Effectiveness of Curcumin Nanoparticles in the Management of Oral Mucositis: A Systematic Review

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Systematic Review

Keywords: Curcumin nanoparticles, oral mucositis, radiotherapy, nanotechnology, pain relief, mouth ulcers

Posted Date: January 6th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-8470615/v1

Additional Declarations: The authors declare no competing interests.

Abstract

Background

Oral mucositis is a painful oral condition with diverse etiology and limited effective treatment modalities. Curcumin, a natural compound from curcumin longa, has anti-inflammatory and healing properties but is poorly absorbed by the body. A few studies have reported how curcumin nanoparticles (CNPs) have been created to solve this problem and improve effectiveness. This study reviewed how well CNPs work in treating oral mucositis.

Methods

We followed PRISMA guidelines and searched major databases for clinical studies using curcumin nanoparticles to treat oral mucositis. Only human studies comparing CNPs to placebos or standard treatments were included. Two reviewers independently selected and analyzed studies. The risk of bias and quality of the studies were assessed using Cochrane's Risk of Bias tool 2 for randomized controlled trials.

Results

Two clinical trials from Iran were included. One trial used nano-curcumin capsules, and the other trial combined capsules with mouthwash. However, both studies showed that CNPs reduced the severity of mucositis, delayed its onset, and assist in mucosal healing. Patients using CNPs had less pain and fewer ulcers by the third week. In additon, CNPs did not had any serious side effects.

Conclusion

CNPs was found a safe and effective option for reducing the severity and pain of oral mucositis. Although the findings are promising, more studies in different countries are needed to confirm these results.

Introduction

Oral mucositis, characterized by painful inflammation and ulceration of the oral tissues, is a common and often unavoidable complication in patients, especially undergoing chemoradiotherapy for head and neck cancers [1, 2]. Affecting up to 80% of individuals [2, 3], it not only causes significant discomfort and impairs nutrition and quality of life, but also disrupts treatment, sometimes requiring dose reductions or interruptions that may reduce treatment success [4]. Despite ongoing efforts, a universally effective therapy for oral mucositis remains unavailable. Patients are commonly managed with palliative

interventions such as mouthwashes, cryotherapy, or photobiomodulation, which may offer symptomatic relief but lack consistent efficacy in preventing or repairing mucosal damage [5].

Curcumin, a bright yellow compound extracted from Curcuma longa (turmeric) [6], has drawn significant interest. It is widely recognized for its anti-inflammatory, antioxidant, antimicrobial, and healing properties [6–8]. Laboratory and animal studies have shown that curcumin reduces inflammation by blocking the NF-κB (Nuclear Factor kappa-light chain) pathway, removes harmful free radicals, and promotes the healing of mucosal tissues by stimulating growth factors like EGF. It also helps prevent secondary infections in damaged tissues [8]. These combined actions make curcumin a promising candidate for managing oral mucositis. However, its effectiveness in humans has been limited because the body absorbs it poorly and breaks it down quickly, a problem known as poor bioavailability [9].

To address this limitation, nano-formulations, including nanomicellar and nanoparticle curcumin, have been developed [10]. These systems enhance solubility, protect the compound from rapid metabolism, and facilitate improved tissue targeting [6, 10]. Clinical investigations confirm their efficacy. For instance, nanomicellar curcumin capsules (80 mg twice daily) significantly reduced the severity of oral mucositis and pain over seven weeks in head and neck cancer patients receiving chemotherapy and/or radiotherapy [11]. Similarly, a 0.1% curcumin nanoparticle mouthwash delayed mucositis onset, with variable impact on incidence [12, 13]. Additional evidence shows that both mouthwash and nanocapsules can reduce oral discomfort and ulceration, with a significant portion of patients remaining ulcer-free after three weeks [13].

Finally, curcumin across various formulations (mouthwashes, gels, capsules, and nano-curcumin) significantly improves outcomes in oral mucositis, reducing pain and lesion severity. However, despite the potential of curcumin, the evidence remains scattered and limited. This review therefore, provides a timely synthesis on the effect of CNPs on oral mucositis.

