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## Aural toilet (ear cleaning) for chronic suppurative otitis media (Review)

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[Intervention Review]

# Aural toilet (ear cleaning) for chronic suppurative otitis media

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## ABSTRACT

### Background

Chronic suppurative otitis media (CSOM), sometimes referred to as chronic otitis media (COM), is a chronic inflammation and often polymicrobial infection (involving more than one micro-organism) of the middle ear and mastoid cavity, characterised by ear discharge (otorrhoea) through a perforated tympanic membrane. The predominant symptoms of CSOM are ear discharge and hearing loss.

Aural toileting is a term describing a number of processes for manually cleaning the ear. Techniques used may include dry mopping (with cotton wool or tissue paper), suction clearance (typically under a microscope) or irrigation (using manual or automated syringing). Dry mopping may be effective in removing mucopurulent discharge. Compared to irrigation or microsuction it is less effective in removing epithelial debris or thick pus. Aural toileting can be used alone or in addition to other treatments for CSOM, such as antibiotics or topical antiseptics.

### Objectives

To assess the effects of aural toilet procedures for people with CSOM.

### Search methods

The Cochrane ENT Information Specialist searched the Cochrane ENT Register; Central Register of Controlled Trials (CENTRAL via the Cochrane Register of Studies); Ovid MEDLINE; Ovid Embase; CINAHL; Web of Science; ClinicalTrials.gov; ICTRP and additional sources for published and unpublished trials. The date of the search was 16 March 2020.

### Selection criteria

We included randomised controlled trials (RCTs) with at least a one-week follow-up involving people (adults and children) who had chronic ear discharge of unknown cause or CSOM, where the ear discharge had continued for more than two weeks.

We included any aural toileting method as the intervention, at any frequency and for any duration. The comparisons were aural toileting compared with a) placebo or no intervention, and b) any other aural toileting method. We analysed trials in which background treatments were used in both arms (e.g. topical antiseptics or topical antibiotics) separately.

### Data collection and analysis

We used the standard Cochrane methodological procedures. We used GRADE to assess the certainty of the evidence for each outcome.

Our primary outcomes were: resolution of ear discharge or 'dry ear' (whether otoscopically confirmed or not), measured at between one week and up to two weeks, two weeks to up to four weeks, and after four weeks; health-related quality of life using a validated instrument; and ear pain (otalgia) or discomfort or local irritation. Secondary outcomes were hearing, serious complications, and the adverse events of ear bleeding and dizziness/vertigo/balance problems.

### Main results

We included three studies with a total of 431 participants (465 ears), reporting on two comparisons. Two studies included only children with CSOM in the community (351 participants) and the other study (80 participants) included children and adults with chronic ear discharge for at least six weeks. None of the included studies reported the outcomes of health-related quality of life, ear pain or the adverse event of ear bleeding.

### Daily aural toileting (dry mopping) versus no treatment

Two studies (351 children; 370 ears) compared daily dry mopping with no treatment. Neither study presented results for resolution of ear discharge at between one and up to two weeks or between two to four weeks. For resolution of ear discharge after four weeks, one study reported the results per person. We are very uncertain whether there is a difference at 16 weeks (risk ratio (RR) 1.01, 95% confidence interval (CI) 0.60 to 1.72; 1 study; 217 participants) because the certainty of the evidence is very low.

No results were reported for the adverse events of dizziness, vertigo or balance problems. Only one study reported serious complications, but it was not clear which group these patients were from, or whether the complications occurred pre- or post-treatment. One study reported hearing, but the results were presented by treatment outcome rather than by treatment group so it is not possible to determine whether there is a difference between the two groups.

### Daily aural toileting versus single aural toileting on top of topical ciprofloxacin

One study (80 participants; 95 ears) compared daily aural toileting (suction) with administration of topical antibiotic (ciprofloxacin) ear drops in a clinic, to a single aural toileting (suction) episode followed by daily self-administered topical antibiotic drops, in participants of all ages. We are unsure whether there is a difference in resolution of ear discharge at between one and up to two weeks (RR 1.09, 95% CI 0.91 to 1.30; 1 study; 80 participants) because the certainty of the evidence is very low. There were no results reported for resolution of ear discharge at between two to four weeks. The results for resolution of ear discharge after four weeks were presented by ear, not person, and could not be adjusted to by person. One patient in the group with single aural toileting and self administration of topical antibiotic ear drops reported the adverse event of dizziness, which the authors attributed to the use of cold topical ciprofloxacin. It is very uncertain whether there is a difference between the groups (RR 0.33, 95% CI 0.01 to 7.95; 1 study; 80 participants, very low-certainty). No results were reported for the other adverse events of vertigo or balance problems, or for serious complications. The authors only reported qualitatively that there was no difference between the two groups in hearing results (very low-certainty).

### Authors' conclusions

We are very uncertain whether or not treatment with aural toileting is effective in resolving ear discharge in people with CSOM, due to a lack of data and the poor quality of the available evidence. We also remain uncertain about other outcomes, including adverse events, as these were not well reported. Similarly, we are very uncertain whether daily suction clearance, followed by antibiotic ear drops administered at a clinic, is better than a single episode of suction clearance followed by self-administration of topical antibiotic ear drops.

## PLAIN LANGUAGE SUMMARY

### Benefits and risks of ear cleaning for people with chronic suppurative otitis media (persistent or recurring ear infection with discharge of pus)

#### Why this is important

Chronic suppurative otitis media (CSOM), also known as chronic otitis media (COM), is an inflammation and infection of the middle ear that lasts for two weeks or more. People with CSOM usually experience recurrent or persistent ear discharge – pus that leaks out from a hole in the eardrum – and hearing loss.

Different approaches can be used to clean the affected ears and remove discharge. These include:

- using cotton wool or tissue paper (dry mopping);
- sucking up material blocking the ear with a small device (usually done under a microscope); or
- washing out the ear (irrigation).

To find out how effective ear cleaning is in people with CSOM, and whether it causes unwanted effects, we reviewed the evidence from research studies. In particular, we wanted to know whether ear cleaning stopped ear discharge, and whether it affected health-related quality of life, or hearing. We also wanted to know if it caused pain, discomfort or irritation in the ear, unwanted effects such as dizziness or ear bleeding, or any serious complications.

## How we identified and assessed the evidence

First, we searched for all relevant studies in the medical literature. We then compared the results, and summarised the evidence from all the studies. Finally, we assessed how certain the evidence was. We considered factors such as the way studies were conducted, study sizes and consistency of findings across studies. Based on our assessments, we categorised the evidence as being of very low, low, moderate or high certainty.

## What we found

We found three studies in 431 people with CSOM. People were followed for between six weeks and six months after treatment.

The studies compared:

- daily dry mopping versus no treatment (two studies, 351 people);
- daily suction combined with antibiotic ear drops administered in a clinic, versus one instance of suction only (in a clinic) followed by daily self-administered antibiotic ear drops (one study, 80 people).

### *Daily dry mopping compared against no treatment*

- We do not know whether dry mopping stops ear discharge, because the evidence on whether people experienced discharge after four weeks was of very low certainty, and no studies looked at the presence of discharge earlier.
- One study reported serious complications, but it was not clear whether the people who reported complications had their ears cleaned with dry mopping or not, or whether the complications occurred before or after treatment. We therefore could not tell whether dry mopping caused serious complications, or how often these occurred.
- One study looked at hearing, but did not report the results in a way that could tell us whether or not dry mopping affects hearing.
- No studies investigated the impact of dry mopping on health-related quality of life, ear pain, dizziness or ear bleeding.

### *Daily suction compared against one instance of suction only, in addition to antibiotic ear drops*

- We do not know whether suction stops ear discharge, because the evidence for between one and two weeks after treatment was of very low certainty, and the results for discharge after four weeks could not be interpreted.
- We do not know if suction affects hearing or dizziness, as the evidence was of very low certainty.
- No studies investigated the impact of suction on health-related quality of life, ear pain, serious complications or ear bleeding.

## What this means

We do not know how effective ear cleaning is for people with CSOM, and whether it causes unwanted effects. There are very few studies in this area, and these provide very low-certainty evidence. Unwanted effects were not well reported in the studies we found. We need researchers to conduct future studies that compare ear cleaning to no cleaning, and compare different cleaning techniques and frequency, so that we can assess the benefits and risks of ear cleaning for people with CSOM.

## How-up-to date is this review?

The evidence in this Cochrane Review is current to March 2020.

## SUMMARY OF FINDINGS

### Summary of findings 1. Aural toileting compared to no aural toileting for chronic suppurative otitis media

#### Aural toileting compared to no aural toileting for chronic suppurative otitis media

**Patient or population:** children with chronic suppurative otitis media

**Setting:** community setting

**Intervention:** aural toileting (dry mopping)

**Comparison:** no aural toileting (no specific treatment)

| Outcomes   | Relative effect (95% CI)   | Number of participants (studies) | Anticipated absolute effects* (95% CI)  |                      |                                    | Certainty of the evidence (GRADE)    | What happens   |
|--|--|----------------------------------|---|----------------------|------------------------------------|--------------------------------------|--|
|  |  |                                  | Without aural toileting   | With aural toileting | Difference                         |                                      |  |
| Resolution of ear discharge - 1 to 2 weeks           | No study reported this outcome at this time point.   |                                  |   |                      |                                    |                                      |  |
| Resolution of ear discharge - 4 weeks or more        | RR 1.01 (0.60 to 1.72)   | 217 (1 RCT)                      | Study population  |                      |                                    | ⊕⊕⊕⊕<br><b>very low</b> <sup>1</sup> | We are uncertain about the effect of aural toileting on resolution of ear discharge (at 4 weeks or more) compared with no treatment. |
| Assessed by: otoscopically confirmed                 |  |                                  | 22.2%   | 22.4% (13.3 to 38.2) | 0.2% more (8.9 fewer to 16.0 more) |                                      |  |
| Follow-up: 16 weeks                                  |  |                                  |   |                      |                                    |                                      |  |
| Health-related quality of life                       | No study reported this outcome.  |                                  |   |                      |                                    |                                      |  |
| Ear pain (otalgia) or discomfort or local irritation | No study reported this outcome.  |                                  |   |                      |                                    |                                      |  |
| Hearing  | Hearing was measured in one study but the results were presented by treatment outcome rather than by treatment group, so it is not possible to determine whether there is a difference between the two groups. |                                  |   |                      |                                    |                                      |  |
| Serious complications                                | —  | 48 (1 RCT)                       | One study reported one case of mastoiditis and one case of meningitis with focal encephalitis. It is not clear which group these patients were from (the study was a five-arm trial of which only two arms are presented here), or whether the complications occurred pre- or post-treatment. |                      |                                    | ⊕⊕⊕⊕<br><b>very low</b> <sup>2</sup> | We are very uncertain about the effect of aural toileting on serious complications compared with no treatment.                       |

Adverse events: dizziness/vertigo/balance problems

No study reported this outcome.

\***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **RCT:** randomised control trial; **RR:** risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

**Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

<sup>1</sup>Downgraded to very low certainty: downgraded by one level due to study limitations (risk of bias) because there was unclear allocation concealment, attrition bias and selective reporting bias. Downgraded by one level for indirectness (only children were included in the study). Downgraded by two levels for imprecision (as the results are based on one small study with wide confidence intervals). Downgraded by one level for suspected publication bias (this area has a known issue with trials not being published in peer-reviewed journals).

<sup>2</sup>Downgraded to very low certainty: downgraded by one level due to study limitations (risk of bias) because it was at high risk of bias for randomisation and was at unclear risk of bias for allocation concealment, attrition bias and selective reporting bias. The study was unblinded. Downgraded by one level for indirectness (only children were included in the study). Downgraded by two levels for imprecision as it was not clear to which group the events could be attributed. Downgraded by one level for suspected publication bias (this area has a known issue with trials not being published in peer-reviewed journals).

## Summary of findings 2. Daily aural toileting compared to single aural toileting episode for chronic suppurative otitis media

### Daily aural toileting compared to single aural toileting episode for chronic suppurative otitis media

**Patient or population:** people (of any age) with otorrhoea for a duration of at least 6 weeks

**Setting:** ENT clinic (Turkey)

**Intervention:** daily external ear channel aspiration and topical antibiotics

**Comparison:** single episode of external ear channel aspiration at first visit and topical antibiotics

| Outcomes                                   | Relative effect (95% CI) | Number of participants (studies) | Anticipated absolute effects* (95% CI) |                       |            | Certainty of the evidence (GRADE)    | What happens  |
|--|--------------------------|----------------------------------|--|-----------------------|------------|--------------------------------------|---|
|  |                          |                                  | Single aural toileting                 | Daily aural toileting | Difference |                                      |   |
| Resolution of ear discharge - 1 to 2 weeks | RR 1.09, (0.91 to 1.30)  | 80 (1 RCT)                       | Study population                       |                       |            | ⊕○○○<br><b>very low</b> <sup>1</sup> | We are uncertain about the effect of daily aural toileting on resolution of ear discharge (at 1 |
|  |                          |                                  | 82.5%                                  | 89.9%                 | 7.4% more  |                                      |   |

|   |   |               |  |                                      |  |
|---|---|---------------|--|--------------------------------------|--|
| Assessed by: unknown - unclear if otoscopically confirmed |   | (75.1 to 100) | (7.4% fewer to 17.5% more)   |                                      | to 2 weeks) compared with single episode of aural toileting.   |
| Resolution of ear discharge - 4 weeks or more             | Kiris 1998 provided results for this outcome by ear, but the results could not be adjusted to provide results per person. |               |  |                                      |  |
| Assessed by: unknown - unclear if otoscopically confirmed |   |               |  |                                      |  |
| Follow-up: 3 months                                       |   |               |  |                                      |  |
| Health-related quality of life                            | No study reported this outcome.   |               |  |                                      |  |
| Ear pain (otalgia) or discomfort or local irritation      | No study reported this outcome.   |               |  |                                      |  |
| Hearing   | —   | 80<br>(1 RCT) | Results were only reported qualitatively, the report stating that "there were no differences in pre- and post audiographic results or bone conduction in either group ..." | ⊕○○○<br><b>very low</b> <sup>2</sup> | We are uncertain about the effect of daily aural toileting on hearing compared with a single episode of aural toileting.   |
| Serious complications                                     | The study did not report that any participant died or had any intracranial or extracranial complications.                 |               |  |                                      |  |
| Adverse events: dizziness                                 | RR 0.33, (0.01 to 7.95)   | 80<br>(1 RCT) | Study population   | ⊕○○○<br><b>very low</b> <sup>3</sup> | We are uncertain about the effect of daily aural toileting on dizziness compared with a single episode of aural toileting. |
| Assessed by: self reported                                |   |               | 2.5%   | 0.8%                                 | 1.7% less  |
| Follow-up: 15 days  |   |               | (0% to 19.9%)  | (2.5% fewer to 17.4% more)           |  |

\***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** confidence interval; **RCT:** randomised control trial; **RR:** risk ratio

#### GRADE Working Group grades of evidence

**High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

**Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect



- <sup>1</sup>Downgraded to very low certainty: downgraded by two levels due to risk of bias (unclear randomisation, allocation concealment, unblinded trial and possible selective reporting). Downgraded by one level due to indirectness: the population is people with otorrhoea for more than six weeks so it is unclear if all included patients had CSOM. Downgraded by one level due to imprecision: the results are from one small study so the confidence intervals are wide.
- <sup>2</sup>Downgraded to very low certainty: downgraded by two levels due to risk of bias (unclear randomisation, allocation concealment, unblinded trial and possible selective reporting). Downgraded by one level due to indirectness: the population is those with otorrhoea so it is unclear if all included patients had CSOM. Downgraded by two levels due to imprecision: the results are from one small study and only reported qualitatively.
- <sup>3</sup>Downgraded to very low certainty: downgraded by two levels due to risk of bias (unclear randomisation, allocation concealment, unblinded trial and possible selective reporting). Downgraded by one level due to indirectness: the population is those with otorrhoea so it is unclear if all included patients had CSOM. Downgraded by two levels due to imprecision: the results are from one small study and only one event was reported resulting in very wide confidence intervals.

## BACKGROUND

This is one of a suite of Cochrane Reviews evaluating the comparative effectiveness of non-surgical interventions for CSOM using topical antibiotics, topical antibiotics with corticosteroids, systemic antibiotics, topical antiseptics and aural toileting (ear cleaning) methods (Table 1).

This review compares the effectiveness of aural toileting (ear cleaning) against other methods of aural toileting or placebo/no treatment for CSOM.

### Description of the condition

Chronic suppurative otitis media (CSOM), which is also often referred to as chronic otitis media (COM), is a chronic inflammation and infection of the middle ear and mastoid cavity, characterised by ear discharge (otorrhoea) through a perforated tympanic membrane.

The predominant symptoms of CSOM are ear discharge and hearing loss. Ear discharge can be persistent or intermittent, and many sufferers find it socially embarrassing (Orji 2013). Some patients also experience discomfort or earache. Most patients with CSOM experience temporary or permanent hearing loss with average hearing levels typically between 10 and 40 decibels (Jensen 2013). The hearing loss can be disabling, and it can have an impact on speech and language skills, employment prospects, and on children's psychosocial and cognitive development, including academic performance (Elemraid 2010; Olatoke 2008; WHO 2004). Consequently, quality of life can be affected. CSOM can also progress to serious complications in rare cases (and more often when cholesteatoma is present): both extracranial complications (such as mastoid abscess, postauricular fistula and facial palsy) and intracranial complications (such as otitic meningitis, lateral sinus thrombosis and cerebellar abscess) have been reported (Dubey 2007; Yorgancilar 2013).

CSOM is estimated to have a global incidence of 31 million episodes per year, or 4.8 new episodes per 1000 people (all ages), with 22% of cases affecting children under five years of age (Monasta 2012; Schilder 2016). The prevalence of CSOM varies widely between countries, but it disproportionately affects people at socio-economic disadvantage. It is rare in high-income countries, but common in many low- and middle-income countries (Mahadevan 2012; Monasta 2012; Schilder 2016; WHO 2004).

