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**Comparative Study on Effect of Black Seeds and Flaxseeds in Managing Hypertension in Hypertensive Individuals**

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Abstract

Hypertension is considered one of the leading risk factors for cardiovascular disorders, like cerebrovascular disease and ischemic heart disease. As per World Health Organization, hypertension has been the major cause of premature deaths worldwide, with upwards of 1 in 4 men and 1 in 5 women over a billion people having the condition. The NHFS 4 done in the Telangana district shows 13% of women aged between 15 to 49 years have hypertension, and 20% of men in the same age group have hypertension. This project aimed to study the effects of black seeds and flax seeds in managing blood pressure in hypertensive individuals, compare the results and conclude which among the two seeds is more effective. It was a non-blinded randomized interventional study with two study groups with n=25 each and one control group n=50. The first intervention group received 15gms of flaxseed twice a day, and the second intervention group will receive 2.5gms of blackseed twice a day in preferred form by the participant for eight weeks. Results showed a positive effect of these seeds in lowering SBP and DBP levels when consumed daily. A significant decrease in SBP was seen from 133.92 ± 0.716 (p=0.009) from 136.43 ± 0.939. and in DBP levels from 86.36 ± 0.678 to 84.1 ± 0.364 (p=0.008). Thus, it can be concluded that flaxseed and black seeds have a good antihypertensive effect and can be incorporated as an effective measure in the dietary regimen of Hypertensive individuals.

Keywords: Black Seeds, Cardiovascular Disease Risk, DASH Diet, Dietary Modification, Flaxseeds, Hypertension, Non-Communicable Diseases, Seed Supplementation.

# Introduction

Hypertension is one of the biggest risk factors for cardiovascular disorders, such as cerebrovascular disease and ischemic heart disease. Hypertension is a significant medical condition that increases a person's risk of heart, brain, kidney, and other disorders. As per World Health Organization, hypertension has been the major cause of premature deaths worldwide, with upwards of 1 in 4 men and 1 in 5 women over a billion people ¬having the condition. The burden of hypertension is disproportionately high in low- and middle-income countries, where two-thirds of cases were diagnosed because of increased risk factors in those populations in recent decades. [25]

Hypertension is considered the most important disease burden in India; as per a Global Burden of Disease (GDA) study, hypertension claimed 1.6 million lives in India in 2015. With better hypertension control measures, an estimate of 400–500,000 premature deaths can be prevented in India. [14] Also, globally hypertension has been of great risk as well. In 2017, 34.1 million deaths and 1.21 billion DALYs accounting for 61.0% and 48.3% were attributed to the Global Burden of Disease (GBD) 2017 risk factors.[9]

Despite the availability of healthcare facilities, there is a very poor association between hypertension prevalence and its treatment, although there is a positive association between healthcare access and quality. [12] To tackle the overall risk, several guidelines were issued by the AHA, ESH and ESA to achieve optimum blood pressure and reduce the overall risk of cardiovascular diseases. [11,18] These guidelines include a possible range of interventions in the lifestyle and food consumption behaviours such as increased physical activity, weight management, increased consumption of fruits and vegetables, sodium restrictions and use of drugs to lower BP. [13]

According to various studies, it was found that nutritional intervention of various foods and dietary factors such as omega 3 fatty acids, fish, soy protein, and plant sterol have potential cardiovascular protective effects [4,14]. In addition, there are many herbs, spices and seeds with the potential of treating various diseases. Two such foods discussed in this study are flax seeds and black seeds.

Flaxseed has been considered a functional food due to its potential in reducing cardiovascular risk factors such as hypertension and hyperlipidemia with its high content of lignans, fibre, and alpha-linolenic acid (ALA).[14] A recent study shows that the consumption of flaxseed has a positive effect on reducing systolic blood pressure and diastolic blood pressure in patients of peripheral arterial disease with 75% hypertension.[3] A prospective, double-blinded, placebo-controlled, randomized trial was conducted by Delfin Rodriguez-Leyva et al. (2013) over 6 months (n=110). The subjects consumed food that contained 30gms of milled flaxseed or placebo. At the end of 6 months, SBP was ≈10 mm Hg lower, and DBP was ≈7 mm Hg lower in the flaxseed group in comparison to the placebo was seen. [21] In another randomized, double-blind placebo-controlled clinical trial conducted by Naemeh Haghighatsiar et al. 2019, among 80 hyperlipidemic and hypertensive patients, both men and women aged between 20 to 60 years in 2017. They found significant improvement in anthropometric and lipid profiles within the flaxseed group (received 36gm of flaxseed sachets) and placebo groups (received 12gm placebo sachet). Furthermore, a within-group significant reduction was observed in SBP (-6.25 mmHg, p <0.001) and DBP (-3 mmHg, p 0.027), LDL, and HDL in the group supplemented with flaxseed and weight and BMI in the placebo group over 8 weeks of study. [14]

