

## Original Research Article

# Comparing the effect of ladies' finger water with fenugreek seeds water on the blood glucose level among subjects with type 2 diabetes mellitus- a randomized controlled trial

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**Received:** 12 October 2020

**Accepted:** 29 December 2020

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## ABSTRACT

**Background:** The primary aim of managing diabetes is to maintain blood glucose level to prevent diabetes induced complications. Studies showed that ladies finger and fenugreek seeds are blood sugar stabilizer. The objective of this randomized active controlled trial was to assess the effect of ladies finger water versus fenugreek seeds water on the blood glucose level among subject with type 2 diabetes.

**Methods:** Total of 180 study participants were selected and equally assigned to three groups by computer generated randomization. Group 1-received ladies finger water and oral antidiabetic drug (OAD); group 2-received fenugreek seeds water and OAD; group 3-received only OAD for 15 days. Pre and post intervention fasting blood sugar (FBS) was assessed by accu-chek Performa glucometer. Wilcoxon signed rank test; one-way analysis of covariance followed by post hoc test with Bon-ferroni correction was done.

**Results:** Analysis was done based on 168 subjects. There was a significant reduction in FBS level with the mean difference of group 1-21.0 mg/dl ( $p<0.001$ ), group 2-20.3 mg/dl ( $p<0.001$ ) and group 3-4.7 mg/dl ( $p=0.068$ ). No significant difference found between group 1 and group 2 ( $p=1.00$ ), but significant difference found between group 1 and group 3 ( $p=0.032$ ); group 2 and group 3 ( $p=0.012$ ). Both ladies finger water and fenugreek seeds water were superior in reduction of FBS than OAD.

**Conclusions:** Ladies finger water or fenugreek seeds water can be used as adjunct along with OAD to control type 2 diabetes mellitus.

**Keywords:** Ladies finger water, Fenugreek seeds water, Oral antidiabetic drug, Type 2 diabetes mellitus, Fasting blood sugar

## INTRODUCTION

Diabetes is a serious, long-term condition with a significant impact on the lives and well-being of people, families, and societies worldwide. Younger adults with type 2 diabetes within the recent years also contributes to the rise in overall type 2 diabetes prevalence, through their longer survival.<sup>1</sup> The global diabetes prevalence in 2019 was estimated as 9.3% (463 million people),

increasing to 10.2% (578 million) by 2030 and 10.9% (700 million) by 2045. The number of people with diabetes in India since 2019 is around 77 million and is relied upon to ascend to 101 million by 2030 and 134 million by 2045. India is the diabetes capital of the world with the greatest number of diabetic clients.<sup>2</sup>

If stricter control of diabetes is achieved, it's possible to delay or reduce number of complications of diabetes. The

treatment with standard regimens is additionally related to problems like higher cost, secondary failure rates, and accompanying side effects. Furthermore, these treatments only modify secondary metabolic derangement and don't address fundamental biochemical change.<sup>3</sup> In a country like India, where cost factor is major hurdle for treatment compliance as more strata are in poor socioeconomic group and health care spending is a smaller amount, there's possibility of use of nutraceuticals alongside the regular antidiabetics to regulate blood glucose levels. A food with a medical-health benefit, including the prevention and treatment of disease is called as Nutraceuticals. It also refers to natural functional/medical foods or bioactive phytochemicals that have health promoting, disease preventing or medicinal properties.<sup>4</sup>

