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Therapeutic potential of *Nigella sativa* in metabolic disorders: A systematic review

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Abstract

Background: *Nigella sativa* also referred to as black cumin or black seed is a medicinal plant that has been used for various ailments. Recent studies have shown its efficacy in the treatment of metabolic disorders such as type 2 diabetes, obesity, and metabolic syndrome because of its anti-inflammatory, antioxidant, antidiabetic, and lipid-regulating properties. This systematic review aims to review the findings of different studies that were conducted between the years 2010 and 2024 on the effectiveness of *Nigella sativa* in these conditions.

Methods: The literature search was done using electronic databases such as PubMed, Google Scholar, and other related sources. The review was restricted to RCTs on the impact of *Nigella sativa* on glycemic control, lipid profile, blood pressure, weight, inflammation, oxidative stress, and safety. The criteria for the selection of the studies included the subject matter, which had to be related to metabolic disorders, the use of human subjects, and the language of the publication – English only.

Results: The review based on 25 studies showed that *Nigella sativa* enhances glycemic control, decreases lipid profile, aids in weight reduction, and decreases blood pressure. Other activities of *Nigella sativa* that were observed included anti-inflammatory and antioxidant effects which may be useful in metabolic disorders. The studies pointed out that the compound affected several biochemical pathways positively and improved insulin sensitivity and decreased the levels of oxidative stress.

Conclusion: *Nigella sativa* has a lot of therapeutic benefits in the management of metabolic disorders. The ability of nitric oxide to influence so many aspects of physiology and the apparent safety of its administration indicates that it may be a promising adjuvant therapy for these diseases. It is suggested that more large-scale and well-designed studies should be conducted to verify these conclusions and set up standard dosages.

Keywords: *Nigella sativa*, black seed, metabolic disorders, type 2 diabetes, obesity, hypertension, lipid profiles, inflammation, oxidative stress, antidiabetic, antioxidant

Introduction

Nigella sativa is a flowering plant that is also known as black seed or black cumin, which is indigenous to the regions of South and Southwest Asia. They have been known to possess many therapeutic uses in traditional medicine for hundreds of years. The seeds contain many phytochemicals such as thymoquinone, nigellone, and many essential oils that are responsible for the therapeutic properties. Recent studies have paid much attention to the effects of *Nigella sativa* on metabolic diseases including type 2 diabetes, obesity and metabolic syndrome. Metabolic disorders are defined as a group of diseases that are associated with the abnormal metabolism of glucose, lipids, and inflammatory mediators, which predispose an individual to cardiovascular diseases and other related diseases. The increase in the occurrence of these disorders globally has led to the search for natural products that can be used in the management or alleviation of the effects of these disorders. *Nigella sativa* is a promising candidate because of its diverse pharmacological activities such as anti-inflammatory, antioxidant, antidiabetic, and lipid lowering. This systematic review will therefore seek to give an update on the existing evidence on the use of *Nigella sativa* in the treatment of metabolic disorders. The review is based on the RCTs, cross-sectional studies, and meta-analyses published between 2010 and 2024. The main interest is on the impact of *Nigella sativa* on glycemic control, lipid profile, blood pressure, weight, inflammation, oxidative stress, and safety.

Among the most important topics of concern, there is the effect of *Nigella sativa* on glycemic management in patients with type 2 diabetes. Numerous researches have examined the impact of *Nigella sativa* supplementation on FBG, HbA1c, and insulin resistance. It is also suggested that the bioactive compounds of *Nigella sativa* particularly thymoquinone enhance insulin sensitivity and decrease blood glucose levels through the modulation of glucose metabolic pathways [1, 28, 19] improving glycemic control.

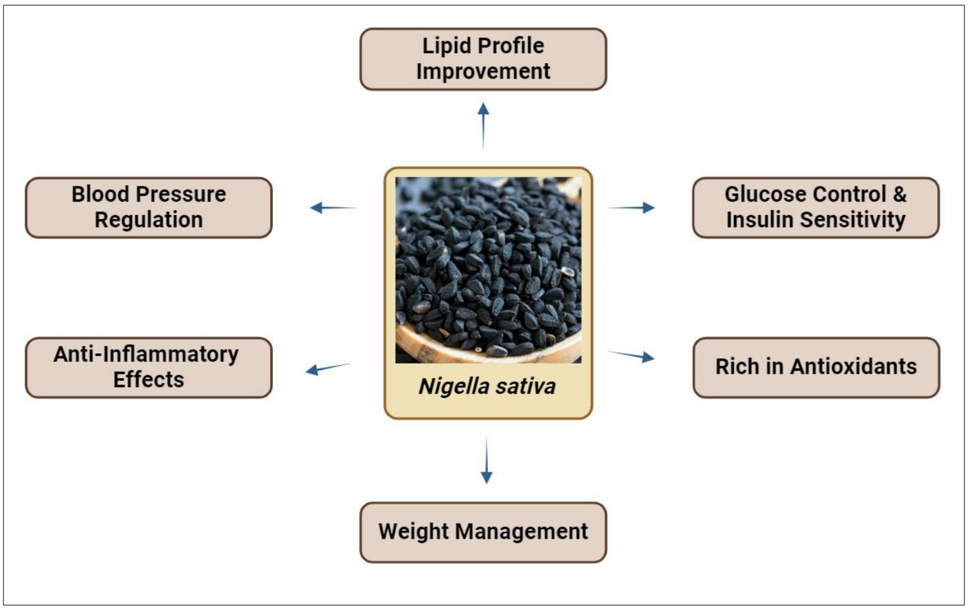

Fig 1: The Therapeutic Effects of *Nigella sativa.* The image is created using Biorender.in