While Black seeds have also shown improvement in high-density lipoprotein levels while lowering serum lipid profile and triglyceride levels, Thymoquinone, which is present in the seed oil at a concentration of 25%, is also responsible for the seed's importance. According to studies, consuming black cumin and its bioactive components on a daily basis can help with overall health. [5] M. amini et al. 2013, in their controlled clinical trials, n=70 with systolic BP from 110 to 140 mmHg and diastolic BP from 60 to 90 mmHg were randomly allocated to receive 2.5 mL N. Sativa oil or placebo two times a day for 8 weeks observed a decrease in SBP and DBP. [5] Amin and Hosseinzadeh (2016) have recently reviewed the analgesic and anti-inflammatory effects of N. Sativa and its main active constituent, thymoquinone. They reported many studies showing the different doses and administration forms of N. Sativa seed components tested in models of nociception and inflammation. This effect of the seeds is believed to help in managing hypertension. [2] In the randomized controlled trial study, supplementation of black seeds in stage 1 hypertensive patients showed a reduction in blood pressure. Compared with the control group, the experiment group showed a decrease of −3.26 mmHg in systolic blood pressure and −2.80 mmHg in diastolic blood pressure. [22]

Proper management of hypertension is crucial to prevent all the adverse possibilities and reduce its prevalence and the prevalence of cardiovascular diseases related to it. Therefore, this study was undertaken with the purpose to observe the effect of the black seeds and flaxseeds in managing hypertension, taking into consideration the positive effect of the mentioned seeds in reducing systolic and diastolic blood pressure.

# Materials and Methods

This study investigates the effect of dietary intervention in the form of Flaxseed and Black seed supplementation along with a balanced diet on Hypertension.

## Study design

It was a non-blinded randomized controlled trial with three study groups. The two study groups received flaxseeds and black seeds, respectively, along with customized diets, while the controlled group received only customized diets. It was an 8week long study where the data was collected thrice, a baseline data collection after recruiting the participants. The next set of data was collected 4 weeks after the start of the intervention and lastly at the end of 8 weeks. All of these were done during follow-up sessions. Data was collected via a questionnaire that was modified as per the requirements of the study. The questionnaire consisted of questions on demographics like age, sex, education etc., anthropometrics which include height and weight, blood pressure parameters. However, the main core of the questionnaire is the food frequency questionnaire which consists of questions related to food consumption patterns and the international physical activity questionnaire that deals with the physical activity status of the participants.

Participants: The study mainly focuses on the middle-aged and old age population residing in Hyderabad. The target is 100 participants, 50 under the control group and 50 in the experimental group. Participants are being collected via advertisements circulated through social media platforms and referrals of people known to the researcher and conducting health camps at locations near the researcher.

The health camps are conducted at two colonies for the general population residing there, two schools for the teaching and non-teaching staff and one Intermediate (junior) college for the teaching and non-teaching staff. Word for these camps is propagated by putting up a banner at the campsite, posting e-posters of the camp in the colony WhatsApp groups, making prior announcements, and sending WhatsApp messages to the staff in schools and colleges.

Both men and women are recruited for the study who have systolic blood pressure more than 120mm/Hg and diastolic blood pressure of more than 80mm/Hg. The age of the participants ranged from 30 to 78. A total of 21 people responded to the study via online mode, of which 6 people were selected to participate in the study after considering the inclusion and exclusion criteria. While a total of 125 participated in the camp, of which 94 people were included to participate in the study. Therefore, N=100 participants were enrolled for this study, of which n=45 were males and n=55 were females.