A tropical vegetable ladies finger (*Abelmoschus esculentus*, mallow family), additionally referred to as Okra, full of a soluble dietary fiber that helps stabilization of blood glucose levels by regulation of the speed of absorption of sugar from the alimentary canal.<sup>5</sup> The antidiabetic property of okra is additionally attributed to its ability of inhibition of enzymes metabolizing carbohydrates, enhancement of production of insulin, regeneration of cell of the pancreas and increased secretion of insulin.<sup>6</sup> Ladies finger is rich in gums and mucilage, carbohydrates, proteins, phytosterols, flavonoids, tannins, phenolic compounds and essential oil possess antioxidant activity helps to regulate blood glucose among diabetes and various other disorders.<sup>5,7-10</sup> The vegetable is extremely low in calories, with a 100 gram serving containing just 33 calories.<sup>11</sup> Similarly the herb fenugreek seeds (*Trigonella foenum-graecum*, *Fabaceae* family) is used for the treatment of diabetes in many parts of the planet, especially in China, Egypt, India and Middle Eastern countries.<sup>12-14</sup> Fenugreek seeds delayed gastric emptying and caused inhibition of glucose transport because the seeds contain 50% pectin that forms colloid suspension when hydrated and may reduce rate of gastric emptying and slow carbohydrate absorption.<sup>15,16</sup> Active compounds of fenugreek seeds included diosgenin, 4-hydroxyisoleucine, soluble fiber, saponins and trigonelle possess antihyperglycemic effect among type 2 diabetes.<sup>17-19</sup> Ladies finger and fenugreek seeds may play a crucial role in controlling blood glucose level among type 2 diabetes. A randomized active controlled trial (RCT) was conducted to compare the effect of ladies finger water versus fenugreek seeds water on the blood glucose level among subjects with type 2 diabetes mellitus.

## METHODS

This active RCT was conducted among 180 clients with type 2 diabetes at primary health center (PHC), Kalapet, Puducherry between September and October 2018. The study was approved by the institutional review board, Pondicherry institute of medical sciences (PIMS) (code no:1823) and also registered in clinical trial registry of India (registration number CTRI/2018/06/014489).

Formal permission was obtained from the directorate of health and family welfare, government of Puducherry for conduct of the study at PHC.

### Inclusion criteria

Clients who were registered and seeking treatment for type 2 diabetes within the age of 30-70 years under Non-communicable disease (NCD) clinic at PHC.

Baseline fasting blood sugar (FBS) level 126 mg/dl and above (as per American diabetes association).<sup>20</sup>

### Exclusion criteria

Clients who are on insulin treatment. Pregnant or lactating women and subjects intending pregnancy. History of comorbidity (hypertension, hypothyroidism and cardiac disease) treatment along with OAD and history of intolerance or hypersensitivity to ladies finger water or fenugreek seeds water were excluded.

### Sample size

The sample size 53 in each group was decided by assuming the effect size of 0.25 (medium), power of 80% and 5% significance level. Accounting for 10% loss to follow up, the size of the study was increased to 180 which were equally divided into three groups by computer-generated randomization.

