



The effects of nigella sativa on anthropometric and biochemical indices in postmenopausal women with metabolic syndrome

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Received: 4 February 2020 / Accepted: 6 March 2020
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Abstract

Purpose This study aimed to compare the nigella sativa vs. placebo effect on anthropometric and biochemical indices in postmenopausal women with metabolic syndrome.

Methods This randomized, double-blinded, placebo-controlled trial was conducted as a third-phase trial among 140 menopausal women within the age of 45–60 years old, who were suffering from metabolic syndrome and were assigned to receive 500 mg nigella sativa or placebo pill once daily. Anthropometric and biochemical parameters including body weight, waist circumference, serum lipid profile, fasting blood sugar, and HbA1C were measured at baseline and 8 weeks after administration the ingredient or placebo.

Results In nigella sativa group, the serum markers such as low-density lipoprotein (115.1 ± 17.6 vs. 127.7 ± 12.6), triglyceride (158.3 ± 14.0 vs. 166.7 ± 16.0), total cholesterol (115.1 ± 17.6 vs. 127.7 ± 12.6), and fasting blood sugar (90.8 ± 16.9 vs. 113.7 ± 12.1) decreased significantly compared with the placebo ($p < 0.001$).

Conclusion Administration of nigella sativa might be recommended for improving lipid profile and blood sugar in postmenopausal women with the metabolic syndrome.

Keywords Menopause · Metabolic syndrome · Nigella sativa

Introduction

Menopause is a transitional period in all women's lives, which often occurs in middle age and lead to hormonal alteration in this phase of life [1]. This period may be challenging for women with many lifestyle complications [2, 3]. The average age of menopause in Asian urban is about 46 years, whereas it is rather more in western country that is 51 years old [4].

Women in menopausal age are at an increased risk of obesity that associated with health risks that may be due to

the decrease in circulating estrogen [5]. Obesity may lead to the metabolic syndrome in menopausal women [6].

Metabolic syndrome is characterized by symptoms such as high blood pressure, dyslipidemia, obesity (especially central obesity), and high blood sugar that they are risk factors for cardiovascular disease [7]. Indeed, menopausal status can be a predictor of the metabolic syndrome [8].

According to the mechanisms of menopausal symptoms, hormone replacement therapy (HRT) is a useful way of combating the undesirable symptoms that often accompany with estrogen deficit [9]. Although HRT may be beneficial for resolving menopausal symptoms and improving quality of life, it has some potential risks such as breast cancer, cardiovascular risk, and thromboembolic events [10]. Thus, nonhormonal treatment is considered for menopausal symptoms in women who wish not to take HRT or contraindicated [11].

Many women seek herbal medicine due to inefficacy or contraindication of biomedical treatments, or cultural or economic status [12]. In the meantime, nigella sativa is a safe and effective alternative choice with various effects on diabetes [13], hypercholesterolemia [14], cancer [15], and osteoporosis [16]. Accordingly, this study was conducted in

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menopausal women with the metabolic syndrome to determine the biochemical and anthropometric effects of *nigella sativa*.

Materials and methods

Study overview

In this study, 140 menopausal women (70 in each group) were recruited. At the first visit, after history taking, physical examination performed and weight and waist circumference were measured. Then their blood tests including complete blood count, fasting blood sugar (FBS), total cholesterol, high-density cholesterol (HDL), triglycerides (TG), and c-reactive protein (CRP) were checked.

The kit used to measure blood sugar, TG, and total cholesterol belonged to Pars Azmoon and measurement kit of the HDL and CRP was related to Bionic Company. Low-density cholesterol was determined through the Friedewald formula. The type of system used was RAXT type 1,000. A general practitioner was responsible for history taking, physical examination, measurement of weight (using the digital scale model QC, type 6173 BV 01015, making China the power measurement Max 150 kg weight) and waist circumference. Blood tests were all performed in one refereed laboratory.

The participants were divided into two equal groups (70 women for each group) by randomization blocks. Pharmaceutical compounds including 500 mg *nigella sativa* or the placebo were administered for each group. *Nigella sativa* extract was posited in vinegar for a week in order to get better reception and then extracted in shape of 500 mg capsules. Tuba Salamatkadeh produced these capsules, and its brand was Shoniz. Case and control groups both received the capsule once daily, along with diet and exercise for 8 weeks. Placebo capsule was made from starch and prepared by the Faculty of Pharmacy of Tehran University. These products were packed into similar envelopes and same appearance, so the patient and drug distributor were not aware of its contents until the opening of the envelopes.

