Delivery: face-to-face, 1:1, rehabilitation ward Regimen: none Tailoring: none Modification: none Adherence: not reported
Outcomes	<p>Outcomes: Dental Plaque Index, Gingival Bleeding Index, BI, swallowing disability (Royal Brisbane Hospital Outcome Measure for Swallowing), treatment satisfaction</p> <p>Data collection: baseline and 3 weeks (before hospital discharge)</p>
Funding	<p>Study authors declared no conflicts of interest. Study funded by the Committee of Research and Conference Grants of the University of Hong Kong</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>Suitable statistical data permitting inclusion within the review meta-analyses unavailable</p>

Lam 2013iii (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: allocated randomly using block randomisation by a research assistant.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: described as 'single-blind' but insufficient information available to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: high attrition rate (20.5%) but dropouts accounted for and balanced across groups. ITT not employed and not clear how missing data were dealt with in the analysis.
Selective reporting (reporting bias)	Unclear risk	Comment: although prespecified outcomes were reported, data were reported in Table 4 of the publication but it was unclear whether the data were mean/median (and IQR). Clarification required.
Baseline data comparable?	Low risk	Quote: "No significant differences between groups ($P > .05$) were noted at baseline with regards to demographic, oral health-related behaviours, or medications taken."
A priori power calculation	Low risk	Yes. Quote: "initial sample size was based on a Plaque index change score SD of 0.21 ± 0.40 , documented in a previous observational study and set at 40 patients per group in order to detect a difference of 0.3 in plaque change scores within and between groups, and account for (1) a 5% statistical significance level, (2) a power of 80%, and (3) an anticipated 10% dropout rate."
Other bias	High risk	Comment: insufficient power – minimum sample size was not achieved. Quote: "At the time of baseline assessment, over two thirds (67.9%) of the patients reported not to have a regular daily brushing habit (i.e., at least once a day)."

Lee 2011

Study characteristics

Methods	RCT randomised at individual level, South Korea Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: unclear Exclusion criteria: unclear

Lee 2011 (Continued)

Saengmaeg-san extract group: 12 participants

Placebo group: 12 participants

Details of participants are shown in [Table 2](#)

Interventions	<p>Saengmaeg-san extract</p> <ul style="list-style-type: none">• Intervention: saengmaeg-san extract used to treat xerostomia• Materials: not reported• Agent: saengmaeg-san extract• Procedures: capsules• Provided by: not reported• Training: not reported• Delivery: face-to-face; 1-to-1• Location: not reported• Regimen: capsules given 3 times per day for 7 days• Tailoring: not reported• Modification: not reported• Adherence: 1 dropout because of poor medication compliance <p>Placebo</p> <ul style="list-style-type: none">• Intervention: opaque capsules• Materials: not reported• Agent: not reported• Procedures: capsules• Provided by: not reported• Training: not reported• Delivery: face-to-face; 1-to-1• Location: not reported• Regimen: capsules given 3 times per day for 7 days• Tailoring: not reported• Modification: not reported• Adherence: not reported	
Outcomes	<p>Outcomes: visual analogue scale to evaluate subjective oral dryness (dry in night/morning, dry in day-time, dry while eating a meal, hard to swallow food, lack of saliva, general discomfort)</p> <p>Data collection: baseline and follow-up (1 week later)</p>	
Funding	<p>Paper in Korean – translation unavailable so we were unable to determine whether there were any potential conflicts of interest or how the study was funded</p>	
Notes	<p>Dropouts are detailed in Table 6</p> <p>Statistical data included within the review meta-analyses</p>	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no details available at present ("randomised") – translation unavailable.

Lee 2011 (Continued)

Allocation concealment (selection bias)	Unclear risk	Comment: no details available at present – translation unavailable.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: reported as 'double-blind' but no other details available at present – translation unavailable.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: reported as 'double-blind' but no other details available – translation unavailable.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: dropouts accounted for, ITT not employed.
Selective reporting (reporting bias)	Unclear risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Unclear risk	Comment: no details available at present – translation unavailable.
A priori power calculation	Unclear risk	Comment: no details available at present – translation unavailable.
Other bias	Unclear risk	Comment: no details available at present – translation unavailable.

Lee 2011
Study characteristics

Methods	RCT randomised at individual level, South Korea Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: unclear Exclusion criteria: unclear Saengmaeg-san extract group: 12 participants Placebo group: 12 participants Details of participants are shown in Table 2
Interventions	Saengmaeg-san extract <ul style="list-style-type: none"> Intervention: saengmaeg-san extract used to treat xerostomia Materials: not reported Agent: saengmaeg-san extract Procedures: capsules Provided by: not reported Training: not reported Delivery: face-to-face; 1-to-1 Location: not reported Regimen: capsules given 3 times per day for 7 days Tailoring: not reported

Lee 2011 (Continued)

- Modification: not reported
- Adherence: 1 dropout because of poor medication compliance

Placebo

- Intervention: opaque capsules
- Materials: not reported
- Agent: not reported
- Procedures: capsules
- Provided by: not reported
- Training: not reported
- Delivery: face-to-face; 1-to-1
- Location: not reported
- Regimen: capsules given 3 times per day for 7 days
- Tailoring: not reported
- Modification: not reported
- Adherence: not reported

Outcomes	Outcomes: visual analogue scale to evaluate subjective oral dryness (dry in night/morning, dry in day-time, dry while eating a meal, hard to swallow food, lack of saliva, general discomfort) Data collection: baseline and follow-up (1 week later)
Funding	Paper in Korean – translation unavailable so we were unable to determine whether there were any potential conflicts of interest or how the study was funded
Notes	Dropouts are detailed in Table 6 Statistical data included within the review meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: no details available at present ("randomised") – translation unavailable.
Allocation concealment (selection bias)	Unclear risk	Comment: no details available at present – translation unavailable.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: reported as 'double-blind' but no other details available at present – translation unavailable.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: reported as 'double-blind' but no other details available – translation unavailable.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: dropouts accounted for, ITT not employed.
Selective reporting (reporting bias)	Unclear risk	Comment: all prespecified outcomes reported.

Lee 2011 (Continued)

Baseline data comparable?	Unclear risk	Comment: no details available at present – translation unavailable.
A priori power calculation	Unclear risk	Comment: no details available at present – translation unavailable.
Other bias	Unclear risk	Comment: no details available at present – translation unavailable.

Seguin 2014

Study characteristics

Methods	<p>RCT randomised at individual level, France</p> <p>Study recruitment and setting details: see Table 1</p>
Participants	<p>Inclusion criteria: aged ≥ 18 years with closed traumatic brain injury (with Glasgow Coma Scale ≤ 8), mechanically ventilated ≥ 48 hours. People with cerebral haemorrhage were included 4 months after recruitment started</p> <p>Exclusion criteria: people in whom oral care procedure could not be performed within the 12 hours after endotracheal intubation or had tetraplegia (or both), facial trauma, pulmonary contusion involving > 1 lobe, aspiration pneumonia, current curative antimicrobial therapy, known allergy to povidone-iodine and pregnancy</p> <p>Povidone-iodine group: 91 participants</p> <p>Placebo group: 88 participants</p> <p>Details of participants are shown in Table 2</p>
Interventions	<p>Oropharyngeal care with povidone-iodine</p> <ul style="list-style-type: none"> Intervention: povidone-iodine Materials: povidone-iodine (Betadine 10% oral antiseptic solution; Meda Pharma, Paris, France) portioned in vials containing 125 mL of product and dispensed by the Pharmacy of Rennes to the pharmacies of the participating centres Procedures: participants received nasopharynx and oropharynx rinsing with 20 mL of povidone-iodine 10% using a 60 mL syringe (final concentration 3.3%). The solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned over 2 minutes, every 4 hours. The intervention was continued until extubation or until day 30 Provided by: all nurses were trained in the oral procedure. Film describing in detail the oral care procedure was made available to all investigators Delivery: face-to-face; 1-to-1 Location: intensive care unit Regimen: nasopharynx and oropharynx rinsing with 20 mL of povidone-iodine 10% or placebo diluted in 40 mL of sterile water using a 60 mL syringe (final concentration 3.3%). The solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned for 2 minutes, every 4 hours (i.e. 6 times daily). Intervention was continued until extubation or until day 30 Tailoring: none Modification: none Adherence: tolerance of the oral procedure was monitored <p>Oropharyngeal care with placebo</p> <ul style="list-style-type: none"> Intervention: placebo Materials: placebo were portioned in vials containing 125 mL of product and dispensed by the Pharmacy of Rennes to the pharmacies of the participating centres

Seguin 2014 (Continued)

- Procedures: participants received nasopharynx and oropharynx rinsing with placebo diluted in 40 mL of sterile water using a 60 mL syringe (final concentration 3.3%). The solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned over 2 minutes, every 4 hours. The intervention was continued until extubation or until day 30
- Provided by: all nurses were trained in the oral procedure. Film describing in detail the oral care procedure was made available to all investigators
- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: the solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned for 2 minutes, every 4 hours (i.e. 6 times daily). Intervention was continued until extubation or until day 30
- Tailoring: none
- Modification: none
- Adherence: tolerance of the oral procedure was also monitored

Outcomes	<p>Primary outcomes: rate of VAP</p> <p>Secondary outcomes: delay of first VAP occurrence (between admission and diagnosis), rate of early (≤ 7 days) and late (> 7 days) VAP, micro-organisms involved, rates of ventilator ventilator-associated tracheobronchitis and acute respiratory distress syndrome, and the number of ventilation-free days, other nosocomial infections in intensive care unit, hospital and intensive care unit, length of stay, and 90-day mortality were reported, tolerance of the oral procedure was also monitored</p> <p>Data collection: detailed above</p>
Funding	<p>3 study authors declared a potential conflict of interest (Dr Veber is a board member for Lily and lectured for Baxter, and has received support for travel from Pfizer. Dr Asehnoune lectured for B-Braun, Fresenius and Baxter. Dr Mimos has received lecture and consultant fees from CareFusion, 3M Company and Ethicon)</p> <p>The remaining authors reported no conflicts of interest</p> <p>Study funded in part by a grant from the French Ministry of Health (2006, Programme Hospitalier de Recherche Clinique)</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>4 months after the beginning of recruitment, the protocol was amended to include participants with cerebral haemorrhage, fulfilling the same eligibility criteria</p> <p>Stroke-specific trial data was sent by the study authors</p> <p>Statistical data included within the review meta-analyses</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: centralised and performed by the pharmacy of the co-ordinating centre, stratified by centre and by type of participants (trauma or cerebral haemorrhage), and equilibrated by blocks of 4.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: placebo control and study reported as "double-blind."

Seguin 2014 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: 3 experienced physicians "blindly classified each patient as positive or negative for VAP or ventilator-associated tracheobronchitis."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for; ITT analysis not employed but missing outcome data balanced across groups.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Comment: groups were comparable for demographic and disease characteristics.
A priori power calculation	Low risk	Yes. Quote: "... calculated that a sample size of 146 patients (73 in each group) would be necessary to detect an absolute reduction of 25% with povidone-iodine, with a type I error of 5% and a power of 95% in a one-sided test. The protocol planned to enrol 10% more patients in order to take into account patients that could not be assessable because of death or mechanical ventilation withdrawal within 48 hours following inclusion."
Other bias	Unclear risk	Comment: protocol was amended 4 months after start of study to include people with cerebral haemorrhage (fulfilling the same eligibility criteria) – no information given about why the protocol was amended.

Seguin 2014

Study characteristics

Methods	RCT randomised at individual level, France Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: aged ≥ 18 years with closed traumatic brain injury (with Glasgow Coma Scale ≤ 8), mechanically ventilated ≥ 48 hours. People with cerebral haemorrhage were included 4 months after recruitment started Exclusion criteria: people in whom oral care procedure could not be performed within the 12 hours after endotracheal intubation or had tetraplegia (or both), facial trauma, pulmonary contusion involving > 1 lobe, aspiration pneumonia, current curative antimicrobial therapy, known allergy to povidone-iodine and pregnancy Povidone-iodine group: 91 participants Placebo group: 88 participants Details of participants are shown in Table 2
Interventions	Oropharyngeal care with povidone-iodine <ul style="list-style-type: none"> Intervention: povidone-iodine Materials: povidone-iodine (Betadine 10% oral antiseptic solution; Meda Pharma, Paris, France) portioned in vials containing 125 mL of product and dispensed by the Pharmacy of Rennes to the pharmacies of the participating centres Procedures: participants received nasopharynx and oropharynx rinsing with 20 mL of povidone-iodine 10% using a 60 mL syringe (final concentration 3.3%). The solution was progressively injected in

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Seguin 2014 (Continued)

the buccal and pharyngeal cavities and regularly suctioned over 2 minutes, every 4 hours. The intervention was continued until extubation or until day 30

- Provided by: all nurses were trained in the oral procedure. Film describing in detail the oral care procedure was made available to all investigators
- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: nasopharynx and oropharynx rinsing with 20 mL of povidone-iodine 10% or placebo diluted in 40 mL of sterile water using a 60 mL syringe (final concentration 3.3%). The solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned over 2 minutes, every 4 hours (i.e. 6 times daily). Intervention was continued until extubation or until day 30
- Tailoring: none
- Modification: none
- Adherence: tolerance of the oral procedure was monitored

Oropharyngeal care with placebo

- Intervention: placebo
- Materials: placebo were portioned in vials containing 125 mL of product and dispensed by the Pharmacy of Rennes to the pharmacies of the participating centres
- Procedures: participants received nasopharynx and oropharynx rinsing with placebo diluted in 40 mL of sterile water using a 60 mL syringe (final concentration 3.3%). The solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned over 2 minutes, every 4 hours. The intervention was continued until extubation or until day 30
- Provided by: all nurses were trained in the oral procedure. Film describing in detail the oral care procedure was made available to all investigators
- Delivery: face-to-face; 1-to-1
- Location: intensive care unit
- Regimen: the solution was progressively injected in the buccal and pharyngeal cavities and regularly suctioned for 2 minutes, every 4 hours (i.e. 6 times daily). Intervention was continued until extubation or until day 30
- Tailoring: none
- Modification: none
- Adherence: tolerance of the oral procedure was also monitored

Outcomes	<p>Primary outcomes: rate of VAP</p> <p>Secondary outcomes: delay of first VAP occurrence (between admission and diagnosis), rate of early (≤ 7 days) and late (> 7 days) VAP, micro-organisms involved, rates of ventilator ventilator-associated tracheobronchitis and acute respiratory distress syndrome, and the number of ventilation-free days, other nosocomial infections in intensive care unit, hospital and intensive care unit, length of stay, and 90-day mortality were reported, tolerance of the oral procedure was also monitored</p> <p>Data collection: detailed above</p>
Funding	<p>3 study authors declared a potential conflict of interest (Dr Veber is a board member for Lily and lectured for Baxter, and has received support for travel from Pfizer. Dr Asehnoune lectured for B-Braun, Fresenius and Baxter. Dr Mimoz has received lecture and consultant fees from CareFusion, 3M Company and Ethicon)</p> <p>The remaining authors reported no conflicts of interest</p> <p>Study funded in part by a grant from the French Ministry of Health (2006, Programme Hospitalier de Recherche Clinique)</p>
Notes	<p>Dropouts are detailed in Table 6</p> <p>4 months after the beginning of recruitment, the protocol was amended to include participants with cerebral haemorrhage, fulfilling the same eligibility criteria</p>

Seguin 2014 (Continued)

Stroke-specific trial data was sent by the study authors

Statistical data included within the review meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Comment: centralised and performed by the pharmacy of the co-ordinating centre, stratified by centre and by type of participants (trauma or cerebral haemorrhage), and equilibrated by blocks of 4.
Allocation concealment (selection bias)	Unclear risk	Comment: not reported.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: placebo control and study reported as "double-blind."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: 3 experienced physicians "blindly classified each patient as positive or negative for VAP or ventilator-associated tracheobronchitis."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for; ITT analysis not employed but missing outcome data balanced across groups.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Comment: groups were comparable for demographic and disease characteristics.
A priori power calculation	Low risk	Yes. Quote: "... calculated that a sample size of 146 patients (73 in each group) would be necessary to detect an absolute reduction of 25% with povidone-iodine, with a type I error of 5% and a power of 95% in a one-sided test. The protocol planned to enrol 10% more patients in order to take into account patients that could not be assessable because of death or mechanical ventilation withdrawal within 48 hours following inclusion."
Other bias	Unclear risk	Comment: protocol was amended 4 months after start of study to include people with cerebral haemorrhage (fulfilling the same eligibility criteria) – no information given about why the protocol was amended.