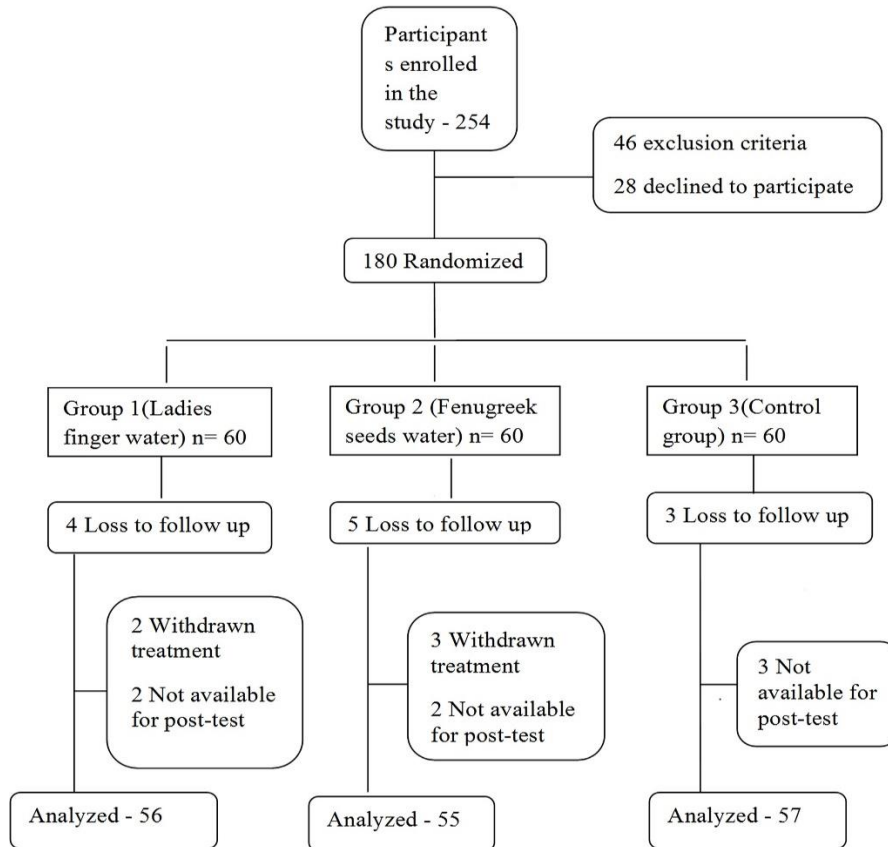
### Pre-intervention procedure

Two healthcare workers were trained to assess biophysiological measurements (height, weight and blood pressure) and FBS by Accu-chek Performa glucometer during enrolment of the study participant. Participant information details, written consent, structured interview guide was completed for all study participants between 6.30 a.m. to 9.30 a.m. at PHC in 12 consecutive days. Method of preparing ladies finger water and fenugreek seeds water were demonstrated to every group separately at the PHC by the investigator after the randomization. Ladies finger 2 packets (40 gm each) packet (50 microns insect proof polyethylene food stuff storage cover) for group 1 and fenugreek seeds 20 gm, 2 Packets (50 microns insect proof polyethylene food stuff storage cover) for group 2 was provided for first 2 days at the PHC after treatment allocation and remaining days through home visit. The investigator purchased ladies finger from the local farmer and also fenugreek seeds from the local supermarket throughout the study period. Joshua digital weighing scale was used to measure quantities of 40 grams Ladies finger and 20 grams Fenugreek seeds for packing. Accu-chek Performa glucometer was verified with PHC laboratory reveals similar result. A detailed intervention protocol is given in Table 1.

**Follow-up**

Interventions compliance sheet (ICS) alongside the method of preparation of either ladies finger water or fenugreek seeds water was distributed to Intervention groups. During home visit, the investigator checked the tick mark in the ICS and also family members were

encouraged to motivate the diabetic client for correct interventions follow up. Per day 15-20 houses were visited for follow up and material distribution. Post-intervention FBS was monitored on 16<sup>th</sup> day between-6.30 a.m. to 9.30 a.m. at the PHC. Flowchart describing enrolment, allocation, follow-up and analysis of study participants is given in Figure 1.



**Figure 1: Flow chart describing enrolment, allocation, and follow up of study participants.**

**Statistical analysis**

Data was entered in excel sheet and analyzed by statistical package for social sciences (SPSS) software (version 20.0). Wilcoxon signed rank test was applied to compare Pre and post intervention FBS within groups. One-way analysis of covariance was applied to compare FBS between groups followed by post hoc test with Bonferroni correction. P value <0.05 was considered statistically significant.

**RESULTS**

Out of 180 study participants, only 168 were included for analysis, 12 study participants were loss to follow up. Baseline data of 12 losses to follow up/withdrawn

participants were analysed and found no difference with the final participant characteristics. Table 2 describes the baseline characteristics of participants. BMI, type of

worker, duration of treatment in years for diabetes, and type of OAD agent were similar for three groups. Statistically significant older participant in control group than fenugreek group and more females in control group than other groups were observed. By 15 days period of intervention, mean difference (MD) of FBS between pre- and post-intervention in group 1 was 21 mg/dl, group 2 was 20.3 mg/dl and group 3 were 4.7 mg/dl respectively (Figure 2). Wilcoxon signed rank test showed a significant reduction in group 1 (Z=-5.30, p<0.001) and group 2 (Z=-5.47, p<0.001), whereas no significant reduction in group 3 (Z=-1.83, p=0.068). The one way analysis of covariance showed main effect of intervention was significant,  $F_{(2,164)}=5.11$ ,  $p=0.007$ , partial  $\eta^2=0.059$ . A post hoc test with Bonferroni correction found significant effect between group 1 and group 3 ( $p=0.032$ ), group 2 and group 3 ( $p=0.012$ ), whereas no significant effect was found between group 1 and group 2 ( $p=1.00$ ). The covariate, pre-test FBS, was also significant,  $F_{(1,164)}=326.01$ ,  $p<0.001$ , partial  $\eta^2=0.665$ , indicating that