### Definition of disease

There is no universally accepted definition of CSOM. Some define CSOM in patients with a duration of otorrhoea of more than two weeks but others may consider this an insufficient duration, preferring a minimum duration of six weeks or more than three months (Verhoeff 2006). Some include diseases of the tympanic membrane within the definition of CSOM, such as tympanic perforation without a history of recent ear discharge, or the disease cholesteatoma (a growth of the squamous epithelium of the tympanic membrane).

In accordance with a consensus statement, here we use CSOM only to refer to tympanic membrane perforation, with intermittent or continuous ear discharge (Gates 2002). We have used a duration of otorrhoea of two weeks as an inclusion criterion, in accordance with the definition used by the World Health Organization, but we

have used subgroup analyses to explore whether this is a factor that affects observed treatment effectiveness (WHO 2004).

Many people affected by CSOM do not have good access to modern primary healthcare, let alone specialised ear and hearing care, and in such settings, health workers may be unable to view the tympanic membrane to definitively diagnose CSOM. It can also be difficult to view the tympanic membrane when the ear discharge is profuse. Therefore, we have also included, as a subset for analysis, studies where participants have had chronic ear discharge for at least two weeks, but where the diagnosis is unknown.

### At-risk populations

Some populations are considered to be at high risk of CSOM. There is a high prevalence of disease among Indigenous people such as the Aboriginal and Torres Strait Islander Australian, Native American and Inuit populations. This is likely due to an interplay of factors, including socio-economic deprivation and possibly differences resulting from population genetics (Bhutta 2016). Those with primary or secondary immunodeficiency are also susceptible to CSOM. Children with craniofacial malformation (including cleft palate) or chromosomal mutations such as Down syndrome are prone to chronic non-suppurative otitis media ('glue ear'), and by extrapolation may also be at greater risk of suppurative otitis media. The reasons for this association with craniofacial malformation are not well understood, but may include altered function of the Eustachian tube, coexistent immunodeficiency, or both. These populations may be less responsive to treatment and more likely to develop CSOM, recurrence or complications.

Children who have a grommet (ventilation tube) in the tympanic membrane to treat glue ear or recurrent acute otitis media may be more prone to develop CSOM; however, their pathway to CSOM may differ and therefore they may respond differently to treatment. Children with grommets who have chronic ear discharge meeting the CSOM criteria are therefore considered to be a separate high-risk subgroup (van der Veen 2006).

### Treatment

Treatments for CSOM may include topical antibiotics (administered into the ear) with or without steroids, systemic antibiotics (given either by mouth or by injection), topical antiseptics and ear cleaning (aural toileting), all of which can be used on their own or in various combinations. Whereas primary healthcare workers or patients themselves can deliver some treatments (for example, some aural toileting and antiseptic washouts), in most countries antibiotic therapy requires prescription by a doctor. Surgical interventions are an option in cases where complications arise or in patients who have not responded to pharmacological treatment; however, there is a range of practice in terms of the type of surgical intervention that should be considered and the timing of the intervention. In addition, access to or availability of surgical interventions is setting-dependent. This series of Cochrane Reviews therefore focuses on non-surgical interventions. In addition, most clinicians consider cholesteatoma to be a variant of CSOM, but acknowledge that it will not respond to non-surgical treatment (or will only respond temporarily) (Bhutta 2011). Therefore, studies in which more than half of the participants were identified as having cholesteatoma are not included in these reviews.

## Description of the intervention

Aural toileting is an umbrella term used to describe the process of manually cleaning the ear. Techniques used may include dry mopping ('wicking', with cotton wool or tissue paper), suction clearance (typically under a microscope) or irrigation (using manual or automated syringing). Dry mopping may be effective in removing mucopurulent discharge, but less effective in removing epithelial debris or thick pus compared to irrigation or microsuction. Aural toileting can be used alone or in addition to other treatments for CSOM, such as antibiotics or topical antiseptics.

The technique and frequency of toileting may have an impact on its effectiveness. It is possible that dry mopping in the community is more effective because it can be delivered frequently, or it may be that less frequent suctioning by a specialist using a microscope is more effective because debris and pus are comprehensively removed. For these reasons, we considered the different aural toileting methods as separate subgroups and pooling only occurred if there was no evidence of a difference in effect.

## How the intervention might work

In aural toileting the ear canal is manually cleaned to remove the pathogenic bacteria and inflammatory mediators that contribute to inflammation, which allows the tympanic membrane to be visualised for diagnosis and facilitates the delivery of topical interventions such as antibiotics or antiseptics to the target area to improve their effectiveness.

There have been reports of pain, bleeding and dizziness and/or vertigo with aural toileting (Addams-Williams 2010; Gray 1988). With suction techniques there is also the potential for noise-induced hearing loss, although no lasting effects have been observed (Addams-Williams 2010).

## Why it is important to do this review

Aural toileting is often used prior to other interventions such as topical antiseptics or antibiotics, but it is not known what role aural toileting alone plays in disease resolution or whether there are important differences in the effectiveness of different techniques. In addition, the use of aural toileting may influence clinical decisions regarding which other treatments to use (for example, systemic or topical treatment). Therefore the effectiveness of aural toilet as an adjunctive treatment is also an important question. Aural toileting is a potentially low-cost treatment that is accessible in most settings; it is even possible to perform some forms of aural toileting such as dry mopping without medical support. The effectiveness of such interventions thus has implications for how and where treatment for CSOM is provided.

## OBJECTIVES

To assess the effects of aural toilet procedures for people with chronic suppurative otitis media.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included studies with the following design characteristics:

- Randomised controlled trials (including cluster-randomised trials where the unit of randomisation is the setting or operator) and quasi-randomised trials.
- Patients were followed up for at least one week.

We excluded studies with the following design characteristics:

- Cross-over trials, because CSOM is not expected to be a stable chronic condition. Unless data from the first phase were available, we excluded such studies.

#### Types of participants

We included studies with patients (adults and children) who had:

- chronic ear discharge of unknown cause; or
- chronic suppurative otitis media.

We defined patients with chronic ear discharge as patients with at least two weeks of ear discharge, where the cause of the discharge was unknown.

We defined patients with chronic suppurative otitis media (CSOM) as patients with:

- chronic or persistent ear discharge for at least two weeks; and
- a perforated tympanic membrane.

We did **not exclude** any populations based on age, risk factors (cleft palate, Down syndrome), ethnicity (e.g. Australian Aboriginal or Torres Strait Islanders) or the presence of ventilation tubes (grommets). Where available, we recorded these factors in the patient characteristics section during data extraction from the studies. If any of the included studies recruited these patients as a majority (80% or more), we analysed them in a subgroup analysis (see [Subgroup analysis and investigation of heterogeneity](#)).

We **excluded** studies where the majority (more than 50%) of participants:

- had an alternative diagnosis to CSOM (e.g. otitis externa);
- had underlying cholesteatoma;
- had ear surgery within the last six weeks.

We did not include studies designed to evaluate interventions in the immediate peri-surgical period, which were focused on assessing the impact of the intervention on the surgical procedure or outcomes.

#### Types of interventions

##### Intervention

All aural toileting methods, frequencies and durations, including but not limited to the following:

- Dry mopping ('wicking'): with cotton bud; Jobson-Horne or other ear probe wrapped in cotton wool; or tissue spears (rolled up tissue papers).
- Irrigation of the external auditory canal using a syringe or similar device. Different solutions (antiseptics versus normal water/saline) and types of irrigation instrument (e.g. manual syringe versus automated irrigation) have been described. Irrigation may be followed by dry mopping or vice versa.
- Microsuction of the external auditory canal to remove discharge.

## Comparisons

The following were the comparators:

- Placebo, no treatment.
- Another method of aural toileting.

There were three potential scenarios for analysis:

- **Aural toileting as a stand-alone treatment:** studies where all participants received no additional treatment or another form of aural toileting (e.g. a study comparing microsuction plus daily dry mopping versus daily dry mopping).
- **Aural toileting as an add-on to antiseptics:** this included studies where all participants also used a daily antiseptic, with or without any other form of aural toileting procedure different to the aural toileting procedure under investigation (for example, daily microsuction plus boric acid ear drops plus dry mopping *versus* daily boric acid ear drops plus dry mopping)
- **Aural toileting as an add-on to topical/systemic antibiotics:** studies where all participants received topical or systemic antibiotics, with or without another form of aural toileting or antiseptics which was a different type to the aural toileting procedure under investigation (for example, daily microsuction plus topical ciprofloxacin ear drops plus dry mopping *versus* daily topical ciprofloxacin plus dry mopping)

Many comparison pairs were possible in this review. The main comparisons of interest that we have summarised and presented in the 'Summary of findings' tables are:

- aural toileting as a main (single) therapy versus placebo or no intervention;
- aural toileting versus placebo or no intervention, where both arms also received topical antibiotics and/or systemic antibiotics as an add-on therapy; and
- aural toileting versus placebo or no intervention, where both arms also received topical antiseptics as an add-on therapy.

## Types of outcome measures

We analysed the following outcomes in the review, but we did not use them as a basis for including or excluding studies.

We extracted and reported data from the longest available follow-up for all outcomes.

## Primary outcomes

- Resolution of ear discharge or 'dry ear' (whether otoscopically confirmed or not), measured at:
  - \* between one week and up to two weeks;
  - \* two weeks to up to four weeks; and
  - \* after four weeks.
- Health-related quality of life using a validated instrument for CSOM (e.g. Chronic Otitis Media Outcome Test (COMOT)-12 (Phillips 2014a; Phillips 2014b; van Dinther 2015), Chronic Otitis Media Outcome Test (COMOT)-15 (Baumann 2011), Chronic Ear Survey (CES) (Nadol 2000).
- Ear pain (otalgia) or discomfort or local irritation.

## Secondary outcomes

- Hearing, measured as the pure-tone average of air conduction thresholds across four frequencies tested (500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) of the affected ear. If this was not available, we reported the pure-tone average of the thresholds measured.
- Serious complications, including intracranial complications (such as otitic meningitis, lateral sinus thrombosis and cerebellar abscess) and extracranial complications (such as mastoid abscess, postauricular fistula and facial palsy), and death.
- Adverse events: dizziness/vertigo/balance problems.
- Adverse events: ear bleeding.

## Search methods for identification of studies

The Cochrane ENT Information Specialist conducted systematic searches for randomised controlled trials and controlled clinical trials. There were no language, publication year or publication status restrictions. The date of the search was 16 March 2020.

## Electronic searches

The Information Specialist searched:

- the Cochrane ENT Register (searched via the Cochrane Register of Studies to 16 March 2020);
- the Cochrane Central Register of Controlled Trials (CENTRAL) (searched via the Cochrane Register of Studies Web to 16 March 2020);
- Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) (1946 to 16 March 2020);
- Ovid EMBASE (1974 to 16 March 2020);
- EBSCO CINAHL (1982 to 16 March 2020);
- LILACS (Latin American and Caribbean Health Science Information database), [lilacs.bvsalud.org](http://lilacs.bvsalud.org) (search to 16 March 2020);
- Web of Knowledge, Web of Science (1945 to 16 March 2020);
- ClinicalTrials.gov, [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (search via the Cochrane Register of Studies to 16 March 2020);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (search to 16 March 2020).

We also searched:

- IndMed (search to 22 March 2018);
- African Index Medicus (search to 22 March 2018).

The search strategies for major databases are detailed in [Appendix 1](#). The Information Specialist modelled subject strategies for databases on the search strategy designed for CENTRAL. The strategies were designed to identify all relevant studies for a suite of reviews on various interventions for chronic suppurative otitis media (Bhutta 2018; Brennan-Jones 2020; Brennan-Jones 2018b; Chong 2018a; Chong 2018b; Head 2020a; Head 2020b). A supplementary search of the major databases was performed for this review. Where appropriate, they were combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane*

*Handbook for Systematic Reviews of Interventions* Version 5.1.0, Box 6.4.b. ([Handbook 2011](#)).

### Searching other resources

We scanned the reference lists of identified publications for additional trials and contacted trial authors where necessary. In addition, the Information Specialist searched Ovid MEDLINE to retrieve existing systematic reviews relevant to this systematic review, so that we could scan their reference lists for additional trials. The Information Specialist also ran non-systematic searches of Google Scholar to retrieve grey literature and other sources of potential trials.

We did not perform a separate search for adverse effects. We considered adverse effects described in the included studies only.

We contacted original authors for clarification and further data if trial reports were unclear and we arranged translations of papers where necessary.

### Data collection and analysis

#### Selection of studies

At least two review authors (KH/LYC) independently screened all titles and abstracts of the references obtained from the database searches to identify potentially relevant studies. At least two review authors (KH/LYC) evaluated the full text of each potentially relevant study to determine whether it met the inclusion and exclusion criteria for this review.

We resolved any differences by discussion and consensus, with the involvement of a third author for clinical and methodological input where necessary.

#### Data extraction and management

At least two review authors (KH/LYC/CBJ/MB) independently extracted data from each study using a standardised data collection form (see [Appendix 2](#)). Whenever a study had more than one publication, we retrieved all publications to ensure complete extraction of data. Where there were discrepancies in the data extracted by different review authors, we checked these against the original reports and resolved any differences by discussion and consensus, with the involvement of a third author or a methodologist where appropriate. We contacted the original study authors for clarification or for missing data whenever possible. If differences were found between publications of a study, we contacted the original authors for clarification. We used data from the main paper(s) if no further information was found.

We included key characteristics of the included studies, such as study design, setting (including location), year of study, sample size, age and sex of participants, and how outcomes were defined or collected in the studies. In addition, we have also collected baseline information on prognostic factors or effect modifiers (see [Appendix 2](#)). For this review, this included the following information whenever available:

- duration of ear discharge at entry to the study;
- diagnosis of ear discharge (where known);
- number people who may have been at higher risk of CSOM, including those with cleft palate or Down syndrome;

- ethnicity of participants including the number who were from Indigenous populations;
- number who had previously had ventilation tubes (grommets) inserted (and, where known, the number who had tubes still in place);
- number who had previous ear surgery;
- number who had previous treatments for CSOM (non-responders, recurrent versus new cases).

We recorded concurrent treatments alongside the details of the interventions used. See the 'Data extraction form' in [Appendix 2](#) for more details.

For the outcomes of interest to the review, we extracted the findings of the studies on an available case analysis basis, i.e. we included data from all patients available at the time points based on the treatment randomised whenever possible, irrespective of compliance or whether patients had received the treatment as planned.

In addition to extracting pre-specified information about study characteristics and aspects of methodology relevant to risk of bias, we extracted the following summary statistics for each trial and each outcome:

- For continuous data: the mean values, standard deviations and number of patients for each treatment group. Where endpoint data were not available, we extracted the values for change from baseline. We analysed data from disease-specific quality of life scales such as COMOT-12, COMOT-15 and CES as continuous data.
- For binary data: the number of participants who experienced an event and the number of patients assessed at the time point.
- For ordinal scale data: if the data appeared to be approximately normally distributed or if the analysis that the investigators performed suggested parametric tests were appropriate, then we treated the outcome measures as continuous data. Alternatively, if data were available, we converted it into binary data.
- Time-to-event outcomes: we did not expect any outcomes to be measured as time-to-event data. However, if outcomes such as resolution of ear discharge were measured in this way, we reported the hazard ratios.

For resolution of ear discharge, we extracted the longest available data within the time frame of interest, defined as from one week up to (and including) two weeks (7 days to 14 days), from two weeks up to (and including) four weeks (15 to 28 days), and after four weeks (28 days or one month).

For other outcomes, we reported the results from the longest available follow-up period.

#### Extracting data for pain/discomfort and adverse effects

For these outcomes, there were potential variations in how studies had reported them. For example, some studies may have reported both 'pain' and 'discomfort' separately whereas others may not. Prior to the commencement of data extraction, we agreed and specified a data extraction algorithm for how data should be extracted.

We extracted data for serious complications as a composite outcome. If a study reported more than one complication and we could not distinguish whether these occurred in one or more patients, we extracted the data with the highest incidence to prevent double counting.

### Extracting data from figures

Where values for primary or secondary outcomes were shown as figures within the paper, we attempted to contact the study authors to try to obtain the raw values. When the raw values were not provided, we extracted information from the graphs using an [online data extraction tool](#), using the best quality version of the relevant figures available.

### Assessment of risk of bias in included studies

At least two review authors (KH/LYC/CBJ/MB) independently assessed the risk of bias of each included study. We followed the guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Handbook 2011](#)), using the Cochrane 'Risk of bias' tool. With this tool we assessed the risk of bias as 'low', 'high' or 'unclear' for each of the following six domains:

- sequence generation;
- allocation concealment;
- blinding of participants, personnel and outcome assessment;
- incomplete outcome data;
- selective reporting;
- other sources of bias.

### Measures of treatment effect

We summarised the effects of dichotomous outcomes (e.g. proportion of patients with complete resolution of ear discharge) as risk ratios (RR) with confidence intervals (CIs). For the key outcomes that are presented in the 'Summary of findings' table, we expressed the results as absolute numbers based on the pooled results and compared to the assumed risk. We also had planned to calculate the number needed to treat to benefit (NNTB) using the pooled results, where the results were moderate or high certainty. The assumed baseline risk would have been either (a) the median of the risks of the control groups in the included studies, this being used to represent a 'medium-risk population' or, alternatively, (b) the average risk of the control groups in the included studies, which is used as the 'study population' ([Handbook 2011](#)). If a large number of studies were available, and where appropriate, we would have also presented additional data based on the assumed baseline risk in (c) a low-risk population and (d) a high-risk population.

Had we had any continuous outcomes, we would have expressed treatment effects as a mean difference (MD) with standard deviation (SD). If different scales were used to measure the same outcome we would have used the standardised mean difference (SMD) and provided a clinical interpretation of the SMD values.

### Unit of analysis issues

#### Cross-over studies

This review did not use data from phase II of cross-over studies.

