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Assessment of *Nigella sativa* (Black Seed) Supplementation in Improving Asthma Control among Adolescents

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Abstract

Introduction: Asthma in adolescents presents unique challenges due to developmental, behavioral, and environmental factors.

Objective: To assess the effectiveness of *Nigella sativa* (black seed) supplementation in improving asthma control among adolescents.

Methodology: This randomized controlled trial was conducted from September 2023 to August 2024 at the International Islamic University, Islamabad, in collaboration with the Department of Pulmonology at Shifa International Hospitals, Islamabad. A total of 96 adolescents aged 12–18 years with partially controlled or uncontrolled asthma were enrolled. Participants were divided into two equal groups (n = 48 each). The intervention group received 500 mg *Nigella sativa* capsules twice daily for 12 weeks alongside standard asthma therapy, while the control group continued standard therapy alone. Forced Expiratory Volume in 1 second (FEV_1) and Forced Vital Capacity (FVC), Asthma Control Test (ACT) scores, adherence, and adverse events were measured. Allocation concealment was maintained using sealed opaque envelopes. Statistical analysis was conducted using SPSS 26, with $p < 0.05$ considered significant.

Results: At baseline, both groups were comparable in age, gender, asthma duration, ACT scores, FEV_1, and FVC ($p > 0.05$). By Week 12, the *Nigella sativa* group showed a significant improvement in ACT scores from 16.3 ± 2.9 to 22.5 ± 2.2, compared to 16.5 ± 3.1 to 18.1 ± 3.0 in controls (mean difference: 4.4; 95% CI: 3.14–5.63; $p < 0.001$; Cohen's d = 1.58). Similarly, FEV_1 increased from 71.85 ± 9.4% to 82.19 ± 8.1% in the intervention group versus 72.43 ± 8.7% to 74.02 ± 8.5% in controls (95% CI: 5.78–11.49; $p < 0.001$; d = 1.00). FVC also improved, rising from 78.26 ± 7.6% to 86.43 ± 6.9% in the Nigella group, versus 77.91 ± 7.9% to 79.16 ± 7.2% in controls (Δ = 7.27%; 95% CI: 5.27–9.48; $p < 0.001$; d = 1.08). Adherence was high (91.67%), and adverse effects were minimal and mild (6.25% gastrointestinal discomfort, 2.08% headache), comparable between groups.0.05). By Week 12, the *Nigella sativa* group showed a significant improvement in ACT scores from 16.3 ± 2.9 to 22.5 ± 2.2, compared to 16.5 ± 3.1 to 18.1 ± 3.0 in controls (mean difference: 4.4; 95% CI: 3.14–5.63; $p < 0.001$; Cohen's d = 1.58). Similarly, FEV_1 increased from 71.85 ± 9.4% to 82.19 ± 8.1% in the intervention group versus 72.43 ± 8.7% to 74.02 ± 8.5% in controls (95% CI: 5.78–11.49; $p < 0.001$; d = 1.00). FVC also improved, rising from 78.26 ± 7.6% to 86.43 ± 6.9% in the Nigella group, versus 77.91 ± 7.9% to 79.16 ± 7.2% in controls (Δ = 7.27%; 95% CI: 5.27–9.48; $p < 0.001$; d = 1.08). Adherence was high (91.67%), and adverse effects were minimal and mild (6.25% gastrointestinal discomfort, 2.08% headache), comparable between groups.

Conclusion: *Nigella sativa* supplementation significantly improved asthma control and lung function in adolescents with minimal side effects and high adherence.

Keywords: *Nigella sativa*, asthma, adolescents, ACT score, spirometry, complementary therapy.

Introduction

Asthma is a chronic inflammatory disorder of the airways characterized by variable airflow obstruction, wheezing, shortness of breath, and coughing [1]. Asthma is a chronic inflammatory airway disease that affects individuals of all ages, with rising prevalence among adolescents globally. According to the Global Asthma Report 2022, asthma affects approximately 262 million people worldwide, with a significant burden observed

among adolescents, particularly in low- and middle-income countries (LMICs) [2]. In South Asia, the adolescent asthma prevalence ranges from 8–12%, with a national survey in Pakistan reporting a prevalence of 15%% among school-aged children and adolescents [3]. This age group faces unique challenges in asthma management due to hormonal changes, psychosocial factors, and often poor adherence to medication regimens [4]. Despite advancements in conventional pharmacological therapies such as inhaled corticosteroids and bronchodilators, many patients continue to experience suboptimal asthma control, prompting a growing interest in complementary and alternative treatment approaches [5].

