INPLASY

Efficacy of Probiotics in the Prevention of Atopic Dermatitis in Infants: A Systematic Review and Meta-Analysis

INPLASY202650128
doi: 10.37766/inplasy2026.5.0128
Received: 23 May 2026
Published: 23 May 2026

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ADMINISTRATIVE INFORMATION

Support - No.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202650129

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 May 2026 and was last updated on 23 May 2026.

INTRODUCTION

Review question / Objective Population – infants aged 0–36 months (both high-risk and general populations); Intervention – any oral probiotic strain(s) initiated within the first 36 months of life, without restrictions on formulation, dosage, frequency, or duration; Comparator – placebo, no intervention, standard care, or any non-probiotic control; Outcomes – primary outcome: prevention of atopic dermatitis (AD) diagnosed by recognized criteria or physician diagnosis; Study design – randomized controlled trials (parallel, cluster, factorial), observational studies (cohort, case–control), and non-randomized intervention studies, requiring full-text articles from peer-reviewed journals.

Condition being studied Whether probiotic supplementation initiated during infancy reduces atopic dermatitis (AD) risk remains unresolved. Our metaanalysis of 18 RCTs (10,195 participants) provides a clear answer: infantonly probiotics show no significant preventive effect (RR = 0.94; 95% CI: 0.72–1.25; p = 0.66). Importantly, the positive effects reported in previous metaanalyses are largely driven by perinatal (maternalplusinfant) regimens, highlighting that prenatal exposure,not infantonly supplementation,is critical for meaningful prevention.

METHODS

Participant or population Infants aged 0–36 months (both high-risk and general populations).

Intervention Any oral probiotic strain(s) initiated within the first 36 months of life, without restrictions on formulation, dosage, frequency, or duration.

Comparator Placebo, no intervention, standard care, or any non-probiotic control.

Study designs to be included Randomized controlled trials (parallel, cluster, factorial), observational studies (cohort, case–control), and

non-randomized intervention studies, requiring full-text articles from peer-reviewed journals.

Eligibility criteria Studies were excluded if any of the following applied: (1) not published in a peer-reviewed journal (e.g., conference abstracts, dissertations, preprints); (2) full text inaccessible despite reasonable efforts; (3) primary outcome (AD incidence or prevalence) not reported or not extractable for infants aged 0–36 months at intervention start; (4) probiotic administered only to the mother (prenatally or during lactation) without a separate infant intervention arm; (5) probiotic administered as part of a complex formulation (e.g., synbiotic, medical food) precluding isolation of its effect; (6) follow-up ending before 3 months of age, insufficient for AD development assessment; (7) duplicate publications (most complete or recent data retained).

Information sources Four electronic databases were searched on 8 January 2026: PubMed, Web of Science, EMBASE, and the Cochrane Library.

Main outcome(s) Primary outcome: prevention of atopic dermatitis (AD) diagnosed by recognized criteria or physician diagnosis.

Quality assessment / Risk of bias analysis Two reviewers independently assessed the risk of bias of included randomized controlled trials using the Cochrane RoB 2 tool. Each study was judged across five domains, with overall risk rated as 'low risk', 'some concerns', or 'high risk'. Disagreements were resolved by discussion or consultation with a third reviewer.

Strategy of data synthesis The strategy combined Medical Subject Headings (MeSH) and free-text terms for three core concepts: (1) infants (e.g., "infant", "newborn", "neonate", "baby", "babies"); (2) probiotics (e.g., "probiotic", "Lactobacillus", "Bifidobacterium", "synbiotic*"); and (3) atopic dermatitis (e.g., "atopic dermatitis", "atopic eczema", "eczema"). Terms were adapted to each database's syntax using Boolean operators (AND, OR). Eligible study types included randomized controlled trials, observational studies, clinical studies, and clinical trials. Reference lists of included articles and relevant reviews were manually screened for additional studies.

Subgroup analysis Analyses were performed using R (version 4.3.0) with meta and metafor packages. Twosided tests with $p < 0.05$ were considered significant. Heterogeneity was quantified using I^2, with low (25%), moderate (50%), and high (75%) thresholds [19]. A fixedeffects model (MantelHaenszel) was used when $I^2 < 50\%$; otherwise, a randomeffects model (DerSimonianLaird) was applied. Publication bias was assessed via funnel plots and Egger's test ($p < 0.05$ indicating significant bias).

Sensitivity analysis Sensitivity analyses were conducted by sequentially excluding individual studies.

Country(ies) involved China.

Keywords Atopic dermatitis; Infants; Probiotics; Prevention;Systematic review; Meta-analysis.

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