### ***The ear as the unit of randomisation: within-patient randomisation in patients with bilateral ear disease***

For data from studies where 'within-patient' randomisation was used (i.e. studies where both ears (right versus left) were randomised) we adjusted the analyses for the paired nature of the data ([Elbourne 2002](#); [Stedman 2011](#)), as outlined in section 16.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Handbook 2011](#)).

### ***The ear as the unit of randomisation: non-paired randomisation in patients with bilateral ear disease***

Some patients with bilateral disease may have received the same treatment in both ears, whereas others received a different treatment in each ear. We did not exclude these studies but we only reported the data if specific pairwise adjustments were completed or if sufficient data were obtained to be able to make the adjustments.

### ***The patient as the unit of randomisation***

Some studies randomise by patient and those with bilateral CSOM received the same intervention for both ears. In some studies the results may be reported as a separate outcome for each ear (the total number of ears is used as the denominator in the analysis). The correlation of response between the left ear and right ear when given the same treatment was expected to be very high, and if both ears were counted in the analysis this was effectively a form of double counting, which may be especially problematic in smaller studies if the number of people with bilateral CSOM was unequal. We did not exclude these studies, but we only reported the results if the paper presented the data in such a way that we could include the data from each participant only once (one data point per participant) or if we had enough information to reliably estimate the effective sample size or inflated standard errors as presented in chapter 16.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Handbook 2011](#)). If this was not possible, we attempted to contact the authors for more information. If there was no response from the authors, then we did not include data from these studies in the analysis.

If we found cluster-randomised trials by setting or operator, we analysed these according to the methods in section 16.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Handbook 2011](#)).

### Dealing with missing data

We attempted to contact study authors via email whenever the outcome of interest was not reported but the methods of the study had suggested that the outcome had been measured. We did the same if not all of the data required for the meta-analysis were reported, unless the missing data were standard deviations. If standard deviation data were not available, we approximated these using the standard estimation methods from P values, standard errors or 95% CIs if these were reported, as detailed in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Handbook 2011](#)). Where it was impossible to estimate these, we contacted the study authors.

Apart from imputations for missing standard deviations, we did not conduct any other imputations. We extracted and analysed data for all outcomes using the available case analysis method.

## Assessment of heterogeneity

We assessed clinical heterogeneity (which may be present even in the absence of statistical heterogeneity) by examining the included studies for potential differences in the types of participants recruited, interventions or controls used, and the outcomes measured. We did not pool studies where the clinical heterogeneity made it unreasonable to do so.

We assessed statistical heterogeneity by visually inspecting the forest plots and by considering the Chi<sup>2</sup> test (with a significance level set at P value < 0.10) and the I<sup>2</sup> statistic, which calculated the percentage of variability that was due to heterogeneity rather than chance, with I<sup>2</sup> values over 50% suggesting substantial heterogeneity ([Handbook 2011](#)).

## Assessment of reporting biases

We assessed reporting bias as within-study outcome reporting bias and between-study publication bias.

### Outcome reporting bias (*within-study reporting bias*)

We assessed within-study reporting bias by comparing the outcomes reported in the published report against the study protocol, whenever this could be obtained. If the protocol was not available, we compared the outcomes reported to those listed in the methods section. If results are mentioned but not reported adequately in a way that allowed analysis (e.g. the report only mentioned whether the results were statistically significant or not), bias in a meta-analysis is likely to occur. We tried to find further information from the study authors, but if no further information could be obtained, we noted this as being a high risk of bias. Where there was insufficient information to judge the risk of bias, we noted this as an unclear risk of bias ([Handbook 2011](#)).

### Publication bias (*between-study reporting bias*)

We intended to create funnel plots if sufficient studies (more than 10) were available for an outcome. If we observed asymmetry of the funnel plot, we would have conducted a more formal investigation using the methods proposed by [Egger 1997](#).

## Data synthesis

We conducted all meta-analyses using Review Manager 5.3 ([RevMan 2014](#)). For dichotomous data, we analysed treatment differences as a risk ratio (RR) calculated using the Mantel-Haenszel methods. We analysed time-to-event data using the generic inverse variance method.

For continuous outcomes, if all the data were from the same scale, we would have pooled the mean values obtained at follow-up with change outcomes and reported this as a MD. However, if the SMD had to be used as an effect measurement, we would not have not pooled change and endpoint data.

When statistical heterogeneity is low, random-effects versus fixed-effect methods yield trivial differences in treatment effects. However, when statistical heterogeneity is high, the random-effects method provides a more conservative estimate of the difference.

## Subgroup analysis and investigation of heterogeneity

We subgrouped studies where most participants (80% or more) met the criteria stated below in order to determine whether

the effect of the intervention was different compared to other patients. Due to the risks of reporting and publication bias with unplanned subgroup analyses of trials, we only analysed subgroups reported in studies if these were prespecified and stratified at randomisation.

We planned to conduct subgroup analyses regardless of whether statistical heterogeneity was observed for studies that included **patients identified as high risk** (i.e. thought to be less responsive to treatment and more likely to develop CSOM, recurrence or complications) and patients with ventilation tubes (grommets). 'High risk' patients include Indigenous populations (e.g. Australian Aboriginal and Torres Strait Islanders, Native Americans and Inuit populations of Alaska, Canada and Greenland), people with craniofacial malformation (e.g. cleft palate), Down syndrome and people with known immunodeficiency.

We planned to present the main analyses of this review in the form of forest plots based on this main subgroup analysis.

- For the **high-risk** group, this applied to the outcomes resolution of ear discharge (dry ear), quality of life, pain/discomfort, development of complications and hearing loss.

For **patients with ventilation tubes**, this applied to the outcome resolution of ear discharge (dry ear) for the time point of four weeks or more because this group was perceived to be at lower risk of treatment failure and recurrence than other patient groups. If statistical heterogeneity was observed, we also conducted subgroup analysis for the effect modifiers below. If there were statistically significant subgroup effects, we presented these subgroup analysis results as forest plots.

For this review, effect modifiers include:

- **Diagnosis of CSOM:** it was likely that some studies would include patients with chronic ear discharge but who had not had a diagnosis of CSOM. Therefore, we subgrouped studies where most patients (80% or more) met the criteria for CSOM diagnosis in order to determine whether the effect of the intervention was different compared to patients where the precise diagnosis was unknown and inclusion into the study was based purely on chronic ear discharge symptoms.
- **Duration of ear discharge:** there is uncertainty about whether the duration of ear discharge prior to treatment has an impact on the effectiveness of treatment and whether more established disease (i.e. discharge for more than six weeks) is more refractory to treatment compared with discharge of a shorter duration (i.e. less than six weeks).
- **Patient age:** patients who were younger than two years old versus patients up to six years old versus adults. Patients under two years are widely considered to be more difficult to treat.

We presented the results as subgroups regardless of the presence of statistical heterogeneity based on the main types of aural toileting methods as follows:

- dry mopping;
- irrigation;
- microsuction.

This was because the different methods of aural toileting were expected to have different treatment effects and possible adverse

effects due to their intensity (e.g. microsuction is thought to be a more intense method than dry mopping).

### Sensitivity analysis

We planned to carry out sensitivity analyses to determine whether the findings were robust to the decisions made in the course of identifying, screening and analysing the trials. We planned to conduct sensitivity analysis for the following factors, whenever possible:

- Impact of model chosen: fixed-effect versus random-effects model.
- Risk of bias of included studies: excluding studies with high risk of bias (we defined these as studies that have a high risk of allocation concealment bias and a high risk of attrition bias (overall loss to follow-up of 20%, differential follow-up observed)).
- Where there was statistical heterogeneity, studies that only recruited patients who had previously not responded to one of the treatments under investigation in the RCT. Studies that specifically recruited patients who did not respond to a treatment could potentially have reduced the relative effectiveness of an agent.

If any of these investigations found a difference in the size of the effect or heterogeneity, we would have mentioned this in the 'Effects of interventions' section and/or presented the findings in a table.

### Summary of findings and assessment of the certainty of the evidence

Using the GRADE approach, at least two review authors (KH/LYC) independently rated the overall certainty of evidence using the GDT tool (<http://www.guidelinedevelopment.org/>) for the main comparison pairs listed in the [Types of interventions](#) section. The certainty of evidence reflects the extent to which we were confident that an estimate of effect was correct and we applied this in the interpretation of results. There are four possible ratings: 'high', 'moderate', 'low' and 'very low' ([Handbook 2011](#)). A rating of 'high' certainty evidence implies that we were confident in our estimate of effect and that further research is very unlikely to change our

confidence in the estimate of effect. A rating of 'very low' certainty implies that any estimate of effect obtained is very uncertain.

The GRADE approach rates evidence from RCTs that do not have serious limitations as high certainty. However, several factors could lead to the downgrading of the evidence to moderate, low or very low. The degree of downgrading was determined by the seriousness of these factors:

- study limitations (risk of bias);
- inconsistency;
- indirectness of evidence;
- imprecision;
- publication bias.

The 'Summary of findings' table presents the following outcomes:

- resolution of ear discharge or 'dry ear':
  - \* at between one week and up to two weeks;
  - \* after four weeks;
- health-related quality of life;
- ear pain (otalgia) or discomfort or local irritation;
- hearing;
- serious complications;
- adverse events: dizziness/vertigo/balance problems.

## RESULTS

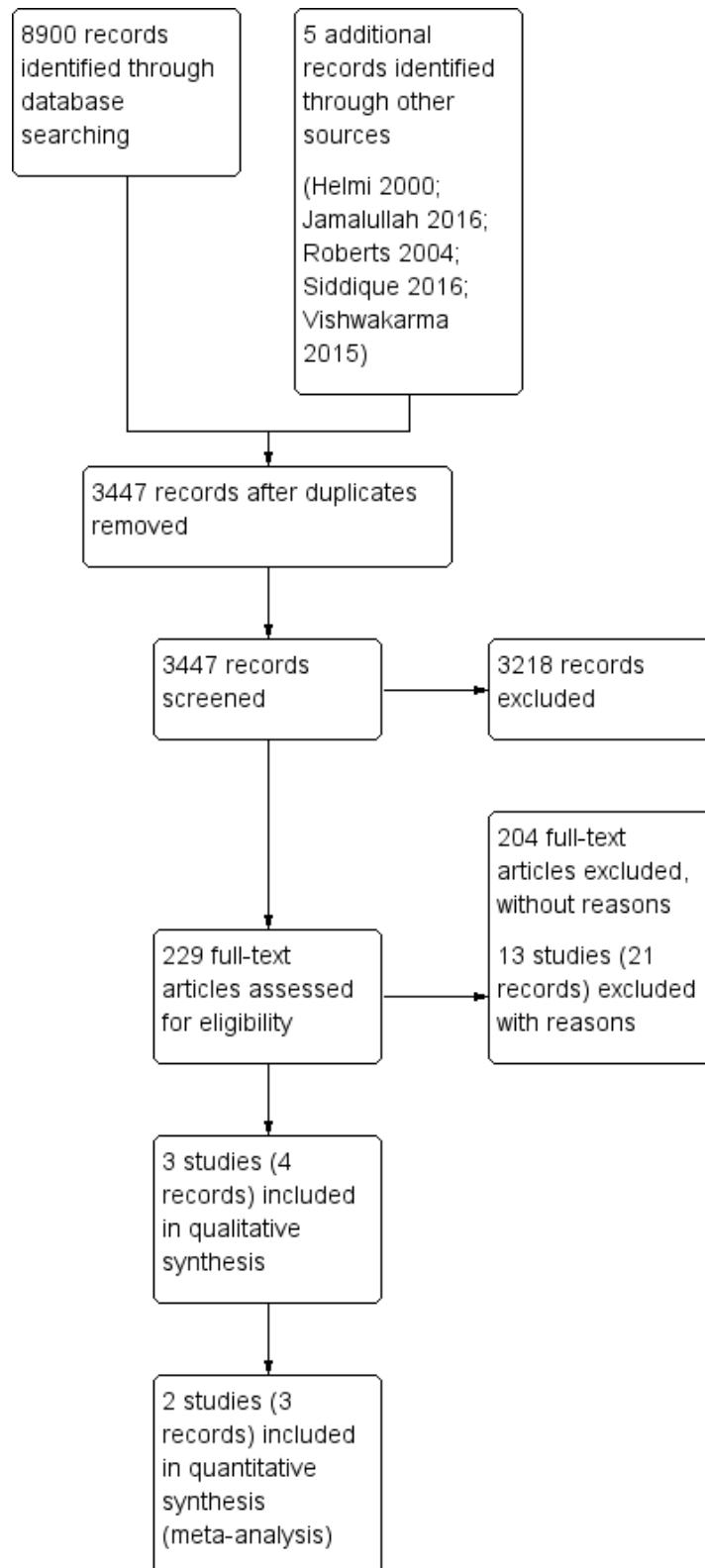
### Description of studies

#### Results of the search

The searches retrieved a total of 8900 references, which reduced to 3447 after removal of duplicates. We identified five additional references from other sources. We screened the titles and abstracts and subsequently removed 3218 references. We assessed 229 full texts for eligibility of which we excluded 225 references; we excluded 21 of these references (13 studies) with reasons recorded in the review (see [Excluded studies](#)). We included four references (three studies). A flow chart of study retrieval and selection is provided in [Figure 1](#).



**Figure 1. Process for sifting search results and selecting studies for inclusion.**



## Included studies

We included three studies (Eason 1986; Kiris 1998; Smith 1996). Table 2 and the Characteristics of included studies table provide a summary of the included studies.

### Study design and sample size

One study was a two-arm trial (Kiris 1998), one was a three-arm trial (Smith 1996) and one was a five-arm trial (Eason 1986). In all cases only two study arms were relevant to this review. Details of the other study arms can be found in the Characteristics of included studies table.

All studies indicated that they were randomised, controlled, parallel-arm studies.

### Sample sizes

The total sample size was 431 (465 ears) and ranged from 48 to 303 participants. Eason 1986 reported the outcome only by number of ears, while the others reported the results by participant (Smith 1996) or gave enough information to determine the number of participants (Kiris 1998) (Table 3).

### Unit of randomisation

The unit of randomisation for each study is presented in Table 3. Two studies used the individual as the unit of randomisation (Eason 1986; Kiris 1998); both of these studies presented results for resolution of ear discharge by ear.

Smith 1996 randomised schools, meaning that all of the participants from the school would receive the same treatment. Only one ear from each of the children participating was reported for this trial. Where bilateral disease was present, the ear on the school's allocated side was recruited although the opposite ear was treated in the same way and was monitored (but not reported). The analysis within the study adjusted for the effect of intra-cluster correlations due to the randomisation by school.

### Location

The studies were conducted in Kenya (Smith 1996), Turkey (Kiris 1998) and the Solomon Islands (Eason 1986).

### Setting of trials

One study was conducted in a community setting (Eason 1986), one in primary schools (Smith 1996), and the third was in an ENT department of a university hospital (Kiris 1998). Two studies included participants after they had been screened through a community-based screening programme to identify patients with CSOM (Eason 1986; Smith 1996).

### Population

#### Age and sex

Two of the studies included only children (Eason 1986; Smith 1996), while the third included both children and adults (mean 26.5 years; Kiris 1998). All studies included males and females. The percentage of males in the studies ranged from 45% to 69%.

#### High-risk populations

Eason 1986 recruited participants from the Solomon Islands, who were considered to be a 'high-risk' Indigenous group. The paper stated that incidence of CSOM in the population was 3.8%

for under 15-year olds. None of the other studies reported the inclusion of any of the 'high-risk' populations as defined by our inclusion criteria (cleft palate, Down syndrome, Indigenous groups, immunocompromised patients).

### Diagnosis (confirmed tympanic membrane perforation/presence of mucopurulent discharge)

In two studies the patients had chronic suppurative otitis media, which was confirmed by otoscopy (Eason 1986; Smith 1996). Although the title and abstract in Kiris 1998 indicated CSOM, the methods section used the criteria of otorrhoea for at least six weeks duration and did not indicate if perforation of the membrane was confirmed.

### Duration of ear discharge

All participants in Smith 1996 had mucopurulent ear discharge. This was not reported for Eason 1986 or Kiris 1998. The duration of discharge at entry into the study was at least two weeks (Smith 1996), at least six weeks (Kiris 1998) and at least three months (Eason 1986).

### Other important effect modifiers

Kiris 1998 confirmed alternative diagnoses after the treatment for some patients but it is unclear how many. This included five ears (5/80 = 6%) identified with cholesteatomas and polypoid hypertrophy in two ears.

None of the other studies identified other important effect modifiers such as the history of, or presence of, ventilation tubes or previous ear surgery.

### Interventions

Details of the interventions, background treatments and treatment durations for each of the included studies are summarised in Table 2.

Two forms of aural toileting are described in the studies. Two studies describe 'dry mopping' with cotton wool wisps twisted around sticks, performed either four times daily by parents (Eason 1986) or on weekdays only by trained 'ear monitors' who were older children (Smith 1996). The third study describes daily external ear channel aspiration performed in clinic, in addition to topical ciprofloxacin (Kiris 1998).

### Comparisons

The three studies on two comparisons:

- Aural toileting by cotton wool (dry mopping) versus no intervention (Eason 1986; Smith 1996).
- Daily aural toileting by aspiration in clinic versus single aural toileting by aspiration, with both groups receiving topical ciprofloxacin (Kiris 1998).

### Outcomes

#### Resolution of ear discharge

All three studies reported resolution of ear discharge or 'dry ear'. However, the length of follow-up for all three studies differed, ranging from six weeks to six months (Table 3).

**Health-related quality of life using a validated instrument**

No studies measured this outcome.

**Ear pain (otalgia) or discomfort or local irritation**

No studies reported this outcome.

