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Clinical Safety & Efficacy of Mustadi Yog in the Management of Respiratory Allergic Disorders (RADS) in Children – A Double-Blind Randomized Placebo-Controlled Study

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KEYWORDS

Mustadi Yog; Respiratory Allergic Disorders; Children; Double Blind Randomized Trial; Placebo Controlled; Ayurvedic Therapy

ABSTRACT:

Background:

Respiratory allergic disorders (RADS) in children often require long term symptomatic management, yet conventional therapies carry risk of adverse effects. Mustadi Yog an Ayurvedic polyherbal formulation has demonstrated immunomodulatory potential in preclinical studies. We evaluated its clinical safety and efficacy as an adjunctive therapy in pediatric RADS.

Methods:

In this double blind, randomized, placebo controlled trial, 60 children (6–12 years) with physician diagnosed RADS were enrolled at the PG Department of Prasuti & Stri Roga, Nitishwar Ayurved Medical College & Hospital, Muzaffarpur, Bihar, between April 2018 and March 2019. Participants were randomized (1:1) to receive Mustadi Yog (Group A, n = 30) or identical placebo (Group B, n = 30) twice daily, in addition to standard symptomatic care, for 8 weeks. The primary endpoint was change in total symptom score (sneezing, nasal congestion, cough) from baseline to week 8. Secondary endpoints included frequency of symptom exacerbations and Pediatric Quality of Life (PQOL) scores. Safety assessments comprised adverse-event monitoring and routine hematology and biochemistry.

Results:

Mustadi Yog administration led to a statistically significant greater reduction in total symptom score at week 8 compared with placebo ($p < 0.05$). Exacerbation frequency was markedly lower in the Mustadi Yog group, and PQOL scores improved significantly versus placebo ($p < 0.05$). No serious adverse events occurred, and all laboratory parameters remained within normal limits, indicating an excellent safety profile.

Conclusion:

Mustadi Yog is a safe and effective adjunctive therapy for reducing symptoms, lowering exacerbation rates, and improving quality of life in children with RADS.

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Introduction

Respiratory allergic disorders (RADS), encompassing allergic rhinitis, allergic asthma, and related upper- and lower-airway reactivity, affect a substantial proportion of children worldwide and can significantly impair quality of life, school performance, and sleep patterns. Conventional pharmacotherapies antihistamines, intranasal corticosteroids, and bronchodilators provide symptomatic relief but are often associated with adverse effects such as sedation, mucosal dryness, and, in the case of systemic steroids, potential impacts on growth and immunity. Consequently, there is growing interest in complementary and integrative approaches that may offer effective symptom control with an improved safety profile [1,2].

Ayurvedic medicine describes RADS under the broad umbrella of *Pratishyaya* (rhinitis) and *Shwasa* (respiratory dyspnea), attributing their pathogenesis to an imbalance of *Vata* and *Kapha* doshas, aggravated by environmental allergens and immature digestive fire (*Agni*) in children. *Mustadi Yog*, a classical polyherbal formulation referenced in the *Yogaratnakara* and allied Ayurvedic texts, combines herbs with proven anti-inflammatory, immunomodulatory, and mucolytic properties. Its principal ingredients such as *Gandhaka* (sulfur), *Trikatu* (three pungent spices), and *Shunthi* (dry ginger) are traditionally employed to pacify *Kapha* and facilitate respiratory clearance, while *Yogavahi* carriers enhance bioavailability [3,4].

Preclinical studies have demonstrated that Mustadi Yog components inhibit pro-inflammatory cytokine release, reduce IgE-mediated mast cell degranulation, and modulate oxidative stress markers. However, robust clinical evidence particularly from double-blind, placebo-controlled trials in the pediatric population remains scarce. While several open-label studies report symptomatic improvements, they lack the methodological rigor necessary to establish efficacy and safety conclusively [5,6].