Materials and Methods:

2.1 Protocol and Registration

This systematic review was developed following the PRISMA guidelines (Appendix I) [14]. The protocol was registered with PROSPERO under the registration number CRD420251045148.

2.2 Eligibility Criteria

This systematic review considered studies eligible if they evaluated the impact of curcumin nanoparticles (CNPs) in patients diagnosed with oral mucositis (OM). Only studies comparing CNPs to placebo, standard of care, or other curcumin formulation. Additionally, studies reporting the clinical outcomes such as mucositis severity, duration, pain scores, or onset time. Eligible studies included randomised controlled trials, non-randomised interventional studies, and observational designs that reported relevant outcome measures. Studies were excluded if they focused solely on curcumin as the

treatment and not the nanoparticles, lacked original data (such as reviews, commentaries, or conference abstracts), or failed to report extractable outcome data. To ensure a comprehensive and inclusive review, no restrictions were placed on language, year of publication, geographic location, or sample size.

2.3 Search Strategy

A thorough and systematic search of the literature was conducted using several major electronic databases, including PubMed, Web of Science, Scopus and Cochrane. To further minimise the risk of publication bias, grey literature was actively explored. In addition, the reference lists of all included studies were carefully reviewed to identify additional relevant publications that may not have been captured through the initial database search.

The search strategy was designed to be both sensitive and comprehensive. It utilised a combination of MeSH and free-text keywords to encompass all relevant terminologies associated with the condition and the biomarker of interest. The final search expression included terms such as “(("Curcumin" OR "Turmeric" OR "Curcuminoids" OR "Diferuloylmethane") AND ("Nanoparticles" OR "Nanotechnology" OR "Nanocurcumin" OR "Nanoformulations" OR "Nanospheres") AND ("Oral Mucositis" OR "Oral Inflammation" OR "Oral Ulcers" OR "Oral Lesions" OR "Stomatitis" OR "Chemotherapy-Induced Mucositis" OR "Radiotherapy-Induced Mucositis"))”. No filters were applied to restrict results based on date, language, or article type. Additional articles were identified by manually searching the bibliographies of included studies, key oral pathology journals, and clinical trial registries.

2.4 Study Selection

All retrieved references were imported into the Rayyan online platform for systematic review screening [15]. Two reviewers independently screened the titles and abstracts of all identified studies based on predefined eligibility criteria. Full-text articles of potentially relevant studies were then retrieved and assessed for final inclusion. Any disagreements between the reviewers were resolved through discussion, and a third reviewer was consulted in cases where consensus could not be reached. The PRISMA 2020 flowchart was used to document the study selection process, including reasons for exclusion at each stage (Fig. 1).

2.5 Data Extraction

Data extraction was performed independently by two reviewers using a standardised and pre-tested data collection form. For each included study, data were collected on the study title, first author, year of publication, journal name, country of origin, funding status, and study design.

Participants' details, such as sample size, age, sex distribution, diagnosis of Oral mucositis, severity, onset, and duration were recorded. Intervention characteristics, including the experimental drug, comparator drug, dose, route of administration, duration were extracted. The primary outcome was the reduction in the severity of the clinical symptoms (Pain levels (VAS), inflammation, redness) and duration, and secondary outcomes included clinical improvements in symptoms associated with oral

mucositis (ulceration, difficulty in swallowing), incidence of adverse side effects and duration of treatment.

Data on study limitations, follow-up duration, withdrawals, and completeness of outcome reporting were also noted. In cases where the required data was unclear or missing, attempts were made to contact the original study authors. Discrepancies in data extraction were resolved through discussion or arbitration by a third reviewer.

2.6 Risk of Bias analysis

The Cochrane tool (RoB2) was used to assess the risk of bias, while publication bias was evaluated using Egger's weighted regression test. If publication bias was detected, the trim-and-fill method was used to estimate its potential impact on the overall effect sizes.