**Hearing**

All three studies reported that hearing status was measured but none of the studies present quantitative results:

- [Eason 1986](#) reports pre-intervention hearing status but does not report post-intervention hearing outcomes.
- [Smith 1996](#) measured pure-tone hearing thresholds, recorded at 0.5 kHz, 1 kHz, 2 kHz, 4 kHz and 8 kHz. The 'post-treatment' results were reported by CSOM status rather than by treatment group.
- [Kiris 1998](#) measured hearing with audiography tests pre- and post-treatment. The results section only provides a narrative statement of no difference between groups.

**Serious complications (including intracranial complications, extracranial complications and death)**

Serious complications such as mastoiditis and encephalitis were specifically mentioned in one study ([Eason 1986](#)), although it is not clear whether the complications occurred pre- or post-treatment.

The other two studies did not specifically mention any evaluation of serious complications.

**Adverse events: dizziness/vertigo/balance problems**

One study mentioned a patient with dizziness ([Kiris 1998](#)), while the others did not specifically mention any evaluation of dizziness, vertigo and balance problems.

**Adverse events: ear bleeding**

No studies reported this outcome.

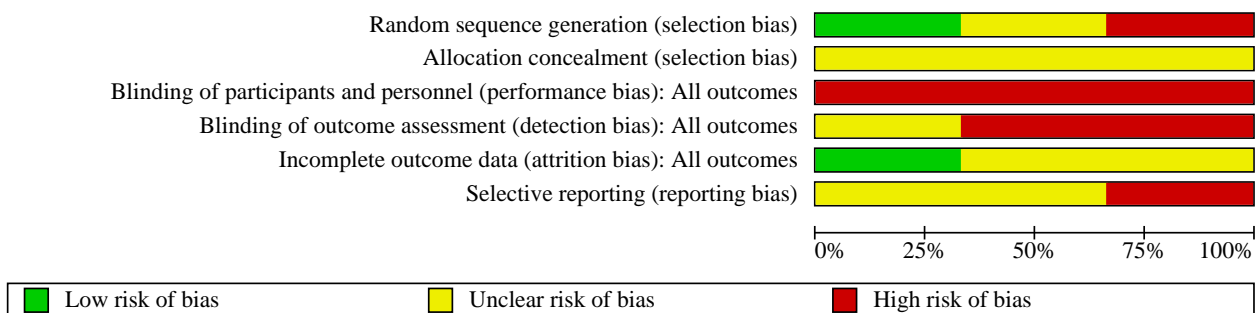
**Excluded studies**

We excluded 21 papers (13 studies) after reviewing the full text. We excluded 20 papers (12 studies) because the comparisons were not appropriate for this review, but were relevant to another Cochrane Review in this suite, and one paper (one study) due to the population characteristics included in their study. Further details for the reasons for exclusion can be found in the [Characteristics of excluded studies](#) table.

**Risk of bias in included studies**

See [Figure 2](#) for the 'Risk of bias' graph (our judgements about each risk of bias item presented as percentages across all included studies) and [Figure 3](#) for the 'Risk of bias' summary (our judgements about each risk of bias item for each included study).

**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.**

|            | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants and personnel (performance bias): All outcomes | Blinding of outcome assessment (detection bias): All outcomes | Incomplete outcome data (attrition bias): All outcomes | Selective reporting (reporting bias) |
|------------|---|---|---|---|--|--------------------------------------|
| Eason 1986 | -   | ?                                       | -   | -   | ?  | ?                                    |
| Kiris 1998 | ?   | ?                                       | -   | -   | +  | -                                    |
| Smith 1996 | +   | ?                                       | -   | ?   | ?  | ?                                    |

**Allocation**

**Sequence generation**

We judged one study to be at high risk of randomisation bias as it did not provide information about the sequence generation and there were unexplained imbalances between the groups (Eason 1986). There were 1.6 times as many patients in the largest group

than the smallest group, with the larger number of patients in the more effective treatment groups. We assessed one study as at unclear risk of bias due to inadequate information (Kiris 1998), whilst we assessed the remaining study as low risk (Smith 1996).

### Allocation concealment

We assessed all three studies as being at unclear risk of allocation concealment bias. Two were due to lack of details provided (Eason 1986; Kiris 1998), while the other was due to the possibility that researchers could have influenced the allocation to treatment group (Smith 1996).

### Performance bias

We assessed all three studies as at high risk of performance bias as no blinding of participants was attempted.

### Detection bias

We assessed two studies as at high risk of detection bias (Eason 1986; Kiris 1998), as neither study indicated that the outcome assessment was blinded. We assessed Smith 1996 as at unclear risk as although outcome assessors were not blinded to treatment group, study investigators tried to minimise the risk of bias by randomly assigning outcome assessors and changing the composition of assessor teams daily.

### Incomplete outcome data

We assessed two studies as being at an unclear risk of attrition bias. Smith 1996 identified that 28% of participants did not attend some of the follow-up appointments, but the reasons for non-attendance were not noted. For Eason 1986 it was not possible to determine if there were any participants lost to follow-up. We assessed the remaining study to be at a low risk of bias (Kiris 1998).

### Selective reporting

We assessed one study as at high risk of selective reporting bias as the outcomes were not clear in the methods section and so it is difficult to know if there were outcomes measured but not reported (Kiris 1998). We assessed the remaining two studies as at unclear risk of selective reporting due to a lack of information (Eason 1986; Smith 1996).

None of the three studies had protocols identified through searches of clinical trials registries.

### Other potential sources of bias

#### Funding

Eason 1986 stated "this study was made possible by a research grant from the Medical Research Council of New Zealand." Smith 1996 stated "the study was supported by the Overseas Development Administration (UK), the Gatsby Charitable Foundation (UK), and the Thrasher Research Fund (USA)". Kiris 1998 did not provide any information.

#### Declarations of interest

None of the studies provided information about conflicts of interest (Eason 1986; Kiris 1998; Smith 1996).

### Effects of interventions

See: [Summary of findings 1](#) Aural toileting compared to no aural toileting for chronic suppurative otitis media; [Summary of findings 2](#) Daily aural toileting compared to single aural toileting episode for chronic suppurative otitis media

### Comparison 1: Aural toileting versus no intervention

Two studies (351 participants; 370 ears) were included in this comparison with chronic suppurative otitis media:

- Eason 1986 (48 children, 67 ears) compared dry mopping four times per day with no specific treatment; and
- Smith 1996 (303 children, 303 ears) compared dry mopping two times per day (except weekends) with no specific treatment.

See also [Summary of findings 1](#).

#### Resolution of ear discharge

Eason 1986 presented the results of ear discharge by ear. Although the number of bilateral cases for each study arm was presented, sufficient data were not presented to allow adjustment of the results by person.

#### Between one week and up to two weeks

No study reported this outcome at this time point.

#### Two weeks to up to four weeks

Eason 1986 did not report the resolution of ear discharge at between two to four weeks in the group that did not receive any treatment, although results were reported for the other study arms.

#### After four weeks

Although two studies reported resolution of ear discharge after four weeks (Eason 1986 reported results at six weeks and Smith 1996 reported results at 16 weeks), Eason 1986 presented the results by ear and adjustment of the results to 'by person' was not possible, so results are presented as a narrative only.

For Smith 1996, it is very uncertain whether there is a difference in resolution of ear discharge with dry mopping compared with no specific treatment (risk ratio (RR) 1.01, 95% confidence interval (CI) 0.60 to 1.72; 1 study; 217 participants; very low-certainty; [Analysis 1.1](#)).

In Eason 1986, the authors reported that at the follow-up point of six weeks after treatment in the group with no treatment, 18% of 41 ears had resolution of ear discharge and in the group with dry mopping, 50% of 26 ears had resolution of ear discharge.

#### Health-related quality of life using a validated instrument

No study reported this outcome.

#### Ear pain (otalgia) or discomfort or local irritation

No study reported this outcome.

#### Hearing

Although Smith 1996 measured hearing, they presented the data with regards to the improvements for those who had resolution of ear discharge (irrespective of treatment group) and those who did not. Therefore it was not possible to identify whether there was a difference in hearing between the two groups (Smith 1996).

Eason 1986 did not evaluate post-intervention hearing.

### **Serious complications (including intracranial complications, extracranial complications or death)**

Eason 1986 reports one case of mastoiditis and one case of meningitis with focal encephalitis. It is not clear which group these patients were from, or whether the complications occurred pre- or post-treatment.

### **Adverse events (dizziness/vertigo/balance problems)**

No study reported this outcome.

### **Adverse events (ear bleeding)**

No study reported this outcome.

### **Subgroup analysis**

We could not undertake any subgroup analysis because there were only two studies in this comparison and for the only outcome where meta-analysis was possible (resolution of ear discharge after four weeks) the results were heterogeneous. Possible reasons for heterogeneity are already discussed in the results section.

### **Comparison 2: Daily aural toileting versus single aural toileting on top of topical ciprofloxacin**

Kiris 1998 included 80 participants (95 ears) with chronic ear discharge for more than six weeks. The investigators randomised one group to receive daily aural toileting with aspiration (suction) in the clinic followed by administration of daily ciprofloxacin ear drops, whereas the comparison group underwent initial aspiration in the clinic but then self-administered ciprofloxacin ear drops at home without further aural toileting. Although this study reported the results by ear, there was sufficient information provided for the resolution of ear discharge at between one and up to two weeks for us to be able to convert the results to 'per person' results.

See also [Summary of findings 2](#).

### **Resolution of ear discharge**

#### **Between one week and up to two weeks**

It is very uncertain if there is a difference between daily suction cleaning with administration of topical antibiotic ear drops (ciprofloxacin) in a clinic and a single aural toileting episode followed by daily self-administered topical antibiotic drops (RR 1.09, 95% CI 0.91 to 1.30; 80 participants; [Analysis 2.1](#); very low-certainty evidence).

#### **Two weeks to up to four weeks**

The study did not report this outcome at this time point.

#### **After four weeks**

Kiris 1998 provided results for this outcome by ear but it was not possible to adjust the results by person. The study authors reported that at three to six months "relapse occurred in six ears in the clinic treated group (12.8%) and in five ears in the self treated group (10.4%)."

### **Health-related quality of life using a validated instrument**

The study did not report this outcome.

### **Ear pain (otalgia) or discomfort or local irritation**

The study did not report this outcome.

### **Hearing**

Kiris 1998 measured hearing but only reported the results qualitatively, stating that "there were no differences in pre- and post-audiographic results or bone conduction in either group". We are very uncertain if there is a difference between the two groups (very low-certainty evidence).

### **Serious complications (including intracranial complications, extracranial complications or death)**

The study did not report that any participant died or had any intracranial or extracranial complications.

### **Adverse events (dizziness/vertigo/balance problems)**

One patient in the group with single aural toileting and self-administration of topical antibiotic ear drops reported dizziness, which the authors attributed to the use of cold topical ciprofloxacin. Due to the very low number of events (one event) it is very uncertain if there is a difference between the groups (RR 0.33, 95% CI 0.01 to 7.95; 80 participants; very-low certainty evidence, [Analysis 2.2](#)).

### **Adverse events (ear bleeding)**

The study did not report this outcome.

### **Subgroup analysis**

Although we had planned to complete subgroup analyses, as only one study was included in this comparison this was not possible.

## **DISCUSSION**

### **Summary of main results**

We identified three studies for this review (Eason 1986; Kiris 1998; Smith 1996). Due to the limited number of studies, the methods used, the choice of outcome measures and the poor reporting of results there was a scarcity of evidence that we could include in the review.

See also [Summary of findings 1](#) and [Summary of findings 2](#).

### **Daily aural toilet (dry mopping) versus no treatment**

Two studies including 351 children (370 ears) with chronic suppurative otitis media (CSOM) compared daily dry mopping with no treatment (Eason 1986; Smith 1996). In Eason 1986 parents were asked to dry mop their children's ear(s) four times per day for six weeks whereas Smith 1996 trained older school children to act as 'ear monitors' and dry mop younger children's ear(s) twice daily on week days for 16 weeks. Only the results from Smith 1996 could be used in the analysis as Eason 1986 presented results by ear and adjustments could not be made to provide results per person. It is unclear if there is a difference in resolution of ear discharge with dry mopping compared with no treatment measured at 16 weeks (risk ratio (RR) 1.01, 95% confidence interval (CI) 0.60 to 1.72; 217 participants). We assessed the evidence to be very uncertain (very low-certainty) due to risk of bias in the study, the imprecision of the result and indirectness as the study only included children. Only one study reported serious complications, but it was not clear which group these patients were from (this was a five-arm study),

or whether the complications occurred pre- or post-treatment. One study reported hearing, but the results were presented by treatment outcome rather than by treatment group so it is not possible to determine whether there is a difference between the two groups. Neither study reported results for resolution of ear discharge at any other time points, health-related quality of life, ear pain or adverse events (dizziness/vertigo/balance problems/ear bleeding).

### Daily aural toileting (suction cleaning) versus single aural toileting (suction cleaning) on top of topical ciprofloxacin

[Kiris 1998](#) (80 participants, 95 ears) compared a single episode of suction cleaning with daily suction cleaning by clinical personnel for people with ear discharge for six weeks or more. All patients also used daily ciprofloxacin ear drops. It is uncertain if there is a difference in resolution of ear discharge at between one and up to two weeks when comparing the two methods (RR 1.09, 95% CI 0.91 to 1.30, 80 participants, very low-certainty evidence). We assessed the results as being very uncertain due to risk of bias in the study, imprecision in the study and indirectness (by including people with 'ear discharge' rather than the diagnosis of CSOM). The study did not provide results for resolution of ear discharge at between two to four weeks and the results for 'relapse' after four weeks (between three to six months) were presented by ear; it was not possible to make adjustments to present the results by person. One event of dizziness was reported in the group that had a single suction cleaning episode, but there is not enough information to determine if there is a difference between the groups (RR 0.33, 95% CI 0.01 to 7.95; 80 participants, very low-certainty evidence). Hearing was measured but the study only reported the results qualitatively, stating that "there were no differences in pre- and post audiographic results or bone conduction in either group". The study did not report results for health-related quality of life, ear pain, serious complications or any other adverse events (vertigo/balance problems/ear bleeding).

### Overall completeness and applicability of evidence

- Only three studies were available and there were many differences between the studies making comparisons difficult.
- There were very few data for outcomes other than resolution of ear discharge. No studies reported health-related quality of life. Adverse events, hearing and serious complications were all poorly reported.
- The length of follow-up in studies ranged from six weeks to six months, meaning that there was limited evidence regarding the long-term effectiveness of aural toileting for the resolution of discharge or healing of the tympanic membrane in people with CSOM.
- Two studies included children with CSOM ([Eason 1986](#); [Smith 1996](#)), but the inclusion criteria varied from discharge of two weeks ([Smith 1996](#)) to three months ([Eason 1986](#)). [Kiris 1998](#) used the term 'CSOM' in the title but in the methods section the inclusion criteria appeared to be only those who had ear discharge for six weeks. No information about membrane perforation was given.
- Two studies were conducted in community settings ([Eason 1986](#); [Smith 1996](#)) and one in secondary care ([Kiris 1998](#)).
- Even where 'dry mopping' was used the interventions varied from twice daily mopping on school days conducted by trained 'ear monitors' who were older students ([Smith 1996](#)), to dry

mopping four times per day completed by trained parents ([Eason 1986](#)).

### Quality of the evidence

Generally the included studies were small and not well reported. There were questions over whether the randomisation was adequate in all except one study. Studies were unblinded and suffered from possible selective reporting bias. This limits our ability to draw firm conclusions.

Of the three included studies, only one clearly described the use of otoscopic confirmation of resolution of discharge. This may have impacted on the accuracy of the diagnostic outcome and therefore the response to treatment.

### Potential biases in the review process

Across our suite of Cochrane CSOM reviews ([Brennan-Jones 2020](#); [Brennan-Jones 2018b](#); [Chong 2018a](#); [Chong 2018b](#); [Head 2020a](#); [Head 2020b](#)), we have identified studies that may have been relevant to the reviews but were only published as abstracts or internal non peer-reviewed reports, or were included in systematic reviews but the full data were not published. This raises a concern that there may have been other studies conducted where the results have not been published, or where the results have been published but would not have been identified through our searches. We reviewed some regional medical databases (such as IndMed and the African Index Medicus) but there is still a concern that unpublished data may be an issue for this review.

### Agreements and disagreements with other studies or reviews

This review is part of a series of reviews on CSOM ([Bhutta 2018](#); [Brennan-Jones 2020](#); [Brennan-Jones 2018b](#); [Chong 2018a](#); [Chong 2018b](#); [Head 2020a](#); [Head 2020b](#)).

There are few previous reviews or guidelines for CSOM. The World Health Organization (WHO) in 2004 suggested that first-line treatment of CSOM should comprise aural toilet and topical antibiotic drops, with second-line treatment comprising an alternative topical antibiotic (guided by the results of microbiological culture) or parenteral antibiotics ([WHO 2004](#)). The Australian government recommendations from 2010 for the treatment of Aboriginal and Torres Strait Islanders gave similar recommendations, with first-line treatment comprising aural toilet (or antiseptic washout) followed by topical antibiotics, and second-line treatment with parenteral antibiotics ([Morris 2010](#)). An expert panel of the American Academy of Otolaryngologists in 2000 came to a similar conclusion ([Hannley 2000](#)).

## AUTHORS' CONCLUSIONS

### Implications for practice

Aural toileting for chronic suppurative otitis media (CSOM) is a common practice utilised by both primary care providers and specialists, although rarely used in isolation. More commonly aural toileting is used as an adjunct to topical antiseptics and antibiotics, which in theory improves delivery of the medication to its target. However, in resource-deprived settings, aural toileting may play an important role in the initial management of CSOM.

There is insufficient evidence from the studies included in this systematic review to suggest there is benefit, as determined by rates of resolution of otorrhoea, from isolated aural toileting or when used in combination with other treatment modalities in the management of CSOM.

There is no evidence in the literature to suggest which method of aural toileting, dry mopping, aspiration or irrigation is associated with improved outcomes of CSOM. There is also insufficient evidence to determine whether aural toileting is associated with adverse events such as ear pain and bleeding.

