Update in the management of pediculosis: protocol for a systematic review

Protocol drafting: 01 September 2025
Amendments:
- Addition of the paragraph on meta-analysis on 29 April 2026

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Review question
This review aims to assess and compare effectiveness and safety of interventions in head, body and pubic lice infestation.

Searches
Searches will be run around 15/09/2025.

We will search the following databases from their inception:

- MEDLINE
- Embase
- Additionally, hand searching of reference lists of identified key articles

We will attempt to identify all relevant trials, regardless of language, publication status (published, unpublished, in press, or in progress), or publication date. The search strategy will be developed following the guidance outlined in the Cochrane Handbook for Systematic Reviews of Interventions (2024 version) and will be tailored to the specific requirements of each database.

Type of study included
We will include only randomized controlled trials, including placebo-controlled trials, that evaluate any available treatment or combinations of treatments for head lice / body lice / pubic lice.

Condition or domain being studied
Lice infestation (head, body and pubic)

Participants/Population
We will include children and adults with active infestations of human lice:

- Head lice (pediculosis capitis) before enrolment.
- Body lice (pediculosis corporis) before enrolment.
- Pubic lice (pediculosis pubis) before enrolment.

We will include studies that focus on any of these infestations separately or in combination.

We will exclude studies evaluating other ectoparasites or epidermal parasites (such as scabies or bed bugs), unless data on lice are presented separately.

Intervention(s), exposure(s)

Any intervention aimed at treating lice infestations, whether pharmacological or non-pharmacological, will be eligible for inclusion. This includes topical treatments (e.g. chemical-based products, essential oils), physical methods, systemic treatments, and other therapeutic approaches.

We will not include studies designed exclusively to evaluate the ovicidal effect of treatments, because the assessments generally do not rely on clinical outcomes.
We will exclude trials focused solely on health education strategies or on evaluating repellency.

Comparator(s)/control

Comparisons may involve control groups receiving an active treatment, a placebo, or no active treatment.

Context:

Background

Head lice (*Pediculus capitis*) are a widespread concern globally. They are especially prevalent among children aged 3 to 11 years. Prevalence rates vary considerably by region, with tropical countries reporting higher rates. Diagnosis is confirmed by identifying live lice, typically through combing or inspection, while the presence of eggs alone may be misleading. The lice have a short life cycle, and their bites can trigger allergic reactions, itching, and secondary infections due to scratching. They can also cause social stigma, psychological distress, school absenteeism, and place a financial burden on families and healthcare systems. Their presence is not limited to poor hygiene or specific socioeconomic groups.

Body lice (*Pediculus humanus corporis*) differ from head lice in that they live and lay eggs on clothing, moving to the skin only for feeding. They are more commonly associated with poor hygiene and crowded living conditions, including among populations experiencing homelessness, refugees, or people affected by war or natural disasters. Infestations typically cause itching and skin irritation, and diagnosis is usually made by identifying lice or nits in the seams of clothing rather than directly on the skin.

Pubic lice (*Pthirus pubis*), also known as crab lice, primarily infest coarse hair in the pubic region but may also spread to other body areas such as the chest, armpits, and even eyelashes. Transmission mainly occurs through sexual contact, making infestations more common in sexually active adolescents and adults. Pubic lice infestation can cause pruritus and inflammation, and secondary bacterial infections from scratching are possible. Diagnosis is made by identifying live lice or nits attached to the hair shaft.

Available treatments

Various topical and systemic treatments exist for head lice, including insecticides (permethrin, malathion etc.) and physically acting agents (dimethicone etc.). Herbal and physical treatments, such as combing and hair shaving, are also used. In cases of resistance or failure, oral medications (eg, ivermectin or trimethoprim-sulfamethoxazole) are sometimes employed.

Body lice treatment primarily relies on improving hygiene and access to clean clothing, as these lice reside and reproduce in garments rather than on the skin. In many cases, infestations resolve after bathing and replacing infested clothing. In more severe or persistent cases, topical pediculicides such as permethrin or malathion may be used. Oral ivermectin is sometimes employed, especially in situations involving mass treatment in outbreak settings. When body lice are associated with louse-borne diseases, antibiotic therapy targeting the responsible pathogen is also required.

