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The Effect of Ginger Powder Supplementation on Blood Pressure of Patients with Type 2 Diabetes: A Double-Blind Randomized Clinical Controlled Trial

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ABSTRACT

Background: Diabetes mellitus is one of the most common chronic metabolic disorders. Nowadays there is an uprising trend toward new approaches in type 2 diabetes management. In this study the effect of Ginger supplementation on blood pressure in type 2 diabetic patients was examined. **Methods**: 81 patients with type 2 diabetes who were referred to Yazd Diabetes Research Center participated in this randomized clinical trial. Patients were randomly divided into two groups; Placebo (PG) and ginger supplemented (GG) groups. GG were supplemented with 3 ginger capsules (1 g ginger powder in each capsule) and PG received placebo. Systolic blood pressure (SBP), diastolic blood pressure (DBP), Pulse pressure (PP) and mean arterial pressure (MAP) were measured before the intervention, 2nd week, 4th week, 6th week, and at the end of the study (8th week). **Results**: The SBP, DBP, PP and MAP were decreased significantly in the GG (P = 0.001) group at the end of week 8 and significantly decreased at the end of the study compared to the beginning of the study. No significant changes were observed in the PG. However, its mean was statistically different between two groups at the end of intervention. **Conclusion**: This study indicated that daily consumption of 3 g of ginger powder in capsules for 8 weeks by patients with type 2 diabetes decreases SBP, DBP, PP and MAP.

Keywords: *Blood pressure, Ginger, Type 2 diabetes*

Introduction

Diabetes mellitus is characterized by chronic hyperglycemia resulting from impaired insulin action/secretion (Alberti and Zimmet, 1998). The prevalence of type 2 diabetes is high in the Middle East; the rate of 7.7% has been reported for Iran (Azimi-Nezhad *et al.*, 2008, Esteghamati *et al.*, 2008). The prevalence of this disorder is progressively increasing around the world (Azimi-Nezhad *et al.*, 2008). About 6.4% or 285 million individuals in the adult population (20–79 years) were affected by diabetes in 2010. It is estimated that by 2030, this rate will increase by 7.7% or 439 million persons, and during 2010–2030, about 69% of the increase will be allocated to developing countries and 20% to developed ones (Shaw *et al.*, 2010). A

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wide variety of therapeutic agents in modern medicine are available against these diseases such as antihypertensive (Angiotensin converting enzyme inhibitors, beta blockers, diuretics, calcium channel blockers etc.) but most of these drugs have potentially serious side effects and high costs, and if the therapy is not regularly monitored, it can lead to toxicity and non-compliance. Most of these drugs are not suitable to be used as a preventive measure against these risk factors (Sanghal *et al.*, 2012).

Virtually about 3/4 of the people of the world trust in traditional treatments especially herbal treatments; until the mid-19th century at least 80% of the medicines were herbal derivatives (Gilani, 2005). The use of herbal medicines including ginger is among different strategies for preventing and controlling diabetes complications (Mozaffari-Khosravi *et al.*, 2013).

Ginger (*Zingiber officinale*) a well-known spices plant, sweet, pungent, heating appetizer has been used in traditional oriental medicines for a long time. Its extract and major pungent principles have been shown to exhibit a variety of biological activities (Ghayur and Gilani, 2005, Wei *et al.*, 2005).

Ginger is reported to possess anti-inflammatory, analgesic, antipyretic, antimicrobial, hypoglycemic, antimigraine, molluscicidal, antischistosomal, anti–motion sickness, antioxidant, hepatoprotective, hypocholesterolemic, and antithrombic activities (Langner *et al.*, 1997). Because of the antithrombic potential of ginger, it may interact with blood-thinning drugs such as warfarin and must be used carefully in patients with blood clotting disorders (Ghayur and Gilani, 2005). The use of ginger in cardiovascular diseases has long been known. Ginger is known to have a diuretic and blood pressure (BP)-lowering effect (Ghayur and Gilani, 2004, Miller and Murray, 1998). In the traditional medicine practice of Pakistan, herbalists prescribe ginger to hypertensive patients to be taken after dinner. Interestingly, a few studies have been carried out to explore the BP-lowering potential of ginger extract and its active constituents; however, conflicting results were obtained (Ghayur and Gilani, 2005, Langner *et al.*, 1997) and the precise mode of action remained to be elucidated (Suekawa *et al.*, 1986, Suekawa *et al.*, 1984, Weidner and Sigwart, 2000).