2.7 Data Synthesis and Statistical Analysis

For continuous outcomes (Pain score, inflammation and redness), we will compute mean differences, along with 95% confidence intervals (CIs). Given the anticipated considerable between-study heterogeneity, we will utilize a random-effects model with 95% confidence interval. The Sidik–Jonkman estimator with Hartaung-Knapp (HK) adjustments will be employed to pool effect sizes.

Between-study heterogeneity will be assessed using Cochran's Q test, I square test, and prediction intervals. Meta-regression and subgroup analyses will be performed to investigate potential sources of heterogeneity. The meta- regression analysis will be carried out with a random-effects model. Furthermore, subgroup interactions will be tested with the chi-square test. Sensitivity analyses will be performed initially using the leave-one-out approach to assess the influence of individual trials on the overall effect estimate.

Results

3.1 Study Characteristics

A total of two randomized controlled trials (RCTs) met the inclusion criteria for this systematic review (Fig. 1). Both studies were conducted in Iran and evaluated the efficacy of curcumin-based nanoparticle formulations in the prevention or treatment of radiotherapy-induced oral mucositis (OM) in patients with head and neck cancers. A summary of individual study characteristics is provided in **Table 1 (Appendix II**).

The study by Delavarian et al. (2019) included 32 patients (19 males and 13 females), with a mean age of 62.18 ± 15.07 years in the treatment group and 55.87 ± 15.33 years in the control group [16]. The study employed a double-blind, placebo-controlled design, with participants receiving oral nano micellar curcumin (SinaCurcumin®) at a dose of 80 mg/day. The comparator was a placebo tablet containing lactose. The intervention began on the first day of radiotherapy and continued for six weeks, with

assessments conducted on days 7, 14, 21, 28, 35, and 42 during which the mucositis was assessed [16]. The second study, by Ramezani et al. (2023), included 45 patients (23 males and 14 females) aged 53.36 ± 15.99 years, all diagnosed with grades 1 to 3 Oral Mucositis [13]. Participants were randomized to receive either curcumin mouthwash (0.1% w/v), curcumin nano capsules (40 mg curcuminoids), or a placebo mouthwash over a three-week period, with weekly follow-ups [13]. The study was single-blinded, with patients unaware of the treatment received. Both studies utilized standard clinical mucositis grading systems: the WHO oral mucositis grading scale [17], with the National Rating Scale (NRS) additionally applied in the Ramezani et al. study [13].

3.2 Formulation and Dosage Comparison

Although both trials used curcumin nanoparticles, they differed in how they were delivered. Delavarian et al. used a commercial nano micellar curcumin (SinaCurcumin®) taken orally at 80 mg/day throughout radiotherapy, aiming for consistent systemic absorption [16]. Ramezani et al., on the other hand, combined topical curcumin mouthwash with oral nano capsules, offering both local and systemic action [13]. Both approaches showed positive outcomes, suggesting that curcumin is effective in various nano formulations and delivery routes [13, 16].

3.3 Efficacy in Reducing Oral Mucositis Severity

Both studies reported that curcumin nanoparticle-based interventions were effective in reducing the severity and progression of oral mucositis compared to placebo controls [13, 16]. In Delavarian et al., oral administration of nano micellar curcumin led to lower mucositis grades at each evaluation point compared to placebo [16]. By day 14, most patients in the treatment group maintained at Grade 0 or Grade 1, whereas the placebo group showed a steady progression to Grade 2 and Grade 3 mucositis by week 3 and beyond [16]. Specifically, none of the study group patients developed grade 1 mucositis after 1 week, while 37.5% of the control group did. After 2 weeks, only 25% of the study group developed grade 1, compared to 50% in the control group [16]. Although mucositis developed in both groups, the onset was delayed, and the severity was reduced in the curcumin group [16]. In Ramezani et al., both curcumin-treated groups (mouthwash and nano capsule) demonstrated a significant reduction in mucositis scores compared to placebo by week 3 ($p < 0.001$).(13) In weeks 1 and 2, no significant differences were observed among the three groups; however, the therapeutic effect became marked at the third week [13]. This highlights the time-dependent efficacy of curcumin formulations in mucosal recovery.

