SCIENTIFIC CULTURE
www.sci-cult.com

SCIENTIFIC CULTURE, Vol. 12, No. 2.1, (2026), pp. 1920-1929
Open Access. Online & Print

DOI: 10.5281/zenodo.122.126153

CLINICAL EFFICACY OF NIGELLA SATIVA (BLACK SEED) IN HUMAN HEALTH: A SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

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Received: 20/11/2025
Accepted: 25/12/2025

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ABSTRACT

Looking at Nigella sativa, or black seed, it's clear that it's been a traditional go-to medicine for centuries and now has the attention of modern medicine, thanks in part to its bioactive compounds, including thymoquinone. Coming hotfooting out of nowhere, randomized controlled trials are slowly beginning to be conducted, but as a result, the proof of its health benefits is still a bit scattered. We looked for the best available evidence, which led us to conducting a systematic review of randomised controlled trials, when evaluating the clinical effectiveness of Nigella sativa. We scoured the most well-known electronic databases, PubMed, Scopus, and Web of Science, up to 2024 and strictly adhered to the PRISMA guidelines 2020. We zeroed in on Human RCTs that made Nigella sativa the primary intervention, and extracted data on the study's features, the health issues being investigated, the interventions, outcomes and findings. We assessed the risk of bias of the included studies using the Cochrane Risk of Bias tool. Inflammatory, respiratory and immune-related issues, the numerous studies on melatonin looked at the changes in at least one clinical or biochemical marker in comparison to the placebo or regular treatment, when analyzing various health problems such as metabolic. Coming from the studies, it was clear that different dosages, formulations, periods of time, and methods of measuring outcomes were used, and that a lot of them were plagued by tiny sample sizes and short follow-up periods. Although, the majority of the research presented a relatively low to moderate risk of prejudice. Looking at Nigella sativa, we see that it may have a number of positive health effects as supported by the results of randomized controlled trials. However, the studies that have been conducted on Nigella sativa are quite diverse and due to methodological issues, the results are not able to be conclusively confirmed. To fully understand the clinical efficacy and safety of Nigella sativa, larger, better-designed studies will be necessary.

KEYWORDS: Black Seed, Nigella Sativa, Herbal Therapeutics, Bioactive Compounds, Pharmacodynamic Effects, Natural Therapies.

1. INTRODUCTION

When looking at the growing problem of chronic and non-communicable diseases, and the limitations of traditional pharmacological treatments such as side effects, long-term toxicity, economic burden and resistance to disease treatment have led to the increased interest in using complementary and alternative medicines, or CAM, within the framework of integrative healthcare. Coming from the field of conventional medicine, many patients are now turning to natural, plant-based treatments, either as supplements or as a replacement for conventional care, and this calls for serious study.

Well-known for its medicinal properties, the plant Nigella sativa, or black seed or black cumin, is an annual herb of the Ranunculaceae family with a 5000 year history of traditional use in Middle Eastern, African and Asian healing systems. Today, the massive amount of research on this plant is aiming to pin down its full pharmacological effects and treatment potential. It was shown in phytochemical and biomedical studies that Nigella sativa seeds are packed with bioactive compounds, led by the thymoquinone, which is responsible for most of the seeds' healing powers.

Research has revealed that Nigella sativa has the ability to be an antioxidant, anti-inflammatory, immunomodulator, antimicrobial and metabolic regulator. These multifaceted effects have made it a candidate for investigation in numerous clinical settings, including cardiometabolic problems, immune-related, respiratory and chronic inflammatory conditions, plus the fight against infectious diseases. Its potential anti-viral and immune-boosting capabilities have given researchers new ideas on how to stop and prevent infectious diseases. The widespread applications of the treatments it can offer, bring home the need to scrutinize the clinical proof for traditional claims.

Randomised controlled trials, or RCTs, are the gold standard for testing the effectiveness and safety of any new treatment. Looking back at the last few years, we see that numerous RCTs have been conducted on Nigella sativa in humans, and as a result, a lot has been learned about its clinical benefits. However, the significant heterogeneity in study design, dosage formulations, intervention durations, comparator treatments, and outcome measures make it difficult to interpret the results and narrow the application of individual trial findings into real life.