To address this gap, we conducted a double-blind, randomized, placebo-controlled trial evaluating Mustadi Yog as an adjunct to standard symptomatic care in children with RADS. This study aimed to quantify its effects on symptom severity, exacerbation frequency, and health-related quality of life, while rigorously monitoring safety through laboratory parameters and adverse-event reporting. The findings are intended to inform evidence-based integration of Ayurvedic therapeutics into pediatric respiratory allergy management.

Materials and Methods

Study Design and Setting

This was a double-blind, randomized, placebo-controlled trial conducted over 12 months from April 2018 to March 2019 in the Post-Graduate Department of Prasuti & Stri Roga at Nitishwar Ayurved Medical College & Hospital, Muzaffarpur, Bihar, India.

Participants

Inclusion Criteria:

- Children aged 6–12 years with physician-diagnosed respiratory allergic disorder (allergic rhinitis or mild-to-moderate allergic asthma) according to ARIA (Allergic Rhinitis and its Impact on Asthma) criteria
- Baseline total symptom score ≥ 4 (see "Outcome Measures")
- Written informed consent from parent/guardian

Exclusion Criteria:

- Severe asthma requiring hospitalization or systemic corticosteroids in past 4 weeks
- Known chronic illnesses (hepatic, renal, cardiac) or immunodeficiency
- Use of any other herbal or investigational product within 4 weeks prior to enrollment
- Known hypersensitivity to any Mustadi Yog ingredients

Sample Size and Randomization

Based on detecting a 20 percent difference in symptom-score reduction between groups with 80 percent power and $\alpha = 0.05$, 26 subjects per arm were required. Allowing for a 15 percent dropout, 60 children were enrolled and randomized 1:1 ($n = 30$ per group) using a computer-generated sequence. Allocation concealment was ensured via sequentially numbered, opaque, sealed envelopes prepared by an independent pharmacist.

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Interventions

- **Group A (Mustadi Yog):** Mustadi Yog powder (Yogavahi base; batch no. MY2018/04) administered orally at 3 g twice daily, mixed with warm water, for 8 weeks.
- **Group B (Placebo):** Identical-looking placebo powder (inert carrier) administered at 3 g twice daily, same schedule. Both groups received standard symptomatic care (oral antihistamines and/or inhaled β_2-agonists) as needed, per ARIA guidelines.

Outcome Measures

- **Primary Endpoint:** Change in total symptom score from baseline to week 8. Children (with parental assistance) recorded daily scores for sneezing, nasal congestion, and cough on a 4-point Likert scale (0 = none; 1 = mild; 2 = moderate; 3 = severe), yielding a daily total score range of 0–9. Weekly mean scores were averaged for analysis.
- **Secondary Endpoints:**
    - **Exacerbation Frequency:** Number of symptom exacerbations (increase in total daily score ≥ 3 above individual baseline for ≥ 2 consecutive days, requiring rescue medication).
    - **Quality of Life:** Pediatric Rhino conjunctivitis Quality of Life Questionnaire (PRQLQ), which assesses symptoms, practical problems, activity limitations, emotions, and non-nose/eye symptoms; each domain scored 0–6.
- **Safety Assessments:** Monitoring of adverse events at each visit; laboratory evaluations (complete blood count, liver and renal function tests) at baseline and week 8.

Study Procedures

Visits occurred at baseline, week 4, and week 8. At each visit:

1. Review of symptom diary and rescue-medication use
2. PRQLQ administration
3. Assessment of adverse events
4. Collection of blood samples for laboratory tests (baseline and week 8 only)

Statistical Analysis

Data were analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY). Continuous variables are presented as mean ± standard deviation (SD); categorical variables as counts and percentages. Between-group comparisons of change scores employed unpaired t-tests (or Mann–Whitney U test if non-normal). Within-group pre- versus post-treatment comparisons used paired t-tests. Exacerbation rates were compared via χ^2 test. A p-value < 0.05 was considered statistically significant.

Results

Participant Disposition and Baseline Characteristics

A total of 60 children were enrolled and randomized equally to the Mustadi Yog and placebo arms. All participants completed the 8-week intervention period, with no dropouts or major protocol deviations. Treatment compliance exceeded 95 percent in both groups, as assessed by returned sachet counts and parental diaries. The two groups were well matched at baseline in terms of age distribution, sex ratio, and symptom severity; all children presented with moderate respiratory allergic symptom scores and comparable quality-of-life impairments prior to randomization.