3.4 Pain Relief and Symptom Management

Pain levels were assessed using the Visual Analog Scale (VAS) or Numerical Rating Scale (NRS). In Ramezani et al., although weeks 1 and 2 did not show significant intergroup differences, by week 3, the VAS scores in both curcumin-treated groups were significantly lower than the placebo group ($p < 0.001$), showing a notable symptom relief on prolonged usage of the medication [13]. Delavarian et al. did not report detailed VAS pain scores, and the study primarily focused on the prevention and reduction of OM severity, the observed improvements directly translate into significant pain relief and better symptom management for patients [16]. By delaying onset, reducing severity, and improving food intake,

nanomicelle curcumin helps alleviate the painful and debilitating effects of oral mucositis, thereby improving the patient's quality of life during critical cancer treatment.

3.5 Inflammation, Redness, and Tissue Healing

Both studies noted reduction in inflammation and erythema, although not quantified using biochemical markers. Delavarian et al. categorized mucositis severity based on presence of erythema, pseudomembrane formation, and ulceration. Participants receiving nanocurcumin maintained lower grades, with minimal or no progression to confluent pseudomembrane or necrosis[16]. The study group had a lower grade of mucositis compared to the control group throughout the treatment. For instance, grade 3 mucositis was observed in 50% of the control group after 3 weeks, while only 33.3% of the study group reached this grade after 4 weeks [16]. At the end of the radiation therapy course, the NCI-CTC v.2 scores indicated that the study group had a mean score of 1 ± 0.84, while the control group had a mean score of 1.78 ± 0.42. This difference was statistically significant (P = 0.005) [16]. Ramezani et al. reported clinical resolution of inflammation and redness by the end of three weeks in the curcumin groups, with mucosal surfaces appearing near normal in most patients, while persistent erythema and ulceration were noted in the placebo group [13].

3.6 Safety and Tolerability

No serious adverse events were reported in either study. Participants tolerated both oral and topical curcumin formulations well, with no discontinuation due to side effects[13, 16]. This reinforces the safety profile of curcumin nanoparticles, making them suitable for extended use during chemoradiotherapy.

3.7 Follow-up and Clinical Impact

The follow-up period in Delavarian et al. extended across six weeks, aligning with the standard course of radiotherapy [16], while Ramezani et al. followed patients for three weeks post-intervention [13]. Both studies concluded that curcumin nanoparticles can effectively reduce severity, delay the onset, and accelerate the healing of oral mucositis, with potential for integration into routine oncology care[13, 16].

3.8 Risk of Bias

Both studies [13, 16] were of low risk, however Ramezani et al study have some concerns due to missing data (Fig. 2).

Discussion

This systematic review evaluated the effectiveness of curcumin nanoparticles in the prevention and management of oral mucositis in patients undergoing radiotherapy for head and neck cancers. The findings from the two included randomized controlled trials demonstrate that curcumin nanoparticles offer a promising therapeutic option having shown delayed onset of oral mucositis with significant reduction in severity and improved tissue healing compared to placebo [13, 16]. These results support

the growing body of evidence which suggests that nano-formulated curcumin has enhanced clinical efficacy compared to traditional curcumin preparations, primarily due to improved bioavailability and targeted tissue delivery [18].

The results of this systematic review, encompassing two randomized controlled trials, provide compelling evidence that curcumin nanoparticle-based interventions are a safe and effective strategy for managing radiotherapy-induced oral mucositis. The findings consistently demonstrate a significant reduction in mucositis severity and pain, delayed onset, and improved tissue healing compared to placebo, confirming the therapeutic potential of this novel formulation [13, 16].

A key strength of the reviewed studies is their focus on nanocurcumin, which addresses the critical issue of poor bioavailability that has historically limited the clinical application of standard curcumin [19]. The distinct delivery methods employed, oral nano micellar capsules in the study by Delavarian et al. and a combination of topical mouthwash and oral nano capsules in Ramezani et al., both yielded positive outcomes [13, 16]. This suggests that the enhanced absorption and targeted delivery provided by nanotechnological approaches are central to the observed efficacy. The fact that both systemic (oral capsules) and local (mouthwash) administrations were successful opens the door for a flexible, multi-modal approach to treatment, where systemic effects can target underlying inflammatory pathways while topical applications provide direct relief to mucosal surfaces [20].