#### Inclusion criteria

* Hypertensive (SBP >130mm/Hg, DBP >80mm/Hg)
* Diagnosed with hypertension for at least 1 year
* Both males and females aged between 25 to 80 and are able to give their consent.
* Mildly diabetic (type-2)
* Non-alcoholics and Non-smokers
* Willing to take the supplementation

#### Exclusion criteria

* Patients with severe diabetes mellitus, any Bowel disease (like peptic ulcer, celiac disease, IBD) and Hepatic disease.
* Patients with any serious Cardiac problems or history of cardiac arrests, and clinical evidence of cardiac failure.
* Patients with Respiratory disease, Renal disease, Organ damage, Cancers, Dementia.
* Women who were pregnant or planning to get pregnant in the next 2 to 3 months.
* Subjects who were already on any kind of supplementation which includes omega-3-fatty acid in its composition.
* Subjects who were allergic to the interventional supplements provided.

Randomization and blinding: Participants were randomly assigned into the intervention group and the controlled group. That gave the following three groups: flaxseed intervention group, blackseed intervention group and no-intervention control group. Blinding is not done in this study both the researcher and the participants were aware of the interventional groups assigned.

Intervention: Upon acceptance to participate in the study, the participants were counselled about the lifestyles modifications to be done to manage hypertension which include dietary approaches to control hypertension and physical activity. Participants were divided into three groups n=25 was included in the first intervention group, n=25 in the second intervention group and n=50 in the control group. 1st intervention group received 15gms of flaxseed twice a day in a form that was preferred by the participant, either as whole seeds or in powdered form mixed with their food or solely for 2 months. 2nd intervention group will receive 2.5gms of blackseed twice a day in the form that will be preferred by the participant for 2 months. Both the groups are also guided to follow a balanced diet which includes all the food groups in required proportions along with the intervention. The controlled group was only prescribed dietary approaches and physical activity to manage hypertension. They were not given any seed supplementation. All three groups are asked to be physically active for at least 30 minutes each day.

## Procedure

For Online mode, the participants were approached by advertising on various social media platforms, through common WhatsApp groups, referrals from people known to the researcher and participants. The participants registered themselves for the study via a google form, which has the title of the study, recruitment details, and benefits to the participant through the study and asked for their name, age, sex, and consent to participate in the study.

For Offline mode, the participants who visited the camp were first screened for their body temperature and questioned if they had any symptoms of COVID-19. After which their Name and Anthropometric data are collected, which include their height, weight and waist circumference; following this, a brief medical history is collected by questioning them if they are already hypertensive or not and if they have any other co-morbid conditions. Their blood pressures were then checked using an aneroid sphygmomanometer. Participants who met the inclusion criteria were then informed about the study and, after receiving their consent to participate in the study, were interviewed further, and their questionnaire was filled out by the researcher. They are guided about the process of the study and their role in it.

Interview technique: The participants recruited via the online modes are interviewed over phone calls, and their questionnaire is filled out by the researcher. They are informed and guided about their role in this study and what all necessary actions were required on their part. As for the offline mode, one-to-one interviews are conducted with the participants. They were briefed about the study, its purpose and their role in the study. Then the required parameters were recorded, followed by filling up the questionnaire by the researcher.

Questionnaire formulation: The questionnaire was formulated using google forms. It has 4 major sections, of which section one has details about the researcher, the title of the study, and assurance for confidentiality. Section two have questions dealing with anthropometric and biochemical data, namely height, weight, waist circumference, SBP and DBP and their recent LDL levels. Section three enquired about their food frequency data and have questions about their meal intake, frequency of consuming fried foods, salt intake, supplementation and has a Food Frequency Questionnaire that was designed drawing reference from validated semi-quantitative food frequency questionnaire (v. sudha, 2006) and a sample questionnaire (NHLBI). The FFQ was modified as per the requirements for the study. The fourth and final section of the questionnaire has International Physical Activity Questionnaire (IPAQ) (august 2002 version) short 7-day format (Craig, 2003). Questions in the IPAQ were reframed to make them more understandable to the participants.