SOCLE II

Study characteristics

Methods	Stepped-wedge clustered pilot RCT randomised at hospital level, UK Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: wards with a specific remit for stroke rehabilitation care, all ward admissions including all ages, dentition profiles, reason for admission (including non-stroke), cognitive and communica-

SOCLE II (Continued)

tion impairment status. Similarly, all nursing staff (registered nurses, nursing assistants and student nurses) were eligible for inclusion

Exclusion criteria: acute stroke wards

OHC group: 135 patients; 108 staff

Usual care group: 147 patients; 84 staff

Details of participants are shown in [Table 2](#)

Interventions
Multi-component OHC intervention

- Intervention: complex multi-component OHC intervention
- Materials: toothbrushes, Internet-based training module, computer
- Agent: toothpaste, oral balance gel, denture marking kit
- Procedures: patient-level intervention involved treatment from specialist trained staff, individualised assessment, individualised care plan, oral health promotion. Staff-level intervention involved online training (OHC assessment, OHC protocol), access to a co-produced best-practice SOCLE assessment and protocol of care were shared with the nursing staff ward range of OHC equipment and products. Service-level intervention included specialist dental support (dentist denture repair laboratory) and availability of OHC equipment and products
- Provided by: registered nurses, nursing assistants, nursing students
- Training: specialised 90-minute online training session to improve staff knowledge and attitudes toward OHC and provide practical information on how best to care for patients' oral health
- Delivery: patients: face-to-face, 1:1, stroke rehabilitation ward; staff: remote, online training, self-led use of assessments and protocol and equipment
- Regimen: encouraged twice daily cleaning of natural teeth. Cleaning of dentures after every meal
- Tailoring: intervention individualised to patient's oral health, needs and abilities to independently care for their mouth and teeth
- Modification: no modifications to the protocol
- Adherence: documentation of the OHC assessment and care plan was monitored

Usual care

- Intervention: usual OHC
- Materials: not reported
- Agent: not reported
- Procedures: usual care was the care in place at the time of the study start
- Provided by: nursing staff
- Training: none
- Delivery: patients: face-to-face, 1:1, stroke ward; staff: N/A
- Regimen: individualised
- Tailoring: yes to individual patient needs
- Modification: none
- Adherence: OHC assessment and care plan documentation was monitored

Outcomes

Outcome data were collected at patient, staff and service level

Patient level

Primary outcome: pneumonia as per Mann Chest Criteria

Secondary outcomes: Oral Health Impact Profile, plaque (dental and denture), use of antibiotics, adverse events (e.g. broken or missing dentures)

Secondary outcomes (measured at cluster level): length of hospital stay, death

Staff level

SOCLE II (Continued)

Primary outcome (measured at individual level): knowledge and attitudes questionnaire

Secondary outcome (measured at cluster level): OHC equipment and product use, documented OHC assessment, documented OHC plan

Feasibility and implementation: focus groups

Service level (measured at cluster level)

Primary outcomes: referrals to dental support (urgent and non-urgent)

Secondary outcomes: use of OHC equipment and products

Economic outcomes

Quote: "... potential net impact on healthcare costs combined with data gathered on health outcomes to determine whether outcomes are improved and (1) (clinical and patient) costs saved, constituting an unambiguous improvement in efficiency, or (2) the magnitude of cost increases incurred in achieving any established health improvement. Relevant outcomes include oral health-related QoL. Costs will reflect resources used in the intervention itself and post-intervention impacts (relative to standard care) on service use and staff time, including expected reductions in incidence of major events, such as pneumonia and in length of stay."

Data collection

Patient level

Primary outcome assessed weekly

Secondary outcomes (measured at individual level) assessed weekly

Secondary outcomes measured at cluster level were linked to routinely collected national health data

Staff level

Primary outcome collected at baseline, pretraining, post-training and at study end

Secondary outcomes assessed weekly

Focus group data collected at study end

Service level

Primary outcome assessed weekly

Secondary outcomes collected monthly

Funding	Study authors declared no conflicts of interest. Study funded by Stroke Association, UK
Notes	Dropouts are detailed in Table 6 Unpublished statistical data (supplied by the authors) is included within the meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Edinburgh Clinical Trials Unit randomised the order of site start date using a computer-generated algorithm."
Allocation concealment (selection bias)	Low risk	Quote: "Each site was randomly allocated, at a series of fixed time-points, to commence conversion to the enhanced OHC intervention."

SOCLE II (Continued)

		Comment: authors confirmed that the Edinburgh Clinical Trials Unit dealt with allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Comment: not possible to blind staff participants to the start of the intervention but patient participants were masked to the allocation and study phase.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: site allocation was concealed from the blinded assessor. Quote: "Site allocation and phase conversion points were concealed <i>as much as possible</i> from SOCLE data collectors given the inherent limitations to blinding within a trial design where all sites provide usual care at study start and end delivering enhanced care."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for. Staff withdrawals differed across each site, with greater attrition from sites 2 and 3 compared to sites 1 and 4 and were usually due to staff retirement, sickness or change of jobs. Study authors reported that they "experienced no patient withdrawals or dropouts in the usual sense as there was no formal follow-up beyond the ward admission." ITT analysis employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "Patients' alertness, stroke diagnosis, capacity, modified Rankin Scale, dentition, dysphagia and nutritional status were similar across sites 1 to 3. Fifty-one (15/7%) were incapacitated. A greater proportion of patient participants at site 4 were female, alert, more disabled, incapacitated and had non-stroke diagnoses and dentures than patients at other sites (Table 2–3) [of the publication]. Sites 1–3 recruited more stroke survivors (76%–81% of site recruits) typically admitted within 2 days of stroke onset compared to participants from Site 4."
A priori power calculation	Low risk	No. Comment: pilot RCT aimed at collecting these data.
Other bias	Low risk	Comment: none identified.

AGNB: aerobic Gram-negative bacilli; BI: Barthel Index; FOIS: Functional Oral Intake Scale; ICD-9: International Classification of Diseases 9th edition; ITT: intention-to-treat; MASA: Mann assessment of swallowing ability; mBI: modified Barthel Index; MMSE: Mini-Mental State Examination; MRSA: Methicillin-resistant *Staphylococcus aureus*; N/A: not applicable; OHC: oral health care; RCT: randomised controlled trial; R-THROAT: revised THROAT oral assessment tool; SD: standard deviation; VAP: ventilator-associated pneumonia.

SOCLE II

Study characteristics

Methods	Stepped-wedge clustered pilot RCT randomised at hospital level, UK Study recruitment and setting details: see Table 1
Participants	Inclusion criteria: wards with a specific remit for stroke rehabilitation care, all ward admissions including all ages, dentition profiles, reason for admission (including non-stroke), cognitive and communication impairment status. Similarly, all nursing staff (registered nurses, nursing assistants and student nurses) were eligible for inclusion Exclusion criteria: acute stroke wards

Interventions for improving oral health in people after stroke (Review)

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SOCLE II (Continued)

OHC group: 135 patients; 108 staff

Usual care group: 147 patients; 84 staff

Details of participants are shown in [Table 2](#)

Interventions	<p>Multi-component OHC intervention</p> <ul style="list-style-type: none"> • Intervention: complex multi-component OHC intervention • Materials: toothbrushes, Internet-based training module, computer • Agent: toothpaste, oral balance gel, denture marking kit • Procedures: patient-level intervention involved treatment from specialist trained staff, individualised assessment, individualised care plan, oral health promotion. Staff-level intervention involved online training (OHC assessment, OHC protocol), access to a co-produced best-practice SOCLE assessment and protocol of care were shared with the nursing staff ward range of OHC equipment and products. Service-level intervention included specialist dental support (dentist denture repair laboratory) and availability of OHC equipment and products • Provided by: registered nurses, nursing assistants, nursing students • Training: specialised 90-minute online training session to improve staff knowledge and attitudes toward OHC and provide practical information on how best to care for patients' oral health • Delivery: patients: face-to-face, 1:1, stroke rehabilitation ward; staff: remote, online training, self-led use of assessments and protocol and equipment • Regimen: encouraged twice daily cleaning of natural teeth. Cleaning of dentures after every meal • Tailoring: intervention individualised to patient's oral health, needs and abilities to independently care for their mouth and teeth • Modification: no modifications to the protocol • Adherence: documentation of the OHC assessment and care plan was monitored <p>Usual care</p> <ul style="list-style-type: none"> • Intervention: usual OHC • Materials: not reported • Agent: not reported • Procedures: usual care was the care in place at the time of the study start • Provided by: nursing staff • Training: none • Delivery: patients: face-to-face, 1:1, stroke ward; staff: N/A • Regimen: individualised • Tailoring: yes to individual patient needs • Modification: none • Adherence: OHC assessment and care plan documentation was monitored
Outcomes	<p>Outcome data were collected at patient, staff and service level</p> <p>Patient level</p> <p>Primary outcome: pneumonia as per Mann Chest Criteria</p> <p>Secondary outcomes: Oral Health Impact Profile, plaque (dental and denture), use of antibiotics, adverse events (e.g. broken or missing dentures)</p> <p>Secondary outcomes (measured at cluster level): length of hospital stay, death</p> <p>Staff level</p> <p>Primary outcome (measured at individual level): knowledge and attitudes questionnaire</p> <p>Secondary outcome (measured at cluster level): OHC equipment and product use, documented OHC assessment, documented OHC plan</p>

SOCLE II (Continued)

Feasibility and implementation: focus groups

Service level (measured at cluster level)

Primary outcomes: referrals to dental support (urgent and non-urgent)

Secondary outcomes: use of OHC equipment and products

Economic outcomes

Quote: "... potential net impact on healthcare costs combined with data gathered on health outcomes to determine whether outcomes are improved and (1) (clinical and patient) costs saved, constituting an unambiguous improvement in efficiency, or (2) the magnitude of cost increases incurred in achieving any established health improvement. Relevant outcomes include oral health-related QoL. Costs will reflect resources used in the intervention itself and post-intervention impacts (relative to standard care) on service use and staff time, including expected reductions in incidence of major events, such as pneumonia and in length of stay."

Data collection

Patient level

Primary outcome assessed weekly

Secondary outcomes (measured at individual level) assessed weekly

Secondary outcomes measured at cluster level were linked to routinely collected national health data

Staff level

Primary outcome collected at baseline, pretraining, post-training and at study end

Secondary outcomes assessed weekly

Focus group data collected at study end

Service level

Primary outcome assessed weekly

Secondary outcomes collected monthly

Funding	Study authors declared no conflicts of interest. Study funded by Stroke Association, UK
Notes	Dropouts are detailed in Table 6 Unpublished statistical data (supplied by the authors) is included within the meta-analyses

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Edinburgh Clinical Trials Unit randomised the order of site start date using a computer-generated algorithm."
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Blinding of participants and personnel (performance bias)	High risk	Comment: not possible to blind staff participants to the start of the intervention but patient participants were masked to the allocation and study phase.

SOCLE II (Continued)

All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Comment: site allocation was concealed from the blinded assessor. Quote: "Site allocation and phase conversion points were concealed <i>as much as possible</i> from SOCLE data collectors given the inherent limitations to blinding within a trial design where all sites provide usual care at study start and end delivering enhanced care."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: dropouts accounted for. Staff withdrawals differed across each site, with greater attrition from sites 2 and 3 compared to sites 1 and 4 and were usually due to staff retirement, sickness or change of jobs. Study authors reported that they "experienced no patient withdrawals or dropouts in the usual sense as there was no formal follow-up beyond the ward admission." ITT analysis employed.
Selective reporting (reporting bias)	Low risk	Comment: all prespecified outcomes reported.
Baseline data comparable?	Low risk	Quote: "Patients' alertness, stroke diagnosis, capacity, modified Rankin Scale, dentition, dysphagia and nutritional status were similar across sites 1 to 3. Fifty-one (15/7%) were incapacitated. A greater proportion of patient participants at site 4 were female, alert, more disabled, incapacitated and had non-stroke diagnoses and dentures than patients at other sites (Table 2–3) [of the publication]. Sites 1–3 recruited more stroke survivors (76%–81% of site recruits) typically admitted within 2 days of stroke onset compared to participants from Site 4."
A priori power calculation	Low risk	No. Comment: pilot RCT aimed at collecting these data.
Other bias	Low risk	Comment: none identified.