Another important observation is the consistently lower mucositis severity scores in the treatment groups. For example, Delavarian et al. noted that those receiving the nano micellar capsules had significantly milder mucositis grades throughout the six-week treatment window, and these differences were statistically meaningful by the end of the study [16]. Similarly, Ramezani et al. reported a clear improvement by the third week in the curcumin groups [13]. These results imply that curcumin nanoparticles not only slow the onset of mucositis but may also promote quicker recovery once symptoms develop. The delayed onset of mucositis observed by Delavarian et al. is also a critical clinical benefit, as it implies that patients can maintain nutritional intake with reduced likelihood of treatment interruptions.

In the same vein, pain relief, which is a primary concern for patients with oral mucositis, was also significantly improved by the nanocurcumin interventions. Ramezani et al.'s findings that both curcumin groups had significantly lower VAS scores by week 3 highlight the clinical relevance of this treatment. While Delavarian et al. did not report detailed pain scores, the observed improvements in mucositis severity, which is directly correlated with pain, suggest a positive impact on patient comfort and quality of life. This is further supported by the noted improvements in symptoms like difficulty swallowing [13, 16].

The safety and tolerability of curcumin nanoparticles, as highlighted by both studies, are major advantages [13, 16].With no serious adverse events and no withdrawals due to side effects, nanocurcumin emerges as a well-tolerated option for a patient population already burdened by the side

effects of cancer treatment. This excellent safety profile, coupled with its demonstrated efficacy, makes it a highly attractive candidate for integration into standard supportive care protocols.

However, despite these strengths, the review has several limitations. The evidence base is restricted to just two studies, both conducted in Iran. While the designs of the trials were rigorous, including a double-blind, placebo-controlled trial, their relatively small sample sizes and limited geographic scope may affect the applicability of the results to wider populations. Also, the lack of detailed reporting on pain scores in one of the studies also represents a gap in the available evidence. Finally, the differences in formulation like micellar capsules, mouthwash and nano capsules, and treatment duration across the studies, while highlighting the versatility of nanocurcumin, make direct comparisons and meta-analysis challenging.

Future research should aim to address these limitations. Larger multi-centre international randomized controlled trials are needed to confirm these findings across diverse populations and cancer types. Studies should also standardize the reporting of outcomes, particularly pain scores, to allow for more robust statistical analysis. Additionally, head-to-head comparisons of different nanocurcumin formulations could provide valuable insights into optimal delivery methods. Finally, investigations into the precise molecular mechanisms of nanocurcumin in human subjects, beyond its established anti-inflammatory and antioxidant properties, would further strengthen the evidence base for its clinical use.

Conclusion

This systematic review provides consistent evidence that curcumin nanoparticle-based formulations are a safe and effective intervention for the prevention and management of oral mucositis. The benefits of CNPs include; delayed onset of mucositis, reduction in pain severity, mucosal healing, and improved patient comfort, with no reported serious adverse effects. Nevertheless, the limited number of available studies, small sample sizes, necessitate caution in generalizing results. Future studies should look toward designing large-scale, multi-center trials with standardized outcome measures and direct comparisons of various nanocurcumin delivery systems are warranted to establish optimal protocols and confirm the broader applicability of these promising findings.

Abbreviations

- CNP: Curcumin NanoParticle
- PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- ROB: Risk Of Bias
- NF-κB: Nuclear Factor kappa-light
- MeSH: Medical Subject Headings
- OM: Oral Mucositis
- GRADE: Grading of Recommendations Assessment, Development, and Evaluation

- VAS: Visual Assessment Scale
- NRS: Numerical Rating Scale
- CI: Confidence Interval

Declarations

Acknowledgments: None

Declaration of conflicting interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Funding statement: None

Ethical approval and informed consent statements: Not Applicable

Data availability statement: All data generated or analyzed during this study are included in this published article and its supplementary information files.