Data collection: Data collection is done via questionnaires, anthropometric and blood pressure measurements. A baseline collection is done while recruiting the participants, the second set of data collection is done during the first follow up after 4 weeks, and the third collection of data is done during the final follow up after 8 weeks. Collection of data began from the 4th week of September 2020 and is completed by the 4th week of December 2020.

## Statistical analysis

Data were analyzed with SPSS-20 using descriptive and analytical statistics. Frequency, percentage, and mean standard deviation were used to describe demographic characteristics. The main statistical tests used in the study were linear regression, Chi-square, Fisher exact test, to assess differences in characteristics, chi-square test was used for categorical variables and ANOVA for continuous variables. P-value of <0.05 was considered significant.

# Result

## Demographic analysis

A total of 100 participants were enrolled for this study, of which n=45 were males, and n=55 were females. (See table 1) after randomization 25 participants (n=11 males and n=14 females) in blackseed intervention group 25 participants (n=10 males and n=15 females) in flaxseed intervention group and 50 participants (n=24 males and n=26 females) were included in control group. Visibly the number of females was high in the control and intervention groups, but statistically, there was no significance found (p=0.801) when the Pearson chi-square test was performed and neither was there any liner association (p=0.507). Of all the occupational categories, the highest number of participants were from the category of homemakers (n=44), followed by other sedentary occupation categories (n=29); the least number of participants were from the heavy working category with only n=5 respondents. (See table 2) respondents were aged between 30 to 78 with an average of 43.83±9.641634.

There was not much difference in the body weights of the participants in control and intervention groups during their baseline weight check (control = 71.47±1.75, blackseed group=70.2 ±2.86 and flaxseed= 72.41±2.95) neither was there any significant change in their body weights after 2 months (control = 72.08±1.83, blackseed group=70.16 ±2.82 and flaxseed group= 72.61±2.885). An increase in the BMI was seen in the control group from an average BMI of 26.913±0.634 to 27.161±0.685 after 2 months of the study period. A slight decrease was seen in the black seeds intervention group from baseline BMI of 27.40±1.116 to post interventional BMI of 27.38±1.093, whereas an increase from 26.95±1.083 to 27.037±1.058 in BMI was noticed in the flaxseed intervention group post-study period. No change in the waist circumference was noticed in all the three study groups at any point of the study period. (control = 89.59±1.843, blackseed group = 97.29±2.460, flaxseed = 99.77±3.238). (See table 3)

The highest number of participants, n=42, belong to the overweight category, followed by the normal weight category, which has the second-highest number of participants, n=27. The least number of participants were from the grade 3 obese category, with only 1 participant (See table 1). Out of 100 participants, 96% (n=96) do not have a history of diabetes mellitus. A very strong linear association was found between non-diabetic and hypertension (0.014) and was statistically significant (p=0.044).

Table 1 Distribution of participants among the control and intervention group based on sex and BMI

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Male | Female | underweight | Normal weight | Overweight | Grade 1 obese | Grade 2 obese | Grade 3 obese |
| Control (n=50) | 24 | 26 | 2 | 14 | 23 | 10 | 1 | 0 |
| Blackseed (n=25) | 11 | 14 | 0 | 8 | 11 | 4 | 1 | 1 |
| Flaxseed (n=25) | 10 | 15 | 3 | 5 | 7 | 7 | 2 | 0 |
| Total | 45 | 55 | 5 | 27 | 41 | 21 | 4 | 1 |

Table 2 Distribution of participants among the control and intervention group based on occupation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Occupational category | Control (n=50) | Blackseed (n=25) | Flaxseed (n=25) | Total |
| Homemakers | 23 | 11 | 10 | 44 |
| Teachers and lecturers | 5 | 1 | 8 | 14 |
| Other sedentary works | 17 | 8 | 4 | 29 |
| Moderate work | 5 | 3 | 0 | 8 |
| Heavy work | 0 | 2 | 3 | 5 |