Ginger has now a high potential for treating many aspects of cardiovascular disease. Reviewing recent trials show that ginger has considerable anti-inflammatory, antioxidant, anti-platelet, hypotensive and hypolipidemic effects in vitro and animal studies (Nicoll and Henein, 2009).

When ginger was used in combination with other herbs, it caused significant physiological changes, including reduction of body weight, skin thickness, and waist/hip circumference (Paranjpe *et al.*, 1990).

In a study accomplished by Arablouet, et al. (2014) in Iran, the effect of ginger consumption on some cardiovascular risk factors in patients with type 2 diabetes mellitus was investigated. The results represented no significant difference in systolic and diastolic blood pressure (Arablou *et al.*, 2014). In another study conducted by Sanghal, et al. (2012) in India, an experimental study was investigated to evaluate the preventive effect of *Zingiber officinale* (ginger) on hypertension and hyperlipidaemia and its comparison with *Allium sativum* (garlic) in rats. In this study, ginger have shown significant preventive effect on systolic blood pressure and lipid level in comparison to control group (Sanghal *et al.*, 2012). Furthermore, in a study done by Ghayur, et al. (2005) in Pakistan, it was found that ginger reduces blood pressure through blockage of voltage-dependent calcium channels. The results of this study showed that the intravenous administration of fresh ginger extract reduces blood pressure effect in anaesthetized rats. In the isolated tissue preparations, ginger extract exhibited a negative inotropic and chronotropic effect while also showing a vasodilator effect through a specific blockade of the voltage dependent Ca^{2+} channels. The vasodilator effect was found to be independent of endothelium (Ghayur and Gilani, 2005).

Despite different scientific evidences there was no agreement regarding various ginger effects and

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few studies have been conducted on ginger and its relation with BP in patients with diabetes. This study was, therefore, carried out to determine the effect of ginger on BP patients with type 2 diabetes.

Materials and Methods

Design and participants: The present study is a randomized, double-blind, placebo-controlled trial with the participation of 88 patients with type 2 diabetes supported by Yazd Diabetes Research Center between January to July 2013.

Inclusion criteria: Having type 2 diabetes for at least 10 years, fasting blood glucose (FBG) < 180 mg/dL and 2h-blood-sugar < 250 mg/dL, no pregnancy or lactation, no autoimmune disorder, no cardiac ischemic or renal diseases, no thyroid and chronic inflammatory diseases, no peptic ulcer and infection, no regular consumption of ginger or other herbal drugs, no sensitivity to ginger, body mass index (BMI) < 40 kg/m^2, no consumption of triglyceride or cholesterol, estrogen, progesterone-lowering drugs, and no consumption of any supplements such as vitamin C, E, and omega-3 during 2 months before starting the study.

Exclusion criteria: Any sensitivity due to ginger consumption reported by the patient or noticed after starting the study, consumption of vitamin, mineral or other nutritional supplements, consumption of alcohol or narcotic drugs, and any variation in patients' routine treatment according to physicians' resolution (i.e., variation in type and dose of the drugs to be consumed, and treatment with insulin).

Dose, type of supplement, and intervention duration: The patients randomly received ginger capsules (3g/day in 3 divided dose; ginger group (GG)) or cellulose microcrystalline (3g/day in 3 divided dose; placebo group (PG)) for 8 weeks. The dried rhizome of ginger was purchased from a valid marker (Bou-Ali Sina herbal drug Researchers Corporation, Ghom, Iran).

Contacting with patients, in order to control their consumption of capsules, response to the relevant questions, and prevention of sample loss, was performed weekly by calling them and every other week via monitoring the patients' referring to Yazd Diabetes Research Center to receive capsules for the next few weeks.

It is worth mentioning that supplements were not totally delivered to the participants. In order to ensure the supplement consumption and placebo by the participants and calculate the rate of capsule consumption, the participants were asked to deliver the empty boxes of capsules first and then receive the new ones needed for next two weeks. The participants were also advised not to change their usual diet, to stop self-reliant changes of their supplements doses, and to stop physical activities during the intervention.