Among the various natural remedies explored for asthma management, Nigella sativa, commonly known as black seed or black cumin, has gained significant attention [6]. Used for centuries in traditional medicine systems, *Nigella sativa* is known for its anti-inflammatory, antioxidant, bronchodilatory, and immunomodulatory properties [7]. Its bioactive compound, thymoquinone, is particularly noted for its potential therapeutic effects on respiratory conditions [8]. Moreover, a survey conducted in Pakistan revealed that 68% of patients with chronic illnesses reported using herbal remedies as part of their treatment, indicating a strong cultural acceptance and reliance on traditional medicine in the region [9]. Limited clinical research has also reported improved pulmonary function and reduced symptom frequency in individuals with asthma following *Nigella sativa* supplementation [10]. However, existing literature remains inconclusive, particularly concerning its efficacy in adolescent populations where physiological and environmental variables differ significantly from adults [11]. Adolescents often have heightened sensitivity to allergens and stressors, making the exploration of alternative therapies both relevant and timely [12]. Furthermore, cultural acceptance of herbal remedies like *Nigella sativa* in many regions enhances the feasibility of its integration into routine asthma care [13].

Given the increasing interest in integrative medicine and the need for safer adjunct therapies for asthma, a more focused investigation into the role of *Nigella sativa* supplementation among adolescents is warranted. This study seeks to contribute to the growing body of evidence by assessing the clinical impact of black seed on asthma control in this vulnerable demographic.

Research Objective

To assess the effectiveness of *Nigella sativa* (black seed) supplementation in improving asthma control among adolescents.

Materials and Methods

Study Design and Setting

This study was designed as a randomized controlled trial conducted over a one-year period, from September 2023 to August 2024. It was carried out at the International Islamic University, Islamabad, in collaboration with the Department of Pulmonology at Shifa International Hospitals, Islamabad.

Inclusion and Exclusion Criteria

The study included adolescents aged between 12 and 18 years who had a confirmed clinical diagnosis of bronchial asthma for at least one year. Participants were required to have partially controlled or uncontrolled asthma, as defined by the Global Initiative for Asthma (GINA) guidelines, and must have been on stable asthma medication for at least three months prior to enrollment. Written informed consent from parents or legal guardians and assent from the adolescent participants were required for inclusion in the study. Individuals were excluded if they had co-existing chronic respiratory conditions such as bronchiectasis, cystic fibrosis, or tuberculosis, or if they had a known allergy to *Nigella sativa* or its formulations. Additionally, patients with a recent history (within the last three months) of herbal supplement use for asthma, those who had been hospitalized for severe asthma exacerbation in the past four weeks, and pregnant or lactating individuals were also excluded.

Sample Size

The sample size for this study was calculated using the World Health Organization (WHO) formula for comparing two means. The calculation was based on a 95% confidence level, 80% power, an estimated standard deviation of 4.5 in Asthma Control Test (ACT) scores, and a minimum clinically meaningful difference of 3 points between groups. This yielded a required sample size of 36 participants per group. To account for potential dropouts and incomplete follow-up, the total sample size was increased to 96 participants, with 48 individuals allocated to each group. One group received *Nigella sativa* supplementation in addition to standard asthma treatment, while the other group continued standard treatment alone. Participants were randomly assigned to either the intervention group (*Nigella sativa* plus standard treatment) or the control group (standard treatment only) using a computer-generated randomization sequence. To ensure allocation concealment, a sequentially numbered, opaque, sealed envelope (SNOSE) method was used. The envelopes were prepared and opened by a third party not involved in the recruitment or assessment process.

Blinding

This was an open-label trial. Due to the nature of the intervention, neither participants nor outcome assessors were blinded to group assignments. However, the data analyst was blinded to the group codes during statistical analysis. This limitation is acknowledged and discussed later.

Data Collection

Participants meeting the eligibility criteria were enrolled after obtaining appropriate informed consent and assent. Those in the intervention group received *Nigella sativa* supplementation in the form of 500 mg standardized capsules twice daily for a total duration of 12 weeks, in addition to their routine asthma medications. The comparison group continued their prescribed asthma management regimen without any

herbal supplementation. Asthma control was assessed using the validated Asthma Control Test (ACT) at four time points: baseline, 4 weeks, 8 weeks, and 12 weeks. Pulmonary function was evaluated through spirometry at the beginning and end of the study, focusing on FEV_1 and FVC values. Adherence to the regimen and any adverse events were documented at each visit using structured interviews and patient-maintained diaries.