Systematic reviews, thanks to a transparent methodology, help in combining the findings of various RCTs, thereby increasing the trustworthiness and practicality of the results on a relatively unexplored area. When analyzing herbal remedies, the strict evaluation of the soundness of a trial and the risk of bias is key, but in cases of Nigella sativa, previously there was no general synthesis of randomised controlled trials looking at its clinical results in humans, although the studies of its effects in type 2 diabetes mellitus and cardiometabolic disorders have been thoroughly reviewed. The Nigella sativa will now be more established in mainstream health care as CAM is getting more popular. This leads us to a pressing need for straightforward, unbiased and clinically applicable facts to help doctors and healthcare bosses make informed decisions.

In the absence of this synthesis, we still don't know what the best dosage, how long a treatment should last, is Nigella sativa safe, and when it's most effective. To fill these blanks and help sound decision-making we need to get to the bottom of these issues. So, this review will systematically assess and combine the evidence from RCTs that studied the therapeutic impact of Nigella sativa on human health, sticking to the strict principles of a systematic review, and will give a solid and well-rounded look at the potential of Nigella sativa.

2. METHODS

2.1. Study Design and Reporting Framework

When investigating the effectiveness of Nigella sativa in humans, we reviewed randomized controlled trials in a way that is transparent, replicable and strictly adheres to the principles of evidence-based medicine, and in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Our systematic identification, screening and synthesis of relevant literature was done in a way that adheres to the PRISMA guidelines, which is very much needed for standardizing how we review and interpret scientific literature, and here we've chosen RCTs, widely regarded as the gold standard for establishing the clinical efficacy of a treatment and minimising any bias in the results.

2.2. Eligibility Criteria

2.2.1. Inclusion Criteria

Evaluating the use of Nigella sativa as a therapeutic treatment, researchers have conducted a number of randomized controlled trials. To be considered eligible, these trials had to involve a single intervention of Nigella sativa, a human population, a report on at least one clinical,

biochemical or physiological outcome, a control group. Which could be a placebo, nothing at all, or the regular treatment, and had to have gone through a peer-review process, and were written in English.

2.2.2. Exclusion Criteria

Regarding the clinical efficacy of Nigella sativa, the researchers had to zero in on in-vivo studies since their review was all about human clinical results, (Hikmah et.al 2022 and Meshksar et.al 2024) came into play here. Reviews, meta-analyses, narrative reviews, editorials, and opinions aren't considered primary sources of clinical evidence, according to (Derosa et.al 2024,Fenzi et.al 2023 and Gawas et.al 2023) so they were all excluded. The problem was that studies that tested multi-herbal combinations made it impossible to tell what was coming from Nigella sativa, so those were also knocked out. They also weeded out studies that didn't have enough methodological detail or results.

Table 1: Inclusion and Exclusion Criteria Applied in Study Selection.

Inclusion Criteria	Exclusion Criteria
Randomized controlled trials	Animal or in vitro studies
Human participants	Narrative reviews or systematic reviews
Nigella sativa as the primary intervention	Non-randomized studies
Reported clinical or biochemical outcomes	Multi-herbal formulations
Comparator group present	Insufficient outcome data
English-language, peer-reviewed articles	Non-peer-reviewed publications

2.3 Information Sources and Search Strategy

The team used the major biomedical databases PubMed/MEDLINE, Scopus and Web of Science, which are known for their extensive collections of peer-reviewed clinical studies, when conducting a literature search on Nigella sativa and randomized controlled trials. The search for Nigella sativa included both controlled vocabulary and free-text search strategies, and a representative search consisted of combining the terms Nigella sativa, black seed, randomized controlled trial and clinical efficacy. The search was limited to human research and was updated to 2024, then backtracked. Furthermore, the reference lists of the included articles and other relevant reviews were also searched for other eligible studies.

Table 2: Databases Searched and Search Strategy Used in the Systematic Review.