Measurements: General information including age, weight, height, gender, marital status, occupation, education, disease duration , type and dose of the drugs required for diabetes control, were accessed and recorded through interviews with the patients. Height was recorded by a standard clinical stadiometer with an accuracy of 0.1 cm. Weight was measured with light clothes and without shoes and a balance with 100g accuracy. Both were done at the beginning of 8^{th} week of the intervention. BMI was calculated as weight in kilograms, divided by height per square meter.

The participants' systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse pressure (PP) and mean arterial pressure (MAP) were measured in the morning before the intervention, 2^{nd} week, 4^{th} week, 6^{th} week and at the end of study (8^{th} week) with an accuracy of 2 mmHg; furthermore, the patients were sitting on a chair and, rested for 5 min, and they were tested by their right arm using a mercury sphygmomanometer (Samsung, Japan). In order to record blood pressure, mean measurement was calculated twice. The PP and the difference between the SBP and the DBP were also measured. The following calculation formula is for the MAP : MAP = DP + 0.333 (SBP − DBP) or [SBP + (2DBP)]/3 (MEANEY *et al.*, 2000).

To study the patients' diet in terms of daily intake of energy, carbohydrate, protein, fiber, and total fat, a 24h-dietary-recall questionnaire was used both at the beginning and the end of the

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intervention. Nutritionist IV software (Nutritionist IV Diet Analysis, First Data Bank Division, Hearst Corp., San Bruno, CA) was utilized to analyze the 24h-dietary-recall data.

Ethical Considerations: The study aims and methods were explained to patients and the informed written consent was received from them if they seemed to be interested in participation. Furthermore,, the research was approved by Ethics Commission of Deputy for Research in Shahid Sadoughi University of Medical Sciences. This study was also registered at the Iranian registry of clinical trials (www.irct.ir) with IRCT 201111306278N2 code.

Data Analysis: The data were analyzed by SPSS version 11 (SPSS Inc., Chicago, IL, USA). Kolmogorov–Smirnov test was used to determine quantitative data distribution, paired t-test to compare normal distribution variables mean in two groups before and after the intervention, and Student t-test to compare the variables mean between two groups. The results of quantitative data with normal distribution were reported as mean±SD. The significance level was set at P-value equal or less than 0.05.

Results

Out of 88 patients who participated in the study, the following cases were excluded from the intervention: 4 patients who had no tendency to continue the study, 1 for her husband's death, and 2 due to travel, the remaining 81 participants were all investigated to the end of the study (**Figure 1**). None of participants in both groups reported any adverse effects.

All the patients received oral hypoglycemic agents, 50 (61.7%) of which were female and 31 (38.3%) male. The mean age of the patients in GG and PG showed to be 49.83 ± 7.23 year and 51.05 ± 7.70 year, respectively. The baseline characteristics of patients did not differ significantly between both groups (**Table 1**). In addition, BMI did not significantly change within each group during the study.

There were no significant differences in daily dietary intake of total energy and some nutrients between two groups at baseline and the end of the intervention (**Table 2**).

The comparison among SBP and DBP, PP and MAP before and after the intervention in GG and PG are given in **Table 3**.

As it is shown in **Table 3**, the SBP was significantly decreased in the GG (P = 0.001) group at the end of the 8th week and at the end of the study compared to the beginning of the study (126.50 ± 13.50 to 109.00 ± 11.27 mmHg). No significant changes were observed in the PG (118.65 ± 13.32 to 117.31 ± 12.70, P = 0.54), however, its mean was statistically different between both groups at the end of the intervention (P = 0.003) (**Table 3**).

The DBP was significantly decreased in the GG (P = 0.001) group at the end of 8th week and at the end of the study compared to the beginning of the study (74.00 ± 7.08 to 66.37 ± 6.20 mmHg). There was no significant change in the PG (72.31 ± 8.37 to 70.24 ± 6.51, P = 0.11), however its mean was statistically different between both groups at the end of the intervention (P = 0.008) (**Table 3**).

The PP was significantly decreased in the GG (P = 0.001) group at the end of the 8th week and at the end of the study compared to the beginning of the study, 52.50 ± 10.31 to 42.62 ± 8.91 mmHg. No significant changes were observed in the PG (46.34 ± 7.66 to 47.07 ± 9.61, P = 0.66). However, its mean was statistically different between both groups at the end of the intervention (P = 0.034) (**Table 3**).

