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# The effects of *Nigella sativa* L. seed oil on BMI, WC and FBS in overweight men: A randomized controlled clinical trial

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## ABSTRACT

**Background and aims:** In recent years, the wide usage of herbal drugs has encouraged the medical scientists to evaluate its effects on health. *Nigella sativa* L. seed (*N. sativa*) as an herbal drug has prescribed in some diseases such as hyperlipidemia and metabolic syndrome. This study was conducted to investigate the effects of *N. sativa* on weight, BMI (Body Mass Index) and FBS (Fasting Blood Sugar) in overweight men.

**Methods:** In this randomized controlled trial, we enrolled seventy eight subjects in two groups to receive 2.5 mL *N. sativa* oil (n=37) or 2.5 mL paraffin oil as placebo (n=30) two times a day orally for 2 months. FBS, weight, height, and WC (Waist Circumference) of subjects were measured before and after intervention in both groups.

**Results:** After intervention, in *N. sativa* group, weight, BMI, FBS, and WC were significantly reduced (P<0.01) compared with baseline and also compared with placebo group.

**Conclusion:** Our results showed that daily intake of 5ml *N. sativa* oil for two months could significantly reduce weight, WC and FBS in over weight men.

**Keywords:** *Nigella sativa*, Overweight, Fasting Blood Sugar, Body Mass Index, Waist Circumference.

Original article

## INTRODUCTION

In recent decades, rapid increases in the obesity and overweight prevalence are widely documented, in different countries and populations, and nowadays, overweight and obesity have mentioned as a major public health concerns.[1,2] Obesity emerged as an epidemic, could accompany by a variety of disorders, such as cardiovascular disease, diabetes, some cancers and so on.[2,3] Previous studies address the reduced physical activity and life style changes, as major causative factors of obesity. According to multi-factorial nature of obesity, researches focus on medical and nonmedical approaches for control increasing trend of obesity pandemic.[2,4,5]

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Recently, a considerable number of studies interested in non-conventional treatments, and many of them examined the effects of functional foods and nutraceuticals.[3]

In the recent years, herbal supplement prescription or diet changes recommendation are used as a Complementary and Alternatives Medicine (CAM).[6] Herbal supplement and medicinal plants have been an important point for researcher to find new treatment for human health problems.[7]

The seeds of *Nigella sativa* Linn (family Ranunculaceae), that commonly known as black seed or black cumin, are traditionally used as herbal medicine all over the world-especially middle east region for the treatment or prevention of a wide range health problem.[8] Black cumin and its major bioactive constituent, thymoquinone have demonstrated that are useful in a variety of disease.[3] This herb traditionally prescribed and has many usages which because of its chemical compounds and biological active ingredients.[9,10] Several studies showed that black cumin (*N. sativa*) has cardio-protective, metabolic syndrome, anti-cancer, anti-diabetic, antioxidant, and immune-modulatory properties.[10-8] Also, a review study suggests a potential role of *N. sativa* and TQ in the management of metabolic syndrome.[10]

In spite of the biochemical parameters such as lipid profile, the effects of *N. sativa* on weight and anthropometric indices are equivocal. Recently, Farzaneh and colleagues demonstrate that 8 weeks *N. sativa* supplementation could reduce BMI of sedentary overweight females.[19]

Therefore, in this study, we are going to find out the effects of *N. sativa* oil consumption for 2 months that accompanied with a usual diet on body weight, WC and FBS in men with BMI ≥25.

## METHODS

Eighty Iranian overweight men aged 20-45 years, referred to the Mahdieh Hospital in Tehran, Iran, that had inclusion criteria were selected.

Inclusion criteria were BMI ≥25, an age of 20-45 years, and had no exercise (they had light physical activity: Doing routine tasks, riding in a car, light activity while sitting).

The individuals who had following criteria were not included to the study: having a chronic illness (e.g., cancer, renal failure, cardiovascular disease, liver, and lung failure), taking vitamin supplements, an inflammatory condition (e.g., lupus), diabetes or use of anti-hyperglycemic drugs, working night shifts, smoking, alcohol consumption or any known allergy or sensitivity to foods. Additional criteria that cause subjects not included in the study were: being on weight control diets or any specific diets at the time, use of medications known to affect body weight or a weight-loss of ≥5 kg in the preceding 6-month.