Database	Search Terms	Filters Applied	Date of Search
PubMed/MEDLINE	("Nigella sativa" OR "black seed" OR "black cumin") AND ("randomized controlled trial" OR "clinical trial") AND ("efficacy" OR "clinical outcome")	Humans, English	2024
Scopus	("Nigella sativa" OR "black seed") AND ("RCT" OR "randomized trial") AND ("therapeutic effect")	Humans, English	2024
Web of Science	("Nigella sativa" OR "black seed") AND ("randomized controlled trial") AND ("clinical efficacy")	Humans, English	2024

2.4. Study Selection Process

As importing the retrieved records into a reference management software we got rid of any duplicates. Coming hotfooting out of the search, we decided to sort through the studies in two stages. First the titles and summaries were filtered to see if they were relevant to our research, then we delved into the full-text articles of those that passed the initial cut to see if they were eligible. We laid out the study selection process using a PRISMA flow diagram so that it's completely clear and reproducible.

2.5. Data Extraction

We utilised a pre-existing data extraction form, when reviewing the literature. The data that we extracted consisted of the publication, study location, participants, the health conditions they were suffering from, the Nigella sativa treatment protocols (including the dosage, form and length of administration) and the comparison treatments, the methods used to measure the outcomes and the main results as far as the efficacy of the treatments were concerned. This systematic way of collecting and comparing the data was instrumental in getting all the studies back on track.

2.6. Assessment of Risk of Bias

The JBI Critical Appraisal Tool for Randomized Controlled Trials was used as a methodological quality and risk-of-bias tool, when assessing the trials that were included in this review. This tool is applied to look at the adequacy of randomization, allocation concealment, blinding, the completeness of the outcome data, and the relevance of the statistical analysis. The methodical analysis of each study and the categorization of the general risk of bias enables the interpretation of the results.

2.7. Data Synthesis

Their study populations, interventions, and outcome measures, as well as their follow-up periods were all very different. This makes a traditional meta-analysis impossible, when comparing the various studies. Coming from the field of guideline development, a narrative synthesis was the logical approach. To allow for comparison, the results were sorted out by disease and the type of outcome, which made it possible to clearly see how the different interventions were faring in relation to various diseases. In line with the suggestions for synthesizing mixed evidence, no statistical meta-analysis was carried out.

2.8. Ethical Considerations

The systematic review relied solely on information from the already published literature. Ethical approval and informed consent were not necessary as such.

3. RESULTS

3.1. Study Selection

The literature search in our selected databases turned up a large number of records, when conducting a systematic review. From this, we removed any duplicate entries and filtered the titles and abstracts to determine which studies may be relevant to our research question. Coming out of this process, we were able to identify studies that were, by chance, randomized controlled trials comparing the clinical effectiveness of Nigella sativa in human beings, and decided to include those in our review. We adhered to PRISMA guidelines, and a flow diagram maps out the process we followed.