The MAP was decreased significantly in the GG (P = 0.001) group at the end of the 8th week and at the end of the study compared to the beginning of the study, 97.66 ± 8.94 to 86.11 ± 7.56 mmHg. No significant changes were observed in the PG (93.79 ± 10.31 to 91.78. ± 8.34, P = 0.99). However, its mean score was statistically different between both groups at the end of the intervention (P = 0.002) (**Table 3**). Furthermore, regarding the BMI mean score, no significant difference was observed between both groups at the beginning and at the end of the study.

[DOR: 20.1001.1.24767417.2018.3.2.4.7]

Table 1. Comparison of the qualitative and quantitative variables between the two groups before the intervention.

Groups/Variables	Placebo (N=41)	Ginger (N=40)	P-value[b]
Age (year)	51.05 ± 7.70[a]	49.83 ± 7.23	0.46
Height (cm)	162.21 ± 9.24	159.00 ± 10.08	0.15
Weight (Kg)	74.63 ± 11.48	71.20 ± 16.08	0.27
Body mass index (Kg/m^2)	28.51 ± 4.95	28.09 ± 5.29	0.71
Gender	N (%)	N (%)	
Male	18 (43.9)	13 (32.5)	0.2[c]
Female	23 (56.1)	27 (67.5)	

[a] : mean±SD; [b]: Student *t-test*; [c] : Chi square *test*

Table 2. Comparison of daily dietary intake of energy and some nutrients before and after the intervention in ginger and placebo groups

Variables	Baseline	End	P-value [c]
Energy (kcal)			
Ginger	1331.74 ± 32 9.70 [a]	1321.22 ± 452.99	0.36
Placebo	1363.35 ± 457.28	1389.14 ± 549.28	0.60
P-value [b]	0.89	0.79	
Carbohydrate (g)			
Ginger	151.04 ± 60.93	145.85 ± 76.99	0.18
Placebo	170.07 ± 72.77	158.07 ± 70.05	0.06
P-value	0.15	0.28	
Protein (g)			
Ginger	54.22 ± 21.44	52.03 ± 16.63	0.58
Placebo	50.91 ± 24.24	54.37 ± 24.94	0.47
P-value	0.51	0.62	
Fat (g)			
Ginger	58.52 ± 14.22	61.04 ± 19.56	0.66
Placebo	55.34 ± 15.65	61.76 ± 26.83	0.06
P-value	0.28	0.66	
Cholesterol (mg)			
Ginger	250.18 ± 362.66	177.58 ± 232.84	0.17
Placebo	170.54 ± 252.64	168.76 ± 179.60	0.15
P-value	0.07	0.78	
Fiber (g)			
Ginger	8.65 ± 4.26	8.31 ± 6.64	0.25
Placebo	9.29 ± 4.01	7.99 ± 4.97	0.07
P-value	0.41	0.84	
Salt (g)			
Ginger	3.47 ± 0.54	3.51 ± 0.65	0.99
Placebo	3.39 ± 0.47	3.63 ± 0.97	0.31
P-value	0.50	0.85	

[a] : mean±SD; [b]: Student *t-test*; [c] : Paired t-*test*

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Table 3. The comparison of the mean of systolic and diastolic blood pressure, pulse pressure and mean arterial pressure before and after the intervention in ginger and placebo groups

Variables	Baseline	WEEK 2	WEEK 4	WEEK 6	WEEK 8	P-value**
Systolic blood pressure (mmHg)						
Ginger	126.50 ± 13.50 [a]	120.62 ± 12.36	115.75 ± 11.74	113.62 ± 9.53	109.00 ± 11.27	‹0.001
Placebo	118.65 ± 13.32	122.56 ± 15.37	121.46 ± 15.01	119.75 ± 12.98	117.31 ± 12.70	0.54
P-value*	0.01	0.53	0.06	0.018	0.003	
Diastolic blood pressure (mmHg)						
Ginger	74.00 ± 7.08	70.62 ± 7.35	68.37 ± 6.63	68.50 ± 6.32	66.37 ± 6.20	‹0.001
Placebo	72.31 ± 8.37	71.70 ± 8.41	71.46 ± 7.92	71.58 ± 8.54	70.24 ± 6.51	0.11
P-value	0.33	0.54	0.06	0.06	0.008	
Pulse pressure (mmHg)						
Ginger	52.50±10.31	50.00 ± 9.26	47.37 ± 10.31	45.12 ± 7.38	42.62 ± 8.91	‹0.001
Placebo	46.34±7.66	50.85 ± 11.66	50.00 ± 10.12	48.17 ± 10.41	47.07 ± 9.61	0.66
P-value	0.003	0.71	0.25	0.13	0.03	
Mean arterial pressure (mmHg)						
Ginger	97.66±8.94	93.17 ± 8.81	89.86 ± 7.68	89.25 ± 7.19	86.11 ± 7.56	‹0.001
Placebo	93.79±10.31	94.63 ± 10.43	84.08 ± 10.33	93.60 ± 9.65	81.78 ± 8.34	0.99
P-value	0.07	0.50	0.04	0.02	0.002	