### Implications for research

The results of this review, current to March 2020, show that we are very uncertain whether there is benefit, as determined by rates of resolution of otorrhoea, from isolated aural toileting or when it is used in combination with other treatment modalities in the management of CSOM. Potential adverse effects and hearing outcomes were poorly reported. The low certainty of the evidence for CSOM treatments in this review is common throughout this suite of seven reviews of CSOM treatments (Bhutta 2018; Brennan-Jones 2020; Brennan-Jones 2018b; Chong 2018a; Chong 2018b; Head 2020a; Head 2020b).

There is insufficient evidence to address the implications of aural toileting for high-risk groups such as immunocompromised patients or Indigenous populations.

Prior to commencing these reviews, we conducted a [scoping review](#) that identified two key questions that clinicians, researchers and consumers would like to see answered:

- Are aural toileting methods effective (compared to no treatment)?
- Are aural toileting methods effective when added to other interventions (e.g. aural toileting, systemic antibiotics)?
- What are the relative effects of different aural toileting methods?
- What are the relative effects of different aural toileting methods when added on to other interventions (e.g. topical antibiotics)?

Due to the very low certainty of the available evidence these questions cannot yet be addressed with any certainty. There is clearly room for more trials examining aural toileting for people with CSOM, including trials that assess the type and duration of toileting. It would be important to know whether aural toileting has benefits or harms when added to other treatments (such as topical antibiotics).

### Suggestions for future trials

This review is one of a suite of reviews of treatments for CSOM, each of which features its own research recommendations. Across all reviews, key features of future research are as follows:

#### Design and methods

- Where the intent is to assess the effectiveness of interventions, randomised controlled trials should be conducted. These trials (including those testing non-systemic interventions) should randomise, analyse and report results by person (not ears).
- In patients with bilateral CSOM, for outcomes that can be reported by ear, such as resolution of ear discharge or recurrence, only one finding should be analysed and reported

per person. We suggest that a single ear be included in the trial (the decision on which ear is to be included and analysed must be made *a priori*, and the method or criteria for the decision must be explicitly specified in the trial protocol and report). Since there are limited data on whether people with bilateral CSOM respond to treatment in the same way as people with unilateral CSOM, or whether both ears respond in the same way to treatment, reporting these factors would be useful.

- Trials need to use appropriate methods for randomisation and allocation concealment to avoid selection bias, and they should be adequately powered.
- Attempts should be made by the investigators to blind participants, healthcare professionals and study personnel to the treatment allocation. Where it is not possible to blind participants and/or clinicians to the treatment received, efforts to blind the outcome assessment and analysis personnel should be made.

#### Population

- Diagnosis of CSOM should be according to the World Health Organization (WHO) criteria, be otoscopically confirmed and include an assessment of hearing level.
- Potentially important patient characteristics (such as existence of ear grommets) should be recorded and presented in the report.
- If patients from 'high-risk' groups are included, these characteristics should be accounted for and explored in the design of the study.

#### Interventions

- All interventions (adjunctive therapies and/or allowed treatment) should be the same apart from the treatments being evaluated.
- Clear reporting of the therapies used should be provided. For aural toileting this should include the methods used, including whether it is administered by healthcare practitioner or patient/carer. Other factors to consider are the frequency and duration of the method and clear descriptions of any additional therapies used (e.g. topical antiseptics). Where background treatments are used across both the treatment groups these should be clearly defined.

#### Outcomes

- There is currently no core outcome set for CSOM, or a widely agreed set of priority outcomes and definitions for CSOM trials. The development of core outcome sets for CSOM, using established methods (Kirkham 2017), would be beneficial for future trials. This would help to ensure that trials are consistent, high-quality and examine appropriate outcomes. The standardisation of outcomes allows for analysis and comparison of data across trials (and treatments) using network meta-analysis or individual participant data meta-analysis.
- The assessment of adverse effects should be defined in the protocol and these should be systematically sought during trials using explicit methods.
- All outcomes (including hearing and balance) should be measured and reported using valid and predefined methods.
- A validated quality of life instrument should be used whenever possible.



- Studies should follow up patients for at least six months and preferably over one year to identify the rate of recurrence of ear discharge, using a pre-agreed definition of recurrence.
- Trials should be registered in a regional or international clinical trials registry and, when published, adhere to reporting guidelines such as CONSORT ([CONSORT 2010](#)). Where publication in a peer-reviewed journal is not possible, results should be included in the clinical trial report.

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## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

**Eason 1986**
**Study characteristics**

|              |   |
|--------------|---|
| Methods      | 5-arm trial with 3 to 6 weeks duration of treatment and 6 weeks duration of follow-up   |
| Participants | <p><b>Location:</b> Solomon Islands, 15 villages around Munda</p> <p><b>Setting of recruitment and treatment:</b> Helena Goldie Hospital, Munda; patients identified through community screening February 1985 to March 1986</p> <p><b>Sample size:</b></p> <ul style="list-style-type: none"> <li><b>Number randomised:</b> 134 children (184 ears)</li> <li><b>Number completed:</b> as above (no loss to follow-up mentioned)</li> </ul> <p><b>Participant (baseline) characteristics:</b></p> <ul style="list-style-type: none"> <li>Age: mean 5.4 ± 3.1 years group 1: 5.2, group 2: 6.3, group 3: 5.3, group 4: 5.0, group 5: 5.1</li> <li>Gender (F/M): 49 (36.6%)/85 (63.4%)</li> <li>Main diagnosis: chronic suppurative otitis media with presence of otorrhoea for more than 3 months and tympanic membrane perforation</li> <li>High-risk population: yes                         <ul style="list-style-type: none"> <li>* Cleft palate (or other craniofacial malformation): not reported (NR)</li> <li>* Down syndrome: NR</li> <li>* Indigenous groups (Australian Aboriginals/Greenland natives): yes (Solomon Islands) - study noted prevalence is 3.8% for under 15-year olds</li> <li>* Immunocompromised: NR</li> </ul> </li> <li>Diagnosis method:                         <ul style="list-style-type: none"> <li>* Confirmation of perforated tympanic membrane: yes (confirmed by otoscopic examination)                                 <ul style="list-style-type: none"> <li><input type="checkbox"/> Central and tubotympanic perforations: 176 (130 were large (&gt; ¼ ear drum); 46 were small)</li> <li><input type="checkbox"/> Marginal tympanic perforations: 4</li> </ul> </li> <li>* Presence of mucopurulent discharge: NR</li> <li>* Duration of symptoms (discharge): mean age at CSOM onset: 1.5 ± 1.0 years; discharge for more than 3 months (inclusion criteria)</li> </ul> </li> <li>Other important effect modifiers:                         <ul style="list-style-type: none"> <li>* Alternative diagnosis of ear discharge: NR</li> <li>* Number who have previously had grommets inserted: NR</li> <li>* Number who have had previous ear surgery: NR</li> <li>* Number who had previous antibiotic treatment for CSOM: NR</li> </ul> </li> </ul> |

**Inclusion criteria:**

**Eason 1986** (Continued)

- Children under 15 years old with CSOM (defined as presence of otorrhoea for more than 3 months and tympanic membrane perforation) living in Munda or principal villages

**Exclusion criteria:**

- None listed

## Interventions

**Group 1 (n = 31, 40 ears):** Sofradex ear drops (0.5% w/v of framycetin sulphate, 0.050% w/v of dexamethasone and 0.005% w/v of gramicidin) (no details on volume or frequency of administration), PLUS oral clindamycin (15 mg/kg/day) into 3 divided oral daily doses, PLUS aural toilet 4 times per day using cotton wool wisps twisted onto orange sticks. Treatment duration = 6 weeks.

**Group 2 (n = 31, 41 ears):** Sofradex ear drops (0.5% w/v of framycetin sulphate, 0.050% w/v of dexamethasone and 0.005% w/v of gramicidin) (no details on volume or frequency of administration), PLUS aural toilet 4 times per day using cotton wool wisps twisted onto orange sticks. Treatment duration = 6 weeks.

**Group 3 (n = 24, 32 ears):** 2% boric acid in 20% alcohol (3 drops after cleaning using intermittent tragal depression to assist middle ear permeation) given 4 times per day, PLUS aural toilet using cotton wool wisps twisted onto orange sticks. Treatment duration = 6 weeks.

**Group 4 (n = 19, 26 ears):** aural toilet 4 times per day using cotton wool wisps twisted onto orange sticks. Treatment duration = 6 weeks.

**Group 5 (n = 29, 41 ears):** no treatment.

All treatments administered by parents.

**Concurrent treatment:** parents were instructed to encourage nose blowing, forbid swimming and insert cotton wool/Vaseline ear plugs before washing.

For each child in groups 2 to 5 one of the authors stayed in the village for the first 3 days of treatment to provide parental tuition and supervision. This was continued by a nurse aid who remained until the medical team returned after 3 weeks. If the ear was then dry, the clinical response was judged good, otological solutions continued for 1 further week only and aural toilet and clindamycin stopped. If the ear was still discharging, all treatment modalities were continued until the second assessment after 6 weeks.

## Outcomes

**Outcomes of interest in the review:**
**Primary outcomes:**

- Complete resolution of ear discharge, measured at 2 to 4 weeks and after 4 weeks. Unclear if otoscopically confirmed.

**Secondary outcomes:**

- NR

## Funding sources

"This study was made possible by a research grant from the Medical Research Council of New Zealand"

## Declarations of interest

No information provided

## Notes

**Unit of randomisation:** person

**Methods for including patients bilateral disease:** counting bilateral ears separately

RCT was part of a larger epidemiological study. Hearing loss was measured for the epidemiological study but not specifically for the RCT. Results are not presented by those who have CSOM and those who do not.

Only treatment groups 4 and 5 were relevant for this review.

**Eason 1986** (Continued)

**Risk of bias**

| Bias  | Authors' judgement | Support for judgement   |
|---|--------------------|---|
| Random sequence generation (selection bias)                               | High risk          | <p><b>Quote:</b> "Children from 15 villages with 184 diseased ears were randomly allocated into five treatment groups."</p> <p><b>Comment:</b> insufficient information about sequence generation method.</p> <p>The largest group had 1.6 times (31 patients/41 ears) the number of participants compared to the number in the smallest group (19 patients/26 ears), with a larger number of patients (31 each) in the more effective treatment groups.</p> <p>Unit of randomisation unclear although it is likely to be by person; results reported by percentage of affected ears.</p> |
| Allocation concealment (selection bias)                                   | Unclear risk       | <p><b>Comment:</b> no details about allocation concealment are provided in the paper.</p>   |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk          | <p><b>Comment:</b> blinding is not specifically stated.</p> <p>The treatment arms involved dry mopping compared to no treatment – blinding of these interventions is impossible.</p>  |
| Blinding of outcome assessment (detection bias)<br>All outcomes           | High risk          | <p><b>Comment:</b> no clear information about who assessed that the ears were "dry" versus "still discharging" - whether this was done by patients or the medical team. No report of otoscopic examination for outcome. Therefore, in the absence of blinding, this is likely high-risk.</p>  |
| Incomplete outcome data (attrition bias)<br>All outcomes                  | Unclear risk       | <p><b>Comment:</b> no dropouts or missing data reported; no statements about missing data.</p>  |
| Selective reporting (reporting bias)                                      | Unclear risk       | <p><b>Comment:</b> no protocol was available on clinicaltrials.gov. The level of reporting is extremely low.</p> <p>Outcome was reported as two categories: "improved" versus "no change" as opposed to "dry ear" versus others. This definition was not provided, and it was unclear whether "improved" means "dry ear" or a reduction of discharge.</p> <p>Insufficient information to permit judgement of 'low-risk' or 'high-risk'.</p>   |

**Kiris 1998**
**Study characteristics**

|              |  |
|--------------|--|
| Methods      | 2-arm, non-blinded, parallel-group RCT, with up to 15 days duration of treatment and 3 to 6 months duration of follow-up   |
| Participants | <p><b>Location:</b> Turkey, 1 site</p> <p><b>Setting of recruitment and treatment:</b> university hospital department of otolaryngology, March to September 1994</p> <p><b>Sample size:</b> 80 people (95 ears)</p> <ul style="list-style-type: none"> <li><b>Number randomised:</b> 40 (47 ears) in clinic aural toilet group, 40 (48 ears) in self aural toilet group</li> </ul> |

**Kiris 1998** (Continued)

- **Number completed:** 40 (47 ears) in clinic aural toilet group, 40 (48 ears) in self aural toilet group

**Participant (baseline) characteristics:**

- Age: mean 26.5 years (range: 21 months to 70 years)
- Gender (F/M): 35 (44%)/45 (56%)
- Main diagnosis: the title and abstract of the paper indicate 'chronic suppurative otitis media' but the methods section only uses 'otorrhoea' of at least 6 weeks duration. No information about perforated tympanic membrane within the results.
- High-risk population: none
  - \* Cleft palate (or other craniofacial malformation): not reported (NR)
  - \* Down syndrome: NR
  - \* Indigenous groups (Australian Aboriginals/Greenland natives): NR
  - \* Immunocompromised: NR
- Diagnosis method:
  - \* Confirmation of perforated tympanic membrane: NR
  - \* Presence of mucopurulent discharge: NR
  - \* Duration of symptoms (discharge): "at least 6 weeks duration between March to September 1994". Unclear whether this is total or since onset of symptoms
- Other important effect modifiers:
  - \* Alternative diagnosis of ear discharge: not explicitly reported but at least 5/80 (6%) were diagnosed with cholesteatoma.
  - \* Number who have previously had grommets inserted: NR
  - \* Number who have had previous ear surgery: NR
  - \* Number who had previous antibiotic treatment for CSOM: NR

**Inclusion criteria:**

- Otorrhoea "of at least six weeks duration between March and Sept 1994."

**Exclusion criteria:**

- NR

**Interventions**

**Intervention (n = 40, 47 ears):** daily external ear channel aspiration. Ciprofloxacin drops administered by clinic personnel, continued until otorrhoea resolved or for 15 days.

**Comparator group (n = 40, 48 ears):** external ear canal aspiration and topical treatment administration by clinic personnel only for the first day (visit). Subsequently administered, by patients (no details about whether patients were told/taught to do any aural toileting). Patients asked to return to clinic as soon as otorrhoea resolved.

**Common/concurrent treatment in both groups:** ciprofloxacin lactate acetate solution, 2 mg/mL, administered twice, with a 5-minute break in between. If age < 15 years; 3 drops twice daily. If age > 15 years; 5 drops twice daily. Clinical personnel and patients were instructed to wait minutes between the 2 applications.

**Outcomes**
**Outcomes of interest in the review:**
**Primary outcomes:**

- Resolution of ear discharge or "dry ear" (whether otoscopically confirmed or not) measured at between 1 week to 2 weeks. Unclear if otoscopically confirmed.

**Secondary outcomes**

- Adverse events: hearing
- Adverse events: aural toilet, dizziness

**Funding sources**

No information provided



**Kiris 1998** (Continued)

| Declarations of interest  | No information provided  |  |
|---|--|--|
| Notes   | <b>Unit of randomisation:</b> person<br><br><b>Methods for reporting people with bilateral ear disease:</b> by ear, counting bilateral ears separately |  |
| <b>Risk of bias</b>   |  |  |
| Bias  | Authors' judgement   | Support for judgement  |
| Random sequence generation (selection bias)                               | Unclear risk   | <b>Quote:</b> "Patients were randomised into two groups..."<br><br><b>Comment:</b> no further information available on methods of sequence generation.   |
| Allocation concealment (selection bias)                                   | Unclear risk   | <b>Quote:</b> "Patients were randomised into two groups..."<br><br><b>Comment:</b> no further information available about allocation concealment.  |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk  | <b>Comment:</b> it was not possible to blind since one group had daily treatment in the clinic, whereas the other group was self-treating at home. This has a risk of bias particularly as they may have been a conflict of interest involved.   |
| Blinding of outcome assessment (detection bias)<br>All outcomes           | High risk  | <b>Quote:</b> "... (self-treated) patients were asked to return to clinic as soon as otorrhoea resolved..." "... treatment (by clinic personnel) continued until otorrhoea resolved."<br><br><b>Comment:</b> there was no description of the involvement of blinded personnel to assess/confirm the resolution of ear discharge. It does not appear that the outcome assessment was blinded. |
| Incomplete outcome data (attrition bias)<br>All outcomes                  | Low risk   | <b>Comment:</b> no dropouts were reported. All patients were included in the analysis, including those who went on to surgery.   |
| Selective reporting (reporting bias)                                      | High risk  | <b>Comment:</b> no trial protocol was identified in clinicaltrials.gov. The methods section does not detail the outcomes that would be measured in the trial and so it is not clear if all of the outcomes measured were reported. There is a lack of information about how some of the outcomes were measured/defined (e.g. hearing).   |

**Smith 1996**

|                              |   |
|------------------------------|---|
| <b>Study characteristics</b> |   |
| Methods                      | 3-arm, non-blinded, cluster-RCT, with up to 16-week duration of treatment and follow-up   |
| Participants                 | <b>Location:</b> Kiambu district, Central Province, Kenya<br><br><b>Setting of recruitment and treatment:</b> 145 primary schools (December 1991 to June 1992)<br><br><b>Sample size:</b> 524 children (145 schools) <ul style="list-style-type: none"> <li>• <b>Number randomised:</b> 221 children in antibiotics plus steroids plus dry mopping group; 201 in dry mopping group, 102 children in 'no specific treatment' group.</li> <li>• <b>Number completed:</b> at 16-week follow-up: 144 children in antibiotics plus steroids plus dry mopping group; 184 in dry mopping group, 73 children in 'no specific treatment' group.</li> </ul> |

**Aural toilet (ear cleaning) for chronic suppurative otitis media (Review)**

**Smith 1996** (Continued)

**Participant (baseline) characteristics:**

- Age: mean age not given. 80% of children were aged 5 to 14 years; 20% were older than 15 years
- Gender (F/M): 241 (46%)/283 (54%)
- Main diagnosis: tympanic membrane perforation associated with purulent otorrhoea that had been present continuously for at least the preceding 2 weeks
- High-risk population:
  - \* Cleft palate (or other craniofacial malformation): not reported (NR)
  - \* Down syndrome: NR
  - \* Indigenous groups Australian Aboriginals/Greenland natives): 0%
  - \* Immunocompromised: NR
- Diagnosis method:
  - \* Confirmation of perforated tympanic membrane: yes (removal of occluding wax or foreign bodies, then otoscopic examination)
  - \* Presence of mucopurulent discharge: yes, 524/524 (100%)
  - \* Duration of symptoms (discharge): at least 2 weeks (inclusion criteria)
- Other important effect modifiers:
  - \* Alternative diagnosis of ear discharge: 0/524 (0%)
  - \* Number who have previously had grommets inserted: NR
  - \* Number who have had previous ear surgery: NR (exclusion criteria: "children with previous ear surgery except tympanocentesis or myringotomy")
  - \* Number who had previous antibiotic treatment for CSOM: NR

**Inclusion criteria:**

- Children in primary school standards 1 to 8 (typically 4 to 12 years) with tympanic membrane perforation associated with purulent otorrhoea that had been present continuously for at least the preceding 2 weeks

**Exclusion criteria:**

- Treatment with antibiotics during the preceding 2 weeks
- Previous significant adverse reaction to systemic or topical antibiotics
- Otomycosis
- Failure to view the tympanic membrane
- Complicated otitis media
- Previous ear surgery (other than tympanocentesis or myringotomy)
- Anatomical predisposition to otitis media
- Congenital malformation of external, middle or inner ear
- Another illness that made trial inclusion potentially dangerous to health
- Otorrhoea that was moist but not purulent

**Interventions**

**Dry mopping alone (n = 201):** twice daily except at weekends. Mops were individually prepared by ear monitors (trained school children approximately 9 to 10 years old) from orange sticks with cotton wool wrapped tightly round the tip but protruding beyond. Treatment duration: until otorrhoea had stopped or 16 weeks.