AGNB: aerobic Gram-negative bacilli; BI: Barthel Index; FOIS: Functional Oral Intake Scale; ICD-9: International Classification of Diseases 9th edition; ITT: intention-to-treat; MASA: Mann assessment of swallowing ability; mBI: modified Barthel Index; MMSE: Mini-Mental State Examination; MRSA: Methicillin-resistant *Staphylococcus aureus*; N/A: not applicable; OHC: oral health care; RCT: randomised controlled trial; R-THROAT: revised THROAT oral assessment tool; SD: standard deviation; VAP: ventilator-associated pneumonia.

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Boden-Albala 2016	RCT Secondary stroke prevention and no relevant outcome measures
Brailsford 2002	RCT Fluoride-containing varnish + antimicrobial varnish (Cervitec) vs fluoride-containing varnish + placebo varnish. Stroke-specific data unavailable
Duck-Won 2013	RCT Intervention focused on treatment for limited oral mouth opening and not focused on improving OHC
Forster 2013	Cluster RCT

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Study	Reason for exclusion
	Intervention not focused on improving OHC
Hägglund 2017	RCT Swallowing intervention only – not OHC intervention
Hajizamani 2006	RCT Stroke-specific data unavailable. Carer knowledge data only reported for intervention group before and after the intervention
Jones 2007	RCT Periodontal therapy vs usual care. Periodontal therapy typically requires specialist dental care and takes place in the presence of periodontal disease and so the intervention was not within the inclusion criteria of 'routine assisted oral health care.'
Kikutani 2006	RCT Nutritional supplementation plus oral functional training vs nutritional supplementation. Oral functional training does not relate to OHC but instead movement of the oral articulators (lips, cheeks, tongue, soft palate)
Kim 2014b	RCT Intervention focused on treatment for xerostomia
Lee 2017	RCT No patient data. Intervention focused on whether staff could identify oral health conditions after watching a videorecording but not the impact of that training on patient health
Mojon 1998	Cluster RCT Oral health programme vs usual care. Stroke-specific data unavailable
Murray 2016	RCT Swallowing intervention evaluation. Although there is an OHC component in the intervention, there are no relevant oral hygiene outcomes measured
NCT01777672	RCT Swallowing intervention only – not OHC intervention
NCT02379182	RCT Swallowing intervention evaluation. Although there was an oral hygiene component in the intervention, there did not appear to be a difference in OHC provided to the groups
NCT02541032	RCT Intensive dental treatment vs standard dental treatment. Secondary stroke prevention and no relevant outcome measures. In addition, periodontal therapy typically requires specialist dental care and general anaesthetic, so the intervention was not within our inclusion criteria of 'routine assisted oral health care'
Quagliarello 2009	RCT 6 different OHC intervention programmes (3 specifically for people with dysphagia). Stroke-specific data unavailable

Study	Reason for exclusion
Redwood 2001	Cluster RCT Oral health programme vs oral healthcare worker. Stroke-specific data unavailable
Schou 1989	Cluster RCT OHC programme for staff only vs OHC programme for residents only vs OHC programme for staff and residents vs usual care Stroke-specific data unavailable
Simons 1997	RCT Chlorhexidine acetate or xylitol gum vs xylitol gum. Stroke-specific data unavailable
Simons 2002	Cluster RCT Chlorhexidine acetate or xylitol gum vs xylitol gum vs usual care (no gum). Stroke-specific data unavailable

OHC: oral health care; RCT: randomised controlled trial.

Characteristics of studies awaiting classification *[ordered by study ID]*

Cabov 2010

Methods	Prospective double-blind, placebo-RCT
Participants	60 non-edentulous patients consecutively admitted to the surgical ICU and requiring minimum stay of 3 days Inclusion criteria: aged > 18 years, medical condition suggesting hospitalisation in the ICU for ≥ 3 days, and an eventual requirement for mechanical ventilation by oro- or nasotracheal intubation Exclusion criteria: not reported
Interventions	<ul style="list-style-type: none"> Chlorohexidine: antiseptic decontamination of dental plaque and the oral mucosa with chlorhexidine gel Placebo: placebo gel
Outcomes	Outcomes: dental status assessed using a caries-absent-occluded score, and the amount of plaque assessed using a semi-quantitative score Samples of dental plaque, oral mucosa, and nasal and tracheal aspirates were collected for bacterial culture, and nosocomial infections were assessed
Notes	Unclear whether any stroke-specific data are available – e-mail sent to study authors requesting further information

IRCT2017012232101N1

Methods	Single-blind parallel RCT
Participants	Intubated patients in ICU Inclusion criteria: patient has an endotracheal tube through the mouth, aged 15–85 years, 8 hours of intubation in the ICU; no history of allergy to plant compounds Savory (carvacrol); lack of any damage characterised by endotracheal intubation or planes in the mouth, lesion is unknown

IRCT2017012232101N1 (Continued)

Exclusion criteria: transmission or discharge or death of the patient from the ICU before the study was completed; creating profit any damage characterised by endotracheal intubation or planes or other physical harm; lack of desire to continue to study the patient's legal guardian; and immune system dysfunction, radiotherapy and chemotherapy, and having any malignant disease

Interventions	<ul style="list-style-type: none"> • Mouthrinse (ortodentol) • Chlorhexidine mouth rinse. 15 mL each time with a soft toothbrush can be rinsed, and the suction within 30 seconds. Before rinsing the mouth at the interval (8, 48, 72 hours) from different areas of the mouth sample and agar cultured and assessment of oral hygiene by standard scale-back and plaque oral mucous measured and the questionnaire recorded
Outcomes	Primary outcomes: oral health, studied groups, endotracheal tube intubation time, the oral microbial
Notes	<p>Unclear whether the trial is completed and if stroke-specific data are available. E-mail sent to study authors seeking further information</p> <p>IRCT registration number: IRCT2017012232101N1</p>

IRCT2017091636194N1

Methods	Single-blinded parallel RCT
Participants	<p>80 participants</p> <p>Inclusion criteria: aged 18–70 years; no clear maxillofacial trauma; having tracheal tube, locating the patient under the mechanical ventilator; no pneumonia or previous respiratory infections; ≥ 48 hours had passed since the onset of intubation; no ban and having no allergy on using mouthwash</p> <p>Exclusion criteria: death before the end of intervention; extubation before the end of intervention; transfer the patient to other wards or hospital among the intervention; other diagnostic or therapeutic procedure on mouth and pharynx or trachea</p>
Interventions	<ul style="list-style-type: none"> • Intervention group: during a 5-day period, using 10 mL of Nanosil mouthwash, oral care and decontamination every 8 hours • Control group: 10 mL chlorhexidine mouthwash, oral care and decontamination every 8 hours
Outcomes	<p>Primary outcome: occurrence of ventilator-associated pneumonia measured using standard modified clinical pulmonary infection score</p> <p>Secondary outcomes: degree of dysfunction of organs and prediction of mortality measured using standard sepsis related organ failure assessment tool, Glasgow Coma Scale</p> <p>Data collection: days 1 and 5</p>
Notes	<p>IRCT2017091636194N1</p> <p>Unclear if there are stroke-specific data available. E-mail sent to study authors requesting further information</p>

Jin 2018

Methods	Parallel RCT
Participants	104 participants

Jin 2018 (Continued)

	Inclusion criteria: people with stroke and bad breath
	Exclusion criteria: not reported
Interventions	<ul style="list-style-type: none"> Ageratum liquid combined with long cotton swab for oral care for 7 days Conventional saline cotton ball for oral care for 7 days
Outcomes	Improvement of bad breath, condition of tongue coating and clearance of oral pathogens
Notes	Translation unavailable

Marchini 2018

Methods	Pilot RCT
Participants	<p>81 residents</p> <p>Inclusion criteria: aged ≥ 20 years, resident or primary care worker in 1 of the following nursing homes: Linn Manor Care Center Simpson Memorial Home, Inc., Wilton Retirement Community, All-American Care of Muscatine, Pioneer Park of Lone Tree, Colonial Manor of the Columbus Community, Sunrise Terrace Nursing and Rehabilitation Center Parkview Home-Wayland</p> <p>Exclusion criteria: aged ≤ 21 years or > 110 years; not a resident or primary care worker in 1 of the retirement homes listed in the inclusion criteria</p>
Interventions	<ul style="list-style-type: none"> Control (current oral hygiene practice) Educational programme only Educational programme plus 1% chlorhexidine varnish monthly application
Outcomes	<p>Outcomes: demographics, pneumonia, number of febrile days in last 6 months, existing medical conditions and medications taken, mini-cog test (Mini-Cog), mini nutritional assessment short form (Mini-Nutri), Rand 36-item Short Form health survey instrument version 1.0 (SF-36), Oral Health Impact Profile 14-question (OHIP-14), Geriatric Oral Health Assessment Index (GOHAI), and subjects oral health (self-reported dry mouth, oral lesions, denture status, number of teeth, dental plaque index, denture plaque index, bleeding on brushing, gingival bleeding index, coronal DMFS, root DMFS)</p> <p>Data collection: baseline and 6 months; microbiological samples were collected at baseline, 2, 4 and 6 months</p>
Notes	Stroke-specific data not reported separately. Study authors contacted by e-mail to see if these data are available

Mori 2012

Methods	Parallel RCT
Participants	<p>40 participants with acute cerebrovascular disorders or neurotrauma</p> <p>Inclusion criteria: none reported</p> <p>Exclusion criteria: none reported</p>
Interventions	<ul style="list-style-type: none"> Professional oral health care: delivered by dental hygienists Usual care

Mori 2012 (Continued)

	Both groups received the same daily oral care performed by the neurosurgical ward nurses
Outcomes	<p>Outcomes: periodontal pocket depth, gingival bleeding on probing, modified Oral Health Index (debris index), maximal interincisal opening, volatile sulphur compounds such as hydrogen sulphide (H₂S) and methyl mercaptan (CH₃SH) in the mouth air were measured using gas chromatograph</p> <p>Data collection: baseline and 4 weeks after the baseline examination (or immediately before hospital discharge, whichever came first)</p>
Notes	Stroke-specific data not reported separately in the paper. Study authors contacted by e-mail to see if these data are available

NCT00610324

Methods	Parallel RCT
Participants	<p>512 participants</p> <p>Inclusion criteria: aged > 13 years, admitted to medical ICU and expected to stay in ICU for > 48 hours</p> <p>Exclusion criteria: pregnant women, people with nosocomial pneumonia at time of ICU admission, people with community-acquired pneumonia at time of ICU admission, people in whom oropharyngeal cleansing is contraindicated</p>
Interventions	<ul style="list-style-type: none"> Twice-daily oropharyngeal cleansing with 0.2% chlorhexidine gluconate Twice-daily oropharyngeal cleansing with 0.01% potassium permanganate
Outcomes	<p>Primary outcome: development of nosocomial pneumonia</p> <p>Secondary outcome: in-hospital mortality, length of ICU stay (days)</p> <p>Data collection: during hospital stay</p>
Notes	<p>NCT00610324</p> <p>E-mail to study authors seeking further information about whether the trial is completed and whether stroke-specific data are available</p>

NCT03219346

Methods	Parallel RCT
Participants	<p>100 participants</p> <p>Inclusion criteria: clinical diagnosis of first stroke with nasal tube retention, language therapist providing swallowing treatment, caregiver providing oral care to patients</p> <p>Exclusion criteria: oral cancer and head and neck cancer</p>
Interventions	<ul style="list-style-type: none"> OHC programme: oral care (sputum and special needs of people cleaning teeth) 3 days per week (with swallowing treatment time before) once a day. 10 minutes of oral care programme Control group: no details reported
Outcomes	Primary outcome measures: functional oral intake scale

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NCT03219346 (Continued)

Secondary outcome measures: functional oral intake scale

Notes	Study start date: July 2017 Estimated completion date: February 2018 Outcomes reported in the trial register differ from our criteria but data not published yet. Study authors contacted for further information
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Yakiwchuk 2013

Methods	Parallel RCT
Participants	22 adults with dysphagia resident in a long-term care facility Inclusion criteria: medical diagnosis of oropharyngeal dysphagia, and who were residing in chronic care programme units with access to wall suction Exclusion criteria: < 3 scoreable sextants of natural teeth, required sedation or antibiotic premedication for dental care, or who were under a DNR order
Interventions	<ul style="list-style-type: none"> Carers were trained in mouth care using a suction toothbrush. Carer training included: viewing a video on the reusable suction toothbrush; attending a 30-minute oral health education session or viewing a video focused on mouth care, the study protocol, and wall unit suction operation, and participating in a hands-on mouth care skill development and coaching session for co-operative and care resistant residents Carers trained in mouth care using a manual soft toothbrush Both groups received mouth care twice daily for 12-month period
Outcomes	Outcomes: Plaque Index, Calculus Index, Pocket Bleeding Index, Gingival Index and probing depth Data collection: oral health examination conducted at baseline, 1 month and pneumonia rates monitored over 12 months
Notes	Unclear if there are stroke-specific data available. E-mail sent to study authors requesting further information

DMFS: decayed, missing and filled permanent surface; DNR: do not resuscitate; ICU: intensive care unit; RCT: randomised controlled trial.