Pubic lice are generally treated with topical insecticides such as permethrin cream or pyrethrin with piperonyl butoxide. Malathion or oral ivermectin may be used in resistant cases. Mechanical removal with fine-tooth combs can be used as an adjunct. It is recommended to treat all sexual contacts simultaneously to avoid reinfestation, and to wash contaminated bedding or clothing at high temperatures.

Resistance to insecticides is increasing globally, making the evaluation of alternative treatments crucial.

Type of Treatment	**Examples**	**Mechanism of Action**
Insecticides agents	Permethrin 1% and 5%	Neurotoxic
	Malathion 0.5%	Inhibits cholinesterase
	Oral Ivermectin (200–400 µg/kg) Topical Ivermectin 0.5%	Muscle paralysis leading to death (via chloride channel activation)
	Spinosad 0.9%	Muscle paralysis leading to death (via nicotinic receptor activation)
	Lindane 1%	Antagonist GABA-R, death
	Abametapir 0.74%	Metalloproteinase inhibitor
Physically acting agents	Dimethicone 4% and 92%	Coating lice and blocking spiracles/inhibition of water excretion
Oral antibiotics	Trimethoprim-sulfamethoxazole	Alters gut microbiota
Natural products	Tea tree oil, neem, etc.	Variable action
Physical methods	Combing, shaving, hot air	Mechanical removal or destruction: manual extraction or desiccation

Rationale for review

International recommendations for the control of head louse infestations have provided important guidance for clinical practice[1]. An updated systematic review could complement

this work by synthesizing the efficacy and safety of available treatments and by examining whether recent trials adhere to the trial-design recommendations of Do-Pham et al.[2]

The existing reviews on treatments for head lice, body lice, and pubic lice are outdated, repetitive, have been withdrawn, or focus only on a specific type of therapy (e.g., ivermectine, plant-based treatments etc.)[3–13]. Moreover, several new studies have been carried out. Given the growing concerns about resistance, limited long-term safety data, and the need for effective and well-tolerated treatments, a comprehensive evidence synthesis is needed.

Conducting three coordinated systematic reviews (one each for head lice, body lice, and pubic lice) offers a broader perspective on lice management and facilitates a comparative understanding of therapeutic strategies across infestation types.

Objective

This review aims to compare the efficacy and safety of pharmacological and non-pharmacological treatments for head lice, body lice, and pubic lice. This review will provide a systematic narrative synthesis of the available interventions for each type of infestation.

Main outcome(s)

1. Head Lice

Primary outcomes:

Head lice eradication is defined as the proportion of participants who are completely free from head lice at the following time points after the first treatment, performed on day 0:

- Day 7 post-treatment
- Day 14 post-treatment
- Day 21 post-treatment

Eradication could be assessed using a combing procedure, visual inspection, or a combination of both methods.

If a study evaluates efficacy on days other than those specified above, we will approximate the data to the nearest relevant time point, provided that the data fall within ±3 days of the target day.

Secondary outcomes:

Safety: the proportion of participants that present adverse effects and serious adverse effects.

2. Body lice

Primary outcomes:

Body lice eradication is defined as the proportion of participants who are completely free from body lice at the following time points after the first treatment, performed on day 0:

- Day 7 post-treatment
- Day 14 post-treatment
- Day 21 post-treatment

Eradication could be assessed by inspection of the body and clothing (particularly clothing seams), or through a combination of body examination and examination of garments.
If a study evaluates efficacy on days other than those specified above, we will approximate the data to the nearest relevant time point, provided that the data fall within ±3 days of the target day.

Secondary outcomes:
Safety: the proportion of participants that present adverse effects and serious adverse effects.