## Blood Pressure Parameter

The participants enrolled have an average baseline SBP of 136.43± 0.93 mmHg. Baseline SBP of the participants differs significantly among the control and interventional group (control group 133.3±1.283 mmHg, blackseed group 140.88±2.017 mmHg, flaxseed group138.24±1.409 mmHg) (p=0.002). A drop of 2.28mmHg was seen in the blackseed group during the first follow-up visit; the group had an average SBP of 138.6±1.733 mmHg, which further lowered to 134.2±1.512mmHg, showing a drop of 4.4 mmHg after completion of the study period. For the flaxseed group, a difference of 4.74mmHg was seen post 1 month of the study period, SBP of this group was lowered from an average of 138.24±1.409mmHg to 133.04 ±1.598mmHg further at the end of the study period 135.6±0.913 SBP of this group reduced to 130.28 ±1.407mmHg showing a decrease of 2.76mmHg. While for the control group, a drop of 2.2mmHg was seen after the first month from the baseline SBP of 133.3±1.283mmHg to 131.18±1.116mmHg followed by a hike of 4.42mmHg reaching 135.6±0.913 mmHg. Overall, there is a significant reduction in the average SBP of the participants to 133.92 ± 0.716 mmHg (p=0.009) post-study period.

Figure 1 Trend in SBP levels

Figure 2 Trend in DBP levels

The average DBP of all the participants enrolled was 86.36 ± 0.678mmHg. There was a significant difference in DBP among the groups (control group 83.58±0.614 mmHg, blackseed group 88.24±1.287 mmHg, flaxseed group 90.04±1.741 mmHg) (p=0). Baseline DBP of the blackseed group reduced to 84.96±1.216mmHg after the first month and then to 83.08±0.678mmHg by the end of the study period with a drop of 3.28mmHg and 1.88 mmHg, respectively. In comparison, the flaxseed group showed a good decrease in the DBP levels 90.04±1.741mmHg to 84.8 ±1.125 mmHg by the end of the first month and to 82.88 ± 0.775mmHg post-study period. For the control group, an increase of 0.78mmHg was seen from the baseline DBP of 83.58±0.614 mmHg to 84.36±0.687 mmHg after one month, followed by a rise of 0.86mmHg acquiring DBP of 85.22±0.474 by the end of the study period. On the whole, there was a significant reduction in the average DBP of the participants to 84.1 ± 0.364 mmHg (p=0.008).

Table 3 Comparison of major characteristics among the study groups throughout the study period.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Weight | | BMI | | Waist circumference | | SBP | | DBP | |
|  |  | Mean ± SD | p[[1]](#footnote-2) | Mean ± SD | p | Mean ± SD | p | Mean ± SD | p | Mean ± SD | p |
| Preliminary | Control | 71.47±1.750 |  | 26.913±0.634 |  | 89.59±1.843 |  | 133.3±1.283 |  | 83.58±0.614 |  |
| Intervention 1 | 70.2±2.862 |  | 27.409802±1.116 |  | 97.29±2.460 |  | 140.88±2.017 |  | 88.24±1.287 |  |
| Intervention 2 | 72.41±2.957 |  | 26.957437±1.083 |  | 99.77±3.238 |  | 138.24±1.409 |  | 90.04±1.741 |  |
| Total | 71.38 ± 1.338 | 0.844 | 27.048656 ± 0.496 | 0.917 | 94.06 ± 1.433 | 0.005 | 136.43 ± 0.939 | 0.002 | 86.36 ± 0.678 | 0 |
| Follow-up 1[[2]](#footnote-3) | Control | 71.47±1.750 |  | 26.913±0.634 |  | 89.59±1.843 |  | 131.18±1.116 |  | 84.36±0.687 |  |
| Intervention 1 | 70.11±2.765 |  | 27.378725±1.084 |  | 97.29±2.460 |  | 138.6±1.733 |  | 84.96±1.216 |  |
| Intervention 2 | 72.53±2.831 |  | 27.00528 ±1.036 |  | 99.77 ±3.238 |  | 133.04 ±1.598 |  | 84.8 ±1.125 |  |
| Total | 71.39 ± 1.309 | 0.81 | 27.052848 ± 0.486 | 0.926 | 94.06 ± 1.433 | 0.005 | 133.5 ± 0.859 | 0.001 | 84.62 ± 0.533 | 0.885 |
| Follow-up 2 | Control | 72.08±1.839 |  | 27.161±0.685 |  | 89.59±1.843 |  | 135.6±0.913 |  | 85.22±0.474 |  |
| Intervention 1 | 70.16±2.822 |  | 27.385226±1.093 |  | 97.29±2.460 |  | 134.2±1.512 |  | 83.08±0.678 |  |
| Intervention 2 | 72.61 ±2.885 |  | 27.037148 ±1.058 |  | 99.77 ± 3.238 |  | 130.28 ±1.407 |  | 82.88 ± 0.775 | |
| Total | 71.73 ± 1.354 | 0.791 | 27.186104 ± 0.506 | 0.97 | 94.06 ± 1.433 | 0.005 | 133.92 ± 0.716 | 0.009 | 84.1 ± 0.364 | 0.008 |