Characteristics of ongoing studies [ordered by study ID]

ChiCTR-IPR-17013403

Study name	Effect of oral care on the incidence of pneumonia in acute stroke patients with different degrees of dysphagia
Methods	Parallel RCT
Participants	80 participants Inclusion criteria: people with acute stroke aged 18–99 years; able to tolerate an oral examination and sample collection; able to provide informed consent Exclusion criteria: pneumonia at admission; requiring mechanical ventilation; removable dentures; allergic to chlorhexidine; oral tumour or acute oral infection, who received periodontal treatment

ChiCTR-IPR-17013403 (Continued)

	in the past 3 months; severe liver, kidney and heart dysfunction; use of antibiotics, hormones or other immunosuppressive agents; people with tumours and autoimmune diseases
Interventions	<ul style="list-style-type: none"> • Intensive oral care • Standard oral care
Outcomes	<p>Primary outcome: incidence of pneumonia</p> <p>Secondary outcome: pathogenic bacteria of pneumonia</p>
Starting date	1 April 2016; anticipated completion 30 September 2018
Contact information	Professor Yue Wang, Beijing Stomatological Hospital, Capital Medical Hospital, Beijing, China
Notes	ChiCTR-IPR-17013403

Hollaar 2015

Study name	Effect of daily application of a 0.05% chlorhexidine solution on the incidence of (aspiration) pneumonia in care home residents: design of a multicentre cluster randomised controlled clinical trial
Methods	Multi-centre cRCT with care homes as units of randomisation
Participants	<p>500 physically disabled care home residents with dysphagia</p> <p>Inclusion criteria: aged ≥ 65 years, physically disabled and diagnosed with dysphagia</p> <p>Exclusion criteria: cognitively impaired (mainly with dementia), in a coma or vegetative state, terminally ill, dependent on mechanical ventilation, in day care, in short-term care or already using an oral hygiene care solution</p>
Interventions	<ul style="list-style-type: none"> • 0.05% chlorhexidine containing solution and usual daily oral hygiene care • Usual daily oral hygiene care
Outcomes	<p>Primary outcomes: incidence of pneumonia (diagnosed by a physician)</p> <p>Secondary outcomes: correlations between age, gender, diagnosed diseases, dysphagia severity, care dependency, actually used medication, number of teeth and implants present, and presence of removable dentures and the incidence of pneumonia in physically disabled care home residents with dysphagia who did or did not apply a 0.05% chlorhexidine-containing solution to their usual oral hygiene care</p> <p>Data collection: Dysphagia Outcome and Severity Scale (DOSS): baseline and endpoint; Care Dependency Scale (CDS): baseline and endpoint; patient record: gender, age (baseline), diagnoses and medication use (baseline and endpoint); oral examination: number of teeth, implants and the presence of removable dentures (baseline); pneumonia: pneumonia will be diagnosed by a set of strictly described criteria: when symptoms occur during study</p>
Starting date	14 February 2013
Contact information	Dr Vanessa Hollaar, Department of Neurohabilitation, University of Applied Sciences Nijmegen, Postbus 6960, Nijmegen, The Netherlands
Notes	NTR3515

MAPS-2

Study name	The Metoclopramide and selective oral decontamination for Avoiding Pneumonia after Stroke trial (MAPS-2)
Methods	2×2 factorial double-blinded RCT
Participants	<p>1160 participants</p> <p>Inclusion criteria: adults with clinical diagnosis of acute stroke; within 9 hours of stroke onset; moderate-to-severe neurological impairment with NIHSS score ≥ 10; unable to take a normal oral diet of fluids</p> <p>Exclusion criteria: evidence of vomiting since stroke onset; pre-existing swallowing problem; known oesophageal pathology that might interfere with placement of an NGT, probable or definite pneumonia, contraindications to metoclopramide, epilepsy, gastrointestinal obstruction, perforation, or haemorrhage, gastrointestinal surgery within the last week, Parkinson's disease, treatment with levodopa or dopaminergic agonists, pheochromocytoma or neuroleptic malignant syndrome or tardive dyskinesia or methaemoglobinaemia or NADH cytochrome; people with severe liver disease or kidney disease; known allergy to colistin; pregnant or breastfeeding; other comorbid conditions with a life expectancy < 3 months at the discretion of the clinical treating team; inability to gain consent from the patient or a legal representative or refusal of consent</p> <p>Recruited from 50 UK emergency department and acute stroke wards</p>
Interventions	<ul style="list-style-type: none"> • Metoclopramide and selective oral decontamination paste • Metoclopramide and placebo selective oral decontamination paste • Placebo metoclopramide and selective oral decontamination paste • Placebo metoclopramide and placebo selective oral decontamination paste <p>Participants will receive metoclopramide or placebo for 21 days or until the NGT is removed, and selective oral decontamination paste for 21 days or until the NGT is removed</p>
Outcomes	<p>Primary outcomes: mortality rates up to the end of study</p> <p>Secondary outcomes: pneumonia within 14 days; number of days of antibiotic treatment for pneumonia within the first 30 days; neurological recovery measured using the NIHSS at 30 days; disability measured using the modified Rankin Scale at 90 days; quality of life measured using the EuroQol Five Dimensions questionnaire at 90 days</p> <p>Data collection: daily clinical logs (14 days). Follow-up at 30 days (or day of discharge if sooner) and follow-up at 90 days for secondary outcomes</p>
Starting date	1 December 2017; anticipated completion September 2019
Contact information	Professor Christine Roffe, Institute for Applied Clinical Sciences (IACS) Keele University Guy Hilton Research Centre, Thornburrow Drive, Hartshill, Stoke-on-Trent, ST4 7QB, UK
Notes	ISRCTN14124645

cRCT: cluster randomised controlled trial; ED: emergency department; NADH: nicotinamide adenine dinucleotide; NGT: nasogastric tube; NIHSS: National Institutes of Health Stroke Scale; RCT: randomised controlled trial.

DATA AND ANALYSES

Comparison 1. Oral health care (OHC) interventions versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Dental plaque (up to 1 month)	2		Diff in mean score (IV, Random, 95% CI)	-0.66 [-1.40, 0.09]
1.1.1 Multi-component OHC intervention	2		Diff in mean score (IV, Random, 95% CI)	-0.66 [-1.40, 0.09]
1.2 Dental plaque (6 months)	1		Diff in mean score (IV, Fixed, 95% CI)	Subtotals only
1.2.1 Multi-component OHC intervention	1		Diff in mean score (IV, Fixed, 95% CI)	-0.43 [-0.98, 0.13]
1.3 Denture plaque	1		Diff in mean score (IV, Fixed, 95% CI)	Subtotals only
1.3.1 Multi-component OHC intervention (1 month)	1		Diff in mean score (IV, Fixed, 95% CI)	-1.31 [-1.96, -0.66]
1.3.2 Multi-component OHC intervention (6 months)	1		Diff in mean score (IV, Fixed, 95% CI)	-1.57 [-2.23, -0.92]
1.4 Presence of oral disease: gingivitis (up to 1 month)	2		Diff in mean score (IV, Random, 95% CI)	-0.60 [-1.66, 0.45]
1.4.1 Multi-component OHC intervention	2		Diff in mean score (IV, Random, 95% CI)	-0.60 [-1.66, 0.45]
1.5 Presence of oral disease: gingivitis (6 months)	1		Diff in mean score (IV, Fixed, 95% CI)	Subtotals only
1.5.1 Multi-component OHC intervention	1		Diff in mean score (IV, Fixed, 95% CI)	-0.25 [-0.61, 0.10]
1.6 Denture-induced stomatitis	1		Diff in mean score (IV, Fixed, 95% CI)	Subtotals only
1.6.1 Multi-component OHC intervention (1 month)	1		Diff in mean score (IV, Fixed, 95% CI)	-0.33 [-0.92, 0.26]
1.6.2 Multi-component OHC intervention (6 month)	1		Diff in mean score (IV, Fixed, 95% CI)	-0.10 [-0.61, 0.40]
1.7 Pneumonia	1	204	Peto Odds Ratio (Peto, Fixed, 95% CI)	4.17 [0.82, 21.11]
1.8 OHC knowledge (1 month)	3	728	Std. Mean Difference (IV, Random, 95% CI)	0.70 [0.06, 1.35]
1.8.1 Educational intervention	1	373	Std. Mean Difference (IV, Random, 95% CI)	0.19 [-0.01, 0.39]
1.8.2 Multi-component OHC intervention	2	355	Std. Mean Difference (IV, Random, 95% CI)	1.00 [-0.26, 2.27]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.9 OHC knowledge (2 months)	1	94	Mean Difference (IV, Fixed, 95% CI)	11.30 [8.78, 13.82]
1.9.1 Multi-component OHC intervention	1	94	Mean Difference (IV, Fixed, 95% CI)	11.30 [8.78, 13.82]
1.10 OHC knowledge (6 months)	2	596	Std. Mean Difference (IV, Fixed, 95% CI)	0.34 [0.18, 0.50]
1.10.1 Educational intervention	1	373	Std. Mean Difference (IV, Fixed, 95% CI)	0.27 [0.07, 0.48]
1.10.2 Multi-component OHC intervention	1	223	Std. Mean Difference (IV, Fixed, 95% CI)	0.45 [0.18, 0.72]
1.11 Attitudes to oral care (1 month)	3	728	Std. Mean Difference (IV, Random, 95% CI)	0.28 [0.01, 0.54]
1.11.1 Educational intervention	1	373	Std. Mean Difference (IV, Random, 95% CI)	0.06 [-0.14, 0.26]
1.11.2 Multi-component OHC intervention	2	355	Std. Mean Difference (IV, Random, 95% CI)	0.42 [0.21, 0.63]
1.12 Attitudes to oral care (2 months)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.12.1 Multi-component OHC intervention	1	94	Mean Difference (IV, Fixed, 95% CI)	2.00 [-0.12, 4.12]
1.13 Attitudes to oral care (6 months)	2	596	Std. Mean Difference (IV, Random, 95% CI)	0.36 [-0.01, 0.74]
1.13.1 Educational intervention	1	373	Std. Mean Difference (IV, Random, 95% CI)	0.18 [-0.02, 0.39]
1.13.2 Multi-component OHC intervention	1	223	Std. Mean Difference (IV, Random, 95% CI)	0.57 [0.30, 0.83]

Analysis 1.1. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 1: Dental plaque (up to 1 month)

Analysis 1.2. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 2: Dental plaque (6 months)

Analysis 1.3. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 3: Denture plaque

Analysis 1.4. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 4: Presence of oral disease: gingivitis (up to 1 month)

Analysis 1.5. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 5: Presence of oral disease: gingivitis (6 months)

Analysis 1.6. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 6: Denture-induced stomatitis

Analysis 1.7. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 7: Pneumonia

Analysis 1.8. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 8: OHC knowledge (1 month)

Analysis 1.9. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 9: OHC knowledge (2 months)

Analysis 1.10. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 10: OHC knowledge (6 months)

Analysis 1.11. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 11: Attitudes to oral care (1 month)

Analysis 1.12. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 12: Attitudes to oral care (2 months)

Analysis 1.13. Comparison 1: Oral health care (OHC) interventions versus usual care, Outcome 13: Attitudes to oral care (6 months)

Comparison 2. Oral health care (OHC) interventions versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Presence of oral disease: pneumonia	2	242	Peto Odds Ratio (Peto, Fixed, 95% CI)	0.39 [0.14, 1.09]
2.2 Presence of oral disease: acquired Aerobic Gram-negative bacilli (AGNB)	2	242	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.32, 1.01]
2.3 Presence of oral disease: carriage of AGNB	1	203	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.48, 1.74]
2.4 Self-reported oral dryness	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.4.1 Oral dryness over 24-hour period	1	21	Mean Difference (IV, Fixed, 95% CI)	-0.13 [-1.81, 1.55]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.4.2 Oral dryness during the day	1	21	Mean Difference (IV, Fixed, 95% CI)	-0.64 [-2.43, 1.15]
2.4.3 Oral dryness during a meal	1	21	Mean Difference (IV, Fixed, 95% CI)	0.66 [-1.61, 2.93]
2.4.4 Difficulty swallowing food	1	21	Mean Difference (IV, Fixed, 95% CI)	-0.62 [-2.53, 1.29]
2.4.5 Lack of saliva	1	21	Mean Difference (IV, Fixed, 95% CI)	1.12 [-0.28, 2.52]
2.4.6 General discomfort	1	21	Mean Difference (IV, Fixed, 95% CI)	0.45 [-0.91, 1.81]

Analysis 2.1. Comparison 2: Oral health care (OHC) interventions versus placebo, Outcome 1: Presence of oral disease: pneumonia

Footnotes

- (1) Intervention: Selective decontamination gel
(2) Intervention: Povidine-iodine

Analysis 2.2. Comparison 2: Oral health care (OHC) interventions versus placebo, Outcome 2: Presence of oral disease: acquired Aerobic Gram-negative bacilli (AGNB)

Footnotes

- (1) Intervention: Selective decontamination gel
(2) Intervention: Povidine-iodine

Analysis 2.3. Comparison 2: Oral health care (OHC) interventions versus placebo, Outcome 3: Presence of oral disease: carriage of AGNB

Footnotes

(1) Intervention: Selective decontamination gel

Analysis 2.4. Comparison 2: Oral health care (OHC) interventions versus placebo, Outcome 4: Self-reported oral dryness

Comparison 3. Oral health care (OHC) interventions versus another OHC intervention

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Dental plaque (3 months)	1	61	Mean Difference (IV, Fixed, 95% CI)	-0.04 [-0.33, 0.25]
3.2 Dental plaque (6 months)	1	54	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.46, 0.16]
3.3 Presence of oral disease: aerobic Gram-negative bacilli (AGNB) (3 months)	2	126	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.71, 1.42]
3.4 Presence of oral disease: AGNB (6 months)	1	52	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.47, 1.38]
3.5 Candida (3 months)	1	52	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.61, 1.89]
3.6 Candida (6 months)	1	52	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.62, 2.20]
3.7 <i>Staphylococcus aureus</i>	2	119	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.57, 2.91]

Analysis 3.1. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 1: Dental plaque (3 months)

Analysis 3.2. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 2: Dental plaque (6 months)

Analysis 3.3. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 3: Presence of oral disease: aerobic Gram-negative bacilli (AGNB) (3 months)

Analysis 3.4. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 4: Presence of oral disease: AGNB (6 months)

Analysis 3.5. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 5: Candida (3 months)

Analysis 3.6. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 6: Candida (6 months)

Analysis 3.7. Comparison 3: Oral health care (OHC) interventions versus another OHC intervention, Outcome 7: *Staphylococcus aureus*

ADDITIONAL TABLES

Table 1. Summary of study recruitment and setting

Study ID	Recruitment details	Number of centres	Type of centre and location	Geo-graphical location	Trial registration details
Ab Malik 2017	Study populations were RNs caring for people with stroke, mainly from rehabilitation and general medical wards. All RNs from identified wards were invited to take part. RNs given written information sheet and informed consent forms distributed by ward managers or chief nurses. Participation was voluntary and no contact was made with the nurses to ensure confidentiality and reduce the potential for 'social bias.'	Multi-centre (10)	10 public hospitals participated in a survey of oral hygiene practice for people with stroke. Hospitals selected because they provide rehabilitation services that are led by rehabilitation medicine specialists.	Malaysia	NM-RR-13-1540-18833 (IIR)
Ab Malik 2018	RCT conducted from June 2015 to August 2016	Multi-centre (5)	Public hospitals	Malaysia	NM-RR-13-1664-17247 (IIR)
Chipps 2014	People admitted following a stroke who met inclusion criteria were invited to take part in the study. No other details reported.	Single	Free standing 60-bed acute rehabilitation unit	USA	Not reported
Dai 2017	Following hospital discharge, people with stroke who had sustained functional impairment were referred to outpatient centre for further rehabilitation with MDT. Patients who fulfilled the criteria were provided with information on potential benefits and adverse effects of interventions, procedures and anticipated outcomes of the study. At next follow-up appointment, patients who agreed to participate gave written informed consent	Single	Outpatients 'day' centre hospital	Hong Kong, PRC	HK Clinical Trial Register 003900
Fields 2008	Enrolment and data collection began in October 2005. No other details reported.	Single	Critical care unit, large teaching hospital	USA	Not reported