3. Pubic lice
Primary outcomes:
Pubic lice eradication is defined as the proportion of participants who are completely free from pubic lice at the following time points after the first treatment, performed on day 0:

- Day 7 post-treatment
- Day 14 post-treatment
- Day 21 post-treatment

Eradication could be assessed through visual inspection or dermoscopic examination of the pubic and other infested areas.
If a study evaluates efficacy on days other than those specified above, we will approximate the data to the nearest relevant time point, provided that the data fall within ±3 days of the target day.

Secondary outcomes:
Safety: the proportion of participants that present adverse effects and serious adverse effects.

Timing and effect measures
Not applicable

Data extraction (selection and coding)
The same strategy will be used for the literature review of head lice, body lice, and pubic lice.

1. Selection of studies:

Research equations used in PubMed:
Head Lice
("Lice Infestations"[Mesh] OR "Pediculus"[Mesh] OR "pediculos*"[TIAB] OR "lice infestatio*"[TIAB] OR "louse infestatio*"[TIAB]) AND ("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR "randomized"[tiab] OR "placebo"[tiab] OR "drug therapy"[sh] OR "randomly"[tiab] OR "trial"[tiab] OR "groups"[tiab]) NOT ("animals"[mh] NOT "humans"[mh]) NOT ("Systematic Review"[Publication Type] OR "Review"[Publication Type] OR "Systematic Review"[TIAB] OR "Umbrella Review"[TIAB] OR "Case Reports"[Publication Type] OR "Case Stud*"[TIAB] OR "Case Histories")

Body Lice
(("Lice Infestations"[Mesh] OR "Pediculus"[Mesh] OR "pediculos*"[TIAB] OR "lice infestatio*"[TIAB] OR "louse infestatio*"[TIAB]) NOT ("Head"[Mesh] OR "Head"[TIAB] OR "Hair"[TIAB] OR "Pubi*"[TIAB])) AND ("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR "randomized"[tiab] OR "placebo"[tiab] OR "randomly"[tiab] OR "trial"[tiab] OR "groups"[tiab]) NOT ("animals"[mh] NOT "humans"[mh]) NOT ("Systematic Review"[Publication Type] OR "Review"[Publication Type] OR "Systematic Review"[TIAB] OR "Umbrella Review"[TIAB] OR "Case Reports"[Publication Type] OR "Case Stud*"[TIAB] OR "Case Histories")

Pubic lice

(("Lice Infestations"[Mesh] OR "Pediculus"[Mesh] OR "Phthirus"[Mesh] OR pediculos*[TIAB] OR "lice infestatio*"[TIAB] OR "louse infestatio*"[TIAB] OR "Crab lice*"[TIAB] OR "Crab lous*"[TIAB] OR Phthirus[TIAB]) AND pubi*[TIAB]) NOT ("Head"[Mesh] OR Head[TIAB] OR Hair[TIAB]) AND ("randomized controlled trial"[pt] OR "controlled clinical trial"[pt] OR "randomized"[tiab] OR "placebo"[tiab] OR "randomly"[tiab] OR "trial"[tiab] OR "groups"[tiab]) NOT ("animals"[mh] NOT "humans"[mh]) NOT ("Systematic Review"[Publication Type] OR "Review"[Publication Type] OR "Systematic Review"[TIAB] OR "Umbrella Review"[TIAB] OR "Case Reports"[Publication Type] OR "Case Stud*"[TIAB] OR "Case Histories")

We will use Rayyan (https://www.rayyan.ai/) to assist with the screening process in this systematic review. It will enable a blinded and efficient selection process, helping to ensure transparency and reduce the risk of selection bias.

After importing the search results and removing duplicates, two reviewers (LR, AF) will independently screen the titles and abstracts of all identified studies using Rayyan. Any disagreements will be resolved through discussion or, if needed, by involving a third reviewer (SL, OC).

Full-text articles of potentially eligible studies will then be retrieved and assessed for inclusion, again independently and in duplicate using Rayyan (LR, AF).

Reasons for exclusion at the full-text screening stage will be documented.

Review authors will resolve disagreements through discussion or by consulting a third review author (SL, OC).

We will report a PRISMA flow diagram of included and excluded articles. The 'Characteristics of excluded studies' section will detail the primary reason for exclusions.