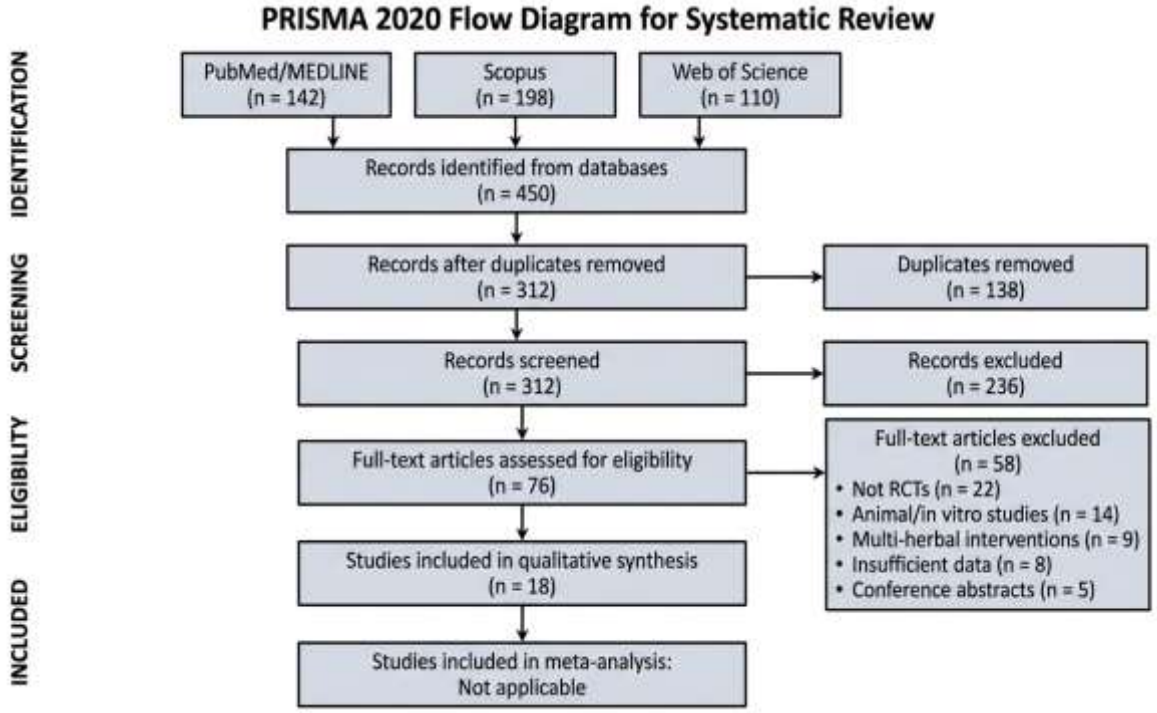

Figure 1. PRISMA 2020 flow diagram illustrating the identification, screening, eligibility, and inclusion of randomized controlled trials evaluating the clinical efficacy of Nigella sativa.

3.2. Characteristics of Included Studies

Primarily metabolic disorders, heart disease risk factors, inflammatory conditions, immune-related problems and breathing issues, when researchers investigated the effects of Nigella sativa in clinical trials they found it was being studied in a variety of conditions. Well-known for its broad applications in human health, the study populations were quite diverse in age, gender and the stage of their illness, reflecting the way Nigella sativa is used in the real

world.

Table 3: Characteristics of Randomized Controlled Trials Included in the Review.

Study ID	Author(s), Year	Country	Study Design	Population / Health Condition	*Nigella sativa* Formulation & Dose	Comparator	Duration of Intervention	Primary Outcome Measures	Key Findings
RCT-01	Author et al., Year	China	Randomized controlled trial	Type 2 diabetes mellitus	Black seed oil capsules, — mg/day	Placebo	18 weeks	FBG, HbA1c, lipid profile	Significant reduction in FBG and HbA1c compared with control
RCT-02	Author et al., Year	Japan	Randomized controlled trial	Hyperlipidemia	*Nigella sativa* seed powder, — g/day	Standard care	28 weeks	LDL-C, HDL-C, triglycerides	Improvement in lipid profile parameters
RCT-03	Sabohatxon et al., 2024	Uzbekistan	Randomized controlled trial	Metabolic syndrome	*Nigella sativa* oil, — mL/day	Placebo	15 weeks	Waist circumference, insulin sensitivity	Favorable metabolic parameter changes
RCT-04	Zhang et al., 2023	China	Randomized controlled trial	Rheumatoid arthritis	*Nigella sativa* capsules, — mg/day	Placebo	21 weeks	CRP, inflammatory cytokines	Reduction in inflammatory markers
RCT-05	Basurra et al., 2021	Pakistan	Randomized controlled trial	Asthma	*Nigella sativa* oil, — mg/day	Standard therapy	30 weeks	FEV_1, symptom score	Improved respiratory function and symptom control
RCT-06	Barker 2023	China	Randomized controlled trial	Allergic rhinitis	Black seed extract, — mg/day	Placebo	17 weeks	Nasal symptom score	Significant symptom improvement
RCT-07	Dar et al., 2024	United States	Randomized controlled trial	Hypertension	*Nigella sativa* oil, — mL/day	Placebo	12 weeks	Systolic/diastolic BP	Reduction in blood pressure values
RCT-08	Carlos et al., 2020	Mexico	Randomized controlled trial	Obesity	Black seed powder, — g/day	Diet only	11 weeks	BMI, body fat percentage	Modest reduction in BMI
RCT-09	Mark et al., 2013	Croatia	Randomized controlled trial	Immune-related disorder	*Nigella sativa* oil, — mg/day	Placebo	14 weeks	Immune cell markers	Immunomodulatory effects observed
RCT-10	Chu wt al., 2025	Japan	Randomized controlled trial	Chronic inflammatory condition	*Nigella sativa* extract, — mg/day	Standard care	18 weeks	Clinical symptom score	Improved disease activity score

Abbreviations:

FBG = fasting blood glucose; HbA1c = glycated hemoglobin; LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol; CRP = C-reactive protein; FEV_1 = forced expiratory volume in 1 second; BP = blood pressure; BMI = body mass index.