All subjects were initially visited by nutritionist, interviewed and questioned about their life style and food habits or any food allergy.

The study was double-blind and block randomization was used for allocation of the subjects to the *N. sativa* oil or placebo groups. Subjects were randomly assigned into *N. sativa* oil and placebo groups, and forty subjects participated in each group of the study. The method of randomization (sequen¬tially-numbered containers by the pharma¬cy department) was used to ensure adequate concealment of allocation in all groups. The subjects in *N. sativa* oil and placebo groups received orally *N. sativa* oil and mineral oil respectively each at the dose of 2.5 ml, two times a day, for 2 months. We select mineral oil as placebo because it is not absorbed by body. All participants were requested to report any adverse effects or reaction.

At the beginning blood sugar and anthropometric indices were measured for all subjects, and they were asked not to

alter previous diet and physical activity during the study. Three 24-h dietary recalls (2 weekdays and 1 for weekend day) were carried out for the assessments and check of food intake at baseline, and end of the study to assess and control dietary intake changes.

All participants were instructed to maintain their usual activity habits. All participants requested to comply with their diets for 2-month. They were called by phone every 15 days to ask about their situations and diet compliance. Also, suggestions to enhance compliance were provided. Weight were determined by standard anthropometric methods in the beginning and after 2-month at the end of the study. Weight was measured to the nearest 0.1 kg on a Seca electronic scale when the subjects were fasting, with no shoes and with light-weight clothing. BMI was calculated as weight (kg) divided by height ($m^2$). Height was determined to the nearest 0.1 cm by using a stadiometer only at baseline and WC was measured to the nearest 0.1 cm with a meter of fabric.[20]

For measuring FBS, each subject must be 12 hours of fasting after eating a light meal for dinner then refer to the lab the next day fasting.

This study protocol was approved by the Ethics Committee of Human Experimentation of Shahid Beheshti University of Medical Sciences and written informed consent was obtained from each participant. The trial was registered in Iranian Registry of Clinical Trial with 144 the number IRCT201011205204N1.

*N. sativa* oil and mineral oil were purchased from local market in the Tehran city. *N. sativa* oil was the product of Barij Essence Company, Kashan, and Iran. *N. sativa* oil had been prepared by cold pre procedure as indicated in its brochure. 0.1 ml of a mixture consisting of chlorophyll and red chili pepper extract in equal proportions dissolved in oil was added to 100 ml of mineral oil and *N. sativa* oil in order to give color and taste to placebo. The *N. sativa* and mineral oils were filled in 150 ml colored bottles and marked as A and B.

In previous study, the concentration of fatty acids and volatile oil in *N. sativa* oil was measured by the gas- liquid chromatography.[21,22]

Data were analyzed using the SPSS statistical software. The results are expressed as mean ± SD. Paired t-test was used for comparison of the measurements before and after the study in each group. Independent t-test used for between groups. $P<0.05$ was considered statistically significant in all statistical tests.

## RESULTS

In this study, 40 subjects participated in each group. Thirteen cases lost to follow-up and they did not return for monthly visit due to personal reasons. Finally, thirty subjects in placebo group and 37 subjects in *N. sativa* group complete the study protocol, and we did statistical analysis on 67 subjects. There are no differences among two groups for age, weight, height, WC, FBS, and BMI (Table 1).

Changes of variables after 2 months intervention for two groups are shown in table 2. As shown in this table, in *N. sativa* group, FBS decreased by 2% and anthropometric indices decreased significantly (weight by 1.76%; BMI by 1.8%; and WC by 1.34%). Furthermore, there were significant differences between the *N. sativa* and placebo groups for weight, BMI, WC, and FBS.