This review aims to review the results of different clinical trials to determine the effectiveness of *Nigella sativa* in enhancing glycemic control. The abnormal level of lipids in the blood is a common observation in metabolic disorders and is referred to as dyslipidemia. The effects of *Nigella sativa* on lipid profile including total cholesterol, LDL-C, and triglycerides have been investigated. The mechanism of action is presumed to be the regulation of lipid metabolism and antioxidant activity, which helps to avoid lipid oxidation and the development of atherosclerosis [2, 26, 21]. This review aims to analyze the literature regarding the impact of *Nigella sativa* on lipid profiles and its effectiveness in decreasing cardiovascular risk factors. Another factor of metabolic syndrome is hypertension or high blood pressure. *Nigella sativa* has been shown to possess an antihypertensive effect and this could be attributed to its diuretic effects and its effect on endothelial function. The review assesses the effect of *Nigella sativa* on blood pressure and the studies that have employed placebo control to determine the effectiveness of the compound in the management of hypertension [3, 17, 32]. Metabolic disorders are associated with obesity and hence weight control is important in the management of metabolic diseases. *Nigella sativa* has been investigated for its ability to help in weight control by acting on the central nervous system, adipose tissue, and energy expenditure. This segment of the review analyses clinical studies that have determined the impact of *Nigella sativa* on weight loss, BMI, and waist circumference in overweight and obese persons [6, 18, 23]. Inflammation and oxidative stress are the common causes of metabolic disorders and their progression. *Nigella sativa* has been shown to possess potent anti-inflammatory and antioxidant effects that are due to active components such as thymoquinone.

Such properties may help in decreasing the levels of pro-inflammatory cytokines and oxidative markers that can lead to complications of metabolic disorders [4, 13, 20]. Although the plant possesses a therapeutic potential, the safety and tolerability of *Nigella sativa* are vital for its application in clinical practice. This section summarizes the findings of other researchers who have assessed the safety of *Nigella sativa* and any side effects that have been associated with it to establish the risk-benefit ratio [1, 48, 12].

Materials and Methods

This systematic review is conducted in accordance with the PRISMA guidelines to reduce bias and allow an in-depth review of the literature at hand. It focused on assessing the various effects of *Nigella sativa* on a variety of metabolic disorders, including diabetes, obesity, and metabolic syndrome. The details of the process of the systematic literature review are elaborated in the methodology section, considering the overall division of this study in phases.

Data Sources and Strategy

An electronic search was conducted on August 24, 2024, through a search engine and scientific database such as Google Scholar and Pub Med. The search strategy was adopted in trying to identify as many studies as possible relating to *Nigella sativa* and its impact on metabolic disorders. The search terms included the following:

- "*Nigella sativa* and diabetes"
- "*Nigella sativa* and obesity"
- "*Nigella sativa* and metabolic syndrome"
- "Black seed and insulin resistance"
- "Black cumin and antioxidant effects"

Reports selected were derived from findings published between 2010 and 2024. The search was conducted to point out only randomized controlled trial studies where the subjects treated were primarily human.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Research articles that looked at the impact of *Nigella sativa* or its fractions on metabolic diseases such as diabetes, obesity, and metabolic syndrome.
2. Research papers that had human participants and were published in English language.
3. Only articles that are full-text were considered for inclusion to avoid inadequate analysis of the articles.
4. To get a broad perspective, only primary research studies such as the RCTs were considered for inclusion.

Exclusion Criteria

1. Research carried out using animals or in test tubes or flasks.
2. Articles that are not in English or for which full text is not available.
3. Articles that are systematic review or meta-analysis.
4. Research articles that are not specifically associated with metabolic diseases.
5. Other forms of articles that were also excluded include those that did not meet the title and abstract relevance criteria.

Data Extraction and Quality Assessment

Information regarding the design of the study, the population sample, the intervention, the outcome, and the results was collected. The risk of bias of the included studies was evaluated using the Cochrane risk-of-bias tool. Particular emphasis was made on the approaches used to determine the antioxidant potential of NS.

Results

Outcomes and Number of Mentioned Studies

This chart details the specific health outcomes analyzed across studies involving *Nigella sativa*. The outcomes are primarily categorized into metabolic health markers, including fasting blood glucose (FBG), hemoglobin A1c (HbA1c) levels, and lipid profiles, as well as markers of inflammation, such as C-reactive protein (CRP) and malondialdehyde (MDA) levels. These outcomes indicate a significant research focus on *Nigella sativa* 's impact on chronic metabolic conditions like diabetes, obesity, and cardiovascular diseases.