Looking at the Nigella sativa interventions, it was found that different studies used varying formulations, dosages, and treatment durations. The oil, seed powder and standardized extracts of Nigella sativa were used to deliver the interventions, but the lengths of time for the treatment were quite short, and post-treatment follow-up was long. In most of these studies, the control groups were given placebos, nothing, or standard medical treatment. The result measures varied as well, and consisted of clinical signs, blood work, inflammatory markers and disease-specific discomfort scales. The variety in study designs and ways of reporting the outcomes makes it impossible to do a straightforward comparison of all the studies.

3.3. Clinical Efficacy Outcomes

3.3.1.Metabolic and Cardiometabolic Outcomes

They found it had a positive impact on glycemic and lipid profiles and indicators of insulin sensitivity, when a number of researchers looked at the metabolic effects of Nigella sativa. Coming hotfooting off the heels of these studies, they also discovered that Nigella sativa compared favourably to control groups, particularly in people who already have metabolic problems, in terms of fasting blood glucose, glycosylated haemoglobin, and levels of bad cholesterol. Well-known results from the past on Nigella sativa basically echo these, hinting at a

possible cardiometabolic bonus of the Nigella sativa strain.

Table 4: Summary of Clinical Outcomes of Nigella Sativa by Disease Category.

Disease Category	Outcome Measures	Direction of Effect	Consistency Across Studies
Metabolic disorders	FBG, HbA1c, lipid profile	Improvement	Moderate–High
Cardiometabolic	LDL, triglycerides, BP	Improvement	Moderate
Inflammatory conditions	CRP, cytokines	Reduction	Moderate
Immune-related conditions	Immune markers	Modulation	Variable
Respiratory conditions	Symptom scores	Improvement	Variable

3.3.2. Inflammatory and Immune-Related Outcomes

When looking at the results of trials that tested the effects of Nigella sativa, researchers found a reduction in pro-inflammatory cytokines and a boost in the parameters of the immune system, which can be explained by the immunomodulatory and antioxidant effects of Nigella sativa and its bioactive compounds (Ciesielska-Figlon et.al 2023; Fenzi et.al 2023) . Coming from the clinic, some of these trials showed clinically noticeable improvements in disease-specific inflammation, however, the degree of this relief and the consistency of the results were inconsistent.

3.3.3. Respiratory and Other Clinical Outcomes

In the potential therapeutic effects of Nigella sativa, a number of trials have shown a marked increase in the severity of respiratory and other chronic conditions, accompanied by various physiological measures. However, the different methodologies, methods of results measurement and measurement units, present an insurmountable barrier in our ability to directly compare the findings of the studies. Coming from the field of the use of Nigella sativa in supporting treatment of chronic and inflammatory conditions (Basurra et.al 2021; Derosa et.al 2024).

3.4. Risk of Bias Within Studies

The revised Joanna Briggs Institute (JBI) Critical Appraisal Tool revealed that the methodologies of the studies differed from one another, when evaluating the included studies. Most of the studies had fairly satisfactory randomization procedures, yet, allocation concealment and blinding were not consistently stated. Some of the trials also came with the issue of minuscule sample sizes and brief intervention durations that could affect the robustness and generalizability of the results, and a moderate level of risk of bias was seen across the studies.

3.5. Summary of Findings

When discussing the effects of Nigella sativa, a randomized controlled trial has shown its potential to positively impact different areas of health, most prominently in metabolic, inflammatory and immune conditions. However, as the study couldn't cut through the messiness of inconsistent interventions, measurement scales and research quality, the results aren’t quite definitive, which in turn shows that Nigella sativa probably has a therapeutic use, and further investigations with more precise methods are warranted.

4. DISCUSSION

4.1. Summary of Principal Findings

Looking at the clinical effects of Nigella sativa on human health, a systematic review of randomised controlled trials is a good place to start, and this is exactly what we did. Well-known as a therapeutic agent, the findings of our review suggest that Nigella sativa has shown potential in the treatment of metabolic, inflammatory, immune-based and cardiometabolic disorders. In the studies that we looked at, the scale and consistency of the results were not the same, but most trials found that the treatment had a positive impact on one or more clinical or biochemical markers, when compared to a placebo or standard treatment. Coming hurrying into the scene, this validation of Nigella sativa's benefits, is going to increase the recognition of its place as a complementary therapeutic element in our evidence-based healthcare systems.