[a]: mean±SD; [b]: Student *t-test*; [c] : Paired t-*test (compared baseline with week 8)*

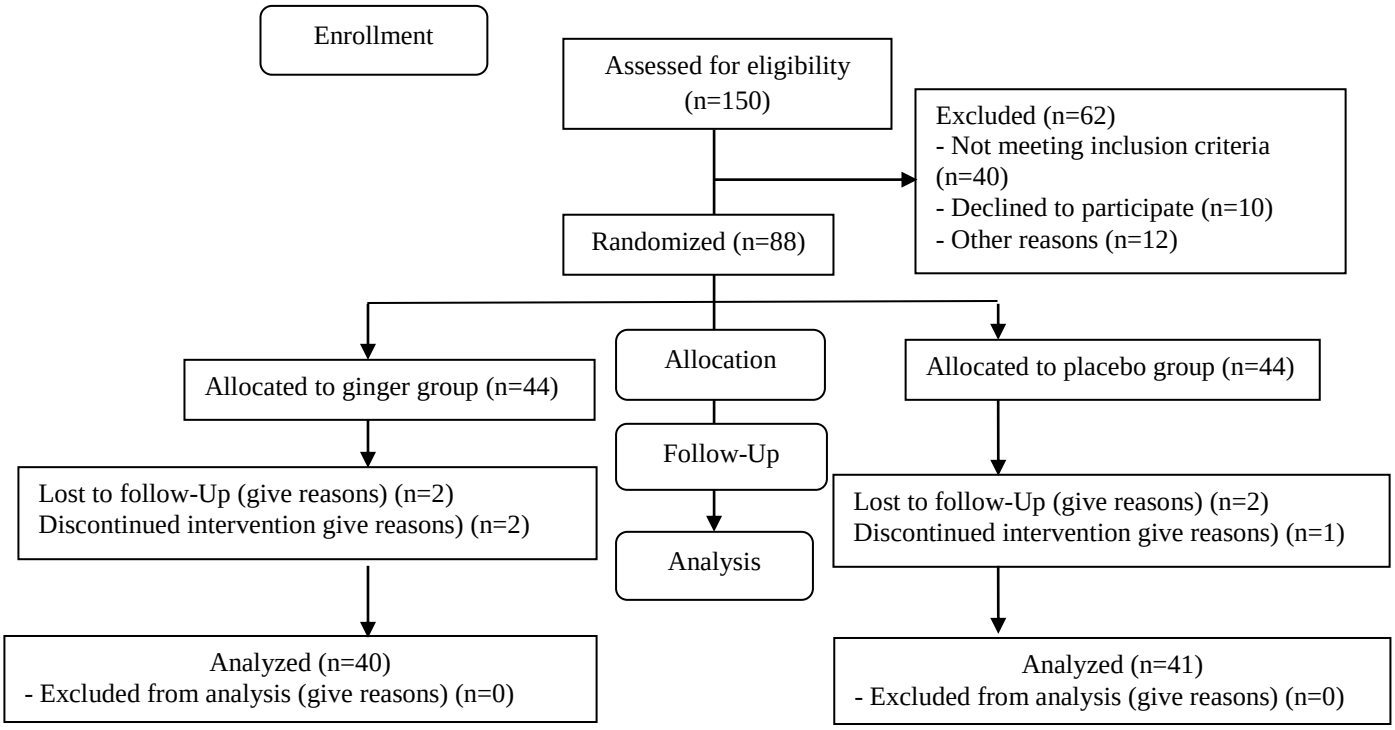

Figure 1. Diagram of the study

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Discussion

The present study indicated that daily consumption of 3g of ginger powder in capsules by patients with type 2 diabetes for 8 weeks causes improvement of blood pressure. In this study, ginger powder consumption for 8 weeks had a significant effect on the SBP and DBP, PP and MAP. The findings are in line with some of previous research studies.