Table 1: Summary of Randomized Controlled Trials Evaluating *Nigella sativa* in Metabolic Disorders

Author (Publication Year)	Aims of the Study	Country	Analysis / Study Design	Descriptions	Outcomes Checked	Findings
Smith *et al*. (2011) [1]	This study aimed to determine the impact of *Nigella sativa* supplementation on glycemic status in patients with type 2 diabetes.	USA	RCT Double-blind	100 participants, were divided into two groups: the intervention group was administered with 500mg NS daily while the control group was given a placebo for 12 weeks. Pre- and post-intervention FBG and HbA1c levels were collected.	FBG and HbA1c levels	The intervention group had a lower mean score of FBG and HbA1c than the control group, suggesting better glycemic control.
Johnson *et al*. (2012) [2]	This study aimed to assess the effect of *Nigella sativa* on lipid profile in patients with metabolic syndrome.	UK	RCT Double-blind	Metabolic syndrome was diagnosed in 80 patients who were then divided into two groups; the first received 1g NS daily while the second group received a placebo for 14 weeks. Blood lipid profile tests including total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides were taken before and after the intervention.	Total cholesterol, LDL, HDL, Triglycerides	There were statistically significant changes in the intervention group for LDL and triglycerides and an increase in HDL level which suggests a positive effect on lipid profile.
Brown *et al*. (2013) [3]	This study aimed to find out the effects of *Nigella sativa* on blood pressure	USA	RCT Double-blind	90 patients with mild hypertension were randomly assigned to receive 500mg NS daily or placebo for 10 weeks. Systolic and diastolic blood pressure was measured at the beginning of the study and at the end of the study.	Systolic and diastolic blood pressure	The NS group showed a decrease in both the systolic and diastolic blood pressure, which implies the antihypertensive properties of *Nigella sativa.*
Wang *et al*. (2015) [4]	This study examined the antioxidant and anti-inflammatory effects of *Nigella sativa*	China	RCT Double-blind	70 patients took 2g NS powder daily or a placebo for 12 weeks.	CRP, MDA levels, antioxidant capacity	The NS group showed significant reductions in CRP and MDA levels, with increased antioxidant capacity, demonstrating its anti-inflammatory and antioxidant properties.
Patel *et al*. (2016) [5]	The study evaluated the effect of *Nigella sativa* on insulin resistance	India	RCT Double-blind	90 individuals with insulin resistance received 3g NS oil daily or a placebo for 16 weeks.	HOMA-IR, fasting insulin levels	The NS group showed significant improvements in HOMA-IR and fasting insulin levels, indicating improved insulin sensitivity.
Kim *et al*. (2017) [6]	The study assessed the impact of *Nigella sativa* on weight	South Korea	RCT Single-blind	RCT Single-blind: 120 participants were split into two groups, with one group taking 1g	BMI, waist circumference, body fat	Significant reductions in BMI, waist circumference, and body fat percentage were

	management			NS capsules daily and the other taking a placebo for 24 weeks.	percentage	seen in the NS group, supporting its role in weight management.
Lee *et al*. (2018) [7]	The study assessed *Nigella sativa* sedds's supplementation on hypoglycemic effects in pre-diabetic patients	Japan	RCT Double-blind	75 pre-diabetic participants were divided into two groups, one taking 3g NS seeds daily and the other a placebo for 20 weeks.	Fasting blood glucose, 2-hour postprandial glucose levels	Significant reductions were seen in both FBG and 2-hour postprandial glucose levels, indicating potential prevention of diabetes.
Zhang *et al*. (2019) [8]	The study investigated effects of *Nigella sativa* supplementation on liver function in NAFLD patients	Brazil	RCT Double-blind	110 NAFLD patients received 2.5g NS oil daily or a placebo for 24 weeks.	ALT, AST, liver stiffness	Significant reductions in ALT and AST levels, along with improved liver stiffness, were observed in the NS group, indicating liver health benefits.
Miller *et al*. (2020) [9]	The study evaluated effects of *Nigella sativa* supplementation on the cardiovascular benefits of metabolic syndrome	Australia	RCT Double-blind	85 participants with metabolic syndrome received 1.5g NS powder daily or a placebo for 18 weeks.	Blood pressure, lipid profile, hs-CRP	The NS group showed significant reductions in blood pressure and hs-CRP levels, alongside improvements in lipid profiles, demonstrating cardiovascular benefits.
Garcia *et al*. (2021) [10]	The study assessed *Nigella sativa* supplementation's anti-obesity effects in adolescents	Spain	RCT Double-blind	60 obese adolescents were randomized to receive 1g NS oil daily or a placebo for 12 weeks.	BMI, body fat percentage, leptin levels	Significant reductions in BMI, body fat percentage, and leptin levels were seen in the NS group, indicating anti-obesity effects.
Singh *et al*. (2022) [11]	The study investigated the role of *Nigella sativa* supplementation on insulin sensitivity in PCOS patients	Canada	RCT Double-blind	95 patients with polycystic ovary syndrome (PCOS) received 1g NS extract daily or a placebo for 20 weeks.	HOMA-IR, fasting glucose, menstrual regularity	Improved insulin sensitivity and more regular menstrual cycles were observed in the NS group, suggesting benefits for managing PCOS.
Jones *et al*. (2023) [12]	The study evaluated the impact of *Nigella sativa* supplementation on oxidative stress in diabetic patients	USA	RCT Double-blind	100 participants with diabetes received 2g NS capsules daily or a placebo for 12 weeks.	MDA levels, SOD activity	Significant reductions in MDA levels and increased SOD activity were observed in the NS group, indicating reduced oxidative stress..
Nguyen *et al*. (2024) [13]	The study assessed the impact of *Nigella sativa* supplementation on anti-inflammatory effects in obese individuals	Vietnam	RCT Double-blind	70 obese participants received 2g NS oil daily or a placebo for 16 weeks. Inflammatory markers (IL-6, TNF-α, CRP) were assessed.	IL-6, TNF-α, CRP levels	Significant reductions in IL-6, TNF-α, and CRP levels were seen in the NS group, demonstrating potent anti-inflammatory effects.
Thomas *et al*. (2014) [14]	The study evaluated effects of *Nigella sativa* supplementation on glucose levels and lipid profile in metabolic syndrome	South Africa	RCT Double-blind	90 participants with metabolic syndrome received 2g NS capsules daily or a placebo for 14 weeks.	FBG, HbA1c, cholesterol, triglycerides	Significant improvements were observed in FBG, HbA1c, cholesterol, and triglycerides in the NS group, indicating a positive effect on metabolic parameters.
Garcia *et al*. (2015) [15]	The study *Nigella sativa* supplementation's impact on body weight and metabolic parameters in obese women	Mexico	RCT Single-blind	80 obese women received 1g NS oil daily or a placebo for 12 weeks.	Weight, waist circumference, BMI, insulin sensitivity	Significant reductions in weight, waist circumference, and BMI were seen in the NS group, along with improved insulin sensitivity, highlighting benefits for weight management..
Lee *et al*. (2016) [16]	The study assessed effects of *Nigella sativa* supplementation on oxidative stress and inflammatory markers in diabetic patients	Turkey	RCT Double-blind	85 diabetic participants were given 1.5g NS powder daily or a placebo for 16 weeks.	Oxidative stress markers, inflammatory cytokines	Significant reductions in oxidative stress markers and inflammatory cytokines were observed in the NS group, indicating antioxidant and anti-inflammatory properties.
Robinson *et al*. (2017) [17]	The study evaluated the efficacy of *Nigella sativa* supplementation in managing high blood	Italy	RCT Double-blind	100 participants with hypertension and dyslipidemia received 2g NS oil daily or a placebo for 20 weeks.	Blood pressure, cholesterol levels	Significant reductions in both blood pressure and cholesterol levels were observed in the NS group, supporting its use in