Primary Outcome: Total Symptom Score

From the first follow-up at Week 4, children receiving Mustadi Yog exhibited a clear and sustained decline in overall symptom burden comprising sneezing, nasal congestion, and cough—relative to the placebo group. By Week 8, the treatment arm demonstrated a markedly greater reduction in mean symptom severity, reflecting both diminished daily symptom intensity and fewer days with moderate-to-severe scores. In contrast, the placebo arm showed only a gradual, modest improvement over the same period. Statistical comparisons confirmed that the Mustadi Yog group's symptom-score reduction was significantly superior ($p < 0.05$) to placebo, indicating a

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robust therapeutic effect emerging early in the course of treatment and maintained through the study's end.

Secondary Outcome: Exacerbation Frequency

Analysis of acute exacerbations—defined as symptom flares necessitating additional rescue medication revealed a pronounced difference between groups. In the Mustadi Yog arm, fewer children experienced any exacerbation during the 8-week period, and those who did encountered shorter episodes with rapidly resolving severity. By contrast, exacerbations in the placebo group were more frequent and of longer duration. These findings demonstrate that Mustadi Yog not only alleviates baseline symptoms but also reduces the occurrence and intensity of breakthrough flares ($p < 0.05$).

Secondary Outcome: Quality of Life

Quality-of-life, assessed via the Pediatric Rhinoconjunctivitis Quality of Life Questionnaire, improved substantially in the Mustadi Yog cohort. Children and their parents reported notable enhancements across key domains nasal and ocular symptom relief, reduced practical disruptions (such as fewer days of school absence or play interruption), increased participation in physical activities, and better emotional well-being. Improvements were evident by mid-treatment and continued to accrue through Week 8. In the placebo group, modest gains occurred predominantly in symptom domains but were not reflected in the broader functional and emotional dimensions. Comparative analyses confirmed a significantly greater overall quality-of-life improvement with Mustadi Yog ($p < 0.05$).

Rescue Medication Use

Rescue medication use mirrored the patterns seen in symptom and exacerbation outcomes. Children in the Mustadi Yog arm required antihistamines or inhaled β_2-agonists on fewer days and at lower total dosages compared with the placebo arm. This reduction in adjunctive medication underscores the clinical relevance of Mustadi Yog as an effective adjunct, diminishing dependence on conventional pharmacotherapy during the treatment period.

Safety and Tolerability

Mustadi Yog exhibited an excellent safety profile. No serious adverse events were reported in either study arm. The incidence of mild, transient adverse complaints such as minimal gastrointestinal discomfort or occasional headache was low and comparable between groups. Routine hematology and biochemical evaluations at baseline and Week 8 showed stable values within normal clinical ranges, with no evidence of hepatic, renal, or hematologic perturbation attributable to Mustadi Yog. These results confirm that the formulation is well tolerated in the pediatric population.

Summary of Findings

Overall, the Mustadi Yog intervention produced clinically meaningful improvements in symptom control, exacerbation prevention, and health-related quality of life in children with respiratory allergic disorders. The onset of benefit was rapid, observable by the fourth week of treatment, and sustained through eight weeks. Safety assessments further validated its tolerability as an adjunct to standard care. Collectively, these outcomes support Mustadi Yog as a promising, well-tolerated complementary therapy for pediatric RADS.

Discussion

This double-blind, randomized, placebo-controlled trial demonstrates that Mustadi Yog, when administered as an adjunct to standard symptomatic care, produces clinically meaningful benefits in children with respiratory allergic disorders (RADS) [7]. Treatment with Mustadi Yog resulted in a rapid and sustained reduction in total symptom burden comprising sneezing, nasal congestion, and cough beginning by Week 4 and persisting through the 8-week intervention [8]. In parallel, Mustadi Yog markedly reduced the frequency and duration of acute exacerbations requiring rescue medication, and yielded significant improvements in health-related quality of life across nasal/ocular symptoms, functional limitations, and emotional well-being domains. The formulation was well tolerated, with no serious adverse events and stable laboratory parameters throughout treatment [9].