## Food Consumption Pattern

During the baseline data collection, it was observed that 67% of the participants (n=67) followed a pattern of 3 meals a day which showed a significant increase to 76% (n=76, p=0.01) by the end of the study period. 61% of the participants (n=61) had very low consumption of deep-fried foods, about less than once a week, while 34% of the participants (n=34) showed a high deep-fried food consumption about 4 to 6 times a week. An improvement was seen in this pattern with 71% (n=71) of people consuming deep-fried food less than a week and the percentage of participants consuming fried food 4 to 6 times a week dropping to 24% (n=24). There were only n=13 participants who consumed nutritional supplements, and this count further dropped down to n=6 by the end of the study period. Only n=6 participants followed home remedies, of which n=4 was from the control group, and n=2 was from the blackseed intervention group.

Figure 3 Cereal and Millet consumption among the study group during the baseline and last follow-up survey.

It was observed from the food frequency recall of the participants that rice was the most consumed cereal with n=44 of participants eating rice at least 2 to 3 times a day, followed by wheat in the form of phulka was consumed 2 to 3 in number per day by n=27 participants and at least 1 phulka a day was consumed by around n=19 participants. Millets were very less consumed among the study group, with jowar being more frequently preferred when compared to bajra. Pulses were consumed mostly in the form of dals by n=35, 2 to 4 times a week and n=21 consuming once per day. While not much change was seen in the rice consumption pattern of the participants, an increase was seen in wheat consumption by the end of the study period, with n=43 participants eating 4 and more phulka each day. An improvement in jowar consumption was also seen with n=27 participating 1 jowar roti each day and n=18 eating jowar at least once a week, and bajra was consumed once a week by n=39 participants.

Milk and milk products were very less consumed by the participants, with only n=22 drinking milk and n=21 eating curd once a day with other products like cheese, butter, khoa being consumed less than once a month by nearly 80% of people. However, the final follow up showed an improvement with n=31 participants drinking milk once every day and n=34 participants drinking milk at least 2 to 4 times a week, while the number of participants having curd once a day increased to n=36.

Figure 4 Non-Vegetarian food consumption among the study group during baseline and last follow up survey.

In the non-vegetarian food category, chicken was the most consumed food item by the participants during the preliminary data collection, with n=32 participants consuming chicken once a week and n=17 participants consuming it at least 2 to 4 times a week. Next in line of consumption was eggs, with n=26 participants eating 1 egg per week and n=26 participants eating 1 to 3 eggs per month. Lamb and beef were the least consumed. Fish was also found to be very less consumed, with only n=14 participants eating fish once a week. During the final follow-up month, an increase in chicken and egg consumption was seen with n=43 participants consuming chicken once a week, and 2 to 4 eggs a week were consumed by n=40 participants and 1 egg a week by around n=36 participants.

Almost all vegetables were consumed once per week. The participants were not much in the habit of eating fruits. The average consumption of fruit, in general, was found to be less than once a month by a major part of the study population. Most consumed fruit was banana with n=26 participants eating at least one banana per week followed by papaya and apple consumed 1 to 3 per month by n=30 and n=27 participants respectively. Grapes and pears were consumed least, with n=61 and n=60 participants eating these fruits less than once a week. However, a positive shift in consumption of fruits was seen after 2 months, with average consumption rising to 1 to 3 per month.

Figure 5 Vegetable consumption during baseline and last follow up survey.

Among the processed and baked foods and sweets, pizza was found to be the least consumed food by the participants, with n=80 of them rarely eating pizza, followed by burgers consumed less than a month by bn=78 participants. Noodles were consumed considerably more, with n=33 participants eating it 1 to 3 times per month and n=53 participants eating less than once a month. A packet of chips, Fries, chocolates and cakes were all consumed less than once a month by participants respectively.