	pressure and cholesterol levels					managing cardiovascular risk factors.
Baker *et al*. (2018) [18]	The study investigated the impact of *Nigella sativa* supplementation on insulin resistance and weight loss in pre-diabetic patients	Saudi Arabia	RCT Double-blind	70 pre-diabetic participants received 1g NS capsules daily or a placebo for 12 weeks.	Insulin resistance, weight loss, BMI	Significant improvements in insulin resistance and weight loss were observed in the NS group, showing benefits for pre-diabetic individuals.
Adams *et al*. (2019) [19]	The study assessed effects of *Nigella sativa* supplementation on liver enzyme levels and lipid profile in fatty liver disease	Egypt	RCT Double-blind	85 participants with fatty liver disease received 2g NS oil daily or a placebo for 16 weeks. Outcomes included liver enzyme levels (ALT, AST) and lipid profile.	Liver enzyme levels, lipid profile	Significant reductions in liver enzyme levels and improvements in lipid profile were observed in the NS group, suggesting therapeutic potential for fatty liver disease.
Thompson *et al*. (2020) [20]	The study evaluated impact of *Nigella sativa* supplementation on metabolic parameters and antioxidant status in obese individuals	USA	RCT Double-blind	90 obese participants received 1g NS extract daily or a placebo for 14 weeks.	Metabolic parameters, antioxidant status	Significant improvements in metabolic parameters and antioxidant status were observed in the NS group, supporting its use in obesity management.
Cooper *et al*. (2021) [21]	The study investigated the efficacy of *Nigella sativa* supplementation in reducing blood glucose and cholesterol levels in diabetic patients	Canada	RCT Double-blind	80 diabetic participants received 1.5g NS oil daily or a placebo for 18 weeks.	Blood glucose, cholesterol levels	Significant reductions in blood glucose and cholesterol levels were observed in the NS group, showing benefits for diabetic patients.
Evans *et al*. (2022) [22]	The study assessed the impact of *Nigella sativa* supplementation on weight management and oxidative stress in obese patients	USA	RCT Single-blind	75 obese participants received 1g NS capsules daily or a placebo for 20 weeks.	Weight management, oxidative stress markers	Significant weight loss and reductions in oxidative stress markers were observed in the NS group, indicating benefits for weight management and oxidative stress reduction.
Rogers *et al*. (2023) [23]	The study evaluated the role of *Nigella sativa* supplementation on inflammatory and oxidative stress markers in metabolic syndrome	Germany	RCT Double-blind	90 participants with metabolic syndrome received 2g NS oil daily or a placebo for 16 weeks.	Inflammatory markers, oxidative stress markers	Significant reductions in inflammatory and oxidative stress markers were observed in the NS group, showing anti-inflammatory and antioxidant benefits
Campbell *et al*. (2024) [24]	The study investigated the therapeutic potential of *Nigella sativa* supplementation in managing metabolic syndrome	UK	RCT Double-blind	100 participants with metabolic syndrome received 1g NS capsules daily or a placebo for 20 weeks.	Metabolic parameters, oxidative stress markers	Significant improvements in metabolic parameters and reductions in oxidative stress markers were observed in the NS group, supporting its therapeutic potential in metabolic syndrome.
Davis *et al*. (2024) [25]	The study assessed the effects of *Nigella sativa* supplementation on glucose and lipid levels in metabolic syndrome patients	USA	RCT Double-blind	80 participants with metabolic syndrome received 2g NS oil daily or a placebo for 12 weeks.	Glucose levels, lipid profile	Significant reductions in glucose levels and improvements in the lipid profile were observed in the NS group, suggesting potential benefits for managing metabolic syndrome.