level of FBS before intervention had a significant effect on level of FBS after therapy (there was a positive relationship between these two variables  $r=0.793$ ,  $p<0.001$ ). Our study interprets that both ladies finger

water and fenugreek seeds water was highly significant and superior in reduction of FBS level among type 2 diabetes than the control group.

**Table 1: Intervention protocol followed.**

Variables	Group-1	Group-2	Group-3
<b>Intervention</b>	Ladies finger water plus OAD	Fenugreek seeds water plus OAD	OAD only
<b>Dosage</b>	40 gm of ladies' finger (large size-2/medium size-3) soaked in 200 ml of warm water for 12 hours, overnight.	20 gm of fenugreek seeds soaked in 200 ml of warm water for 12 hours, overnight.	As per M.O order
<b>Duration</b>	15 consecutive days	15 consecutive days	15 consecutive days
<b>Time</b>	Early morning in an empty stomach.	Early morning in an empty stomach.	As per M.O order
<b>Method of preparation</b>	Followed by hand hygiene, 40 gm of ladies' finger was washed under cold water. Clip both ends off the pods and then slit the pods vertically into half with a knife. Place the pods in a glass of 200 ml warm water then cover it with lid. Soak the pods overnight, up to 12 hours. Next day morning, squeeze the pods into the water to release any leftover sap and discard it.	Followed by hand hygiene, 20 gm of fenugreek seeds was soaked in 200 ml of warm water overnight up to 12 hours. Next day morning, mash the seeds with spoon and drain the water into another glass.	
<b>Material distribution</b>	Ladies finger was distributed by the investigator for the first two days at PHC after completion of all procedure and trained the participants to prepare ladies finger water themselves.	Fenugreek seeds was distributed by the investigator for the first two days at PHC after completion of all procedure and trained the participants to prepare fenugreek seeds water themselves.	