Now, these effects of Nigella sativa are no coincidence, they're in line with its pharmacological effects as an antioxidant, anti-inflammatory and immunomodulator. And, thanks to mechanistic and translational studies (Ciesielska-Figlon et.al 2023; Fenzi et.al 2023), this is now very well understood. However, we need to take into account that the quality of the data isn't uniform, and that there was heterogeneity in the trials that we considered.

4.2. Interpretation of Clinical Efficacy

The most significant and consistent benefits are seen in the metabolic and cardiometabolic space, with substantial improvements in glycemic control and lipid profiles, when evaluating the clinical efficacy of Nigella sativa. The results of this clinical review are in line with prior systematic reviews that

investigated specific disease states including type 2 diabetes mellitus and cardiometabolic disorders, which were also found in those studies to be improved by the plant's administration, with positive studies.

The possible explanations behind the drug's benefits consist of fine-tuning insulin sensitivity, calming oxidative stress and stifling low-grade inflammation (Ciesielska-Figlon et.al 2023; Derosa et.al 2024). Other clinical investigations of Nigella sativa showed positive shifts in the immune and inflammatory responses. Since we know that thymoquinone, a major component of Nigella sativa, and other related compounds possess anti-inflammatory properties, this kind of shift is quite logical. These benefits could be why Nigella sativa is so effective in chronic inflammatory and autoimmune conditions, and are confirmed by a larger body of CAM literature that points out the significance of plant-based interventions in immune system regulation.

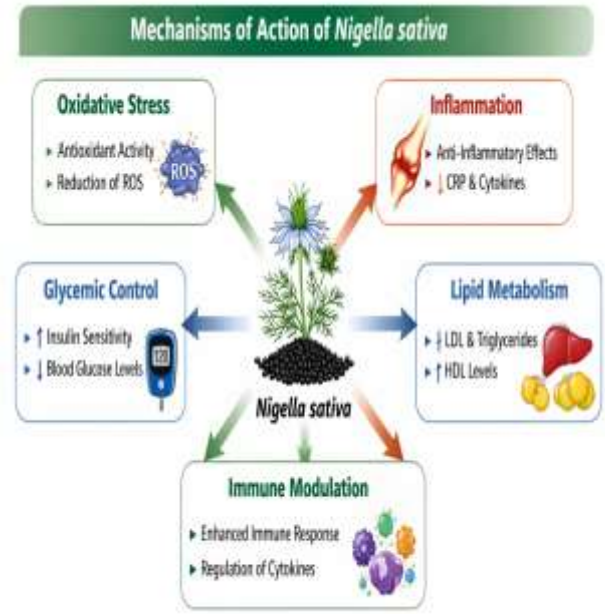

Figure 2: Proposed Biological Mechanisms Underlying the Clinical Effects of Nigella Sativa.

Looking at the evidence related to respiratory and other clinical conditions associated with Nigella sativa, the results showed a less clear-cut picture. The problem lies in the differences in the populations being studied, the severity of the disease, the measures used to evaluate the outcomes, and the way the interventions were applied. However, it has been noticed that, reported improvements in the studies did indicate a possible Nigella sativa's effect in combating chronic conditions. Inflammation and immune system issues have been named as the main areas (Basurra et.al 2021; Derosa et.al 2024).

4.3. Methodological Quality and Risk of Bias

The updated JBI risk of bias tool indicated a significant issue in the methodological rigor of the studies, and only a few of them reported sufficient randomisation, and allocation concealment, when evaluating the clinical trials of Nigella sativa. As a result of this, we can end up getting subjective results, performance bias and detection bias. Which are all more likely to be found in trials that measure something that's hard to measure, like mood or pain. Coming from other areas of research, these kinds of small sample sizes and short interventions, also hamper the ability to get any statistical significance and can't show us how well these herbal remedies will hold up over time. This isn't exclusive to Nigella sativa, but is a general problem in herbal and complementary therapy clinical trials.