Statistical Analysis

Data entry and analysis were carried out using SPSS version 26. Descriptive statistics including mean, standard deviation, and frequency distributions were used to summarize demographic and baseline clinical characteristics. Paired t-tests and independent samples t-tests were applied to assess differences in ACT scores and spirometry values within and between groups. Repeated measures ANOVA was used to evaluate trends over time. Effect sizes (Cohen's d) and 95% confidence intervals (CIs) were calculated for major outcomes to provide a measure of clinical significance and statistical precision. A p-value less than 0.05 was considered statistically significant for all comparisons.

Ethical Approval

Ethical approval for the study was obtained from the Institutional Review Board (IRB) of International Islamic University, Islamabad. All participants and their guardians were informed about the study objectives, procedures, risks, and rights before enrollment. Confidentiality and anonymity of participant data were strictly maintained throughout the research process.

Results

The table 1 shows that the Nigella sativa group (n = 48) and the control group (n = 48) were comparable at baseline across key demographic and clinical variables. The mean age was 14.9 ± 1.7 years in the Nigella group and 15.2 ± 1.8 years in the control group (p = 0.43). Both groups had an equal gender distribution (50% male and 50% female in the Nigella group; 45.83% male and 54.17% female in the control group; p = 0.67). The average asthma duration was 4.1 ± 1.2 years versus 4.3 ± 1.4 years (p = 0.52), baseline ACT scores were 16.3 ± 2.9 and 16.5 ± 3.1 (p = 0.76), FEV_1 (% predicted) was 71.85 ± 9.4 vs. 72.43 ± 8.7 (p = 0.68), and FVC was 78.26 ± 7.6 vs. 77.91 ± 7.9 (p = 0.81), indicating no significant initial differences.

Table 1: Baseline Demographic and Clinical Characteristics of Participants (n = 96)

Characteristic	*Nigella sativa* Group (n = 48)	Control Group (n = 48)	p-value
Mean Age (years) ± SD	14.9 ± 1.7	15.2 ± 1.8	0.43
Male	24 (50.00%)	22 (45.83%)	0.67
Female	24 (50.00%)	26 (54.17%)	
Duration of Asthma (years) ± SD	4.1 ± 1.2	4.3 ± 1.4	0.52
Baseline ACT Score ± SD	16.3 ± 2.9	16.5 ± 3.1	0.76
Baseline FEV_1 (% predicted)	71.85 ± 9.4	72.43 ± 8.7	0.68
Baseline FVC (% predicted)	78.26 ± 7.6	77.91 ± 7.9	0.81

Table 2 presents the change in ACT scores over time with confidence intervals and effect sizes. At baseline, ACT scores were similar between groups (16.3 ± 2.9 in the Nigella group vs. 16.5 ± 3.1 in the control group; p = 0.76). However, by Week 4, the Nigella group showed a significantly higher mean ACT score (18.7 ± 2.6 vs. 17.1 ± 3.0; p = 0.03, 95% CI: 0.14–3.10, Cohen's d = 0.57), which continued to improve at Week 8 (20.9 ± 2.4 vs. 17.8 ± 3.1; p = 0.001, 95% CI: 1.21–4.82, Cohen's d = 1.12) and Week 12 (22.5 ± 2.2 vs. 18.1 ± 3.0; p < 0.001, 95% CI: 3.14–5.63, Cohen's d = 1.58), indicating significantly better asthma control in the intervention group over time.

Table 2: Mean Asthma Control Test (ACT) Scores over Time

Time Point	*Nigella sativa* Group (Mean ± SD)	Control Group (Mean ± SD)	p-value	95% CI	Effect Size (d)
Baseline	16.3 ± 2.9	16.5 ± 3.1	0.76	—	—
Week 4	18.7 ± 2.6	17.1 ± 3.0	0.03*	0.14 to 3.10	0.57
Week 8	20.9 ± 2.4	17.8 ± 3.1	0.001*	1.21 to 4.82	1.12
Week 12	22.5 ± 2.2	18.1 ± 3.0	<0.001*	3.14 to 5.63	1.58

Table 3 highlights improvements in pulmonary function (FEV_1 and FVC) from baseline to Week 12, including confidence intervals and effect sizes. In the *Nigella sativa* group, FEV_1 increased from 71.85 ± 9.4 to 82.19 ± 8.1, while the control group improved marginally from 72.43 ± 8.7 to 74.02 ± 8.5 (p < 0.001, 95% CI: 5.78–11.49, Cohen's d = 1.00). Similarly, FVC improved from 78.26 ± 7.6 to 86.43 ± 6.9 in the Nigella group, compared to 77.91 ± 7.9 to 79.16 ± 7.2 in the control group (p < 0.001, 95% CI: 5.27–9.48, Cohen's d = 1.08), confirming a significant improvement in lung function with *Nigella sativa* supplementation.