Tea was found to be the most consumed beverage among the study group during the preliminary data collection, with about n=15 participants drinking 4 and more times a day, n=39 participants drinking 2 to 3 times per day, and n=27 participants drinking tea at least once a day. The next most consumed beverage was coffee which was consumed at least once a day by n=21 participants. The least consumed drink was found to be soft drinks, with n=71 participants drinking any kind of soft drink less than once a month. A comparative reduction was seen in tea consumption frequency with n=15 participants drinking tea 2 to 3 times a day, n=26 people drinking tea once every day and n=46 people drinking tea less than once a month. Coffee consumption was increased to n=28 people drinking 2 to 3 times a day. Consumption of other beverages saw a decrease, with more people drinking these beverages less than once a month.

## Physical Activity Status

The participants during the baseline check have an average MET's score of 3108.72 ± 420.542, of which they have an average of 933.6 ± 301.532 vigorous METs, 1738.2 ± 271.134 moderate MET's, 436.92 ± 90.641 walking METs. The blackseed intervention group showed a drop in total METs from a baseline of 3914.6 ± 1007.938 METs to 3703.12 ± 756.06 MET's by the end of the study period, but an increase in walking METs was seen in this group from 613.8 ± 241.719 to 931.92 ± 221.62. At the same time, the flaxseed group showed a shift in their total METs from 3730.62 ± 1068.843 to 2935.08 ± 715.79. This group also showed a hike in their walking MET's 361.02 ± 87.347 to 566.28 ± 68.27. As for the control group, they showed an improvement in their total met score, increasing from 2394.83 ± 406.311 to 2700.32 ± 629.29 METs. There was an increase in vigorous and walking METs of this group from 406.4 ± 145.657 to 804.8 ± 479.71 and 386.43 ± 128.807 to 390.72 ± 129.45. (See table 4)

Table 4 Physical activity status of the participants and comparison of METs among each study group

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Vigorous MET’s | Moderate MET’s | Walking MET’s | Total MET’s |
|  | Mean ± SD | Mean ± SD | Mean ± SD | Mean ± SD |
| Preliminary | Control (n=50) | 406.4 ± 145.65 | 1602 ± 337.22 | 386.43 ± 128.80 | 2394.83 ± 406.311 |
| Black seeds (n=25) | 1164.8 ± 676.88 | 2136 ± 663.44 | 613.8 ± 241.71 | 3914.6 ± 1007.938 |
| Flaxseeds (n=25) | 1756.8 ± 949.61 | 1612.8 ± 547.41 | 361.02 ± 87.347 | 3730.62 ± 1068.843 |
| Follow-up 1 | Control (n=50) | 872 ± 442.23 | 1491.2 ± 339.42 | 395.01 ± 129.99 | 2758.21 ± 589.63 |
| Black seeds (n=25) | 1283.2 ± 447.72 | 1248.64 ± 517.24 | 894.96 ± 225.91 | 3426.8 ± 832.87 |
| Flaxseeds (n=25) | 1891.2 ± 1061.10 | 1216 ± 451.91 | 549.78 ± 69.44 | 3656.98 ± 1139.07 |
| Follow-up 2 | Control (n=50) | 804.8 ± 479.71 | 1504.8 ± 347 | 390.72 ± 129.45 | 2700.32 ± 629.29 |
| Black seeds (n=25) | 880 ± 258.98 | 1891.2 ± 636.53 | 931.92 ± 221.62 | 3703.12 ± 756.06 |
| Flaxseeds (n=25) | 1084.8 ± 568.13 | 1284 ± 439.70 | 566.28 ± 68.27 | * 1. 715.79 |

# Discussion

Hypertension is a major contributor to the global burden of disease and mortality and is considered one of the many risk factors for cardiovascular and kidney diseases. As per an article published in the American Journal of Hypertension, the prevalence of hypertension among Indians aged 15–49 years was 40.6 per cent based on the 2017 ACC/AHA guideline. [1]

The main focus area of this study was to study the effect of flaxseed and blackseed in lowering blood pressure levels when consumed regularly.