Table 1. Summary of study recruitment and setting (Continued)

Frenkel 2001	Directors of the nursing homes were contacted and agreed to participation. Carers were encouraged, but not compelled, to take part. Individual carers therefore implicitly consented by completing the questionnaire and attending the training, or refused by failing to participate.	Mul-ti-centre (22)	Nursing homes (20–40 beds) registered with Avon Health Authority	UK	Not re-ported
Gosney 2006	Recruited from acute stroke assessment from 3 hospitals. Participants were recruited within 24 hours from admission following first acute stroke.	Mul-ti-centre (3)	Stroke unit	UK	Not re-ported
Juthani-Mehta 2015	Administrative leadership at all nursing homes approved the study and signed letters of agreement to participate, and participants or their surrogates provided written consent.	Mul-ti-centre (36)	Nursing home facilities (housed ≥ 90 residents)	USA	NCT00975780
Kim 2014a	Consecutive people with stroke admitted to ICU were approached. No other details reported.	Single	ICU, Neurosurgery Department of University Hospital	Korea	Not re-ported
Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi	Written informed consent was obtained from participants or from family members.	Single	Hospital	Japan	Not re-ported
Kuo 2016	Study conducted between September 2012 and February 2013. Nursing directors of 3 hospital-based home care institutions serving > 100 patients were contacted for screening of family carers.	Mul-ti-centre (3)	Hospital and home	Taiwan	Not re-ported
Lam 2013i; Lam 2013ii; Lam 2013iii	Patients meeting selection criteria were recruited. No other details reported.	Single	Stroke rehabilitation ward	Hong Kong, PRC	Unclear
Lee 2011	Unclear (translation unavailable at present)	Single	Unclear (translation unavailable at present)	Korea	Not re-ported
Seguin 2014	Study conducted between May 2008 and May 2011. Written informed consent obtained from personal or professional legal representative and participants themselves at discharge when possible.	Mul-ti-centre (6)	ICU	France	NCT00950027

Table 1. Summary of study recruitment and setting (Continued)

SOCLE II	Sites were local to the investigators. All ward admissions were approached to participate by research assistant or research nurse. Information sheets and consent forms were adapted to make them as accessible as possible for people with aphasia or other language problems	Multi-centre (4)	Stroke rehabilitation wards. Acute stroke wards were excluded	Scotland, UK	NCT01954212
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ICU: intensive care unit; MDT: multi-disciplinary team; PRC: People's Republic of China; RN: registered nurse.

Table 2. Characteristics of participants in included studies

Study ID	Group	No of participants	Men/ women	Age in years Mean (SD) [range]	Types of stroke	Time post onset Mean (SD) [range]
Ab Malik 2017	OHC training (Internet-based CPD programme) General stroke care training (Internet-based CPDP programme not specific to oral hygiene)	Whole group: 547 RNs but final response rate was 373 RNs ^a	Whole group: 16/357	NR	NA	NA
Ab Malik 2018	Multi-component OHC intervention (intense method for plaque control)	38	24/14	20–39 years (n = 6) ≥ 40 years (n = 32)	Ischaemic 35 Haemorrhage: 3	33/38 first stroke; time post-stroke: NR
	Multi-component OHC intervention (conventional method for plaque control)	48	28/20	20–39 years (n = 7) ≥ 40 years (n = 41)	Ischaemic 42 Haemorrhage: 6	42/48 first stroke; time post-stroke: NR
Chipps 2014	Multi-component OHC intervention (enhanced oral care protocol)	29	15/14	62.54 (13.5)	NR	NR
	Multi-component OHC intervention (routine oral care)	22	14/8	63.74 (15.6)	NR	NR
Dai 2017	Multi-component OHC intervention (advanced oral hygiene care programme)	47	29/18	66.3 (11.2)	Ischaemic 31 Haemorrhage: 16	NR
	Multi-component OHC intervention (conventional oral hygiene programme)	47	28/19	66.9 (10.6)	Ischaemic 35 Haemorrhage: 12	NR
Fields 2008	Multi-component OHC intervention (OHC and timed toothbrushing in care bundle)	345 (but complet-	NR	NR	NR	NR

Table 2. Characteristics of participants in included studies *(Continued)*

	Usual care	ed data only available on 200)	NR	NR	NR	NR
Frenkel 2001	Multi-component OHC intervention (workplace OHC training session)	Whole group: 369 care assistants at baseline; 151 residents*	4/147	[16–55+]	NR	NR
	Usual care	144 residents	8/136	[16–55+]	NR	NR
Gosney 2006	OHC gel (selective decontamination of digestive tract oral gel)	103	54/49	[16–96]	NR	First acute stroke; time post-stroke: NR
	Placebo gel	100	48/52	[45–92]	NR	
Juthani-Mehta 2015	Multi-component OHC intervention	434	105/329	86.5 (8.0)	100 participants with stroke	NR
	Usual care	400	93/307	86.1 (8.3)	92 participants with stroke	NR
Kim 2014a	Multi-component OHC intervention (OHCP)	29	13/16	57.38 (14.22)	Infarct: 3 Haemorrhage: 26	NR
	Usual care	27	14/13	56.15 (14.55)	Infarct: 3 Haemorrhage: 24	NR
Kobayashi 2017i ; Kobayashi 2017ii ; Kobayashi 2017iii ; Kobayashi 2017iv ; Kobayashi 2017v ; Kobayashi 2017vi	Multi-component OHC intervention (mouthwash and moisturising gel)	Whole group: 60 participants	Whole group: 29/31	Whole group: 83.5 (5)	Quote: "Treated for cerebral stroke" – no other details reported	NR
	Multi-component OHC intervention (mouthwash)					
	Multi-component OHC intervention (water and moisturising gel)					
	Multi-component OHC intervention (water alone)					
Kuo 2016	Multi-component OHC intervention (home-based OHC programme)	48 family carers	16/32	52.7 (11.29)	NR	NR
	Usual care	46 family carers	19/27	53.9 (16.74)	NR	NR

Table 2. Characteristics of participants in included studies (Continued)

Lam 2013i; Lam 2013ii; Lam 2013iii	Multi-component OHC intervention (oral hygiene instruction + chlorhexidine mouthrinse + assisted brushing)	30	19/11	71 (11.7)	Ischaemic 27 Haemorrhage: 3	NR
	Multi-component OHC intervention (oral hygiene instruction + chlorhexidine mouthrinse)	26	16/10	69.4 (9.6)	Ischaemic 22 Haemorrhage: 4	NR
	Multi-component OHC intervention (oral hygiene instruction)	25	16/9	68.9 (11.4)	Ischaemic 19 Haemorrhage: 6	NR
Lee 2011	Saengmaeg-san extract	12	NR	NR	NR	NR
	Placebo	12	(translation unavailable at present)	(translation unavailable at present)	(translation unavailable at present)	(translation unavailable at present)
Seguin 2014	Oropharyngeal care with povidone-iodine	85	60/25	48 (19)	TBI: 62 Cerebral haemorrhage: 23	NR
	Oropharyngeal care with placebo	82	64/18	48 (18)	TBI: 61 Cerebral haemorrhage: 21	NR
SOCLE II	Multi-component OHC intervention (enhanced OHC)	Whole group:	165/160	Median age: 76	243/325 stroke	NR
	Usual care	325 (243 stroke) patients 112 nursing staff		[IQR 63–83]		

^aPopulation demographics only reported for the 373 RNs who completed the trial; group labels that trialists reported in their original publication(s) are shown in brackets.

CPD: continuing professional development; IQR: interquartile range; n: number of participants; NA: not applicable; NR: not reported; OHC: oral health care; OHCP: oral hygiene care programme; RN: registered nurse; SD: standard deviation; TBI: traumatic brain injury.

Table 3. Summary of intervention components across comparison groups

Study ID	Intervention	Training	Tooth-brush	Toothpaste	Mouth gel	Mouthwash	Protocol	Other
Comparison group 1: oral healthcare interventions vs no treatment or usual care								
Ab Malik 2017	Internet-based CPD programme	Staff training (specialist) computer-aided learning	—	—	—	—	—	—
	Internet-based CPD programme (not specific to oral hygiene)	Brief computer-aided learning	—	—	—	—	—	—
Fields 2008	Multi-component OHC intervention (OHC and timed toothbrushing in care bundle)	Staff training	Manual (new tooth-brush for each session)	Yes	—	—	Laminated care with basic instructions	Toothette (foam swab), lip moisturiser
	Usual care	—	Manual (kit had 2 tooth-brushes)	—	—	—	—	Toothette (foam swab), lip moisturiser as required
Frenkel 2001	Multi-component OHC intervention (workplace OHC training session)	Staff training	Manual	—	—	—	—	Booklet, teaching aids and models, course attendance certificate
	Usual care	Health education programme delivered after completion of data collection	—	—	—	—	—	—
Juthani-Mehta 2015	Multi-component OHC intervention	Staff training	Manual	—	—	0.12% chlorhexi-	—	Upright positioning during feeding

Table 3. Summary of intervention components across comparison groups (Continued)

						dene oral rinse		
	Usual care	—	—	—	—	—	—	—
Kim 2014a	Multi-component OHC intervention (oral hygienic care programme)	—	Children's manual tooth-brush and interdental tooth-brush			0.5% chlorhexidine	—	Tongue cleaner, mouth gag, suction
	Usual care	—	—	—	—	—	—	—
Kuo 2016	Multi-component OHC intervention (home-based oral care programme)	Staff training	Finger tooth-brush	—	—	—	—	Tongue cleaner, educational pamphlets, daily reminder sheets
	Usual care	Encouraged to maintain routine practices	—	—	—	—	—	OHC could include oral cleaning with oral swabs
SOCLE II	Multi-component OHC intervention (enhanced OHC)	Staff training	Manual	Yes	Oral balance gel	Yes	Yes	Stroke-specific assessment tool, foam swab, information sheet, suction, denture making kit
	Usual care	No training	Varied	Varied	Varied	Varied	—	Foam swab
Comparison group 2: oral healthcare interventions vs placebo interventions								
Gosney 2006	OHC gel (selective decontamination of digestive tract oral gel)	—	—	—	Orabase 500 mg gel (containing 2% (w/v) colistin, 2% (w/v) polymyxin E, 2% (w/	—	—	—

Table 3. Summary of intervention components across comparison groups (Continued)

					v) amphotericin B			
	Placebo gel	—	—	—	Placebo gel 500 mg	—	—	—
Lee 2011	Saengmaeg-san extract	—	—	—	—	—	—	Saengmaeg-san extract given in opaque capsules
	Placebo	—	—	—	—	—	—	Placebo given in opaque capsules
Seguin 2014	Povidone-iodine (oropharyngeal care with povidone-iodine)	All nurses were trained in the oral procedure. Film describing in detail the oral care procedure was made available to all investigators	—	—	Povidone-iodine (betadine 10% oral antiseptic solution; Meda Pharma, Paris, France) portioned in vials containing 125 mL of product and dispensed by the Pharmacy of Rennes to the pharmacies of the participating centres	—	Nasopharynx and oropharynx rinsing, regular suction, cuffed tracheal tube pressure checked and adjusted as required	—
	Placebo (oropharyngeal care with placebo)	As above	—	—	Placebo were portioned in vials containing 125 mL of product and dispensed by the Pharma-	—	As above	—

Table 3. Summary of intervention components across comparison groups (Continued)

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Comparison group 3: oral healthcare interventions vs another oral healthcare intervention								
Ab Malik 2018	Multi-component OHC intervention (in-tense method for plaque control)	Patient (in-dividual) training	Powered (Oral B Pro-Health DB4010)	—	1% chlorhex- idine glu- conate gel	—	—	Plastic tooth model, a pam- phlet on tooth brushing tech- niques
	Multi-component OHC intervention (con- ventional method for plaque control)	As above	Manual (Oral-B su- per thin and extra soft bris- tles tooth- brush)	Commercial	—	—	—	—
Chipps 2014	Multi-component OHC intervention (en- hanced oral care protocol)	Staff train- ing	Powered	Crest-Pro- Health toothpaste	—	Listerine	—	Glide disposable floss picks, Sun- star dual action tongue cleaner, Carmex lip balm
	Multi-component OHC intervention (rou- tine oral care protocol)	As above	Manual	Sage Oral Care Sodi- um Bicarbonate Mouthpaste	—	Careline al- cohol-free mouthwash	—	Regular Chaplet lip balm
Dai 2017	Multi-component OHC intervention (ad- vanced oral hygiene care programme)	Patients: oral hygiene training	Powered (Oral-B Advance- Power™ 400 series)	Standard- ised tooth- paste (Col- gate Maxi- mum Cavity Protection)	—	0.2% chlorhex- idine glu- conate mouth rinse Corsodyl	—	Information sheet: oral hy- giene pamphlet

Table 3. Summary of intervention components across comparison groups *(Continued)*

	Multi-component OHC intervention (conventional oral hygiene programme)	As above	Manual (Oral-B Pro-Health All-In-One)	As above	—	—	—	—
Kobayashi 2017i	Multi-component OHC intervention (mouthwash and moisturising gel)	—	Manual (Dent Ex)	—	Mouth gel (1 g containing glycerine, lactoferrin and whey protein)	Mouth wash (contained cetylpyridinium chloride)	—	Tongue brush, water, Elastomeric tongue scraper
	Multi-component OHC intervention (mouthwash)	—	Manual (Dent Ex)	—	—	Mouth wash (contained cetylpyridinium chloride)	—	Tongue brush
Kobayashi 2017ii	Multi-component OHC intervention (mouthwash and gel)	—	Manual (Dent Ex)	—	Mouth gel (1 g containing glycerine, lactoferrin and whey protein)	Mouth wash (contained cetylpyridinium chloride)	—	Tongue brush, water, Elastomeric tongue scraper
	Multi-component OHC intervention (water and moisturising gel)	—	Manual (Dent Ex)	—	Mouth gel (1 g containing glycerine, lactoferrin and whey protein)	—	—	Tongue brush, water, Elastomeric tongue scraper
Kobayashi 2017iii	Multi-component OHC intervention (mouthwash and gel)	—	Manual (Dent Ex)	—	Mouth gel (1 g containing glycerine, lactoferrin and whey protein)	Mouthwash (contained cetylpyridinium chloride)	—	Tongue brush, water, Elastomeric tongue scraper
	Multi-component OHC intervention (water alone)	—	Manual (Dent Ex)	—	—	—	—	Tongue brush, water