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Figures

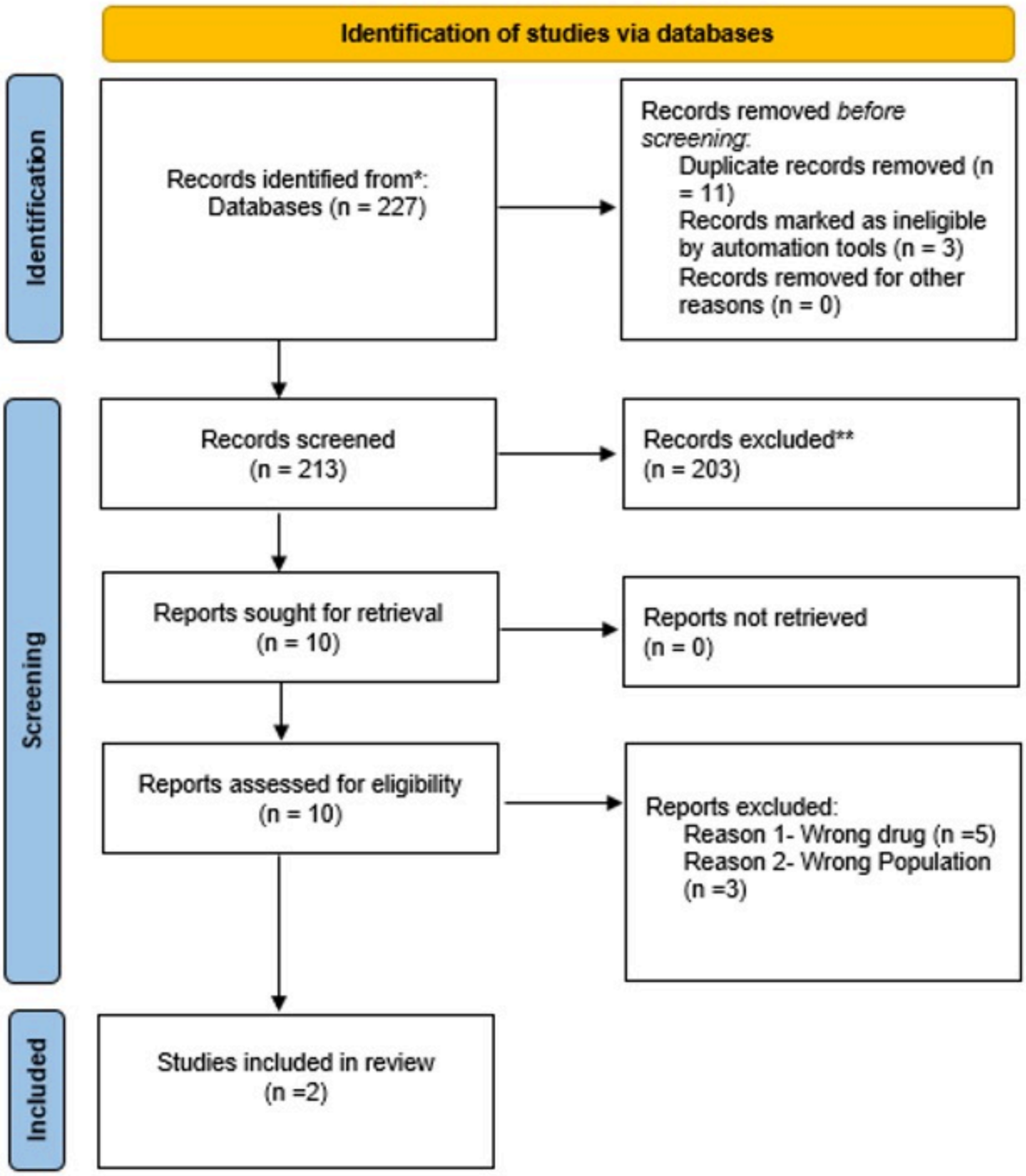

Figure 1

Study selection, screening process (PRISMA Diagram)