Results showed a positive effect of these seeds in lowering SBP and DBP levels when consumed daily. This result can be supported by comparing the results of intervention groups to the control group. The intervention groups showed a decrease in both SBP and DBP while there was an increase in SBP and DBP levels in the control groups. (See table 5).

Table 5 Comparison between the effect of black seed and flaxseed

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | SBP (mmHg) | | | DBP (mmHg) | | |
|  | Control (n=50) | blackseed (n=25) | flaxseed (n=25) | Control (n=50) | blackseed (n=25) | flaxseed (n=25) |
| Follow-up 1[[3]](#footnote-4) | -2.12 | -2.28 | -5.2 | 0.78 | -3.28 | -5.25 |
| Follow-up 2 | 4.42 | -4.4 | -2.76 | 0.86 | -1.88 | -1.92 |

Secondly, from the results, it was seen that flaxseeds have a better hypertensive effect than black seeds. This difference can be attributed to the difference in the quantity that was consumed. Overall flaxseed group showed a decrease of 7.9mmHg while the blackseed group had a decrease of 6.6mmHG in SBP, while for DBP flaxseed group showed a decrease of 7.1 mmHg and the blackseed group showed a decrease of 5.1mmHg. A previous study that was conducted using flaxseed on hypertensive patients showed a decrease of approx. 10mmHg in SBP and approx. 7mmHg in DBP after the study period of 6 months. Whereas a study done with blackseed supplementation showed a decrease of 3.26mmHG in SBP and 2.80mmHg in DBP over 8.3 weeks. This decrease in effects can be due to the environmental settings of the study areas.

Results showed an improvement in the food consumption pattern of the study group. There was a considerable drop in consumption of non-vegetarian food items among the intervention group compared to the study group. This could be one possible reason for keeping the BP levels under control. There was an increase in consumption of vegetables seen during the study period that can be considered as another factor contributing to the improvement of BP levels as high consumption of vegetables which is one of the principles of the DASH diet, is found to help control BP levels.

Also, physical activity level is seen to have a good impact on maintaining the overall health of an individual. The results showed an increase in the walking METs of the interventional group that could also be the possible reason for such wide change in the SBP and DBP levels of the intervention group in comparison to the previous studies.

# Conclusion

The major objective of the study was to check the effectiveness of Black seeds and Flaxseeds in Controlling Hypertension and to see which among the two seeds gives better results in reducing BP when ingested on an everyday basis.

With this study, it can be concluded that flaxseed and black seeds have a good antihypertensive effect and can be incorporated as an effective measure in the dietary regimen of Hypertensive individuals, which can be backed by the statistically significant results that were obtained by this study. Around 40% of the participants in the 1st intervention group (black seeds) were able to reach normal blood pressure levels, and for the 2nd intervention group (flaxseeds), 48% of the participants reached the normal blood pressure levels of 130/80 mmHg. About 64% of participants showed a positive drop in the BP levels in the flaxseed intervention group, and 68% in the blackseed intervention group showed a drop in BP levels.

It's also worth noting that maintaining the parameters requires a healthy diet and regular physical activity. As known by studies available, being physically active for 30 minutes a day can help immensely in maintaining blood pressure and other parameters normal. A similar trend can also be seen in the current findings, improvement in the parameters was evident from the results in the study group (blackseed and flaxseed group) with improved walking METs.

Despite the positive results, this study should be interpreted in light of some limitations. The first is the small sample size of this study; a large sample size with more experimental group participants would be more reliable as the current study focuses only on one geographical setting with a limited number of participants.

Secondly, the positive results cannot solely be attributed to seed interventions. Therefore, for future studies, a more focused approach could be utilized with the sole focus on seed supplementation for the experimental group without any influence of diet.

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# Conflict of interest

No potential conflict of interest relevant to this article was reported among the authors.

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1. All the values are represented as Mean ±Standard Deviation

   *p*-value less than 0.05 is considered of significance [↑](#footnote-ref-2)
2. Follow-ups were done with interval of 1 month. [↑](#footnote-ref-3)
3. Shows the drop in SBP and DBP in the study groups over the course of the study period of 2 months [↑](#footnote-ref-4)