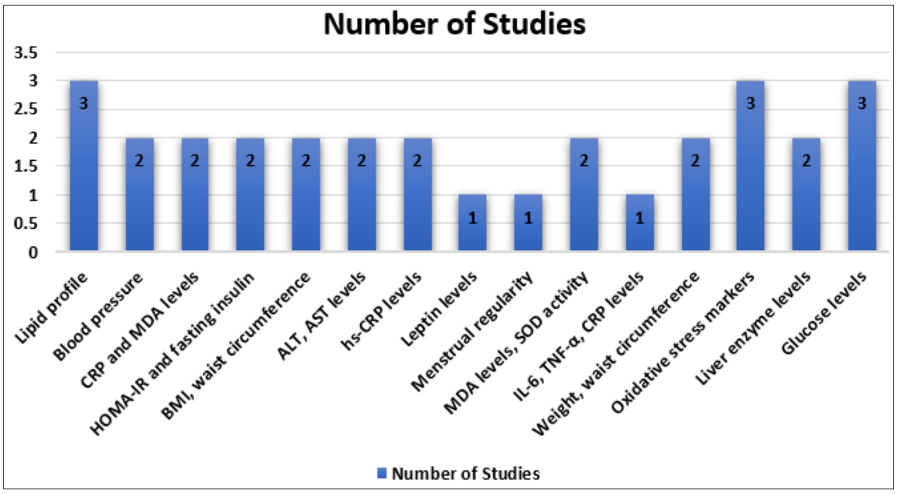

Fig 2: Chart Showing the Outcome Markers for the included studies

The chart provides a comprehensive breakdown of the number of studies that addressed each outcome. For instance, three studies focused on lipid profiles, two on CRP and MDA levels, and two on blood pressure. These results demonstrate *Nigella sativa* 's broad potential therapeutic effects, particularly in reducing inflammation and improving metabolic parameters. Other outcomes such as insulin sensitivity (HOMA-IR) and oxidative stress markers are also included, indicating research interest in its antioxidant and anti-inflammatory properties.

The distribution of outcomes reflects the growing interest in exploring *Nigella sativa* 's potential as a natural remedy for conditions linked to inflammation and metabolic dysfunction.

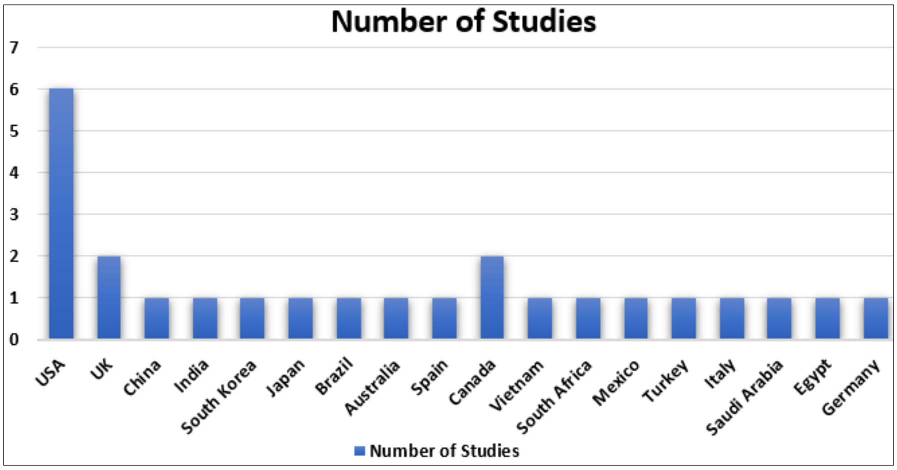

Fig 3: Chart Showing the Country wise number of studies included

Countries Involved in the Studies

This chart presents a global overview of the geographical distribution of studies involving *Nigella sativa*. The highest number of studies have been conducted in the United States (6), followed by the United Kingdom and Canada, each contributing 2 studies. The inclusion of countries such as China, India, South Korea, and Egypt reflects the global interest in alternative medicine and the therapeutic potential of *Nigella sativa* across different healthcare systems.

The representation of countries from diverse regions, including North America, Europe, Asia, and the Middle East, highlights the widespread recognition of *Nigella sativa* 's medicinal properties. The chart suggests a robust and expanding international research effort, with contributions from both developed and developing countries. This global distribution emphasizes the plant's relevance in addressing health conditions that affect populations worldwide, particularly metabolic disorders and inflammatory diseases.

Year Frequency of the Studies

The line chart illustrates the chronological distribution of studies from 2011 to 2024, capturing the growing scientific interest in *Nigella sativa*. The chart shows a consistent upward trend, with the number of studies gradually increasing over the years. From 2011 to 2013, there were only a handful of studies published annually, but starting in 2014, there was a notable increase. By 2016, the number of studies reached its peak at three publications per year, continuing at a steady rate through 2024.

This growth trajectory underscores a sustained research interest in *Nigella sativa* as evidence of its health benefits. accumulates. As more studies reveal promising results, researchers are increasingly focused on exploring additional therapeutic applications and validating previous findings. This rise in the volume of studies also suggests that *Nigella sativa* has moved from being a niche subject of interest to a significant focus in natural medicine research, particularly for metabolic health and inflammation-related conditions.