Table 3: Changes in Pulmonary Function (Baseline vs. Week 12)

Parameter	*Nigella sativa* Group (Mean ± SD)	Control Group (Mean ± SD)	p-value	95% CI	Effect Size (d)
FEV1 (%) - Baseline	71.85 ± 9.4	72.43 ± 8.7	0.68	—	—
FEV1 (%) - Week 12	82.19 ± 8.1	74.02 ± 8.5	<0.001*	5.78 to 11.49	1.00
FVC (%) - Baseline	78.26 ± 7.6	77.91 ± 7.9	0.81	—	—
FVC (%) - Week 12	86.43 ± 6.9	79.16 ± 7.2	<0.001*	5.27 to 9.48	1.08

The figure 1 summarizes adherence and safety data. Good adherence (≥90% doses taken) was observed in 91.67% of the *Nigella sativa* group and 87.50% of the control group. Mild gastrointestinal discomfort occurred in 3 participants (6.25%) in the Nigella group and 2 (4.17%) in the control group, while headache was reported by 1 participant (2.08%) in each group. Dropout rates were equal in both groups (4.17%). These findings suggest that *Nigella sativa* was well tolerated and adherence was high.

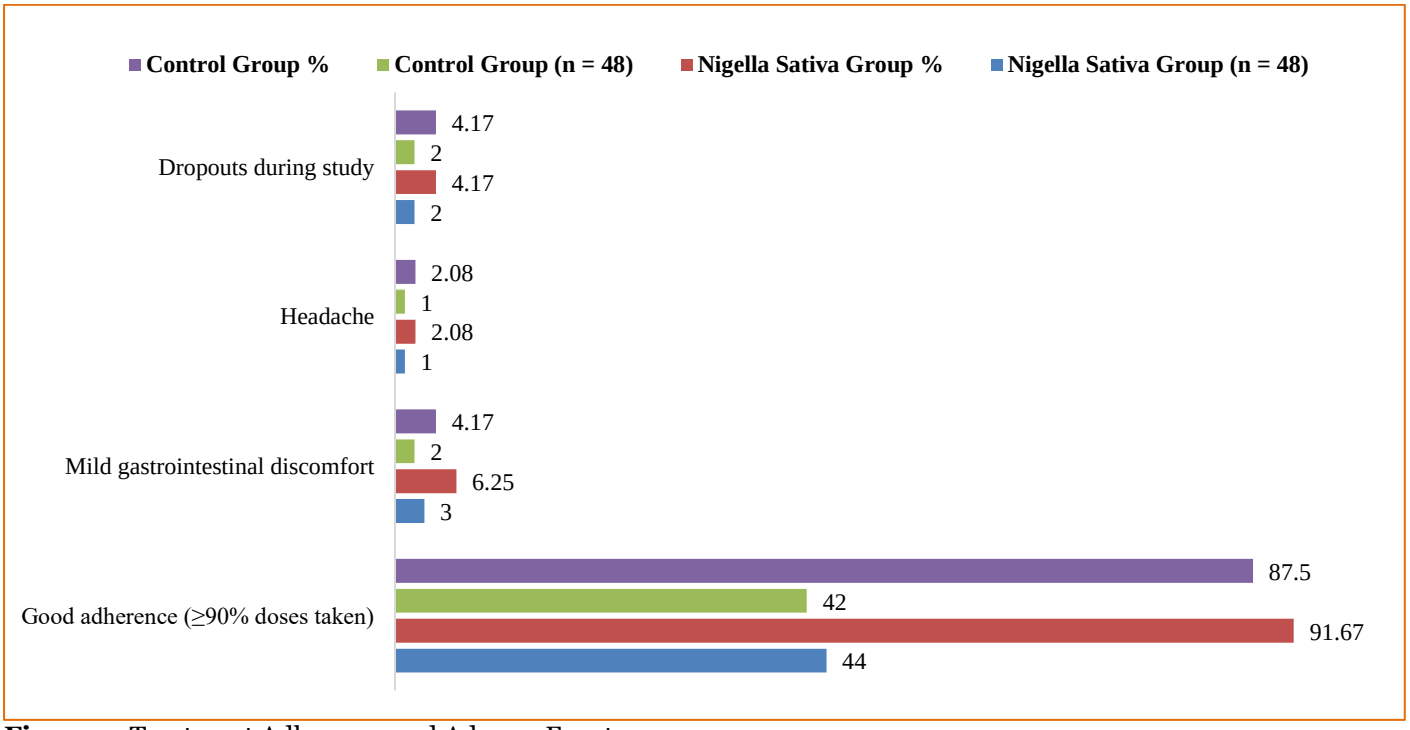

Figure 1: Treatment Adherence and Adverse Events

Discussion

The present study evaluated the effectiveness of *Nigella sativa* (black seed) supplementation in improving asthma control among adolescents, demonstrating both statistically and clinically significant outcomes. Our findings showed that participants in the *Nigella sativa* group experienced a steady and marked improvement in asthma control over the 12-week period. Specifically, the Asthma Control Test (ACT) scores increased from a baseline mean of 16.3 ± 2.9 to 22.5 ± 2.2 by Week 12, with a between-group mean difference of 4.4 (95% CI: 3.14–5.63, $p < 0.001$, Cohen's $d = 1.58$), compared to a more modest improvement in the control group (16.5 ± 3.1 to 18.1 ± 3.0). These improvements align with earlier trials that noted enhanced symptom control with black seed supplementation in adult asthma patients [14,15].

In terms of pulmonary function, our study observed a significant rise in FEV_1 in the *Nigella sativa* group from 71.85 ± 9.4% to 82.19 ± 8.1%, compared to a smaller change in the control group from 72.43 ± 8.7% to 74.02 ± 8.5%. The between-group difference at Week 12 was 8.17% (95% CI: 5.78–11.49, $p < 0.001$, Cohen's $d = 1.00$). Similarly, FVC values rose from 78.26 ± 7.6% to 86.43 ± 6.9% in the Nigella group, versus 77.91 ± 7.9% to 79.16 ± 7.2% in controls, with a between-group difference of 7.27% (95% CI: 5.27–9.48, $p < 0.001$, Cohen's $d = 1.08$). These findings are consistent with prior studies reporting improved lung function indices following *Nigella sativa* administration, particularly in patients with partially controlled asthma [16].