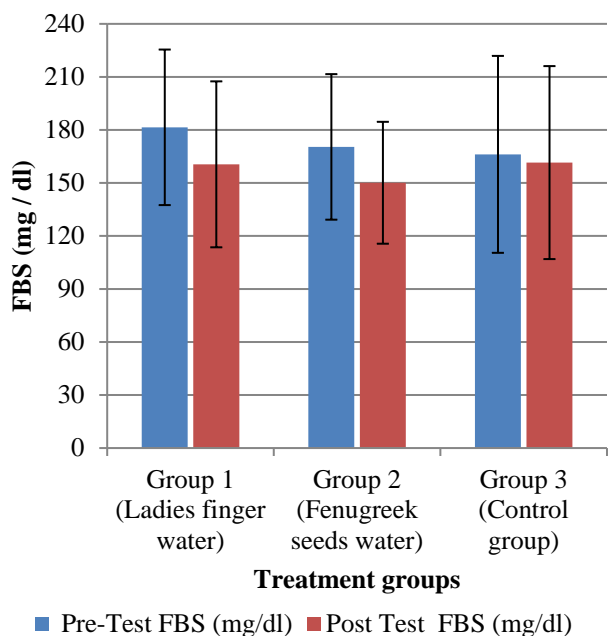
M.O-Medical officer

**Table 2: Demographic characteristics of study participants.**

Variables	Group 1 (ladies finger water, n=56) (%)	Group 2 (fenugreek seeds water, n=55) (%)	Group 3 (Control group, n=57) (%)
<b>Age (mean <math>\pm</math> SD) (year)</b>	53.3 $\pm$ 8.7	51.1 $\pm$ 8.4	55.5 $\pm$ 9.8
<b>Gender</b>			
Male	23 (41.1)	29 (52.7)	14 (24.6)
Female	33 (58.9)	26 (47.3)	43 (75.4)
<b>Type of worker</b>			
Sedentary worker	38 (67.9)	28 (50.9)	40 (70.2)
Moderate worker	17 (30.4)	23 (41.8)	15 (26.3)
Heavy worker	1 (1.8)	4 (7.3)	2 (3.5)
<b>Type of habits</b>			
Alcohol consumption	7 (12.5)	5 (9.1)	3 (5.3)
Smoking	1 (1.8)	0	0
Both alcohol and smoking	1 (1.8)	5 (9.1)	1 (1.8)
None	47 (83.9)	45 (81.8)	53 (93)
<b>Duration of treatment (mean<math>\pm</math>SD)</b>	3.7 $\pm$ 4.2	3.4 $\pm$ 3.3	3.9 $\pm$ 3.7
<b>Body mass index (mean<math>\pm</math>SD)</b>	25.9 $\pm$ 3.5	26.3 $\pm$ 4.9	25.6 $\pm$ 3.7
<b>Type of oral antidiabetic drug*</b>			
Sulfonylureas	0	2 (3.6)	1 (1.8)
Biguanides	22 (39.3)	24 (43.6)	24 (42.1)
Combination of sulfonylureas and biguanides	29 (51.8)	28 (50.9)	30 (52.6)

n-number of participants, SD-Standard deviation, %-Percentage, remaining study participant receives alternative medicine\*.





**Figure 2: Mean and standard deviation of pre-test and post-test FBS (mg/dl) by groups.**

## DISCUSSION

In the present study, ladies finger water and fenugreek seeds water were administered as adjunct therapy along with OAD among type 2 diabetes for 15 days. FBS was significantly reduced in ladies finger water (MD-21 mg/dl,  $p < 0.001$ ) and fenugreek seeds water (MD-20.3 mg/dl,  $p < 0.001$ ), whereas no significant reduction in control group (MD-4.7 mg/dl,  $p > 0.05$ ).

Our finding that ladies finger water was effective in reducing FBS is supported by a study that showed ladies finger juice significantly reduced the FBS with 15 days period of treatment among type 2 diabetes.<sup>21</sup> Rochee et al proved that MD of FBS was reduced upto 18.76 mg/dl when ladies finger was used in a divided doses for 2 months among type 2 diabetes.<sup>22</sup> Another similar study done by Murad et al found that ladies finger was effective in controlling blood glucose level among type 2 diabetes and MD of FBS was reduced by 16.63 mg/dl in 3 months.<sup>23</sup> Fatima et al found that a low glycaemic index of ladies finger is rich in dietary fibre helps to control blood glucose level than pointed gourd among diabetes.<sup>24</sup> A review article interprets that presence of high amount of Myricetin (natural flavonoid) in ladies finger helps to control blood glucose level and diabetes associated complication.<sup>25</sup> Animal (rabbit) experiment found that ladies finger water had significant reduction in FBS (25 mg/dl) when metformin was used as a standard for 10 days treatment.<sup>26</sup> Another study observed that the aqueous extract of powdered ladies finger had maximum effect in reduction of blood glucose when glibenclamide was used as a standard.<sup>9</sup> Animal experiment with rat showed significant reduction in blood glucose

level, glycated haemoglobin and improvement on lipid profile compared with the diabetic non-treated control and comparable with metformin positive control.<sup>27</sup> Mice model observed the antidiabetic activity with the mechanism of action by increasing insulin secretion, increasing insulin sensitivity, and inhibiting carbohydrate absorption in the intestine by the extract of ladies finger with a dose of 50 mg/kg body weight but couldn't inhibit alpha-glucosidase and alpha-amylase enzyme.<sup>28</sup> In contrast, one study found that co administration of water soluble fraction of ladies finger with metformin significantly reduced the metformin absorption.<sup>29</sup>