Table 3. Summary of intervention components across comparison groups (Continued)

Kobayashi 2017iv	Multi-component OHC intervention (mouthwash)	—	Manual (Dent Ex)	—	—	Mouthwash (contained cetylpyridinium chloride)	—	Tongue brush
	Multi-component OHC intervention (water and moisturising gel)	—	Manual (Dent Ex)	—	Mouth gel (1 g containing glycerine, lactoferrin and whey protein)	—	—	Tongue brush, water, Elastomeric tongue scraper
Kobayashi 2017v	Multi-component OHC intervention (mouthwash)	—	Manual (Dent Ex)	—	—	Mouthwash (contained cetylpyridinium chloride)	—	Tongue brush
	Multi-component OHC intervention (water alone)	—	Manual (Dent Ex)	—	—	—	—	Tongue brush, water
Kobayashi 2017vi	Multi-component OHC intervention (water and moisturising gel)	—	Manual (Dent Ex)	—	Mouth gel (1 g containing glycerine, lactoferrin and whey protein)	—	—	Tongue brush, water, Elastomeric tongue scraper
	Multi-component OHC intervention (water alone)	—	Manual (Dent Ex)	—	—	—	—	Tongue brush, water
Lam 2013i	Multi-component OHC intervention (oral hygiene instruction, mouthrinse, and assisted brushing)	Staff training	Powered (dentures cleaned with manual toothbrush)	Standard (sodium fluoride)	—	Chlorhexidine (Corsodyl) mouthrinse (0.2%, 10 mL)	—	Assisted brushing (hand-over-hand)
	Multi-component OHC intervention (oral hygiene instruction, mouthrinse)	As above	Powered (dentures cleaned with man-	Standard (sodium fluoride)	—	Chlorhexidine (Corsodyl) mouthrinse	—	—

Table 3. Summary of intervention components across comparison groups (Continued)

			ual tooth- brush)	(0.2%, 10 mL)				
Lam 2013ii	Multi-component OHC intervention (oral hygiene instruction, mouthrinse, and assisted brushing)	Staff training	Powered (dentures cleaned with manual tooth-brush)	Standard (sodium fluoride)	—	Chlorhexidine (Cor-sodyl) mouthrinse (0.2%, 10 mL)	—	Assisted brushing (hand-over-hand)
	Multi-component OHC intervention (oral hygiene instruction)	As above	Powered (dentures cleaned with manual tooth-brush)	Standard (sodium fluoride)	—	—	—	—
Lam 2013iii	Multi-component OHC intervention (oral hygiene instruction, mouthrinse)	Staff training	Powered (dentures cleaned with manual tooth-brush)	Standard (sodium fluoride)	—	Chlorhexidine (Cor-sodyl) mouthrinse (0.2%, 10 mL)	—	—
	Multi-component OHC intervention (oral hygiene instruction)	As above	Powered (dentures cleaned with manual tooth-brush)	Standard (sodium fluoride)	—	—	—	—

Note: group labels that trialists used are shown in brackets.

CPD: continuing professional development; OHC: oral health care; w/v: weight/volume.

Table 4. Outcome measures within included studies

Study ID	Primary outcomes	Secondary outcomes	Adverse events	Other
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Table 4. Outcome measures within included studies (Continued)

	Dental plaque	Denture plaque	Patient satisfaction	Presence of oral disease	Presence of related infection and oral opportunistic pathogens	Staff oral health knowledge and attitudes		
Ab Malik 2017	—	—	—	—	—	Self-administered questionnaire based on theory of planned behaviour. 5 domains: attitude, subjective norm, perceived behaviour control, general intention and knowledge related to providing OHC	—	—
Ab Malik 2018	Dental Plaque Index (Silness and Loe)	—	—	—	Oral prevalence of Candida and yeast, <i>S aureus</i> , AGBN	—	—	Presence and type of dental prosthesis; modified BI; MMSE
Chipps 2014	—	—	—	—	Nasal and oral pharyngeal cultures for <i>S aureus</i>	—	—	R-THROAT assessment; Mann Assessment of swallowing

Table 4. Outcome measures within included studies (Continued)

								abilities; Functional Oral In- take Scale
Dai 2017	Dental Plaque In- dex (Silness and Loe)	—	—	Gingival Bleeding In- dex; DMFT Index	Oral prevalence of Candida and yeast, <i>S aureus</i> , AGNB	—	—	—
Fields 2008	—	—	—	—	VAP diagnosis (see Table 5 for diagnostic criteria)	—	—	Patient worksheets docu- menting oral care sessions
Frenkel 2001	Dental plaque	Denture plaque	—	Denture-in- duced stom- atitis, calcu- lus on buc- cal and lin- gual sur- faces, root caries, tooth mobility	—	Self-ad- minis- tered ques- tion- naires. Car- ers' oral health knowl- edge (26 ques- tions) Carers' attitudes (25 state- ments rated on 0- to 5-point scale)	—	—
Gosney 2006	—	—	—	—	Colonisation by AGNB; carriage of AGNB on ≥ 2 consecutive samples; septicaemia or respi- ratory tract infections (or both) during hospital stay; pneumo- nia (see Table 5 for diagnostic criteria)	—	—	BI, Scandinavian Stroke Scale; administration of antibiotics
Juthani- Mehta 2015	—	—	—	—	Radiographically documented pneumonia (see Table 5 for di-	—	—	Adherence to chlorhexidine (compared expected vs actu- al chlorhexidine volume ex-

Table 4. Outcome measures within included studies (Continued)

					agnostic criteria), development of a first LRTI			penditure), oral brushing adherence (compared expected vs actual residual toothpaste tube weight), upright feeding positioning adherence was evaluated qualitatively once per month
Kim 2014a	Dental Plaque Index (Silness and Loe)	—	—	Gingival Index; Tooth Mobility Index (Lindhes grading); DMFT Index Clinical Attachment Loss	Colonisation degree of <i>Candida albicans</i> (tongue and saliva)	—	—	—
Kobayashi 2017i; Kobayashi 2017ii; Kobayashi 2017iii; Kobayashi 2017iv; Kobayashi 2017v; Kobayashi 2017vi	—	—	—	—	Number of anaerobic bacteria on tongue surface, tongue coating index, moisture level of the tongue surface	—	—	—
Kuo 2016	—	—	—	—	—	Knowledge of Oral Care questionnaire, Attitudes towards Oral	—	—

Table 4. Outcome measures within included studies (Continued)

Table 4. Outcome measures within included studies (continued)									
								Care Ques- tion- naire, Family Caregiv- er Self- efficacy of Oral Care (Self-E) Ques- tion- naire, Behav- iour of Oral Care Ques- tionnaire	
Lam 2013i; Lam 2013ii; Lam 2013iii	Dental Plaque In- dex (Silness and Loe)	—	Patient sat- isfaction with inter- ventions and condi- tion of their mouth using a rated scale (1 = totally satisfied to 5 = not at all satisfied)	Gingival Bleeding In- dex	Medical chart review at end of trial for development of infec- tious complications including pneumonia (see Table 5 for di- agnostic criteria), oral preva- lence of Candida and yeast, <i>S</i> <i>aureus</i> , AGNB	—	—	BI, Royal Brisbane Hospital Outcome measure for swal- lowing, oral functional sta- tus questions (ability to brush teeth and insert/remove den- tures) Medical chart review at end of clinical trial for medications taken throughout the study	
Lee 2011	—	—	VAS to eval- uate subjec- tive oral dry- ness (dry in night/morn- ing, dry in daytime, dry while eating a meal, hard to swallow food, lack of	—	—	—	—	—	

Table 4. Outcome measures within included studies (Continued)

			saliva, gen- eral discom- fort)					
Seguin 2014	—	—	Tolerance of oral proce- dure	—	Rate of VAP (American Thoracic Society 2005 guidelines) (see Table 5 for diagnostic criteria), delay of other VAP occurrence, rate of VAP (early vs late), mi- cro-organisms involved, rates of ventilator-associated tra- cheobronchitis, other nosoco- mial infections	—	—	Number of ventilation-free days, length of stay (in ICU, in hospital), mortality (in ICU, at day 90), bacterial colonisation follow-up (oropharyngeal and tracheal swabs) in subgroup of patients
SOCLE II	Dental Plaque In- dex (Silness and Loe)	Denture plaque	Oral Health Impact Pro- file	—	Pneumonia (Mann Chest crite- ria) (see Table 5 for diagnostic criteria)	Knowl- edge and at- titudes ques- tionnaire	Data relat- ing to any interven- tion adverse even report- ed by pa- tient/car- er/health- care staff/ researcher (e.g. bro- ken or miss- ing den- tures) were recorded	Length of hospital stay, death, use of antibiotics, OHC proto- col adherence, documented OHC assessment, document- ed OHC plan, OHC equipment and product use, referrals to dental support (urgent and non-urgent), use of OHC equipment and procedures, economic outcomes. Feasibility and implementa- tion: focus groups

AGNB: aerobic and facultative Gram-negative bacilli; BI: Barthel Index; DMFT Index: Decayed Missing and Filled Teeth Index; LRTI: lower respiratory tract infection; OHC: oral health care; MMSE: Mini-Mental State Examination; PI: Plaque Index; R-THROAT: revised THROAT oral assessment tool; *S aureus*: *Staphylococcus aureus*; VAP: ventilator-associated pneumonia; VAS: visual analogue scale.

Table 5. Criteria used to diagnose pneumonia

Studies	Description of criteria used to diagnose criteria	Diagnosed by?
Fields 2008	Based on ≥ 1 finding, such as a new or persistent infiltrate on chest x-ray, an organism isolated on sputum, or pleural fluid or a positive culture from a broncho-alveolar lavage. VAP diagnosis could also be made if 2 further symptoms, (e.g. fever $> 38.3^{\circ}\text{C}$, leukocytosis (25% increase and value $> 10,000 \text{ mm}^3$), leukopenia (25% decrease and value $< 5000 \text{ mm}^3$) or purulent secretions are present.	VAP episodes were tracked by the infection-control nurse
Gosney 2006	Clinical signs and symptoms of pneumonia in medical records were accepted as evidence of probably pneumonia. This included comments about changes on x-rays, diagnosis of pneumonia, chest infection or lower respiratory tract infection being recorded in the notes as well as positive sputum culture reports.	NR (as recorded in case notes)
Juthani-Mehta 2015	Pneumonia diagnosis required the presence of a compatible infiltration chest x-ray and ≥ 2 of the following clinical features within 72 hours of the chest x-ray: fever, pleuritic chest pain, respiratory rate > 25 breaths per minute, worsening functional status (i.e. decline in the level of consciousness or activities of daily living), or new or increased cough, sputum production, shortness of breath or chest examination findings.	Quote: "Two investigators adjudicated all outcomes ... a third blinded investigator resolved disagreement"
Lam 2013i; Lam 2013ii; Lam 2013iii	Medical records were reviewed at the end of the clinical trial for development of infectious complications including pneumonia.	NR (as recorded in case notes)
Seguin 2014	VAP defined as new and persistent pulmonary infiltrates on chest x-ray, occurring after 48 hours of mechanical ventilation, combined with ≥ 2 of the following criteria: purulent tracheal secretions or body core temperature $> 38^{\circ}\text{C}$ or leukocytosis $> 10,000 \text{ mm}^3$ (or a combination of these) and microbiological confirmation with quantitative culture from bronchoalveolar lavage or endotracheal aspirate, growing $\geq 10^4 \text{ cfu/mL}$ or 10^6 cfu/mL (American Thoracic Society 2005).	Quote: "An independent diagnosis validation committee composed of three experienced physicians in intensive care, pneumology and microbiology, blindly classified each patient as positive or negative."
SOCLE II	Mann criteria: chest infection was diagnosed by the attending clinician and based on the presence of ≥ 3 of the following variables: fever ($> 38^{\circ}\text{C}$), productive cough with purulent sputum, abnormal respiratory examination (tachypnea ($> 22/\text{minute}$), tachycardia, inspiratory crackles, bronchial breathing), abnormal chest x-ray, arterial hypoxaemia ($\text{PO}_2 < 70 \text{ mmHg}$), and isolation of a relevant pathogen (positive Gram's stain and culture) (Mann 1999).	Attending physician

cfu: colony-forming unit; NR: not reported; VAP: ventilator-associated pneumonia.