**Comparator group (n = 102):** no specific treatment

**Concurrent treatment:** the clinical officer removed any occluding wax or foreign body at the start of the trial. All participants received multivitamins. No other concurrent treatment was given.

Children were withdrawn from the trial if antibiotics were prescribed.

**Outcomes**
**Outcomes of interest in the review:**
**Primary outcomes:**

- Complete resolution of ear discharge, measured after 4 weeks (otoscopically confirmed)

**Smith 1996** (Continued)

**Secondary outcomes:**

- Hearing

|                          |   |
|--------------------------|---|
| Funding sources          | The study was supported by the Overseas Development Administration (UK), the Gatsby Charitable Foundation (UK) and the Thrasher Research Fund (USA).  |
| Declarations of interest | No information provided   |
| Notes                    | <p><b>Unit of randomisation:</b> school</p> <p><b>Methods for including patients with bilateral disease:</b> each school had one side and for bilateral cases the ear of the school's assigned side was entered in the trial.</p> <p>This was a 3-arm trial:</p> <ol style="list-style-type: none"> <li>1. Dry mopping only</li> <li>2. Dry mopping plus topical antibiotics plus steroids plus systemic antibiotics</li> <li>3. Control group</li> </ol> |

**Risk of bias**

| Bias  | Authors' judgement | Support for judgement  |
|---|--------------------|--|
| Random sequence generation (selection bias)                               | Low risk           | <p><b>Quote:</b> "Interventions were allocated randomly within each quintuplet, by a random numbers table, in the ratio of two schools for dry mopping, two for dry mopping plus antibiotics, and one control."</p> <p><b>Comment:</b> adequate sequence generation.</p>   |
| Allocation concealment (selection bias)                                   | Unclear risk       | <p><b>Quote:</b> "Interventions were allocated randomly within each quintuplet, by a random numbers table, in the ratio of two schools for dry mopping, two for dry mopping plus antibiotics, and one control."</p> <p><b>Comments:</b> matching schools were arranged in groups of 5 according to 3 principles: whether situated in a tea or coffee plantation, agro-ecological zone and numbers of pupils. There is a possibility that the researchers could have influenced the allocation to treatment group. There is no good information relating to the baseline characteristics of the schools in each group.</p>  |
| Blinding of participants and personnel (performance bias)<br>All outcomes | High risk          | <p><b>Quote:</b> "Control group received no specific treatment."</p> <p>"Our inability to mask the treatment allocation may have biased the results."</p> <p><b>Comment:</b> the participants and personnel were not blinded to treatment group.</p>   |
| Blinding of outcome assessment (detection bias)<br>All outcomes           | Unclear risk       | <p><b>Quote:</b> "Some team members believed before the trial started that dry mopping and antibiotics are the most effective treatment for the disease, and that dry mopping alone is not effective. They might therefore have been biased in their clinical examination."</p> <p>"They therefore knew which treatment was being given. Parents, ear monitors, and teacher-supervisors of children in the dry-mopping plus antibiotics group may have realised that antibiotics were being given and assumed that they would be more effective. This treatment might therefore have been given more assiduously than the others."</p> <p>"Potential biases due to the fact that the study could not be blinded were kept to a minimum by random assignment of teams and changing of team com-</p> |

**Smith 1996** (Continued)

position each day; by close monitoring of the performance of ear monitors, teacher-supervisors, and teams; and by the use of clearly defined and easily recognisable outcomes."

**Comment:** it appears that the outcome assessors were not blinded to treatment group. The primary outcome (clinical resolution) was assessed by physicians and so lack of blinding could have led to bias in the results.

|  |              |  |
|--|--------------|--|
| Incomplete outcome data (attrition bias)<br>All outcomes | Unclear risk | <b>Comment:</b> the paper provides information for the number of children attending each of the 4-week follow-ups from 8 weeks to 16 weeks. The number of children who were randomised to dry mopping alone but were not seen at 16 weeks was 57/201 (28%) and the equivalent number in the control group at 16 weeks was 29/102 (28%). The number not attending was similar for both groups although the reasons for non-attendance were not provided.  |
| Selective reporting (reporting bias)                     | Unclear risk | <b>Quote:</b> "The average hearing threshold level for each child was calculated with the hearing thresholds for 1dB, 2dB, and 4dB at each visit. The effects of resolution and healing of the eardrum on the hearing threshold were investigated for each treatment group at 8, 12, and 16 weeks by ANOVA."<br><br><b>Comment:</b> the analysis does not appear to look at hearing loss per treatment group. No published protocol was identified through clinicaltrials.gov. The outcomes which were presented in the methods sections are well reported in the results section, although hearing results are not presented by treatment group but by improvement in CSOM. |

CSOM: chronic suppurative otitis media; F: female; HPMC: hydroxypropyl methyl-cellulose; M: male; NR: not reported; RCT: randomised controlled trial; WHO: World Health Organization

**Characteristics of excluded studies** [ordered by study ID]

| Study                                      | Reason for exclusion   |
|--|--|
| <a href="#">Boesorire 2000 unpublished</a> | COMPARISON: steroids added onto topical antibiotics (see CSOM-4)   |
| <a href="#">Browning 1988</a>              | COMPARISON: variety of topical antibiotics plus steroids (see CSOM-4)  |
| <a href="#">Fliss 1990</a>                 | COMPARISON: variety of systemic antibiotics (see CSOM-2)   |
| <a href="#">Gendeh 2001 unpublished</a>    | COMPARISON: steroids added onto topical antibiotics (see CSOM-4)   |
| <a href="#">Gupta 2015</a>                 | COMPARISON: antibiotic versus antiseptic (see CSOM-6)  |
| <a href="#">Helmi 2000 unpublished</a>     | COMPARISON: steroids added onto topical antibiotics (see CSOM-4)   |
| <a href="#">I-HEAR-BETA</a>                | COMPARISON: systemic antibiotic versus none (see CSOM-2), topical antiseptic versus none (see CSOM-5), topical antiseptic versus topical antibiotic (see CSOM-6) |
| <a href="#">IRCT2016082313136N4</a>        | POPULATION: patients had otomycosis  |
| <a href="#">Loock 2012</a>                 | COMPARISON: variety of topical antiseptics (see CSOM-5), topical antibiotic versus topical antiseptic (see CSOM-6)   |
| <a href="#">Minja 2006</a>                 | COMPARISON: systemic antibiotic versus none (see CSOM-2) and topical antiseptic versus none (see CSOM-5)   |
| <a href="#">Nwokye 2015</a>                | COMPARISON: variety of systemic antibiotics (see CSOM-2)   |

**Aural toilet (ear cleaning) for chronic suppurative otitis media (Review)**

| Study                        | Reason for exclusion   |
|------------------------------|--|
| Papastavros 1989             | COMPARISON: topical antiseptic versus none (see CSOM-5)          |
| Subramaniam 2001 unpublished | COMPARISON: steroids added onto topical antibiotics (see CSOM-4) |

For details of Cochrane Reviews CSOM-1 to CSOM-6 see [Table 1](#).

## DATA AND ANALYSES

### Comparison 1. Aural toileting versus no aural toileting

| Outcome or subgroup title                   | No. of studies | No. of participants | Statistical method              | Effect size       |
|---|----------------|---------------------|---------------------------------|-------------------|
| 1.1 Resolution of ear discharge (4 weeks +) | 1              | 217                 | Risk Ratio (M-H, Fixed, 95% CI) | 1.01 [0.60, 1.72] |

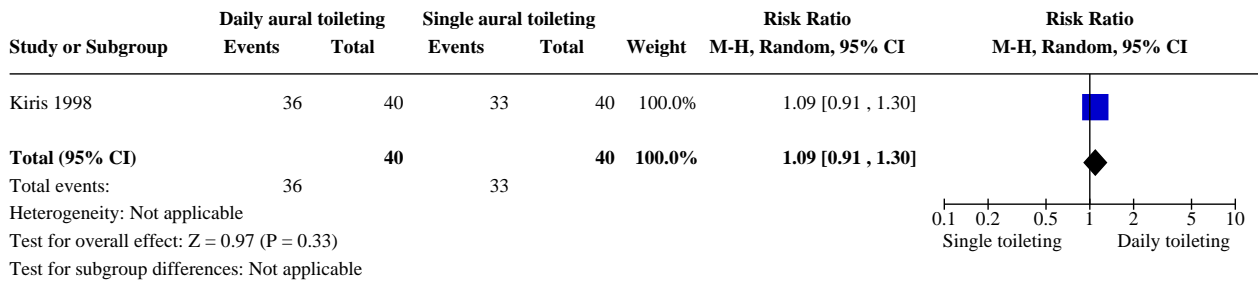
#### Analysis 1.1. Comparison 1: Aural toileting versus no aural toileting, Outcome 1: Resolution of ear discharge (4 weeks +)

| Study or Subgroup                             | Aural toileting |            | No treatment |           | Weight        | Risk Ratio               |                    | Risk Ratio |  |
|---|-----------------|------------|--------------|-----------|---------------|--------------------------|--------------------|------------|--|
|   | Events          | Total      | Events       | Total     |               | M-H, Fixed, 95% CI       | M-H, Fixed, 95% CI |            |  |
| Smith 1996                                    | 32              | 144        | 16           | 73        | 100.0%        | 1.01 [0.60, 1.72]        |                    |            |  |
| <b>Total (95% CI)</b>                         |                 | <b>144</b> |              | <b>73</b> | <b>100.0%</b> | <b>1.01 [0.60, 1.72]</b> |                    |            |  |
| Total events:                                 | 32              |            | 16           |           |               |                          |                    |            |  |
| Heterogeneity: Not applicable                 |                 |            |              |           |               |                          |                    |            |  |
| Test for overall effect: Z = 0.05 (P = 0.96)  |                 |            |              |           |               |                          |                    |            |  |
| Test for subgroup differences: Not applicable |                 |            |              |           |               |                          |                    |            |  |

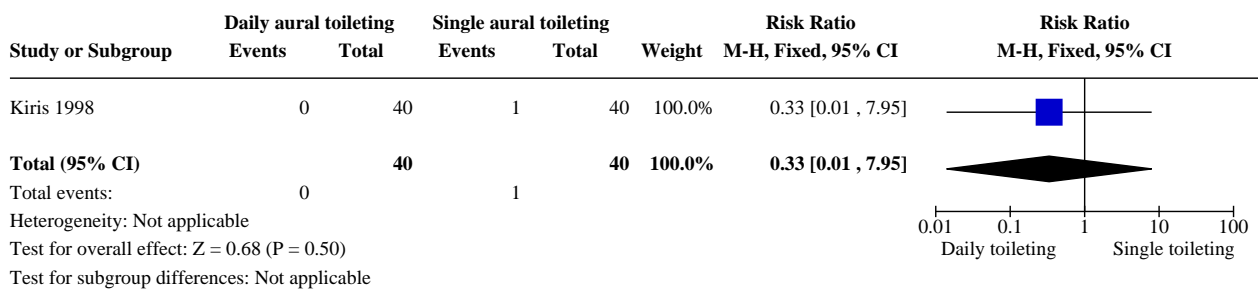
### Comparison 2. Daily aural toileting versus single aural toileting

| Outcome or subgroup title                      | No. of studies | No. of participants | Statistical method               | Effect size       |
|--|----------------|---------------------|----------------------------------|-------------------|
| 2.1 Resolution of ear discharge (1 to 2 weeks) | 1              | 80                  | Risk Ratio (M-H, Random, 95% CI) | 1.09 [0.91, 1.30] |
| 2.2 Vertigo/dizziness/tinnitus                 | 1              | 80                  | Risk Ratio (M-H, Fixed, 95% CI)  | 0.33 [0.01, 7.95] |

**Analysis 2.1. Comparison 2: Daily aural toileting versus single aural toileting, Outcome 1: Resolution of ear discharge (1 to 2 weeks)**



**Analysis 2.2. Comparison 2: Daily aural toileting versus single aural toileting, Outcome 2: Vertigo/dizziness/tinnitus**



**ADDITIONAL TABLES**

**Table 1. Table of Cochrane Reviews**

|                                   | Topical antibiotics with steroids | Topical antibiotics | Systemic antibiotics | Topical antiseptics | Aural toileting (ear cleaning) |
|-----------------------------------|-----------------------------------|---------------------|----------------------|---------------------|--------------------------------|
| Topical antibiotics with steroids | Review CSOM-4                     |                     |                      |                     |                                |
| Topical antibiotics               | Review CSOM-4                     | Review CSOM-1       |                      |                     |                                |
| Systemic antibiotics              | Review CSOM-4                     | Review CSOM-3       | Review CSOM-2        |                     |                                |
| Topical antiseptics               | Review CSOM-4                     | Review CSOM-6       | Review CSOM-6        | Review CSOM-5       |                                |
| Aural toileting                   | Review CSOM-4                     | Not reviewed        | Not reviewed         | Not reviewed        | Review CSOM-7                  |
| Placebo (or no intervention)      | Review CSOM-4                     | Review CSOM-1       | Review CSOM-2        | Review CSOM-5       | Review CSOM-7                  |

CSOM-1: Topical antibiotics for chronic suppurative otitis media ([Brennan-Jones 2020](#)).  
 CSOM-2: Systemic antibiotics for chronic suppurative otitis media ([Chong 2018a](#)).  
 CSOM-3: Topical versus systemic antibiotics for chronic suppurative otitis media ([Chong 2018b](#)).  
 CSOM-4: Topical antibiotics with steroids for chronic suppurative otitis media ([Brennan-Jones 2018b](#)).  
 CSOM-5: Topical antiseptics for chronic suppurative otitis media ([Head 2020a](#)).  
 CSOM-6: Antibiotics versus topical antiseptics for chronic suppurative otitis media ([Head 2020b](#)).

CSOM-7: Aural toilet (ear cleaning) for chronic suppurative otitis media ([Bhutta 2018](#)).