In follow-up period, the participants were tracked for the incidence of any side effects. In their last follow-up visit after 8 weeks, they were requested to go to the same lab to take the needed biochemicals and measured their weight and waist circumference.

Inclusion criteria

Based on metabolic syndrome definition [17], the participants who had three of five criteria including waist circumference greater than 88 cm, TG \geq 150 mg/dl, HDL < 50 mg/dl, systolic blood pressure >130 mmHg or diastolic

blood pressure > 85 mmHg, and FBS \geq 100 and who wish to participate were recruited in the study.

Exclusion criteria

The exclusion criteria included diabetes mellitus type one or two, gouty arthritis, blood pressure more than stage 1 (systolic blood pressure over 139 mmHg and diastolic blood pressure over 89 mmHg), acute or chronic coronary artery disease or a history of cardiovascular events, liver disorders (elevated liver enzymes more than three times the normal), chronic kidney disease (creatinine level >1.5 mg/dl), strong family history of dyslipidemia, performing moderate or vigorous exercise, taking supplements or traditional drugs, consumption of alcohol within the past month, and undergoing basic treatment of hyperlipidemia (cholesterol > 240 mg/dl, TG > 200 mg/dl, and LDL > 150).

Statistical issues

Treatment groups were initially compared on the baseline demographic variables with chi-square tests and independent samples *t*-tests. The one-sample Shapiro–Wilk test was used to test the normal distribution of the data. The Wilcoxon signed-rank test was applied to compare the mean score of the variables before and after the interventions and Kruskal–Wallis test for comparing the variables among two groups. Data were analyzed using SPSS version 22. *p* values less than 0.05 were considered statistically significant.

Results

In this study, 140 participants with inclusion criteria were recruited. No one left or refused in the middle of the study. Demographic variables at the baseline were not significant between two groups. Demographic and obstetrics variables in two groups are listed in Table 1.

Anthropometric variable and biochemical indices before and after intervention are listed in Table 2. All indices before intervention were not significantly different between groups. As it shown in the Table 2, FBS ($p < 0.001$), total

Table 1 Demographic and obstetric variables in two groups

Demographic	<i>Nigella sativa</i> ^a	Placebo	<i>p</i>
Age (years)	3.3 ± 50.6	3.5 ± 50.5	0.864
Gravid (numbers)	1.56 ± 3.2	1.3 ± 3.5	0.330
Delivery (number)	1.4 ± 2.9	0.6 ± 3.2	0.296
Abortion (number)	0.3 ± 0.6	0.2 ± 0.6	0.892

^aMean ± SD

Table 2 Anthropometric and biochemical variables in two groups before and after intervention

Variables	Nigella sativa ^a		Placebo		<i>p</i>
	Baseline	After treatment	Baseline	After treatment	
Height (cm)	4.8 ± 158.7		4.5 ± 158.4		0.749
Waist circumference (cm)	107.6 ± 9.3	106.6 ± 9.8	107.3 ± 10.0	107.7 ± 10.1	0.661
Weight (kg)	5.2 ± 71.5	71.1 ± 5.0	5.0 ± 71.7	71.7 ± 4.9	0.521
HbA1c (g/dl)	5.7 ± 0.6	5.5 ± 0.6	5.7 ± 0.6	5.7 ± 0.6	0.085
Fasting blood sugar (mg/dl)	117.9 ± 3.6	90.8 ± 16.9	117.9 ± 3.8	113.7 ± 12.1	<0.001
Total cholesterol (mg/dl)	218.7 ± 10.3	196.4 ± 19.7	218.1 ± 13.6	216.4 ± 19.6	<0.001
LDL cholesterol (mg/dl)	129.5 ± 13.3	115.1 ± 17.6	130.1 ± 13.2	127.7 ± 12.6	<0.001
HDL cholesterol (mg/dl)	37.3 ± 8.1	42.0 ± 6.9	38.4 ± 6.3	40.0 ± 6.9	0.094
Triglyceride (mg/dl)	172.7 ± 14.0	158.3 ± 14.0	172.3 ± 12.7	166.7 ± 16.0	<0.001