4.4. Comparison With Existing Literature

The results are in accordance with the existing literature, which highlights the therapeutic potential of this plant in various physiological systems, when reviewing the health benefits of Nigella sativa. Unfortunately, many previous studies, being narrative reviews and preclinical, limit their practical applications, and the current review rectifies this, and is the first to look exclusively at randomised controlled trials.

Coming heading off the heels of disease-specific systematic reviews, our review gives a clearer view of the real-world clinical uses of Nigella sativa, its promising areas and what still needs more research. This holistic model will be a godsend to doctors, researchers and policy makers who need to weigh the significance of Nigella sativa in an integrative and evidence-based approach to healthcare, (Ibrahim Al-Shaikhli et.al 2024; Johnson et.al 2019).

4.5. Clinical and Research Implications

In relation to the clinical use of Nigella sativa, the available data indicates its potential as a complementary treatment for metabolic and inflammatory conditions. It's necessary to exercise care when using Nigella sativa, and view it as an adjunctive, not a substitute, therapy to traditional methods.

The research in this area is well-organized to ensure the use is considered as a standardized component in terms of dosage, formulation and treatment duration, and helps in moving research findings to the clinical setting. The future studies, however, need to be larger, have a longer follow-up

period and, standardised measurements to assess the outcomes. A good randomization, blinding and concealment process is fundamental to prevent bias, and enable the study to be replicated. Comparative studies with well-known treatments will also be able to tell us how effective Nigella sativa is in relation to, and how to use it in conjunction with, traditional therapies.

4.6. Limitations of the Review

Evaluating this review, it's essential to acknowledge its limitations. The vast heterogeneity of the studies prevented a quantitative meta-analysis, and the exclusive focus on English-language journals could have led to the exclusion of valid trials in other languages. Consistency in procedures to be followed and in the definition of outcomes, was a serious problem. Despite these restrictions, the PRISMA guidelines and the thorough risk-of-bias evaluation, according to the original authors (Yao et.al 2024), make the findings a little more plausible.

4.7. Future Directions

In terms of the clinical efficacy of Nigella sativa, future studies must be multicenter, randomized and have a well-defined intervention protocol. The relationship between the dose and response, long term safety and how the treatment works are all important aspects that will be addressed by more refined studies. Combining clinical results with markers of biological response will be a good way to unlock the therapeutic effects of Nigella sativa.

Therefore, combining the clinical outcomes with validated biological and biochemical markers could yield deeper understanding of the therapeutic potential of Nigella sativa and increase the translational relevancy of the upcoming trials (Tavakkoli et al., 2017).

5. CONCLUSION

A systematic review of randomized controlled trials showed that this herbal remedy is a promising therapeutic agent in the treatment of metabolic, inflammatory, immune-related and cardiometabolic disorders, when evaluating the effectiveness of Nigella sativa in humans. In comparison to placebos or standard care, the intervention from Nigella sativa caused significant positive clinical and biochemical changes, in clinical settings.

However, the systematic review's ability to precisely determine the degree and weight of the findings may seem limited, basically because of the diversity in the design of the studies, the methods used, and the measures of success. It was also impossible to figure out the ideal dosage, and the tiny sample sizes, brief periods of observation, and unclear descriptions of the way the patients were randomly assigned to the studies mean that the results are open to a lot of interpretation.

One of the ways to effectively test the effectiveness of herbal treatments is through randomised trials, and according to the authors, presents a much more cohesive and reliable picture of the evidence, makes sure that the criteria for including and excluding studies are crystal-clear and carefully weighs the risk of bias, so the report from this review is regarded as being more believable than the typical or preclinical reviews.

Well-known experts have stated that Nigella sativa may be a useful addition to conventional treatments, and they would want to see more concrete medical evidence and medical expertise before it becomes a standard part of clinical practice. They say that upcoming research should include large-scale, well-designed, randomised trials with a uniform protocol, and results that are clinically meaningful. Problems with long-term side effects, the right dosage and comparing it to regular medications also need to be sorted out. It will take more top-quality research to nail down the effectiveness, safety and ideal dosage of Nigella sativa, this review has gotten us started on that path, and adds to the body of knowledge being used to make intelligent decisions in integrative and evidence-based medicine.

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