**Table 2. Summary of study characteristics**

| Ref ID<br>(no. of participants)  | Setting                               | Population  | Intervention                              | Comparison  | Treatment      | Follow-up      | Background treatment  | Notes                 |
|--|---------------------------------------|---|---|---|----------------|----------------|-----------------------|-----------------------|
| <b>Daily dry mopping versus no specific treatment</b>  |                                       |   |   |   |                |                |                       |                       |
| <a href="#">Eason 1986</a><br>(n = 48 people, 67 ears)   | Solomon Islands, villages (community) | Children with CSOM for more than 3 months<br>Mean age 5.4 years   | 4 times daily aural toilet (dry mopping)  | No treatment  | 3 to 6 weeks   | 6 weeks        | None                  | Part of a 5-arm trial |
| <a href="#">Smith 1996</a><br>(n = 303 people)   | Kenya (school)                        | Children with CSOM for more than 2 weeks<br>Mean age not given.<br>80% of children were between 5 and 14 years. | Twice daily dry mopping (except weekends) | No specific treatment                                 | Up to 16 weeks | Up to 16 weeks | None                  | Part of a 3-arm trial |
| <b>Daily suction cleaning PLUS topical antibiotics versus single suction cleaning PLUS topical antibiotics</b> |                                       |   |   |   |                |                |                       |                       |
| <a href="#">Kiris 1998</a><br>(n = 80 people, 95 ears)   | Turkey (ENT clinic)                   | Otorrhoea with at least 6 weeks duration<br>Mean: 26.5 years (range 21 months to 70 years)                      | Daily external ear channel aspiration     | Single external ear channel aspiration at first visit | 15 days        | 3 to 6 months  | Topical ciprofloxacin | —                     |

CSOM: chronic suppurative otitis media



**Table 3. Resolution of ear discharge outcome**

| Reference  | Unit of randomisation | Reported                        | Definition   | Otoscopically confirmed? | Time points                                      | Notes   |
|------------|-----------------------|---------------------------------|--|--------------------------|--|---|
| Eason 1986 | Person                | Ear                             | "dry" or "not discharging"   | Unclear                  | 2 to 4 weeks (3 weeks)<br>4+ weeks (6 weeks)     | Although the results were presented by ear, sensitivity analysis based on converting the results to people did not affect the outcome so we used the results in this review.  |
| Kiris 1998 | Person                | Ear, person could be determined | Resolution of otorrhoea  | Unclear                  | 1 to 2 weeks (between 3 to 12 days of treatment) | The results are presented by ear but sufficient data existed to provide the data by person. The base case assumption is that most of the cases were unilateral disease, which provides the most conservative estimate of effect size. |
| Smith 1996 | School                | Person                          | "resolution": absence of otorrhoea at 2 successive visits<br><br>"healed": complete repair of the tympanic membrane perforation at any visit | Otoscopically confirmed  | 4+ weeks (16 weeks)                              | —   |

## APPENDICES

### Appendix 1. Search strategies

| CENTRAL (the Cochrane Register of Studies)   | MEDLINE (Ovid)                                 | Embase (Ovid)                                  |
|--|--|--|
| 1 MESH DESCRIPTOR Otitis Media EXPLODE ALL AND CENTRAL:TARGET                      | 1 exp Otitis Media/                            | 1 exp otitis media/                            |
| 2 ("otitis media" or OME):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET               | 2 ("otitis media" or OME).ab,ti.               | 2 ("otitis media" or OME).ab,ti.               |
| 3 MESH DESCRIPTOR Tympanic Membrane Perforation EXPLODE ALL AND CENTRAL:TARGET     | 3 exp Tympanic Membrane Perforation/           | 3 exp eardrum perforation/                     |
| 4 MESH DESCRIPTOR Tympanic Membrane EXPLODE ALL AND CENTRAL:TARGET                 | 4 exp Tympanic Membrane/                       | 4 exp eardrum/                                 |
| 5 ("ear drum*" or eardrum* or tympanic):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET | 5 ("ear drum*" or eardrum* or tympanic).ab,ti. | 5 ("ear drum*" or eardrum* or tympanic).ab,ti. |
| 6 #4 OR #5 AND CENTRAL:TARGET  | 6 4 or 5                                       | 6 4 or 5                                       |
| 7 (perforat* or hole or ruptur*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET        | 7 (perforat* or hole or ruptur*).ab,ti.        | 7 (perforat* or hole or ruptur*).ab,ti.        |
| 8 #6 AND #7 AND CENTRAL:TARGET   | 8 6 or 7                                       | 8 6 and 7                                      |
| 9 #1 OR #2 OR #3 OR #8 AND CENTRAL:TARGET  | 9 1 or 2 or 3 or 8                             | 9 1 or 2 or 3 or 8                             |
| 10 MESH DESCRIPTOR Suppuration EXPLODE ALL AND CENTRAL:TARGET                      |  |  |

(Continued)

|  |  |   |
|--|--|---|
| <p>11 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or discomfort or earach* or mucopurulen*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>12 (pain):AB,TI,TO AND CENTRAL:TARGET</p> <p>13 #10 or #11 or #12 AND CENTRAL:TARGET</p> <p>14 MESH DESCRIPTOR Chronic Disease EXPLODE ALL AND CENTRAL:TARGET</p> <p>15 MESH DESCRIPTOR Recurrence EXPLODE ALL AND CENTRAL:TARGET</p> <p>16 (chronic* or persist* or recurr* or repeat*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>17 #14 OR #15 OR #16 AND CENTRAL:TARGET</p> <p>18 #9 AND #17 AND #13 AND CENTRAL:TARGET</p> <p>19 ((chronic* or persist* or recurr* or repeat*) NEAR (ear or ears or aural) NEAR (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or mucopurulen* or pain* or discomfort or disease*)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>20 ((earach* near (chronic or persist* or recurr* or repeat*)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>21 MESH DESCRIPTOR Otitis Media, Suppurative EXPLODE ALL AND CENTRAL:TARGET</p> <p>22 (CSOM):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>23 #20 OR #21 OR #22 OR #18 OR #19 AND CENTRAL:TARGET</p> | <p>7 (perforat* or hole or ruptur*).ab,ti.</p> <p>8 6 and 7</p> <p>9 1 or 2 or 3 or 4 or 8</p> <p>10 exp Suppuration/ n</p> <p>11 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or moist or wet or mucopurulen* or discomfort or pain* or earach*).ab,ti.</p> <p>12 10 or 11</p> <p>13 exp Chronic Disease/</p> <p>14 exp Recurrence/</p> <p>15 (chronic* or persist* or recurr* or repeat*).ab,ti.</p> <p>16 13 or 14 or 15</p> <p>17 9 and 12 and 16</p> <p>18 ((chronic or persist*) adj3 (ear or ears or aural) adj3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or mucopurulen* or pain* or discomfort or disease*)).ab,ti.</p> <p>19 CSOM.ab,ti.</p> <p>20 exp Otitis Media, Suppurative/</p> <p>21 (earach* adj6 (chronic or persist* or recurr* or repeat*)).ab,ti.</p> <p>22 17 or 18 or 19 or 20 or 21</p> | <p>10 exp suppuration/</p> <p>11 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or moist or wet or mucopurulen* or discomfort or pain* or earach*).ab,ti.</p> <p>12 10 or 11</p> <p>13 exp chronic disease/</p> <p>14 exp recurrent disease/</p> <p>15 (chronic* or persist* or recurr* or repeat*).ab,ti.</p> <p>16 13 or 14 or 15</p> <p>17 9 and 12 and 16</p> <p>18 exp suppurative otitis media/</p> <p>19 CSOM.ab,ti.</p> <p>20 ((chronic or persist*) adj3 (ear or ears or aural) adj3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or mucopurulen* or pain* or discomfort or disease*)).ab,ti.</p> <p>21 (earach* adj3 (chronic or persist* or recurr* or repeat*)).ab,ti.</p> <p>22 17 or 18 or 19 or 20 or 21</p> |
|--|--|---|

**Web of Science (Web of Knowledge)**

**CINAHL (EBSCO)**

**Cochrane ENT Register (the Cochrane Register of Studies)**

|  |   |   |
|--|---|---|
| <p>#1 TOPIC: ("otitis media" or OME)</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#2 TOPIC: (("ear drum*" or eardrum* or tympanic) AND (perforat* or hole or ruptur*))</p> | <p>S21 S17 OR S18 OR S19 OR S20</p> <p>S20 TX ((chronic or persist*) N3 (ear or ears or aural) N3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or</p> | <p>1 ("otitis media" or OME):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> <p>2 (("ear drum*" or eardrum* or tympanic)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> |
|--|---|---|

(Continued)

|  |  |  |
|--|--|--|
| <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#3 #2 OR #1</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#4 TOPIC: ((suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or moist or wet or mucopurulen* or discomfort or pain* or earach*) AND (chronic* or persist* or recurr* or repeat*))</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#5 #4 AND #3</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#6 TOPIC: (((chronic or persist*) NEAR/3 (ear or ears or aural) NEAR/3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or mucopurulen* or pain* or discomfort)))</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#7 TOPIC: ((earach* NEAR/3 (chronic or persist* or recurr* or repeat*)))</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> <p>#8 #7 OR #6 OR #5</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=All years</p> | <p>otorh* or otoliquor* or active or weep* or wet or moist or mucopurulen* or pain* or discomfort))</p> <p>S19 TX (earach* N3 (chronic or persist* or recurr* or repeat*))</p> <p>S18 TX csom</p> <p>S17 S9 AND S12 AND S16</p> <p>S16 S13 OR S14 OR S15</p> <p>S15 TX chronic* or persist* or recurr* or repeat*</p> <p>S14 (MH "Recurrence")</p> <p>S13 (MH "Chronic Disease")</p> <p>S12 S10 OR S11</p> <p>S11 TX suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or moist or wet or mucopurulen* or discomfort or pain* or earach*)</p> <p>S10 (MH "Suppuration+")</p> <p>S9 S1 OR S2 OR S3 OR S8</p> <p>S8 S6 AND S7</p> <p>S7 TX perforat* or hole or ruptur*</p> <p>S6 S4 OR S5</p> <p>S5 TX "ear drum*" or eardrum* or tympanic</p> <p>S4 (MH "Tympanic Membrane")</p> <p>S3 (MH "Tympanic Membrane Perforation")</p> <p>S2 TX "otitis media" or OME</p> <p>S1 (MH "Otitis Media+")</p> | <p>3 (perforat* or hole or ruptur*):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> <p>4 #2 AND #3 AND INREGISTER</p> <p>5 #4 OR #1 AND INREGISTER</p> <p>6 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or discomfort or earach* or mucopurulen*):AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER</p> <p>7 (pain):AB,TI,TO AND INREGISTER</p> <p>8 #6 OR #7 AND INREGISTER</p> <p>9 (chronic* or persist* or recurr* or repeat*):AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER</p> <p>10 #5 AND #8 AND #9 AND INREGISTER</p> <p>11 (csom):AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER</p> <p>12 (((chronic* or persist* or recurr* or repeat*) and (ear or ears or aural) and (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or mucopurulen* or pain* or discomfort or disease*))) :AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER</p> <p>13 ((earach* and (chronic or persist* or recurr* or repeat*)):AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER</p> <p>14 #10 OR #11 OR #12 OR #13 AND INREGISTER</p> |
|--|--|--|

| ClinicalTrials.gov   | ICTRP (WHO Portal)   | Other   |
|--|--|---|
| <p><b>Search 1 (clinicaltrials.gov):</b></p> <p>(chronic OR persistent OR recurrence OR recurrent) AND (suppuration OR pus OR discharge OR otorrhea or active OR mucopurulent)</p> | <p>otitis media AND chronic OR ear discharge OR earache OR wet ear OR weep</p> | <p><b>LILACS</b></p> <p>TW:"otitis media" OR "TW:"ear discharge" OR TW:earache OR</p> |

(Continued)

AND

Condition: "Otitis Media" OR OME

AND

Study type: interventional

**Search 2 (clinicaltrials.gov):**

(chronic OR persistent OR recurrence OR recurrent) AND (earache OR "ear ache" OR "ear pain" OR "ear discharge" OR "wet ear" OR "moist ear" OR "weeping ear")

AND

Study type: interventional

**Search 3 (clinicaltrials.gov):**

("ear drum" OR eardrum OR "tympanic membrane") AND (hole OR perforation OR rupture)

AND

Study type: interventional

**Search 4 (the Cochrane Register of Studies):**

1 ("otitis media" or OME):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

2 (("ear drum\*" or eardrum\* or tympanic)):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

3 (perforat\* or hole or ruptur\*):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

4 #2 AND #3 AND INSEGMENT

5 #4 OR #1 AND INSEGMENT

6 (suppurat\* or pus or purulen\* or discharg\* or mucosal or otorrh\* or otorh\* or otoliquor\* or active or weep\* or wet or moist or discomfort or earach\* or Mucopurulen\*):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

7 (pain):AB,TI,TO AND INSEGMENT

8 #6 OR #7 AND INSEGMENT

9 (chronic\* or persist\* or recurr\* or repeat\*):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

10 #5 AND #8 AND #9 AND INSEGMENT

11 (csom):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

12 (((chronic\* or persist\* or recurr\* or repeat\*) and (ear or ears or aural) and (suppurat\* or pus or purulen\* or discharg\* or mucosal or otorrh\* or otorh\* or otoliquor\* or active or weep\* or wet or moist or Mucopurulen\* or pain\* or discomfort or disease\*)))):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

13 ((earach\* and (chronic or persist\* or recurr\* or repeat\*)):AB,EH,KW,KY,MC,MH,TI,TO AND INSEGMENT

ing ear OR moist ear OR CSOM OR OME AND chronic OR tympanic membrane AND perforation OR eardrum AND hole OR eardrum AND perforation

((TW:eardrum OR TW:tympanic) AND (TW:perforation OR hole)) OR ((TW:wet OR moist OR weeping) AND TW:ear)

AND:

Filter: Controlled Clinical Trial

**IndMed**

Chronic Suppurative Otitis Media OR Chronic Otitis Media OR CSOM

**African Index Medicus**

"chronic suppurative otitis media"

OR

"chronic otitis media"

OR

CSOM

(Continued)

14 #10 OR #11 OR #12 OR #13 AND INSEGMENT

15 (nct\*):AU AND INSEGMENT

16 #14 AND #15

In addition to the strategy above (which was applied to the six other reviews in this CSOM suite) we also carried out the following supplementary searches, which we did not combine with a randomised controlled trial filter and which excluded the references retrieved with the above searches.

| CENTRAL (the Cochrane Register of Studies)  | Cochrane ENT Register (the Cochrane Register of Studies)   | MEDLINE (Ovid)   |
|---|--|--|
| 1 MESH DESCRIPTOR Ear EXPLODE ALL AND CENTRAL:TARGET  | 1 ("otitis media" or OME):AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER  | 1 exp Ear Diseases/<br>2 exp Ear/<br>3 ("otitis media" or OME).ab,ti.  |
| 2 MESH DESCRIPTOR Ear Diseases EXPLODE ALL AND CENTRAL:TARGET   | 2 (("ear drum*" or eardrum* or tympanic)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER   | 4 exp Tympanic Membrane Perforation/<br>5 exp Tympanic Membrane/<br>6 ("ear drum*" or eardrum* or tympanic).ab,ti.   |
| 3 ("otitis media" or OME):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET  | 3 (perforat* or hole or ruptur*):AB,EH,KW,KY,M-C,MH,TI,TO AND INREGISTER   | 7 5 or 6<br>8 (perforat* or hole or ruptur*).ab,ti.  |
| 4 MESH DESCRIPTOR Tympanic Membrane Perforation EXPLODE ALL AND CENTRAL:TARGET  | 4 #2 AND #3 AND INREGISTER   | 9 7 and 8<br>10 1 or 2 or 3 or 4 or 9  |
| 5 MESH DESCRIPTOR Tympanic Membrane EXPLODE ALL AND CENTRAL:TARGET  | 5 #4 OR #1 AND INREGISTER  | 11 exp Suppuration/<br>12 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or discomfort or earach* or Mucopurulen*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET |
| 6 ("ear drum*" or eardrum* or tympanic):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET  | 6 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or discomfort or earach* or Mucopurulen*):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER                               | 13 11 or 12<br>14 10 and 13  |
| 7 #5 OR #6  | 7 (pain):AB,TI,TO AND INREGISTER   | 15 exp Otitis Media, Suppurative/<br>15 ((microsuction* or propulse or "propulse"):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER  |
| 8 ((perforat* or hole or ruptur*.):AB,EH,KW,KY,M-C,MH,TI,TO AND CENTRAL:TARGET  | 8 #6 OR #7 AND INREGISTER  |  |
| 9 #7 AND #8   | 9 (chronic* or persist* or recur* or repeat*):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER   |  |
| 10 #2 OR #1 OR #3 OR #4 OR #9   | 10 #5 AND #8 AND #9 AND INREGISTER   |  |
| 11 MESH DESCRIPTOR Suppuration EXPLODE ALL AND CENTRAL:TARGET   | 11 (csom or earach*):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER  |  |
| 12 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or discomfort or earach* or Mucopurulen*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET | 12 (((ear or ears or aural) NEAR (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or Mucopurulen* or pain* or discomfort)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER |  |
| 13 (pain*):AB,TI AND CENTRAL:TARGET   | 13 #10 OR #11 OR #12 AND INREGISTER  |  |
| 14 #12 OR #11 OR #13  | 14 (((ear or ears or aural) near (toilet* or care or hygiene or syring* or irrigat* or probe or swab* or wash* or clean* or clear* or suck or suction)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER   |  |
| 15 #14 AND #10  | 15 ((microsuction* or propulse or "propulse"):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER   |  |
| 16 MESH DESCRIPTOR Otitis Media, Suppurative EXPLODE ALL AND CENTRAL:TARGET   |  |  |
| 17 (CSOM or earach*):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET   |  |  |

(Continued)

|   |  |  |
|---|--|--|
| <p>18 (((ear or ears or aural) near (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or Mucopurulen* or pain* or discomfort))):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>19 #16 OR #15 OR #17 OR #18</p> <p>20 (((ear or ears or aural) near (toilet* or care or hygiene or syring* or irrigat* or probe or swab* or wash* or clean* or clear* or suck or suction))):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>21 ((microsuction* or propulse or "pro pulse")):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>22 ((dry near mop*)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>23 (((cotton or tissue) near (wool or bud or spear*)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>24 ((chrome near syring*)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>25 ((jobson near horn)):AB,EH,KW,KY,MC,MH,TI,TO AND CENTRAL:TARGET</p> <p>26 #20 OR #21 OR #22 OR #23 OR #24 OR #25</p> <p>27 #26 AND #19</p> | <p>16 ((dry near mop*)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> <p>17 (((cotton or tissue) near (wool or bud or spear*)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> <p>18 ((jobson near horn)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> <p>19 ((chrome near syring*)):AB,EH,KW,KY,MC,MH,TI,TO AND INREGISTER</p> <p>20 #15 OR #14 OR #16 OR #17 OR #19 OR #18 AND INREGISTER</p> <p>21 #13 AND #20 AND INREGISTER</p> | <p>16 (CSOM or ear-ach*).ab,ti.</p> <p>17 ((ear or ears or aural) adj3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or Mucopurulen* or pain* or discomfort)).ab,ti.</p> <p>18 14 or 15 or 16 or 17</p> <p>19 ((ear or ears or aural) adj3 (toilet* or care or hygiene or syring* or irrigat* or probe or swab* or wash* or clean* or clear* or suck or suction)).ab,ti.</p> <p>20 (microsuction* or propulse or "pro pulse").ab,ti.</p> <p>21 (dry adj3 mop*).ab,ti.</p> <p>22 ((cotton or tissue) adj3 (wool or bud or spear*)).ab,ti.</p> <p>23 (jobson adj3 horn).ab,ti.</p> <p>24 (chrome adj3 syring*).ab,ti.</p> <p>25 19 or 20 or 21 or 22 or 23 or 24</p> <p>26 18 and 25</p> |
|---|--|--|

| Embase (Ovid)                                  | CINAHL (EBSCO)   |   |
|--|--|---|
| 1 exp ear disease/                             | S25 S17 AND S24  | — |
| 2 exp ear/                                     | S24 S18 OR S19 OR S20 OR S21 OR S22 OR S23             |   |
| 3 ("otitis media" or OME).ab,ti.               | S23 TX (chrome N3 syring*)                             |   |
| 4 exp eardrum perforation/                     | S22 TX (chrome N3 syring*)                             |   |
| 5 exp eardrum/                                 | S21 TX ((cotton or tissue) N3 (wool or bud or spear*)) |   |
| 6 ("ear drum*" or eardrum* or tympanic).ab,ti. | S20 TX dry N3 mop*)                                    |   |
| 7 5 or 6                                       | S19 TX (microsuction* or propulse or "pro pulse")      |   |