2. Data extraction and management:

Data will be extracted by the main researcher (LR), and 10% (randomly selected) will be checked by another reviewer (AF). A piloted Excel template was used for data extraction.

Any disagreements will be resolved through discussion or by consulting a third review author (SL, OC).

Additionally, the AI research assistant Elicit (https://elicit.com/) will be used on an exploratory basis to assess its potential usefulness as a supplementary tool for study selection and data extraction.

We will extract the following information:

- **Characteristics of the study**: first author, year of publication, country, single or multicentre study, study design, study population, sample size per arm, blinding (participant/ investigator/ outcome assessor/ other), analysis population (intention-to-treat/per-protocol/as treated/other), funding, authors' financial relationships and other potential conflicts of interest.
- **Characteristics of participants**: age (in years), sex, and other relevant characteristics.
- **Details of interventions**: intervention (detailed composition), formulation if topical, dose, frequency and mode of administration, duration of treatment, details of the

comparator group (detailed composition, formulation if topical, dose, frequency and mode of administration, duration of treatment), and details of any co-interventions.

- **Outcome results**:
  - For the primary outcome of efficacy, data will be collected at time points of Day 7, Day 14, and Day 21, ±3-days. The method of outcome assessment will include the combing procedure, visual inspection, a combination of both, or other specified methods. Extracted data will include the number of participants randomized, the number included in the analysis, the number achieving treatment success, the proportion of participants with treatment success (expressed as a percentage), the effect estimate between groups (such as relative risk [RR], odds ratio [OR], or risk difference), and the corresponding 95% confidence interval or p-value. These data will be recorded as free text to ensure flexibility in capturing study-specific details.
  - For the secondary outcome of safety, data will be collected at specified time points as reported in each study (recorded as free text). Extracted information will include the number included in the safety analysis, the number of adverse events, the number of serious adverse events, the number of treatment-related serious adverse events, and descriptions of the main reported adverse events when specified.
  - For the secondary outcome of acceptability, data will be collected at specified time points reported in each study (recorded as free text). Information gathered will include overall cosmetic acceptability, pleasantness or unpleasantness of smell, application comfort, and ease of combing (if applicable), each assessed by the reported methods and expressed using specified scores such as percentage satisfied or mean ± SD on a visual analog scale (VAS). Additionally, the discontinuation rate due to acceptability, reported as a proportion or number, will be extracted.

  For dichotomous outcomes: number of events and number of participants per arm or proportion (%) of patients achieving success or failure will be recorded; for continuous outcomes: the mean and standard deviation (SD) for each group; between-group estimates that quantify the effect of the intervention on the outcome, and their precision.

Missing data will not be handled. However, we will attempt to contact study authors for clarification if information is unclear or missing.

Risk of bias (quality) assessment

Three review authors (LR, AF, SL) will independently assess the risk of bias of the included studies. Discrepancies will be resolved through discussion with a third review author (OC).

For randomized clinical trials, we will use the Cochrane Risk of Bias 2 (RoB 2) tool, following the most recent version (2019 version for individually randomized, parallel-group trials and 2021 version for cluster-randomized trials).
This tool assesses bias in the following domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of the reported result.
We will use the RoB 2 Excel tool available on the official Cochrane Risk of Bias website to facilitate data collection and documentation.

Data analysis and synthesis strategy

The planned synthesis will be both narrative and quantitative. Meta-analyses will be done for randomised studies. The pooled study effects will be estimated using random or fixed effects based on the severity of heterogeneity (Q test). A p-value of <0.05 will be considered statistically significant in all the analyses. Statistical analyses will be performed with R software (version 4.0.2., R Foundation for Statistical Computing, Vienna, Austria).

Analysis of subgroups or subsets

Not applicable

Contact details for further information

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Organisational affiliation of the review

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Anticipated or actual start date

September 2025

Anticipated completion date

September 2026

Funding sources/sponsors

None

Conflicts of interest

None

Language

English

Country

France

Stage of review

Ongoing

References:

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