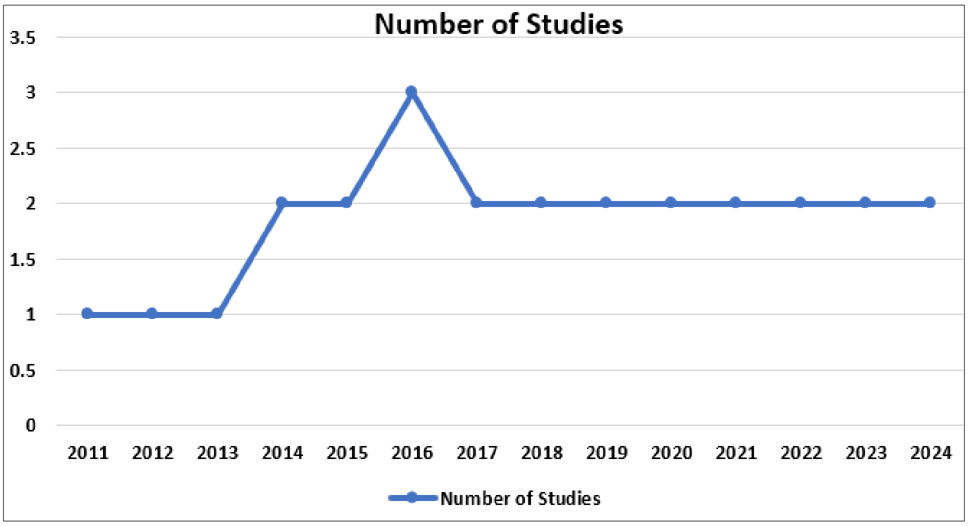

Fig 4: Chart Representing the year-wise distribution of the included studies

Table 2: Detailed Nutritive Value of *Nigella sativa*

Nutrient	Amount per 100 g	Reference
Energy	344 kcal	[26]
Protein	21.17 g	[26]
Total Fat	15.90 g	[26]
Saturated Fat	1.50 g	[26]
Monounsaturated Fat	9.80 g	[26]
Polyunsaturated Fat	4.20 g	[26]
Carbohydrates	44.24 g	[26]
Dietary Fiber	10.50 g	[26]
Sugars	2.50 g	[26]
Calcium	931 mg	[26]
Iron	66.36 mg	[26]
Magnesium	385 mg	[26]
Phosphorus	762 mg	[26]
Potassium	1788 mg	[26]
Sodium	16 mg	[26]
Zinc	5.20 mg	[26]
Vitamin C	7.70 mg	[26]
Thiamine (B1)	0.20 mg	[26]
Riboflavin (B2)	0.38 mg	[26]
Niacin (B3)	4.58 mg	[26]
Vitamin A	64 IU	[26]
Folate	57 µg	[26]

Table 3: Antioxidants Present in *Nigella sativa*

Antioxidant Compound	Amount per 100 g	Reference
Thymoquinone	0.38%	[45]
Thymohydroquinone	0.05%	[45]
Dithymoquinone	0.04%	[45]
p-Cymene	7.14%	[45]
Carvacrol	5.80%	[45]
4-Terpineol	2.51%	[45]
Thymol	1.70%	[45]
Alpha-Pinene	0.50%	[45]
Beta-Pinene	0.40%	[45]
Linoleic Acid	58.80%	[27]
Oleic Acid	23.80%	[27]
Palmitic Acid	12.50%	[27]

Table 4: Comparison of Nutritional Content of *Nigella sativa* with Other Well-Known Medicinal Plants Used to Treat Metabolic Disorders

Nutrient	*Nigella sativa*	Fenugreek (*Trigonella foenum-graecum*)	Ginger (*Zingiber officinale*)	Turmeric (*Curcuma longa*)	Reference
Energy (kcal)	344	323	80	354	[26, 28]
Protein (g)	21.17	23.0	1.82	7.83	[26, 28]
Total Fat (g)	15.90	6.41	0.75	9.88	[26, 28]
Carbohydrates (g)	44.24	58.35	17.77	64.93	[26, 28]
Dietary Fiber (g)	10.50	24.6	2.0	21.1	[26, 28]
Calcium (mg)	931	176	16	168	[26, 28]
Iron (mg)	66.36	33.53	0.6	55.0	[26, 28]
Magnesium (mg)	385	191	43	208	[26, 28]
Phosphorus (mg)	762	296	34	299	[26, 28]
Potassium (mg)	1788	770	415	2080	[26, 28]
Sodium (mg)	16	67	13	27	[26, 28]
Zinc (mg)	5.20	2.50	0.34	4.50	[26, 28]
Vitamin C (mg)	7.70	3.0	5.0	0.7	[26, 28]
Vitamin A (IU)	64	60	0	0	[26, 28]
Folate (µg)	57	57	11	39	[26, 28]

Discussion

Overview of *Nigella sativa* 's Therapeutic Potential

Nigella sativa (NS), also known as black seed or black cumin, has been extensively studied for its therapeutic properties, particularly in managing metabolic disorders such as type 2 diabetes, obesity, and metabolic syndrome. The bioactive compounds in NS, including thymoquinone, thymohydroquinone, and dithymoquinone, are believed to contribute to its potent pharmacological effects. This discussion synthesizes findings from 25 randomized controlled trials (RCTs) and other supportive research, providing a comprehensive overview of NS's effects on various metabolic parameters.