(Continued)

|   |  |
|---|--|
| 8 (perforat* or hole or ruptur*).ab,ti.   | S18 TX ((ear or ears or aural) N3 (toilet* or care or hygiene or syring* or irrigat* or probe or swab* or wash* or clean* or clear* or suck or suction))   |
| 9 7 and 8   | S17 S14 OR S15 OR S16  |
| 10 1 or 2 or 3 or 4 or 9  | S16 TX ((ear or ears or aural) N3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or Mucopurulen* or pain* or discomfort)) |
| 11 exp suppuration/   | S15 TX CSOM or earach*   |
| 12 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or moist or wet or Mucopurulen* or discomfort or pain* or earach*).ab,ti.                    | S14 S10 AND S13  |
| 13 11 or 12   | S13 S11 OR S12   |
| 14 10 and 13  | S12 TX suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or moist or wet or Mucopurulen* or discomfort or pain* or earach*)                   |
| 15 exp suppurative otitis media/  | S11 (MH "Suppuration+")  |
| 16 (CSOM or earach*).ab,ti.   | S10 S1 OR S2 OR S3 OR S4 OR S9   |
| 17 ((ear or ears or aural) adj3 (suppurat* or pus or purulen* or discharg* or mucosal or otorrh* or otorh* or otoliquor* or active or weep* or wet or moist or Mucopurulen* or pain* or discomfort)).ab,ti. | S9 S7 AND S8   |
| 18 14 or 15 or 16 or 17   | S8 TX perforat* or hole or ruptur*   |
| 19 ((ear or ears or aural) adj3 (toilet* or care or hygiene or syring* or irrigat* or probe or swab* or wash* or clean* or clear* or suck or suction)).ab,ti.   | S7 S5 OR S6  |
| 20 (microsuction* or propulse or "pro pulse").ab,ti.  | S6 TX "ear drum*" or eardrum* or tympanic  |
| 21 (dry adj3 mop*).ab,ti.   | S5 (MH "Tympanic Membrane")  |
| 22 ((cotton or tissue) adj3 (wool or bud or spear*)).ab,ti.   | S4 (MH "Tympanic Membrane Perforation")  |
| 23 (jobson adj3 horn).ab,ti.  | S3 TX "otitis media" or OME  |
| 24 (chrome adj3 syring*).ab,ti.   | S2 (MH "Ear+")   |
| 25 19 or 20 or 21 or 22 or 23 or 24   | S1 (MH "Ear Diseases+")  |
| 26 18 and 25  |  |

## Appendix 2. Data extraction form

|   |               |
|---|---------------|
| REF ID:   | Study title:  |
| Date of extraction:                               | Extracted by: |
| Name and email address of correspondence authors: |               |

General comments/notes (internal for discussion):

**FLOW CHART OF TRIAL:**

|  | <b>Intervention</b>            | <b>Comparison</b>              |
|--|--------------------------------|--------------------------------|
|  | <i>(name the intervention)</i> | <i>(name the intervention)</i> |
| No. of people screened                                     |                                |                                |
| No. of participants randomised - all                       |                                |                                |
| No. randomised to each group                               |                                |                                |
| No. receiving treatment as allocated                       |                                |                                |
| No. not receiving treatment as allocated                   |                                |                                |
| - Reason 1   |                                |                                |
| - Reason 2   |                                |                                |
| No. that dropped out <sup>1</sup>                          |                                |                                |
| (no follow-up data for any outcome available)              |                                |                                |
| No. excluded from analysis <sup>2</sup> (for all outcomes) |                                |                                |
| - Reason 1   |                                |                                |
| - Reason 2   |                                |                                |

<sup>1</sup>This includes patients who withdrew and provided no data, or did not turn up for follow-up.

<sup>2</sup>This should be the people who were excluded from all analyses (e.g. because the data could not be interpreted or the outcome was not recorded for some reason). This is the number of people who dropped out, plus the people who were excluded by the authors for some reason (e.g. non-compliant).

**INFORMATION TO GO INTO THE 'CHARACTERISTICS OF INCLUDED STUDIES' TABLE:**

|              |   |
|--------------|---|
| Methods      | X arm, double-/single-/non-blinded, [multicentre] parallel-group/cross-over/cluster RCT, with x duration of treatment and x duration of follow-up   |
| Participants | <p><b>Location:</b> [country, rural?, no. of sites etc.]</p> <p><b>Setting of recruitment and treatment:</b> [specialist hospital? general practice? school? state YEAR]</p> <p><b>Sample size:</b></p> <ul style="list-style-type: none"> <li>• <b>Number randomised:</b> x in intervention, y in comparison</li> <li>• <b>Number completed:</b> x in intervention, y in comparison</li> </ul> |



(Continued)

**Participant (baseline) characteristics:**

- Age:
- Gender (F/M): number of females (%)/number of males (%)
- Main diagnosis: *[as stated in paper – state the diagnostic criteria used]*
- High risk population: Yes/No
  - \* Cleft palate (or other craniofacial malformation): y/N (%)
  - \* Down syndrome: n/N (%)
  - \* Indigenous groups (Australian Aboriginals/Greenland natives): n/N (%)
  - \* Immunocompromised: n/N (%)
- Diagnosis method *[if reported]*:
  - \* Confirmation of perforated tympanic membrane: Yes/No/NR or unclear *[Method]*
  - \* Presence of mucopurulent discharge: Yes/No/NR or unclear – if 'yes', record n/N (%)
  - \* Duration of symptoms (discharge): x weeks
- Other important effect modifiers, if data available:
  - \* Alternative diagnosis of ear discharge (where known): n/N (%)
  - \* Number who have previously had grommets inserted (and, where known, number where grommets are still in place): n/N (%)
  - \* Number who have had previous ear surgery: n/N (%)
  - \* Number who have had previous antibiotic treatment for CSOM: n/N (%)

**Inclusion criteria:**

- *[State diagnostic criteria used for CSOM, if available]*

**Exclusion criteria:**

Interventions

**Intervention (n = x):** drug name, method of administration, dose per day/frequency of administration, duration of treatment

For aural toileting: who does it, methods or tools used, frequency, duration

**Comparator group (n = y):**
**Concurrent treatment:**

Use of additional interventions (common to both treatment arms):

Outcomes

**Outcomes of interest in the review:**
**Primary outcomes:**

- Resolution of ear discharge or 'dry ear' (whether otoscopically confirmed or not), measured at between 1 week to 2 weeks, 2 to 4 weeks and after 4 weeks
- Health-related quality of life using a validated instrument (e.g. COMQ-12, COMOT-15, CES)
- Ear pain (otalgia) or discomfort or local irritation

**Secondary outcomes**

- Hearing, measured as the pure-tone average of air conduction thresholds across 4 frequencies tested (at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz), of the affected ear. If this is not available, the pure-tone average of the thresholds measured.
- Serious complications, including intracranial complications (such as otitic meningitis, lateral sinus thrombosis and cerebellar abscess) and extracranial complications (such as mastoid abscess, postauricular fistula and facial palsy), and death.
- Adverse effects from treatment (this will be dependent on the type of treatment reviewed).

Funding sources

"No information provided"/"None declared"/State source of funding

(Continued)

Declarations of interest "No information provided"/"None declared"/State conflict

Notes

**Clinical trial registry no:** (if available)

**Unit of randomisation:** person/ears/other (e.g. cluster-randomised by hospital/school)

[In the case of randomisation by person]:

**Methods for including patients with bilateral disease, for example:**

- Random selection of one ear as the 'study ear'
- Selecting worse/least affected ear as the 'study ear'
- Counting bilateral ears separately
- Reporting 2 sets of results (please specify)
- Other (please state)
- Not stated

#### RISK OF BIAS TABLE:

(See table 8.5d in the *Cochrane Handbook for Systematic Reviews of Interventions*: <http://handbook.cochrane.org/>).

| Bias  | Authors' judgement    | Support for judgement    |
|---|-----------------------|--------------------------|
| Random sequence generation (selection bias)               | High/low/unclear risk | Quote: "..."<br>Comment: |
| Allocation concealment (selection bias)                   | High/low/unclear risk | Quote: "..."<br>Comment: |
| Blinding of participants and personnel (performance bias) | High/low/unclear risk | Quote: "..."<br>Comment: |
| Blinding of outcome assessment (detection bias)           | High/low/unclear risk | Quote: "..."<br>Comment: |
| Incomplete outcome data (attrition bias)                  | High/low/unclear risk | Quote: "..."<br>Comment: |
| Selective reporting (reporting bias)                      | High/low/unclear risk | Quote: "..."<br>Comment: |

#### FINDINGS OF STUDY

##### CONTINUOUS OUTCOMES

Other summary statistics/Net Mean difference (95% CI) P values etc.

| Results (continuous data table)  |   |    |   |                                       |    |   |  |
|--|---|----|---|---------------------------------------|----|---|--|
| Outcome  | Intervention<br>(name the intervention) |    |   | Comparison<br>(name the intervention) |    |   |  |
|  | Mean                                    | SD | N | Mean                                  | SD | N |  |
| <b>Disease-specific health-related quality of life</b>   |   |    |   |                                       |    |   |  |
| (COMQ-12, COMOT-15, CES) <sup>1</sup>  |   |    |   |                                       |    |   |  |
| Time point: (state)  |   |    |   |                                       |    |   |  |
| <b>Hearing:</b>  |   |    |   |                                       |    |   |  |
| [Measurement method: include frequencies and report results separately if they are presented in the paper]   |   |    |   |                                       |    |   |  |
| Time point: [xx]   |   |    |   |                                       |    |   |  |
| Comments:  |   |    |   |                                       |    |   |  |
| [If there is no information apart from (vague) narration, quote here]  |   |    |   |                                       |    |   |  |
| [If information is in the form of graphs, used this software to read it: <a href="http://arohatgi.info/WebPlotDigitizer/app/">http://arohatgi.info/WebPlotDigitizer/app/</a> , and save a copy of your charts in a folder] |   |    |   |                                       |    |   |  |

<sup>1</sup>State the measurement method: this will be instrument name/range for patient-reported outcomes.

## DICHOTOMOUS OUTCOMES

| Results (dichotomous data table)   |  |   |   |   |                                   |   |
|--|--|---|---|---|-----------------------------------|---|
| Outcome  | Ap-<br>plica-<br>ble re-<br>view/<br><br>Inter-<br>ven-<br>tion <sup>1</sup> | Group A - inter-<br>vention arm         |   | Group B – con-<br>trol                  |                                   | Other<br>sum-<br>mary<br>statis-<br>tics/Notes            |
|  |  | No. of<br>peo-<br>ple<br>with<br>events | No. of<br>peo-<br>ple<br>analysed<br>with | No. of<br>peo-<br>ple<br>with<br>events | No. of<br>peo-<br>ple<br>analysed | P val-<br>ues,<br>RR<br>(95%<br>CI),<br>OR<br>(95%<br>CI) |
| <b>Resolution of ear discharge or 'dry ear' at 1 to 2 weeks</b>                              |  |   |   |   |                                   |   |
| [Measurement method or definition used: not/unclear if/otoscopically confirmed] <sup>1</sup> |  |   |   |   |                                   |   |
| Time point: [State actual time point]  |  |   |   |   |                                   |   |
| <b>Resolution of ear discharge or 'dry ear' at 2 to 4 weeks</b>                              |  |   |   |   |                                   |   |
| [Measurement method or definition used: not/unclear if/otoscopically confirmed]              |  |   |   |   |                                   |   |
| Time point: [xx]   |  |   |   |   |                                   |   |
| <b>Resolution of ear discharge or 'dry ear' after 4 weeks</b>                                |  |   |   |   |                                   |   |
| [Measurement method or definition used: not/unclear if/otoscopically confirmed]              |  |   |   |   |                                   |   |
| Time point: [xx]   |  |   |   |   |                                   |   |
| <b>Ear pain/discomfort/local irritation</b>  |  |   |   |   |                                   |   |
| [Measurement method or definition used e.g. patient-reported]                                |  |   |   |   |                                   |   |
| Time point: [xx]   |  |   |   |   |                                   |   |
| <b>Suspected ototoxicity</b>   |  |   |   |   |                                   |   |
| [Measurement method or definition used]  |  |   |   |   |                                   |   |
| Time point: [xx]   |  |   |   |   |                                   |   |
| <b>Sensorineural hearing loss</b>  |  |   |   |   |                                   |   |
| [Measurement method or definition used]  |  |   |   |   |                                   |   |
| Time point: [xx]   |  |   |   |   |                                   |   |
| <b>Tinnitus</b>  |  |   |   |   |                                   |   |

---

(Continued)

[Measurement method or definition used]

Time point: [xx]

---

**Dizziness/vertigo/balance**

[Measurement method or definition used]

Time point: [xx]

---

**Serious complications:**

[State whether the paper had prespecified looking for this event, how it was diagnosed]

Time point: state length of follow-up of the trial

Note down the page number / table where info was found for ease of checking

---

**Otitic meningitis**

[How was this diagnosed?]

---

**Lateral sinus thrombosis**

[How was this diagnosed?]

---

**Cerebellar abscess**

[How was this diagnosed?]

---

**Mastoid abscess/mastoiditis**

[How was this diagnosed?]

---

**Postauricular fistula**

[How was this diagnosed?]

---

**Facial palsy**

[How was this diagnosed?]

---

**Other complications**

[How was this diagnosed?]

---

**Death**

[How was this diagnosed?]

---

**Multiple serious complications**

---

(Continued)

[How was this diagnosed?]

---

Comment/additional notes:

If any calculations are needed to arrive at the data above, note this down here.

---

<sup>1</sup>State briefly how this was measured in the study, especially whether there was deviation from what was expected in the protocol.

For adverse events, note down how these were collected, e.g. whether the adverse event was one of the prespecified events that the study planned to collect, when it was collected and how/who measured it (e.g. as reported by patients, during examination and whether any scoring system was used).

## HISTORY

Protocol first published: Issue 6, 2018

Review first published: Issue 9, 2020

## CONTRIBUTIONS OF AUTHORS

Mahmood F Bhutta: helped to scope, design and write the protocol; reviewed the analyses of results, helped write the review and provided clinical guidance at all stages of the review. Reviewed and edited the text of the review.

Karen Head: scoped the review, designed and wrote the protocol. Screened the search results and selected studies; carried out data extraction, 'Risk of bias' assessment and statistical analyses; helped to write the text of the review.

Lee Yee Chong: scoped, designed and wrote the protocol. Screened the search results and selected studies; carried out data extraction, 'Risk of bias' assessment and statistical analyses; reviewed and edited the text of the review.

Jessica Daw: helped to write, review and edit the text of the review.

Anne GM Schilder: clinical guidance at all stages of the review; reviewed the analyses and reviewed and edited the text of the review.

Martin J Burton: clinical guidance at all stages of the review; reviewed the analyses and reviewed and edited the text of the review. Wrote the abstract for the review.

Christopher G Brennan-Jones: clinical guidance at all stages of the review; reviewed the analyses; reviewed and edited the text of the review.

## DECLARATIONS OF INTEREST

Mahmood F Bhutta: Professor Mahmood Bhutta has received an honorarium from Novus Therapeutics for advice on an experimental treatment for otitis media (not related to any treatment in this review).

Karen Head: none known.

Lee Yee Chong: none known.

Jessica Daw: none known.

Anne GM Schilder: Professor Anne Schilder was until March 2020 the joint Co-ordinating Editor of Cochrane ENT, but had no role in the editorial process for this review. Her evidENT team at UCL is supported in part by the National Institute of Health Research (NIHR) University College London Hospitals Biomedical Research Centre. The research is funded by the NIHR and EU Horizon2020. She is the national chair of the NIHR Clinical Research Network ENT Specialty. She is the Surgical Specialty Lead for ENT for the Royal College of Surgeons of England's Clinical Trials Initiative. In her role as director of the NIHR UCLH BRC Deafness and Hearing Problems Theme, she acts as an advisor on clinical trial design and delivery to a range of biotech companies, most currently Novus Therapeutics.

Martin J Burton: Professor Martin Burton is joint Co-ordinating Editor of Cochrane ENT, but had no role in the editorial process for this review.

Christopher G Brennan-Jones: Dr Brennan-Jones's research team is primarily funded by the Australian NHMRC and the WA Department of Health. He sits on the national Technical Advisory Group responsible for developing treatment guidelines for otitis media in Australia.

---

## SOURCES OF SUPPORT

### Internal sources

- No sources of support supplied

### External sources

- National Institute for Health Research, UK  
Infrastructure funding for Cochrane ENT
- NHMRC Centre of Research Excellence in Ear and Hearing Health of Aboriginal and Torres Strait Islander Children, Australia

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In our protocol the main comparison pairs that would be reported in 'Summary of findings' tables ([Types of interventions](#)) did not include the comparison of daily aural toileting compared with single episode of aural toileting (where all participants received topical antibiotics as an add-on therapy). The authors and peer reviewers felt that this was an important comparison so we have now considered it to be a 'main comparison' and presented the results as a 'Summary of findings' table.