**Table 1:** The demographic and baseline data comparison in *N. sativa* oil and placebo groups (mean ± SD)

| Variables | Placebo (n=30) | *N. sativa* (n=37) | P* |
|---|---|---|---|
| Age | 32.1±4.7 | 31.6±6.7 | 0.466 |
| weight | 82.6±16.9 | 79.6±13.8 | 0.565 |
| Height | 175.8±7.3 | 173.6±7.2 | 0.644 |
| BMI | 26.6±4.4 | 26.3±3.9 | 0.519 |
| WC | 88.7±12 | 87.6±13 | 0.307 |
| FBS | 92.3±13 | 96.6±9 | 0.059 |

**: Independent sample t-test.*

**Table 2:** Changes in the variables in placebo and *N. sativa* groups

| Variables | Placebo (n=30) | | P¹ | *N. sativa* (n=37) | | P¹ | P² |
|---|---|---|---|---|---|---|---|
| | Pre-test | Post-test | | Pre-test | Post-test | | |
| Weight (kg) | 82.6±16.9 | 82.3±16.4 | 0.128 | 79.6±13.8 | 78.1±12.1 | <0.01 | 0.019 |
| BMI (kg/m²) | 26.6±4.4 | 26.5±4.2 | 0.145 | 26.3±3.9 | 25.9±3.4 | <0.01 | 0.017 |
| WC (cm) | 88.7±12 | 88.9±11.7 | 0.244 | 87.6±13 | 86.5±11.6 | <0.01 | 0.003 |
| FBS (cm) | 92.3±13 | 92.4±12.7 | 0.526 | 96.6±9 | 94.5±7 | <0.01 | 0.004 |

*P¹: Difference between pre and post-test (Paired T-test); P²: Comparison of difference between two groups (One-way ANOVA).*

# DISCUSSION

The present trial was designed to evaluate the comparison effect of a balanced natural diet with and without *N. sativa* oil on weight reduction in males with BMI ≥25 over a 2-month period. The results presented in this work show significant effects of *N. sativa* supplementation in FBS and anthropometric indices in overweight and obese men. The principal finding is that the *N. sativa* intake for 2 months was successful in meaningful weight loss.

Nowadays, increased prevalence of overweight and obesity in the community, and the risk of chronic diseases associated with obesity encourage us to find ways to reduce weight.

The effect of *N. sativa* oil on weight and BMI in present study is consisting with the previous study indicating the effects of *N. sativa* oil on weight and BMI.[19,23,24] Data has been reported that *N. sativa* could reduce weight and WC significantly in central obese men.[23] In two recent studies, Ibrahim et al. found that weight in menopausal women tended to be reduced after orally intake of 1 gram of *N. sativa* seeds powder for two months.[24] Farzaneh and et al. reported a significant reduction in BMI of

overweight female.[19] Accordingly, in a systematic review, *N. sativa* was found to have acceptable anti-obesity effects.[6] However, the indicated mechanisms are not clear. We need more research to understand and explore of the mechanisms and the reason of *N. sativa* effects on anthropometric indices. We guess that this effect might be due to *N. sativa* lipid profile and high unsaturated fatty acids content.[21] It is assumed that chronic consumption of *N. sativa* oil may lead to increased resting energy expenditure due to high unsaturated fatty acids, which may influence diet-induced thermogenesis.[25]

We also observed that *N. sativa* intake for eight weeks was able to reduce fasting blood glucose significantly by 2%. This result is in agreement with the results obtained by researchers who observed that *N. sativa* supplementation could significantly decrease FBS in human subjects or animal models.[9,13-15,17,24] Furthermore, Najmi et al. found that *N. sativa* intake could improve postprandial glucose 2 hours after glucose intake.[9]

FBS is one of the most important indexes for the diagnosis of the metabolic syndrome.[9] The hypoglycemic effect of *N. sativa* was mediated through multiple pathways.[24] According to previous study, *N. sativa* intake increases the β-cells function and reduction in insulin resistant at target tissues.[15,26] Since, several studies have reported the antioxidant effects of *N. sativa*, the proposed mechanism for this effect is unknown, but it seems that antioxidant effects of *N. sativa* may be affected to FBS and insulin sensitivity.[14,16-18,27,28] It is need to mention that *Nigella sativa* oil contains 10.2 mg tocopherol per 100g that is responsible for 73.5 percent of antioxidant's function.[29]

This study is not without limitation. Participants in our study were males; therefore, our results may not be generalized to females. In addition, it is possible that errors may have occurred in the participant's self-reported dietary intake. However, further studies are needed to demonstrate theories on the effects of *N. sativa* oil on weight-loss.

## CONCLUSION

In conclusion, *N. sativa* has useful effects on FBS, weight, and WC. However, more research is needed to determine the *N. sativa* mechanism of actions.

## CONFICT OF INTEREST

All authors have no conflict of interest to disclose.

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