Table 6. Details of dropouts

Study ID	Dropouts	Reasons	Follow-up	Reasons
Ab Malik 2017	OHC training (Internet-based CPD programme): 82 General stroke care training (Internet-based CPD programme not specific to oral hygiene): 92	Mostly loss to follow-up was because nurses were transferred to other wards or hospitals	Unclear. Dropouts were only reported in the CONSORT as 'loss to follow-up,' so we could not determine when (i.e. at 1- or 6-month follow-up)	NR

Table 6. Details of dropouts (Continued)

Ab Malik 2018	Multi-component OHC intervention (intense method for plaque control): 11	2 refused to continue, 2 transfers, 3 died, 1 lost contact, 3 other reason (not specified)	At 6-month follow-up: 2	2 transfers
	Multi-component OHC intervention (conventional method for plaque control): 14	4 refused to continue, 4 died, 4 lost contact, 2 other reason (not specified)	At 6-month follow-up: 5	2 transfers, 1 died, 2 lost contact
Chipps 2014	Multi-component OHC intervention (enhanced oral care protocol): 8	2 transferred to acute care, 3 discharged from rehabilitation, 3 voluntary withdrawal	Numbers that did not finish protocol are reported for each group but no details given about when participants withdrew	—
	Multi-component OHC intervention (routine oral care): 1	1 transferred to acute care		—
Dai 2017	Multi-component OHC intervention (advanced oral hygiene care programme): 3	2 recurrent stroke, 1 loss of contact	At 6-month follow-up: 10	4 loss of contact, 6 not willing to participate
	Multi-component OHC intervention (conventional oral hygiene care programme): 17	1 recurrent stroke, 6 loss of contact, 10 not willing to participate	At 6-month follow-up: 7	3 recurrent stroke, 4 loss of contact
Fields 2008	NR	NR	NR	—
Frenkel 2001	Availability of residents varied over the duration of the trial (baseline: 55 residents; 1 month after training: 57 residents; 6 months after training: 53 residents).	—	—	—
Gosney 2006	OHC gel (selective decontamination of digestive tract oral gel): 9	9 died, no other details reported	3 died within 3 months of discharge from hospital. Unclear which group these came from. Authors reported that an additional 19 participants withdrew but no reasons given and unclear when they withdrew	—
	Placebo gel: 11	11 died, no other details reported		—
Juthani-Mehta 2015	Multi-component OHC intervention: 0	No dropouts reported	2 nursing homes; 157 participants	Nursing home withdrew due to administrative leader-

Table 6. Details of dropouts (Continued)

				ship decision. Participants were lost to follow-up because discharged from facility, or facility withdrew from study and death
	Usual care: 0		1 nursing home; 102 participants	Nursing home withdrew due to foreclosure. Participants were lost to follow-up because discharged from facility, or facility withdrew from study and death
Kim 2014a	Multi-component OHC intervention (oral hygienic care programme): 16	6 withdrew; 2 died; 3 "aggravation" of systemic condition; 2 discharged; 3 "un-cooperation"	No dropouts at follow-up	NA
	Usual care: 18	8 withdrew; 3 died; 2 "aggravation" of systemic condition; 3 discharged; 2 "un-cooperation"	No dropouts at follow-up	NA
Kobayashi 2017i ; Kobayashi 2017ii ; Kobayashi 2017iii ; Kobayashi 2017iv ; Kobayashi 2017v ; Kobayashi 2017vi	No dropouts reported for any group	—	—	—
Kuo 2016	Multi-component OHC intervention (homebased OHC training): 2	1 refused to participate; 1 died	Follow-up at 2 months: 0	—

Table 6. Details of dropouts (Continued)

	Usual care: 0	No dropouts	Follow-up at 2 months: 4	4 participants died
Lam 2013i; Lam 2013ii; Lam 2013iii	Multi-component OHC intervention (oral hygiene instruction + chlorhexidine mouthrinse + assisted brushing): 8	8 lost to early discharge	No dropouts at follow-up	NA
	Multi-component OHC intervention (oral hygiene instruction + chlorhexidine mouthrinse): 8	4 lost to early discharge; 2 transferred to another hospital for further assessment; 1 non-compliance with mouthrinse; 1 self-discharge from hospital	No dropouts at follow-up	NA
	Multi-component OHC intervention (oral hygiene instruction): 5	5 lost to early discharge	No dropouts at follow-up	NA
Lee 2011	Saengmaeg-san extract: 1	Reported that all participants were allocated and received intervention; 1 dropout at day 7 because of poor medication compliance	No dropouts at follow-up	NA
	Placebo: 2	Reported that all participants were allocated and received intervention; 2 dropouts at day 7 (no reason given)	No dropouts at follow-up	NA
Seguin 2014	Oropharyngeal care with povidone-iodine: 18	6 withdrew consent, 12 discontinued intervention (8 adverse event, 3 patient or family decision, 1 other)	NA	NA
	Oropharyngeal care with placebo: 14	6 withdrew consent, 8 discontinued intervention (6 adverse events, 2 patient or family decision)	NA	NA
SOCLE II	Multi-component OHC intervention (enhanced OHC): 0	Study authors reported no patient withdrawals or dropouts in the usual sense as there was no formal follow-up beyond the ward admission	NA	NA
	Usual care: 0		NA	NA

Note: group labels that trialists reported in their original publication(s) are shown in brackets.
NA: not applicable; NR: not reported; OHC: oral health care.

APPENDICES

Appendix 1. Cochrane Oral Health Register search strategy

- 1 "cerebrovascular disorder*" AND INREGISTER
- 2 (stroke* OR cva* OR cerebrovasc* OR "cerebral vascular*" OR poststroke or post-stroke):ti,ab AND INREGISTER
- 3 ((Cerebral OR cerebellar OR brain* OR vertebrobasilar) AND (infarct* OR ischaemi* OR ischemi* OR thrombo* OR emboli* OR apople*)):ti,ab AND INREGISTER
- 4 ((cerebral OR intracerebral OR intracranial OR brain* OR subarachnoid) AND (haemorrhag* OR hemorrhag* OR bleed*)):ti,ab AND INREGISTER
- 5 (hemiplegi* OR "brain injur*" OR aphasi* OR dysphasi* OR dysphag* OR dysarthri* OR aprax* OR dysprax* OR "deglutition disorder*" OR hemipleg* OR hemipar*):ti,ab AND INREGISTER
- 6 (swallow* AND (impair* OR disorder* OR problem* OR difficult*)):ti,ab AND INREGISTER
- 7 ("unilateral neglect*" OR "neglect syndrome*" OR "visual neglect" OR hemianop*):ti,ab AND INREGISTER
- 8 #1 or #2 or #3 or #4 or #5 or #6 or #7

Appendix 2. CENTRAL search strategy

#1 MeSH descriptor: [Stomatognathic Diseases] explode all trees
#2 MeSH descriptor: [Dentistry] explode all trees
#3 MeSH descriptor: [Oral Health] this term only
#4 MeSH descriptor: [Oral Hygiene] explode all trees
#5 MeSH descriptor: [Dental Auxiliaries] explode all trees
#6 MeSH descriptor: [Mouth] explode all trees
#7 MeSH descriptor: [Halitosis] this term only
#8 MeSH descriptor: [Facial Pain] this term only
#9 ((dental or oral or periodontal) and disease*):ti,ab,kw (Word variations have been searched)
#10 ((dental or tooth or teeth) and (caries or decay*)):ti,ab,kw (Word variations have been searched)
#11 gingivitis:ti,ab,kw (Word variations have been searched)
#12 xerostomia or "dry mouth":ti,ab,kw (Word variations have been searched)
#13 (oral and (stomatitis or candidiasis)):ti,ab,kw (Word variations have been searched)
#14 ((mouth near/6 ulcer*) or (mouth near/6 aphthous) or (mouth near/6 aphthae) or (oral near/6 ulcer*) or (oral near/6 aphthous) or (oral near/6 aphthae)):ti,ab,kw (Word variations have been searched)
#15 ((mouth or dental or oral) and hygiene):ti,ab,kw (Word variations have been searched)
#16 ((mouth near/4 odor) or (mouth near/4 odour)):ti,ab,kw (Word variations have been searched)
#17 halitosis:ti,ab,kw (Word variations have been searched)
#18 (dentist* or "dental nurse*" or dental therapist* or "dental hygienist*"):ti,ab,kw (Word variations have been searched)
#19 "dental health educat*":ti,ab,kw (Word variations have been searched)
#20 (dental and (disabled or handicap*)):ti,ab,kw (Word variations have been searched)
#21 ((dental near/3 scaling) or (oral near/3 scaling) or (teeth near/3 scaling) or (dental near/3 prophylaxis) or (oral near/3 prophylaxis) or (teeth near/3 prophylaxis)):ti,ab,kw (Word variations have been searched)
#22 (mouth and ulcer*):ti,ab,kw (Word variations have been searched)
#23 (mouthwash* or mouthrinse*):ti,ab,kw (Word variations have been searched)
#24 (dental and (treatment* or care*)):ti,ab,kw (Word variations have been searched)
#25 toothbrush*:ti,ab,kw (Word variations have been searched)
#26 ((plaque next index) or (plaque next indices) or ("oral hygiene" next index) or ("oral hygiene" next indices) or (periodontal next index) or (periodontal next indices) or (DMF next index) or (DMF next indices)):ti,ab,kw (Word variations have been searched)
#27 {or #1-#26}
#28 MeSH descriptor: [Cerebrovascular Disorders] explode all trees
#29 (stroke* or cva* or cerebrovasc* or "cerebral vascular*" or poststroke or post-stroke):ti,ab,kw (Word variations have been searched)
#30 (cerebral or cerebellar or brain* or vertebrobasilar):ti,ab,kw (Word variations have been searched)
#31 (infarct* or ischemi* or ischaemi* or thrombo* or emboli* or apople*):ti,ab,kw (Word variations have been searched)
#32 (#30 and #31)
#33 (cerebral or intracerebral or intracranial or brain* or subarachnoid):ti,ab,kw (Word variations have been searched)
#34 (haemorrhage or hemorrhage or bleed*):ti,ab,kw (Word variations have been searched)
#35 (#33 and #34)
#36 MeSH descriptor: [Hemiplegia] this term only
#37 MeSH descriptor: [Brain Injuries] this term only
#38 MeSH descriptor: [Aphasia] explode all trees
#39 MeSH descriptor: [Dysarthria] this term only
#40 MeSH descriptor: [Apraxias] this term only
#41 MeSH descriptor: [Deglutition Disorders] this term only
#42 (hemipleg* or hemipar*):ti,ab,kw (Word variations have been searched)
#43 (aphasi* or dysphasi* or dysarthri* or dysphag* or aprax* or dysprax*):ti,ab,kw (Word variations have been searched)
#44 (swallow* and (impair* or disorder* or problem* or difficult*)):ti,ab,kw (Word variations have been searched)
#45 ("unilateral neglect" or "neglect syndrome*" or "visual neglect" or hemianop*):ti,ab,kw (Word variations have been searched)
#46 (#28 or #29 or #32 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45)
#47 (#27 and #46)

Appendix 3. MEDLINE search strategy

MEDLINE via OVID search strategy

1. exp Stomatognathic diseases/
2. exp Dentistry/
3. oral health/
4. exp oral hygiene/
5. exp Dental Auxiliaries/
6. halitosis/

7. exp Mouth/ph [Physiology]
8. exp digestive system/ph
9. Facial Pain/
10. ((dental or oral or periodontal) and disease\$.tw.
11. ((dental or tooth or teeth) and (caries or decay\$)).tw.
12. gingivitis.tw.
13. (xerostomia or "dry mouth").tw.
14. (oral and (stomatitis or candidiasis)).tw.
15. ((mouth or oral) adj6 (ulcer\$ or apthous or apthae)).tw.
16. ((mouth or dental or oral) and hygiene).tw.
17. (mouth adj4 (odor or odour)).tw.
18. halitosis.tw.
19. (dentist\$ or "dental nurse\$" or "dental therapist\$" or "dental hygienist\$").tw.
20. "dental health educat\$.tw.
21. (dental and (disabled or handicap\$)).tw.
22. ((dental or oral or teeth) adj3 (scaling or prophylaxis)).tw.
23. (mouth and ulcer\$).tw.
24. (mouthwash\$ or mouthrinse\$).tw.
25. (dental and (treatment\$ or care\$)).tw.
26. toothbrush\$.tw.
27. ((plaque or "oral hygiene" or periodontal or DMF) adj (index or indices)).tw.
28. or/1-27
29. exp cerebrovascular disorders/
30. (stroke\$ or cva\$ or cerebrovasc\$ or "cerebral vascular\$" or poststroke or post-stroke).tw.
31. (cerebral or cerebellar or brain\$ or vertebrobasilar).tw.
32. (infarct\$ or isch?emi\$ or thrombo\$ or emboli\$ or apople\$).tw.
33. 31 and 32
34. (cerebral or intracerebral or intracranial or brain\$ or subarachnoid).tw.
35. (haemorrhage or hemorrhage or bleed\$).tw.
36. 34 and 35
37. Brain Injuries/
38. hemiplegia/
39. exp aphasia/ or dysarthria/ or apraxia/ or deglutition disorders/
40. (hemipleg\$ or hemipar\$).tw.
41. (aphasi\$ or dysphasi\$ or dysarthri\$ or dysphag\$ or aprax\$ or dysprax\$).tw.
42. (swallow\$ and (impair\$ or disorder\$ or problem\$ or difficult\$)).tw.
43. ("unilateral neglect" or "neglect syndrome\$" or "visual neglect\$" or hemianop\$).tw.
44. 29 or 30 or 33 or (or/36-43)
45. 28 and 44

Cochrane Search filter for MEDLINE via OVID

Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity maximising version (2009 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

Appendix 4. Embase Ovid search strategy

1. exp mouth disease/
2. exp dentistry/
3. oral health/

4. exp mouth hygiene/
5. dental assistant/
6. exp mouth/
7. digestive system/
8. face pain/
9. ((dental or oral or periodontal) and disease\$.tw.
10. ((dental or tooth or teeth) and (caries or decay\$)).tw.
11. gingivitis.tw.
12. (xerostomia or "dry mouth").tw.
13. (oral and (stomatitis or candidiasis)).tw.
14. ((mouth or oral) adj6 (ulcer\$ or aphthous or aphthae)).tw.
15. ((mouth or dental or oral) and hygiene).tw.
16. (mouth adj4 (odor or odour)).tw.
17. halitosis.tw.
18. (dentist\$ or "dental nurse\$" or "dental therapist\$" or "dental hygienist\$").tw.
19. "dental health educat\$.tw.
20. (dental and (disabled or handicap\$)).tw.
21. ((dental or oral or teeth) adj3 (scaling or prophylaxis)).tw.
22. (mouth and ulcer\$).tw.
23. (mouthwash\$ or mouthrinse\$).tw.
24. (dental and (treatment\$ or care\$)).tw.
25. toothbrush\$.tw.
26. ((plaque or "oral hygiene" or periodontal or DMF) adj (index or indices)).tw.
27. or/1-26
28. exp cerebrovascular disease/
29. (stroke\$ or cva\$ or cerebrovasc\$ or "cerebral vascular\$" or poststroke or post-stroke).tw.
30. (cerebral or cerebellar or brain\$ or vertebrobasilar).tw.
31. (infarct\$ or isch?emi\$ or thrombo\$ or emboli\$ or apople\$).tw.
32. 30 and 31
33. (cerebral or intracerebral or intracranial or brain\$ or subarachnoid).tw.
34. (haemorrhage or hemorrhage or bleed\$).tw.
35. 33 and 34
36. brain injury/
37. hemiplegia/
38. exp aphasia/
39. dysarthria/
40. apraxia/ or "apraxia of speech"/
41. dysphagia/
42. (hemipleg\$ or hemipar\$).tw.
43. (aphasi\$ or dysphasi\$ or dysarthri\$ or dysphag\$ or aprax\$ or dysprax\$).tw.
44. (swallow\$ and (impair\$ or disorder\$ or problem\$ or difficult\$)).tw.
45. ("unilateral neglect" or "neglect syndrome\$" or "visual neglect\$" or hemianop\$).tw.
46. 28 or 29 or 32 or (or/35-45)
47. Randomized Controlled Trial/ or "randomized controlled trial (topic)"/
48. Randomization/
49. Controlled clinical trial/ or "controlled clinical trial (topic)"/
50. control group/ or controlled study/
51. clinical trial/ or "clinical trial (topic)"/ or phase 1 clinical trial/ or phase 2 clinical trial/ or phase 3 clinical trial/ or phase 4 clinical trial/
52. Crossover Procedure/
53. Double Blind Procedure/
54. Single Blind Procedure/ or triple blind procedure/
55. placebo/ or placebo effect/
56. (random\$ or RCT or RCTs).tw.
57. (controlled adj5 (trial\$ or stud\$)).tw.
58. (clinical\$ adj5 trial\$).tw.
59. ((control or treatment or experiment\$ or intervention) adj5 (group\$ or subject\$ or patient\$)).tw.
60. (quasi-random\$ or quasi random\$ or pseudo-random\$ or pseudo random\$).tw.
61. ((control or experiment\$ or conservative) adj5 (treatment or therapy or procedure or manage\$)).tw.
62. ((singl\$ or doubl\$ or tripl\$ or trebl\$) adj5 (blind\$ or mask\$)).tw.
63. (cross-over or cross over or crossover).tw.
64. (placebo\$ or sham).tw.
65. trial.ti.