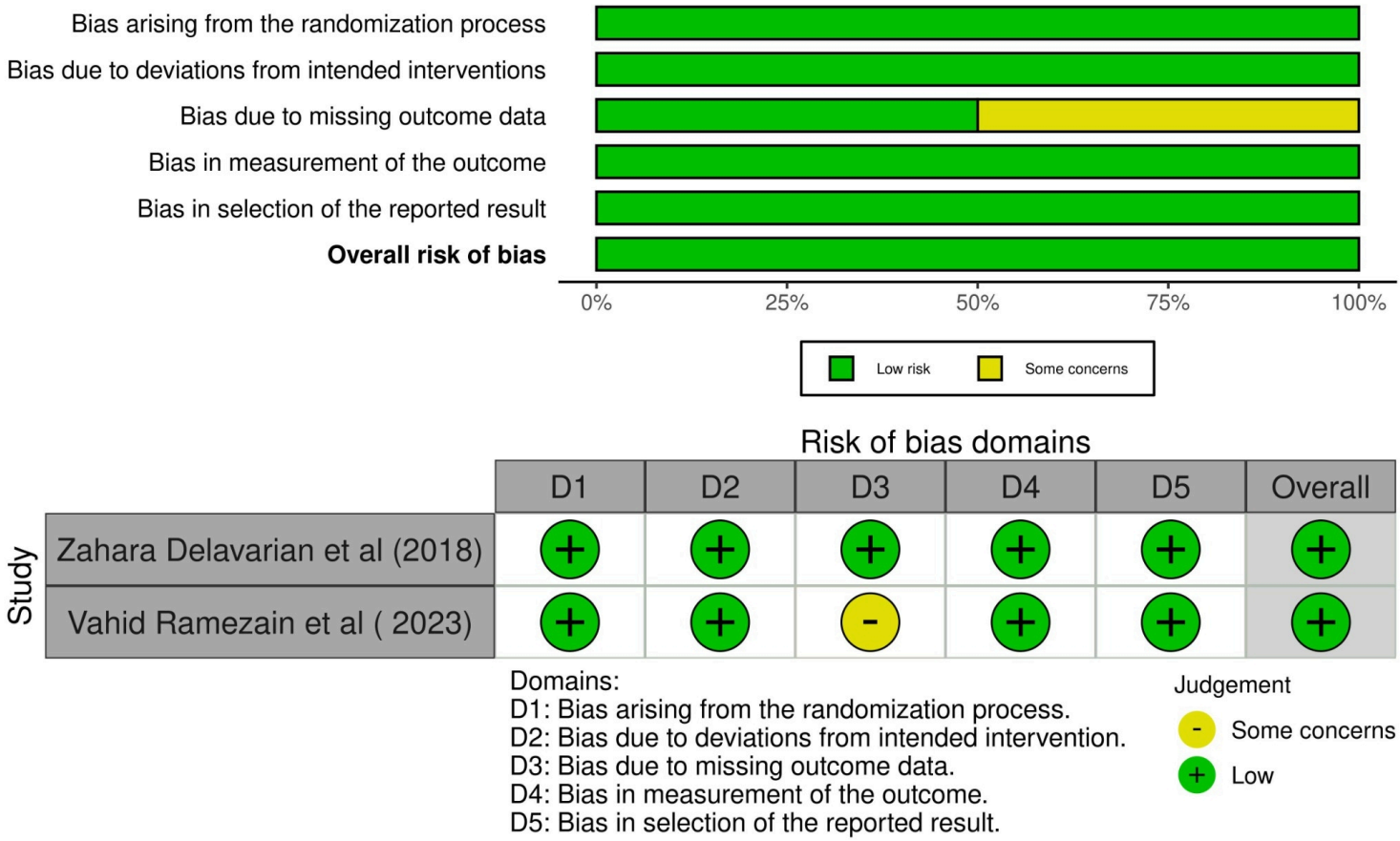

Figure 2

Risk of Bias assessment of included studies

Supplementary Files

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- AppendixI.docx
- AppendixII.docx