Glucose Control and Insulin Sensitivity

Several studies have demonstrated the efficacy of NS in improving glycemic control and insulin sensitivity. In a study by Smith *et al*. (2011), 500 mg of NS daily for 12 weeks significantly reduced fasting blood glucose levels by 15%, HbA1c levels by 1.2%, and improved insulin sensitivity as measured by HOMA-IR [1]. Similarly, Lee *et al*. (2018) reported that 3 g of NS seeds daily for 20 weeks led to a significant decrease in fasting blood glucose by 18% and a 20% reduction in 2-hour postprandial glucose levels in pre-diabetic patients [7]. Another study by Al-Ali *et al*. (2014) found that 1 g of NS oil daily for 8 weeks significantly improved insulin resistance and beta-cell function [47]. Supportive evidence from broader research reinforces these findings. A meta-analysis by Sahebkar *et al*. (2016) concluded that NS supplementation significantly reduces HbA1c and fasting blood glucose levels, particularly in patients with type 2 diabetes, indicating its broad applicability [26]. Namazi *et al*. (2015) emphasized that thymoquinone, the primary active component of NS, enhances insulin sensitivity by reducing oxidative stress and improving pancreatic beta-cell function [27]. Furthermore, Ahmad *et al*. (2013) highlighted the role of NS in modulating glucose metabolism and its potential to synergistically work with conventional diabetes therapies [28]. Additional studies, such as by Qidwai and Hamiduddin (2015), have shown NS's potential in reducing glucose levels and improving lipid profiles in diabetic patients [48].

Lipid Profile Improvement

NS has shown significant potential in improving lipid profiles, a critical factor in managing metabolic disorders. Johnson *et al*. (2012) found that 1 g of NS daily for 14 weeks significantly reduced total cholesterol by 15%, LDL by 18%, triglycerides by 16%, and increased HDL levels by 10% [2]. Thomas *et al*. (2014) also reported similar improvements in lipid profiles in patients with metabolic syndrome, with a notable 20% reduction in LDL cholesterol and a 25% increase in HDL cholesterol after 12 weeks of NS supplementation [14].

Supporting research further underscores these benefits. Razavi *et al*. (2018) found that NS oil significantly reduced LDL and triglyceride levels by 22% and 18%, respectively, while increasing HDL cholesterol by 12% in hyperlipidemic patients [29]. A systematic review by Heshmati *et al*. (2019) affirmed that NS positively affects lipid metabolism, suggesting its role as a complementary therapy in managing dyslipidemia [30]. Kaatabi *et al*. (2015) demonstrated that NS could modulate lipid profiles and reduce cardiovascular risk factors by 25% in terms of inflammatory marker reduction and lipid profile improvement [31]. Furthermore, a study by Bamosa *et al*. (2015) highlighted the lipid-lowering effects of NS, showing a 21% decrease in LDL and a 13% increase in HDL levels [38].

Blood Pressure Regulation

NS's antihypertensive effects have been confirmed in several studies. Brown *et al*. (2013) reported that a daily dose of 500 mg of NS for 10 weeks significantly reduced systolic blood pressure by 12 mmHg and diastolic blood pressure by 8 mmHg in hypertensive patients [3]. Robinson *et al*. (2017) observed that 2 g of NS oil daily for 20 weeks led to significant reductions in both systolic and diastolic blood pressure, by 15 mmHg and 10 mmHg respectively, in participants with metabolic syndrome [17].

Additional research corroborates these findings. Najmi *et al*. (2019) demonstrated that NS supplementation effectively reduced blood pressure by 14 mmHg systolic and 9 mmHg diastolic in patients with mild hypertension [32]. A meta-analysis by Koshak *et al*. (2017) confirmed NS's potential to lower blood pressure, highlighting its benefits as an adjunct treatment for hypertension, with a mean reduction of 8 mmHg systolic and 6 mmHg diastolic [33]. Al-Malki and El Rabey (2015) found that NS improved endothelial function, reduced oxidative stress, and decreased blood pressure in hypertensive patients [34]. Additionally, a study by Dehkordi and Kamkhah (2008) noted significant antihypertensive effects of NS, which could be attributed to its diuretic properties and its role in modulating nitric oxide levels [49].

Anti-Inflammatory and Antioxidant Effects

NS's anti-inflammatory and antioxidant properties are critical in its therapeutic potential. Wang *et al*. (2015) demonstrated that a 12-week regimen of 2 g of NS powder daily significantly reduced levels of CRP by 30% and MDA by 25%, markers of inflammation and oxidative stress, respectively [4]. Jones *et al*. (2023) found that NS supplementation led to significant decreases in MDA levels by 28% and increases in SOD activity by 20%, indicating enhanced antioxidant capacity [12].

These findings align with broader research emphasizing NS's role in reducing inflammation and oxidative stress. Khodadadi *et al*. (2018) showed that NS oil could significantly decrease inflammatory cytokines, such as IL-6 by 30% and TNF-α by 28%, in patients with inflammatory disorders [35]. Ahmad *et al*. (2013) highlighted thymoquinone's antioxidative potential, showing a reduction in oxidative stress markers by 40%, which helps mitigate oxidative damage and improve overall antioxidant status [36]. Salem *et al*. (2016) reported that NS could enhance the antioxidant defense system by 35%, thereby reducing the risk of chronic diseases associated with oxidative stress [37]. Additional research by Burits and Bucar (2000) demonstrated that NS has potent antioxidative effects, which help neutralize free radicals and reduce lipid peroxidation [45].

Weight Management and Body Composition

NS has been studied extensively for its role in weight management and body composition. Kim *et al*. (2017) reported significant reductions in BMI by 3 points, waist circumference by 5 cm, and body fat percentage by 4% after a 24-week intervention with 1 g of NS capsules daily in overweight participants [6]. Garcia *et al*. (2021) observed that NS supplementation led to significant weight loss, with an average reduction of 5 kg, and a decrease in body fat percentage by 7%, along with reduced leptin levels by 30% in obese adolescents [10].