In contrast to this study, Arablou et al. studied the effect of ginger consumption on some cardiovascular risk factors in patients with type 2 diabetes mellitus in Iran. Sixty three patients were analyzed; Ginger group (n = 33) and control group (n = 30). There were no significant differences in SBP and DBP and waist circumference between two groups (Arablou *et al.*, 2014).

In another study conducted by Sanghal et al in India, an experimental study to evaluate the preventive effect of *Zingiber officinale* (ginger) on hypertension and hyperlipidaemia and its comparison with *Allium sativum* (garlic) in rats were investigated. Total 18 rats were taken and divided equally into three (control, ginger and garlic) groups by random selection. Ginger and garlic (500 mg/kg orally) were given to two separate groups of rats fed on high fat diet for a period of 7 weeks. In this study, ginger have shown significant preventive effect on the SBP and lipids level in comparison to the control group (Sanghal *et al.*, 2012) which was in line with the present study SBP results. Furthermore, Ghayur et al. in Pakistan, investigated whether or not ginger decreases the blood pressure through blockage of voltage-dependent calcium channels. The results of this study showed that the intravenous administration of fresh ginger extract causes the effect of lowering blood pressure in anaesthetized rats. In the isolated tissue preparations, ginger extract showed a negative inotropic and chronotropic effect as well as a vasodilator effect through specific blockage of the voltage dependent Ca^{2+} channels. The vasodilator effect was found to be independent of endothelium (Ghayur and Gilani, 2005). These results are in agreement with the present study.

Reviewing the previous studies showed that research studies conducted on the effect of ginger powder (in capsules) on blood pressure of the patients with diabetes are very constrained. Moreover, the results of research endeavors conducted on human and animals have turned out to be contradictory caused by disparity in people's response. It can be the result of the patient's difference at the onset of diabetes, experimental group weight, and other measured indices at the beginning of the study. Furthermore, most of the published articles did not have any reference to the type and dose of the drug consumed by the patients; however, it was not the case in this study. The patients with type 2 diabetes were investigated. An eight- week Ginger supplement contributed to significant variation in blood pressure.

Diabetes mellitus is one of the most common chronic metabolic disorders (Shaw *et al.*, 2010). Ginger is an herbal drug which is similar to NSAIDs. Therefore, it can regulate biochemical pathways which are activated with chronic inflammation (such as diabetes) (Grzanna *et al.*, 2005). Accordingly, ginger has the potential to provide not only the cheaper and natural alternative but also the effective preventive remedy for the risk factors (hypertension) of ischemic heart disease (IHD) to develop. Therefore, it reduces the chances of developing various cardiovascular disorders with considerably less side effects (Sanghal *et al.*, 2012).

No side effects have been reported in humans for the use of Ginger . Daily Ginger doses of greater than 4g in patients receiving concomitant blood-thinning drugs such as warfarin or aspirin can be taken with caution. Ginger, in people who suffer from gallstones interference can increase bile production (Al-Achi, 2009, Bordia *et al.*, 1997).

The high percentage of the patient's compliance with consuming capsules can be regarded as a strong point of the study. Regarding the limitations of the present study, short period

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of supplementation can be mentioned i.e., two months; therefore, for the forthcoming similar investigation a longer study duration is suggested. Moreover, the effectiveness of long-term use of Ginger supplement and its effects on inflammation-related parameters and inflammatory hormones have also been suggested.

Conclusions

This study indicated that daily consumption of 3g of ginger powder in capsules for 8 weeks by patients with type 2 diabetes leads to decrease the SBP and DBP, PP and MAP. Therefore, consumption of this supplement is appropriate for the patients; however, to identify its other effects, some further studies are needed.

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Authors' contribution

The study was designed by Mozaffari-Khosravi H and Talaei B. statistical analysis was performed by Naderyan Feli S. Data collection and writing manuscript were performed by all authors. All authors reviewed the paper and confirmed it.

Conflict of interest

Nothing was found to declare.

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