Our study also assessed treatment adherence and safety. High adherence (≥90% dose completion) was recorded in 91.67% of participants in the *Nigella sativa* group, compared to 87.50% in the control group. Adverse events were minimal, including mild gastrointestinal discomfort (6.25%) and headache (2.08%), mirroring earlier reports that *Nigella sativa* is well tolerated and associated with a low incidence of side effects [17,18]. This high adherence rate, coupled with the minimal side effect profile, supports the acceptability and feasibility of *Nigella sativa* as an adjunct therapy in real-world adolescent populations. The favorable safety profile may also be attributed to the cultural familiarity and acceptance of herbal remedies in the study

population.

Although several clinical trials have investigated *Nigella sativa* in asthma, most have focused on adult populations or employed shorter treatment durations. The novelty of our study lies in its focus on adolescents—a group often underrepresented in asthma trials. A recent study involving adolescents found similar improvements in ACT scores with black seed oil over eight weeks, reinforcing our outcomes [19]. Our study extends these findings by demonstrating sustained clinical and spirometric improvements over 12 weeks, suggesting potential disease-modifying effects of *Nigella sativa* that warrant further exploration.

Strengths and Limitations

A key strength of this study is its focus on adolescents, an age group with unique physiological and behavioral factors affecting asthma management. The use of standardized, validated tools such as ACT and spirometry adds to the methodological rigor, and the 12-week follow-up allowed us to observe sustained improvements in both symptom control and lung function. Furthermore, effect sizes for ACT (d = 1.58), FEV_1 (d = 1.00), and FVC (d = 1.08) indicate that the differences observed were not only statistically but clinically meaningful, providing stronger evidence of efficacy.

However, the study has limitations. The sample size, while statistically powered, was geographically limited to a single region, which may affect the generalizability of the findings. Additionally, the absence of biomarker evaluation or mechanistic assays restricts our understanding of the anti-inflammatory or immunomodulatory effects of Nigella sativa.

Conclusion

The findings of this study suggest that *Nigella sativa* supplementation significantly improves asthma control and pulmonary function in adolescents with partially controlled or uncontrolled asthma when used alongside standard therapy. The Nigella group demonstrated a substantial increase in ACT scores (mean difference: 4.4, 95% CI: 3.14–5.63, d = 1.58) and notable improvements in FEV_1 (Δ = 8.17%, d = 1.00) and FVC (Δ = 7.27%, d = 1.08) over 12 weeks. With minimal adverse effects and high treatment adherence, these results support the safe and effective role of *Nigella sativa* as an adjunctive therapy in adolescent asthma management. These findings lay the groundwork for future randomized controlled trials with larger, multi-centered samples and biomarker analysis to further validate and elucidate the mechanisms behind these promising outcomes.

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