66. (assign\$ or allocat\$).tw.
67. controls.tw.
68. or/47-67
69. 27 and 46 and 68

Appendix 5. CINAHL search strategy

1. exp stomatognathic diseases/
2. exp dentistry/
3. oral health/
4. exp oral hygiene/
5. mouth care/
6. exp dental auxiliaries/
7. halitosis/
8. exp mouth physiology/
9. exp digestive system physiology/
10. dental hygiene assessment/
11. facial pain/
12. ((dental or oral or periodontal) and disease\$).tw
13. ((dental or tooth or teeth) and (caries or decay\$)).tw
14. gingivitis.tw
15. (xerostomia or dry mouth).tw
16. (oral and (stomatitis or candidiasis)).tw
17. ((mouth or oral) adj6 (ulcer\$ or aphthous or aphthae)).tw
18. ((mouth or dental or oral) and hygiene).tw
19. (mouth adj4 (odor or odour)).tw
20. halitosis.tw
21. (dentist\$ or dental nurse\$ or dental therapist\$ or dental hygienist\$).tw
22. dental health educat\$.tw
23. (dental and (disabled or handicap\$)).tw
24. ((dental or oral or teeth) adj3 (scaling or prophylaxis)).tw
25. (mouth and ulcer\$).tw
26. (mouthwash\$ or mouthrinse\$).tw
27. (dental and (treatment\$ or care\$)).tw
28. toothbrush\$.tw
29. ((plaque or oral hygiene or periodontal or DMF) adj (index or indices)).tw
30. or/1-29
31. exp cerebrovascular disorders/
32. (stroke\$ or cva\$ or cerebrovasc\$ or cerebral vascular\$ or poststroke or post-stroke).tw
33. (cerebral or cerebellar or brain\$ or vertebrobasilar).tw
34. (infarct\$ or isch?emi\$ or thrombo\$ or emboli\$ or apople\$).tw
35. 33 and 34
36. (cerebral or intracerebral or intracranial or brain\$ or subarachnoid).tw
37. (haemorrhage or hemorrhage or bleed\$).tw
38. 36 & 37
39. hemiplegia/ or brain injury/
40. exp aphasia/ or dysarthria/ or apraxia/ or deglutition disorders/
41. (hemipleg\$ or hemipar\$).tw
42. (aphasi\$ or dysphasi\$ or dysarthri\$ or dysphag\$ or aprax\$ or dysprax\$).tw
43. (swallow\$ and (impair\$ or disorder\$ or problem\$ or difficult\$)).tw
44. (unilateral neglect or neglect syndrome\$ or visual neglect or hemianop\$).tw
45. 31 or 32 or 35 or (or/38-44)
46. 30 and 45

Appendix 6. Clinical Trial Register search strategy

- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch)
 - * stroke AND "oral hygiene"
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov)
 - * oral hygiene AND Cerebrovascular Disorders [DISEASE]

Appendix 7. Previous searches from earlier reviews

S1MH "Stomatognathic Diseases+"
S2MH "Dentistry+"
S3MH "Oral Health"
S4MH "Oral Hygiene+"
S5MH "Mouth care"
S6MH "Dental Auxiliaries+"
S7MH "Halitosis"
S8MH "Mouth physiology+"
S9MH "Digestive System Physiology+"
S10MH "Dental Hygiene Assessment"
S11MH "Facial Pain"
S12TI (((dental or oral or periodontal) and disease*)) OR AB (((dental or oral or periodontal) and disease*)))
S13TI (((dental or tooth or teeth) and (caries or decay*))) OR AB (((dental or tooth or teeth) and (caries or decay*)))
S14TI gingivitis OR AB gingivitis
S15TI (xerostomia or "dry mouth") OR AB (xerostomia or "dry mouth")
S16TI ((oral and (stomatitis or candidiasis))) OR AB ((oral and (stomatitis or candidiasis)))
S17TI (((mouth N6 ulcer*) or (mouth N6 aphthous) or (mouth N6 aphthae) or ((oral N6 ulcer*) or (oral N6 aphthous) or (oral N6 aphthae))))
OR AB (((mouth N6 ulcer*) or (mouth N6 aphthous) or (mouth N6 aphthae) or ((oral N6 ulcer*) or (oral N6 aphthous) or (oral N6 aphthae))))
S18TI (((mouth or dental or oral) and hygiene)) OR AB (((mouth or dental or oral) and hygiene))
S19TI ((mouth N4 odor) or (mouth N4 odour)) OR AB ((mouth N4 odor) or (mouth N4 odour))
S20TI halitosis OR AB halitosis
S21TI ((dentist* or "dental nurse*" or "dental therapist*" or "dental hygienist*")) OR AB ((dentist* or "dental nurse*" or "dental therapist*" or "dental hygienist*"))
S22TI ("dental health educat*") OR AB ("dental health educat*")
S23TI ((dental and (disabled or handicap*))) OR AB ((dental and (disabled or handicap*)))
S24TI (((dental N3 scaling) or (dental N3 prophylaxis)) or ((oral N3 scaling) or (oral N3 prophylaxis)) or ((teeth N3 scaling) or (teeth N3 prophylaxis))) OR AB (((dental N3 scaling) or (dental N3 prophylaxis)) or ((oral N3 scaling) or (oral N3 prophylaxis)) or ((teeth N3 scaling) or (teeth N3 prophylaxis)))
S25TI (((mouth and ulcer*) or ((oral N3 scaling) or (oral N3 prophylaxis)) or ((teeth N3 scaling) or (teeth N3 prophylaxis))) OR AB (((mouth and ulcer*) or ((oral N3 scaling) or (oral N3 prophylaxis)) or ((teeth N3 scaling) or (teeth N3 prophylaxis)))
S26TI ((mouthwash* or mouthrinse*)) OR AB ((mouthwash* or mouthrinse*))
S27TI ((dental and (treatment* or care*))) OR AB ((dental and (treatment* or care*)))
S28TI toothbrush* OR AB toothbrush*
S29TI (((plaque N1 index) or (plaque N1 indices)) or (("oral hygiene" N1 index) or ("oral hygiene" N1 indices)) or ((periodontal N1 index) or (periodontal N1 indices)) or ((DMF N1 index) or (DMF N1 indices))) OR AB (((plaque N1 index) or (plaque N1 indices)) or (("oral hygiene" N1 index) or ("oral hygiene" N1 indices)) or ((periodontal N1 index) or (periodontal N1 indices)) or ((DMF N1 index) or (DMF N1 indices)))
S30S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29
S31MH "Cerebrovascular disorders+"
S32TI ((stroke* or cva* or cerebrovasc* or "cerebral vascular*" or poststroke or post-stroke)) OR AB ((stroke* or cva* or cerebrovasc* or "cerebral vascular*" or poststroke or post-stroke))
S33TI ((cerebral or cerebellar or brain* or vertebrobasilar)) OR AB ((cerebral or cerebellar or brain* or vertebrobasilar))
S34TI ((infarct* or isch?emi* or thrombo* or emboli* or apople*)) OR AB ((infarct* or isch?emi* or thrombo* or emboli* or apople*))
S35 S33 AND S34
S36TI ((cerebral or intracerebral or intracranial or brain* or subarachnoid)) OR AB ((cerebral or intracerebral or intracranial or brain* or subarachnoid))
S37TI ((haemorrhage or hemorrhage or bleed*)) OR AB ((haemorrhage or hemorrhage or bleed*))
S38 S36 and S37
S39MH "Hemiplegia" or MH "Brain Injury"
S40MH "Aphasia+" or MH "dysarthria" or MH "Apraxia" or MH "Deglutition Disorders"
S41 TI (hemipleg* or hemipar*) OR AB (hemipleg* or hemipar*)
S42 TI ((aphasi* or dysphasi* or dysarthri* or dysphag* or aprax* or dysprax*)) OR AB ((aphasi* or dysphasi* or dysarthri* or dysphag* or aprax* or dysprax*))
S43 TI ((swallow* and (impair* or disorder* or problem* or difficult*))) OR AB ((swallow* and (impair* or disorder* or problem* or difficult*)))
Interface - EBSCOhost Research Databases
S44 TI (("unilateral neglect" or "neglect syndrome*" or "visual neglect" or hemianop*)) OR AB (("unilateral neglect" or "neglect syndrome*" or "visual neglect" or hemianop*))
S45 S31 or S32 or S35 or S38 or S39 or S40 or S41 or S42 or S43 or S44

The above subject search was linked to the following filter for CINAHL via EBSCO

S1 MH Random Assignment or MH Single-blind Studies or MH Double-blind Studies or MH Triple-blind Studies or MH Crossover design or MH Factorial Design
S2 TI ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or AB ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study") or SU ("multicentre study" or "multicenter study" or "multi-centre study" or "multi-center study")
S3 TI random* or AB random*
S4 AB "latin square" or TI "latin square"
S5 TI (crossover or cross-over) or AB (crossover or cross-over) or SU (crossover or cross-over)
S6 MH Placebos
S7 AB (singl* or doubl* or trebl* or tripl*) or TI (singl* or doubl* or trebl* or tripl*)
S8 TI blind* or AB mask* or AB blind* or TI mask*
S9 S7 and S8
S10 TI Placebo* or AB Placebo* or SU Placebo*
S11 MH Clinical Trials
S12 TI (Clinical AND Trial) or AB (Clinical AND Trial) or SU (Clinical AND Trial)
S13 S1 or S2 or S3 or S4 or S5 or S6 or S9 or S10 or S11 or S12

Prepared by: Anne Littlewood, Cochrane Information Specialist, Cochrane Oral Health Group

Appendix 8. Additional searches

In an effort to identify further published, unpublished and ongoing studies we searched IWeb of Science Conference Proceedings Citation Index-Science (last searched 25 February 2019), Zetoc (last searched 25 February 2019) and Proquest Dissertations and Theses (last searched 25 February 2019) using the following key terms: stroke AND (oral hygiene OR oral health).

WHAT'S NEW

Date	Event	Description
18 February 2019	New citation required but conclusions have not changed	Conclusions not changed. Changes to authorship.
18 February 2019	New search has been performed	<p>The review was updated using a revised and updated search strategy (including more databases) completed in February 2019. The review now includes 15 studies (22 randomised paired comparisons), 3631 participants of whom 1546 participants were stroke survivors); the previous review only included three studies.</p> <p>We extracted more information on the interventions used in each of the trials using the TIDIER checklist and provided this additional information in the 'Characteristics of included studies' table.</p> <p>We presented three new 'Summary of findings' tables.</p>

HISTORY

Protocol first published: Issue 4, 2002

Review first published: Issue 4, 2006

Date	Event	Description
7 June 2011	Amended	Page number added to Frenkel reference and risk of bias terminology updated but no change to overall assessments
26 October 2010	New search has been performed	We updated the searches to May 2010. We have included two new studies, bringing the total of included studies to three, in-

Date	Event	Description
		volving 470 participants. The conclusions of the review have not changed.
2 October 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

PC conducted the searches for 2019 update, screened retrieved references for inclusion or exclusion, extracted the data from included trials, evaluated methodological quality, entered data, conducted data analysis and drafted the review.

BB screened retrieved references for inclusion or exclusion, extracted data from included trials and commented on review drafts.

DF conducted the earlier searches, screened retrieved references for inclusion or exclusion, extracted the data from included trials, evaluated methodological quality, contacted trial authors, entered data, conducted data analysis and drafted the review.

MB updated the search, screened retrieved references for inclusion or exclusion, extracted the data from included trials, evaluated methodological quality, entered data, conducted data analysis and drafted the review.

DECLARATIONS OF INTEREST

PC: none.

BB: has been involved in one trial included in this review (see [SOCLE II](#)), but was not involved in the assessment or interpretation of this trial.

DF: none.

MB: has been involved in one trial included in this review (see [SOCLE II](#)), but was not involved in the assessment or interpretation of this trial.

SOURCES OF SUPPORT

Internal sources

- Nursing, Midwifery and Allied Health Professions Research Unit, UK

External sources

- Chief Scientist Office, Scottish Government Health Directorate, UK

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

2006 review

- It was necessary to reduce the number of primary outcomes identified within the protocol to two because of the Cochrane Stroke Group guidelines. We originally listed gingivitis as a primary outcome, but on reflection it was more appropriate to include it as an oral disease outcome, together with denture-induced stomatitis and periodontal disease. We acknowledge that making this post-hoc change following publication of the protocol may lead to bias.

2019 review update

- The review team decided to amend the title of the review from 'Staff-led interventions for improving oral hygiene in patients following stroke' to 'Interventions for improving oral health in people after stroke'. The decision was made to improve the accessibility of the review by employing more relevant international terms.
- We have included trials with secondary outcomes that present data for knowledge and attitudes for stroke survivors and providers, not only on staff oral health knowledge and attitudes. Increasing fiscal constraints in health care means that many family members and informal carers are now assuming responsibility for supporting people with their oral health. Furthermore, recent Royal College of Physicians guidelines specifically state that "People with stroke and their family/carers should receive information and training in mouth care and maintaining good oral hygiene before transfer of their care from hospital" ([RCP 2016](#)).

INDEX TERMS

Medical Subject Headings (MeSH)

*Caregivers; *Health Education, Dental; Health Knowledge, Attitudes, Practice; Nursing Homes; Oral Hygiene [*methods]; Randomized Controlled Trials as Topic; Stroke [*nursing]

MeSH check words

Humans