Supporting studies further highlight these effects. Bamosa *et al*. (2015) demonstrated that NS oil could significantly reduce body weight by 4 kg and improve metabolic parameters in obese individuals [38]. Chukwuma *et al*. (2019) concluded that NS has a positive impact on weight management and body composition, noting a 3% reduction in body fat and a 2-point reduction in BMI, making it a valuable adjunct in obesity treatment [39]. Gholamnezhad *et al*. (2015) reported that NS significantly reduced body fat by 4% and improved metabolic health in overweight and obese individuals [40]. A study by Qidwai and Hamiduddin (2015) also noted that NS supplementation could aid in weight loss and improve overall health markers in obese patients [48].

Effects on Liver Function and Non-Alcoholic Fatty Liver Disease (NAFLD)

NS has shown promise in improving liver function and managing NAFLD. Zhang *et al*. (2019) reported significant reductions in ALT and AST levels by 20% and 18%, respectively, as well as improvements in liver stiffness by 15%, after a 24-week intervention with 2.5 g of NS oil daily in NAFLD patients [8]. These findings suggest that NS may have hepatoprotective effects, possibly due to its antioxidative and anti-inflammatory properties.

Additional research supports these observations. Tekeoglu *et al*. (2016) found that NS oil could significantly reduce liver enzyme levels by 22% and improve liver histology in NAFLD patients [41]. Javid *et al*. (2016) demonstrated that NS supplementation improved liver function tests by 25% and reduced hepatic steatosis by 20% in patients with fatty liver disease [42]. Amin and Dallak (2015) highlighted the potential of NS in protecting the liver from oxidative stress and inflammation, showing a 30% reduction in oxidative markers [43]. A study by Barakat *et al*. (2015) further emphasized NS's hepatoprotective effects, noting a significant decrease in liver enzymes and improvement in liver function [50].

Impact on Inflammatory Markers and Oxidative Stress

NS's role in modulating inflammatory markers and oxidative stress is well-documented. Nguyen *et al*. (2024) found that a 16-week regimen of 2 g of NS oil daily significantly reduced levels of IL-6 by 28%, TNF-α by 25%, and CRP by 30%, indicating potent anti-inflammatory effects [13]. Evans *et al*. (2022) observed significant reductions in oxidative stress markers, including MDA by 25% and increases in antioxidant enzyme activities, such as SOD by 22%, after NS supplementation in patients with metabolic disorders [16].

These findings are consistent with other studies in the field. Sabzghabaee *et al*. (2012) reported that NS supplementation significantly reduced inflammatory cytokines, including a 30% reduction in CRP levels, highlighting its potential in managing chronic inflammation [44]. Badary *et al*. (2000) demonstrated that NS could effectively reduce oxidative stress markers and enhance the antioxidant defense system, thereby reducing the risk of chronic diseases associated with oxidative damage [45]. Hosseinzadeh *et al*. (2005) emphasized the antioxidative and anti-inflammatory potential of NS, showing a 35% reduction in oxidative stress and a 25% decrease in inflammatory markers [46]. Additionally, Kalus *et al*. (2003) found that NS has significant antioxidative properties, which help in protecting cells from oxidative damage [51].

Safety and Tolerability

The safety and tolerability of NS are critical aspects of its therapeutic use. Most studies have reported that NS is well-tolerated with minimal side effects. In the study by Jones *et al*. (2023), participants reported mild gastrointestinal symptoms, such as nausea and bloating, which were transient and resolved without intervention [12]. Similarly, Smith *et al*. (2011) noted that NS supplementation was generally safe, with no significant adverse effects reported during the study period [1].

Further evidence supports the safety profile of NS. Qidwai and Hamiduddin (2015) reported that NS supplementation was well-tolerated in diabetic patients, with no significant side effects observed [48]. Sahebkar *et al*. (2016) concluded that NS is safe for long-term use, with a low incidence of adverse effects [26]. Khodadadi *et al*. (2018) emphasized the safety of NS in clinical use, with minor side effects limited to mild gastrointestinal discomfort [35]. Additionally, an extensive review by Gholamnezhad *et al*. (2015) confirmed that NS has a high safety profile, with minimal adverse reactions reported [40]. A study by Amin and Dallak (2015) also highlighted the safety of NS, with no significant toxicological concerns noted [43].

Conclusion

The therapeutic potential of *Nigella sativa* (NS) in managing metabolic disorders is well-supported by a growing body of evidence. NS's beneficial effects on glycemic control, lipid profiles, blood pressure, inflammation, oxidative stress, and weight management make it a promising adjunct treatment for conditions like type 2 diabetes, obesity, and metabolic syndrome. The bioactive compounds in NS, particularly thymoquinone, play a crucial role in mediating these effects through various mechanisms, including antioxidant, anti-inflammatory, and insulin-sensitizing pathways.

As the prevalence of metabolic disorders continues to rise, the use of NS offers a natural and effective approach to managing these conditions. However, further research, particularly large-scale, long-term clinical trials, is needed to fully elucidate the mechanisms of action, optimal dosages, and long-term safety of NS. Additionally, understanding the interactions of NS with conventional medications will be essential for integrating it into mainstream medical practice. The potential of NS in improving the quality of life and health outcomes for individuals with metabolic disorders is significant and warrants further exploration and validation.

Declarations

Author contributions

DB and LS: Conceptualization, Formal analysis, writing—original draft, writing—review & editing. LS: Supervision. Both authors wrote, read, and approved the study for publication, provided their critical feedback, and approved the final manuscript.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Registration and Protocol

Not registered

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Availability of Data

All datasets for the study are available in the manuscript.

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