^aMean ± SD**Table 3** Anthropometric and biochemical variables mean changes in two groups

Variables	Nigella sativa ^a	Placebo	<i>p</i>
Waist circumference	1.0 ± 1.6	0.2 ± 4.0	0.134
Weight (kg)	71.5 ± 5.2	71.7 ± 5.0	0.054
HbA1c (g/dl)	-0.2 < 0.3	-0.0 ± 0.1	<0.001
Fasting blood sugar (mg/dl)	-27.1 ± 18.2	-4.2 ± 12.2	<0.001
Total cholesterol (mg/dl)	-22.2 ± 19.6	-1.7 ± 13.6	<0.001
LDL cholesterol (mg/dl)	-14.3 ± 14.4	-2.4 ± 6.7	<0.001
HDL cholesterol (mg/dl)	4.6 ± 6.5	1.6 ± 4.3	<0.001
Triglyceride (mg/dl)	-14.3 ± 9.2	-5.5 ± 10.5	<0.001

^aMean change ± SD

cholesterol ($p < 0.001$), LDL ($p < 0.001$), and TG ($p < 0.001$) in nigella sativa group were significantly decreased compared with control.

As demonstrated in Table 3, the mean differences in nigella sativa group in waist circumference, weight, and all biochemical markers were significantly more than alterations in placebo group although changes in anthropometric variables were not significantly different ($p > 0.05$).

Discussion

Nigella sativa as a miracle seed seems to have a wide spectrum of pharmacological actions include antidiabetic, anticancer, immunomodulator, anti-inflammatory, and antioxidant properties [18]. In this study, after nigella sativa administration for 8 weeks, biochemical indices but not anthropometric parameters had significant improvement across the groups.

Participants who administered nigella sativa had better glucose profile in our study. This is similar to Bamosa et al.'s trial [13] that supplementary use of nigella sativa in

type-II diabetes mellitus patients via oral administration resulted in improvement in HbA1C and fasting blood glucose but the weight change was not significant. Also, Meral et al. [19] showed that nigella sativa in rat models had significant antioxidant effects beside the impacts on blood glucose levels. However, in our study the antioxidant effects were not assessed as a main limitation.

Sabzghabae et al. [14] reported LDL and TG decline after 1-month treatment with nigella sativa. But in their study the increase in HDL cholesterol and reduction in fasting blood glucose were not significant. In our study with the lower dose but longer time of use, nigella sativa had significant effects especially in fasting blood glucose and glycemic index. Interestingly, nigella sativa has the probable beneficial role in management of postmenopausal symptoms [20, 21]. Human study about histological findings after use of nigella sativa can be assessed beside their relationships with metabolic alterations.

Since nigella sativa is a tropical herbal remedy in middle east since many years ago [22], it may be used more extensively in various aspects of health status [23]. Although it has no significant adverse effects on liver, heart, kidney, and pancreas, blood cells and biochemical indices were reported to be improved by nigella sativa in the study by Zaoui et al. [24]. Indeed, anti-inflammatory, antimicrobial, and antineoplastic effects are reported for this herbal medication [25] that can encourage further studies about other possible effects of this tropical remedy.

The limitations of our study are low participants number, short follow-up period, and lack of multiple treatment doses for nigella sativa.

These results demonstrated that treatment with nigella sativa may exert therapeutic effects by improving lipid profile, blood sugar, and HbA1c. However, further studies with larger age range can help to understand efficacy of this ingredient in women with the metabolic syndrome in other age groups beside the safety matters across them.

Data availability

The datasets used during the current study are available from the corresponding author on reasonable request.

Author contributions M.S.: project development and manuscript writing. M.G.: data collection and management and manuscript editing. E.F.: manuscript editing and data management. F.K.: data management. All authors have read and approved the manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval and consent to participate The protocol of the study was approved by the ethical committee of Tehran University of Medical Sciences. The participants subsequently submitted a written consent form to participate in the trial. This trial was conducted according to the principles of the Helsinki Declaration.

Consent for publication Written consent was signed upon admission by the patient included in this study to use their information in research studies and as available for review. No personal information had been published and the identity of the participants had not transpired.

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