Interpretation of Findings

The observed symptom relief and exacerbation reduction support the hypothesized anti-inflammatory and

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immunomodulatory effects of Mustadi Yog's herbal constituents. Sulfur (Gandhaka) and Trikatu (Piper longum, Piper nigrum, Zingiber officinale) are known to enhance respiratory clearance, while dry ginger (Shunthi) exerts mucolytic and antioxidant actions. Together, these botanicals likely modulate local airway inflammation and oxidative stress, leading to reduced mucosal edema, decreased mast-cell degranulation, and stabilization of bronchial hyperreactivity. The quality-of-life benefits—manifesting as improved sleep, school attendance, and emotional comfort reflect the broader impact of sustained symptom control on daily functioning in pediatric patients [10].

Comparison with Existing Literature

Although Ayurvedic therapies are widely used in clinical practice for allergic rhinoconjunctivitis and asthma, high-quality randomized controlled trials in pediatric populations are scarce. Open-label studies have suggested symptomatic improvements with various polyherbal formulations, but methodological limitations lack of blinding, small sample sizes, and heterogeneous outcome measures have precluded definitive conclusions [11]. This trial's rigorous design and standardized endpoints add robust evidence to the field, aligning with preclinical data on Mustadi Yog's bioactivity but extending it into the clinical domain. The magnitude of symptom-score reduction and quality-of-life gains observed compares favorably with those reported for intranasal corticosteroids and leukotriene modifiers in pediatric allergic rhinitis, suggesting that Mustadi Yog may serve as a complementary strategy to minimize conventional drug exposure [12].

Strengths

Key strengths of this study include its double-blind, placebo-controlled design and high treatment compliance (> 95 percent), which minimize bias and enhance internal validity. The use of validated outcome measures daily symptom diaries based on ARIA criteria and the Pediatric Rhinoconjunctivitis Quality of Life Questionnaire ensures comparability with other clinical trials. Systematic safety monitoring, including routine hematology and biochemistry, provides comprehensive tolerability data. Moreover, the absence of dropouts underscores the feasibility and acceptability of Mustadi Yog in the target population.

Limitations

Several limitations warrant consideration. First, the study's 8-week duration captures short-term efficacy and safety but precludes assessment of long-term outcomes, such as sustained remission or potential cumulative benefits. Second, although symptomatic care was standardized according to ARIA guidelines, rescue medication use was guided by individual symptom perception, which may introduce variability. Third, the trial enrolled children with mild-to-moderate RADS; results may not generalize to severe asthma or comorbid conditions. Finally, mechanistic biomarkers—such as serum IgE, cytokine profiles, or oxidative stress markers were not measured, limiting insight into the formulation's precise immunological effects.

Clinical and Research Implications

The favorable efficacy and safety profile of Mustadi Yog suggests it may be integrated as an adjunctive therapy in pediatric RADS management. By reducing symptom burden and rescue-medication reliance, Mustadi Yog holds promise for improving patient adherence and minimizing conventional drug side effects. Clinicians should consider its incorporation—particularly in settings where Ayurvedic medicine is culturally accepted and readily available.

Future research should extend treatment duration and include follow-up assessments to evaluate sustained benefits and relapse rates. Parallel mechanistic studies exploring changes in immunoglobulin levels, cytokine expression, and airway inflammation biomarkers would elucidate underlying pathways. Investigations in more severe asthma phenotypes and adolescent populations would further define the formulation's therapeutic scope.

Conclusion

This trial provides compelling evidence that Mustadi Yog is a safe, well-tolerated, and effective adjunctive therapy for children with respiratory allergic disorders. Its clinical benefits rapid symptom relief, fewer exacerbations, and enhanced quality of life support its wider adoption and warrant larger, longer-term studies to confirm and extend these findings.

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