With regard to fenugreek seeds water, our study is consistent with a clinical trial which found that after taking fenugreek seeds water for 8 weeks had significant reduction in FBS among type 2 diabetes.<sup>30</sup> A clinical trial among client with type 2 diabetes using 15 gm of fenugreek seeds water reported a significant reduction in glucose after the meal.<sup>31</sup> Another clinical trial proved that fenugreek seeds water significantly reduced FBS and HbA<sub>1c</sub> within 6 months.<sup>32</sup> A 10 days RCT of stress induced hyperglycemia (SIH) in critically ill patient used 3 gm of fenugreek seeds powder by gavage twice a day along with routine medication found significant reduction in mean blood glucose levels and good prognosis observed than the control group with routine medication.<sup>33</sup> Another 3 month RCT found a significant reduction in FBS and lipid profile after intake of 2 gm fenugreek (capsule form three times per day along with metformin) than 5 gm glibenclamide (once a day along with metformin) among uncontrolled type 2 DM.<sup>34</sup> A multicentric clinical trial evaluated the effect of fenugreek seed (cap. Fenfuro 500 mg twice a day for 3 months) found that a significant reduction in fasting plasma sugar at 30, 60 and 90 days of treatment than placebo group and 48.8% of subjects reported reduced the dosage of antidiabetic therapy in Fenfuro group.<sup>35</sup> Few studies assessed the impact of fenugreek seeds on blood glucose level showed significant improvement in diabetes control when assessed in terms of fasting blood sugar levels.<sup>36,37</sup> Broad-spectrum therapeutic efficacy and medicinal properties of fenugreek seeds on metabolic disorders have been demonstrated in animal studies suggest that fenugreek may also contain a constituent which stimulates insulin production or sensitization.<sup>38,39</sup>

The dosage fixed with each intervention of our study is based on the pilot study conducted among 30 (10 subjects in each group) type 2 diabetic subjects with 40 mg ladies' finger for group 1 and 20 mg fenugreek seeds for group 2 which was well tolerated by all subjects without any adverse effect, hence same dose was fixed for the main study. Common cold was reported by three subjects in group 1 and two in group 2 within first 3 days of intervention. However, they continued the treatment for remaining days. One person developed a severe cold in group 2 and withdrawn the treatment on 3<sup>rd</sup> day of intervention. Other than cold no adverse effect found with our intervention. Major limitation of our study is less intervention period (15 days). We are unable to

document dosage reduction among study subjects due to less intervention period of study. Similar studies at longer duration will help to explore various beneficial findings.

## CONCLUSIONS

The primary aim of managing diabetes is to maintain blood glucose level to prevent diabetes induced complications. Results of study showed that adjunct therapy of ladies finger water or fenugreek seeds water are superior in reduction of FBS than OAD alone. Therefore, nutraceuticals like ladies finger or fenugreek seeds have ability to reduce insulin resistance which helps to increase effectiveness of OAD and reduces need for a high dose of multiple OAD among type 2 diabetics.

## ACKNOWLEDGEMENTS

Authors would like to thank all participants who have actively participated in the study. Our profound gratitude to IRB for approval of this study and directorate of health and family welfare services, Govt. of Puducherry for given permission to conduct this study at PHC. Our heartfelt thanks to Dr. Hepzibai Mary and staff, PHC, Kalapet for their overall support and help for successful completion of this study in a given time. Extend our sincere thanks to Dr. Bhuvaneswari and staff, PHC, Muthialpet for successful completion of pilot study. Also, our sincere gratitude to all the experts Dr. Sridharan, Siddha nodal officer, directorate of Indian system of medicine and homeopathy, government of Puducherry; Dr. Ashok Kumar Das, professor, dept. of general medicine and endocrinology, Dr. Anil. J. Purthy, registrar, professor and head, department of community medicine, Dr. Joy Bazroy, professor, department of community medicine, PIMS; Mr. R. S. Ramesh, assistant professor, department of community nursing, JIPMER; Dr. Raji Sugumar, professor and head, dept. of research and home science, Bharathidasan govt. college for women, Puducherry for validating the contents of the study and providing their valuable suggestions for the successful completion of this study.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Radhika R, Navaneetha M, Ravichandran K, Hemavathi P. Comparing the effect of ladies finger water with fenugreek seeds water on the blood glucose level among subjects with type 2 diabetes mellitus-a randomized controlled trial. *Int J Clin Trials* 2021;8(1):10-6.