

## Comparative Study on the Effect of *Plantago psyllium* and *Ocimum basilicum* Seeds on Anthropometric Measures in Nonalcoholic Fatty Liver Patients

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**How to cite this article:** Akbarian SA, Asgary S, Feizi A, Iraj B, Askari G. Comparative study on the effect of *Plantago psyllium* and *Ocimum basilicum* seeds on anthropometric measures in nonalcoholic fatty liver patients. *Int J Prev Med* 2016;7:114.

### ABSTRACT

**Background:** Due to the attribution of fatty liver with some chronic diseases such as obesity, finding a way to control obesity can be useful for the management of fatty liver. This study was performed to assess the effects of *Plantago psyllium* (PP) and *Ocimum basilicum* (OB) on anthropometric measurements in people with hepatic steatosis.

**Methods:** All patients with nonalcoholic fatty liver disease (NAFLD) were enrolled in this four-arm parallel, randomized, and single blind trial. They randomly assigned into four groups receiving (1) OB 10 g/day; (2) PP 10 g/day; (3) mix of OB and PP 10 g/day; and (4) control group without placebo for 12 weeks. Anthropometric measurements were assessed during study baseline and after 12 weeks intervention. The data were analyzed using paired sample *t*-test for within group and analysis of covariance for between groups.

**Results:** In within group analysis, weight and body mass index show a significant reduction after 12 weeks intervention. In addition, soft lean mass and lean body mass were decreased in PP and mixed of PP and OB groups significantly; another group (OB) shows the same result for mass body fat. Although in intervention groups, we see considerable reduction, between group changes did not demonstrate the same consequences.

**Conclusions:** The results of this study showed that administration of OB, PP, or mix of them for 12 weeks does not affect any of the anthropometric measures in NAFLD.

**Keywords:** Fiber, mucilage, nonalcoholic fatty liver, obesity, *Ocimum basilicum*, *Plantago psyllium*, weight

### INTRODUCTION

Nonalcoholic fatty liver disease (NAFLD) as a silent killer with accumulating extra fat in hepatocytes more than

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DOI:  
10.4103/2008-7802.191865

5% with no history of alcohol abuse, follows by creating inflammation, nonalcoholic steatohepatitis, which leads to liver fibrosis and finally liver cirrhosis.<sup>[1]</sup> High prevalence of NAFLD in diabetic patients and obese individuals showed the relationship between NAFLD and these chronic diseases which insulin resistance considered as the main reason.<sup>[2]</sup> Due to 25%–30% prevalence of total population,<sup>[3]</sup> finding solutions for NAFLD has an exclusive importance in public health.

Even though life styles modifications such as weight lose<sup>[4]</sup> are suggested, nutritional patterns changes are considered as important approaches in NAFLD management.<sup>[5]</sup> Simple carbohydrates, especially fructose and sucrose cause fat accumulation in body tissues such as liver.<sup>[6]</sup> Many studies assessed effect of nutrients such as Vitamin D, symbiotic and green tea as a solution.<sup>[7-9]</sup> Moreover, most NAFLD patients daily consume much lower fiber than required amounts.<sup>[10]</sup>

*Plantago psyllium* (PP) and *Ocimum basilicum* (OB) as two types of high fiber and mucilage (10%–15%),<sup>[11]</sup> plant seeds can consider as the key solution of NAFLD by decreasing appetite with occupying stomach and decreasing food glysemic index.

## METHODS

### Trial design

Present study is a four-arm parallel, randomized, and single blind trial conducted in Sedigheh Tahereh, Isfahan Endocrine and Metabolism Research Center in August 2014 to March 2015. We selected new cases of NAFLD at their first time referral to Fatty Liver Clinic.

### Study population, eligibility and consent

We recruited men and women between 27 and 74 years old diagnosed with fatty liver ultrasonography, a well-established technique.<sup>[12]</sup> Individuals with steady using of fiber supplements, insulin injection, and drugs such as corticosteroids, anticonvulsants, and antiepileptic, also pregnant, lactating, hemochromatosis, and cirrhosis patients were excluded. All participants filled informed consent before involved in the study.

### Intervention and monitoring

We supplied PP and OB seeds from the center of Iran, Isfahan, which packaged in 2.5 g parts for daily (10 g) usage. Each pack should be eaten 20–30 min before lunch and dinner with only a glass of water and no additional sugar or even artificial sweeteners for 3 months. We followed patient with weekly texting and monthly calling.

Mucilage of PP and OB absorb water and get a sticky and viscose condition which leads to unpleasant feeling, so we lost participants and mentioned in Figure 1.

### *Plantago psyllium* and *Ocimum basilicum* components

We measured macronutrients and fiber components of PP and OB. Crude fiber by assessment tool (PP: 33 and OB: 31%) and dietary fiber by Association of Official Analytical Chemists (AOAC) 199/43 method (PP: 80 and OB: 59%),<sup>[13]</sup> carbohydrate by Fehling method (PP: 0.5 and OB: 1%),<sup>[14]</sup> protein by Kjeldahl method (PP: 18 and OB: 25%),<sup>[15]</sup> and fat by Soksele method<sup>[16]</sup> (PP: 1.5 and OB: 20%) were measured at the beginning of study.

### Outcome measures

We assessed all anthropometric measurements at the beginning and end of the study. Heights were measured with a standard tape and without shoes to the nearest 0.5 cm. Weight to the nearest 0.1 kg, percent body fat (PBF %), body mass index (BMI), soft lean mass (SLM kg), mass body fat (MBF kg), and also both MBF and SLM for trunk were all measured by Body Composition Analyzer device (Janex Medical Company, ioi 353 model). Then, 3-day food records of 2 usual days and 1 day off and a 2-day physical activity record were taken. Physical activity was calculated as a metabolic equivalent task minute per day spent on all activities with accurate each activity time.

### Sample size, randomization, and blinding

We allocated 120 participants in four groups with permuted block randomization of size 4. We provided a list of randomized numbers that had 4 numbers in each group then, one blinded staff of Fatty Liver Clinic put the selected patients in four different groups (1: OB, 2: PP, 3: OB and PP mixed, and 4: Control) secretly. Because patients should pour the seeds into a glass of water, they could not be blinded. But, laboratory staff, one ultrasound specialist, and who explained the records and consumption structures of the intervention were blinded in this study.

### Statistical analysis

Quantitative and qualitative variables were expressed as mean  $\pm$  standard error (or median [inter quartile range]) and frequency (percentage). Normality of quantitative variables was evaluated using Kolmogorov–Smirnov test and Q-Q plot. Nonnormal variables were subjected to logarithmic transformation. Within group analysis for quantitative variables was conducted using paired samples *t*-test. Within group analysis for quantitative variables was conducted using paired samples *t*-test. For between group comparisons analysis of covariance (ANCOVA) was used and baseline values of dependent variables, age and energy intake were adjusted. Chi-square or Fisher exact tests (if appropriate) were used for comparing the qualitative variables between groups. Statistical analyses carried out by the use of Statistical Package for the Social Sciences (SPSS) version 16 (SPSS, Inc, Chicago, IL, USA).

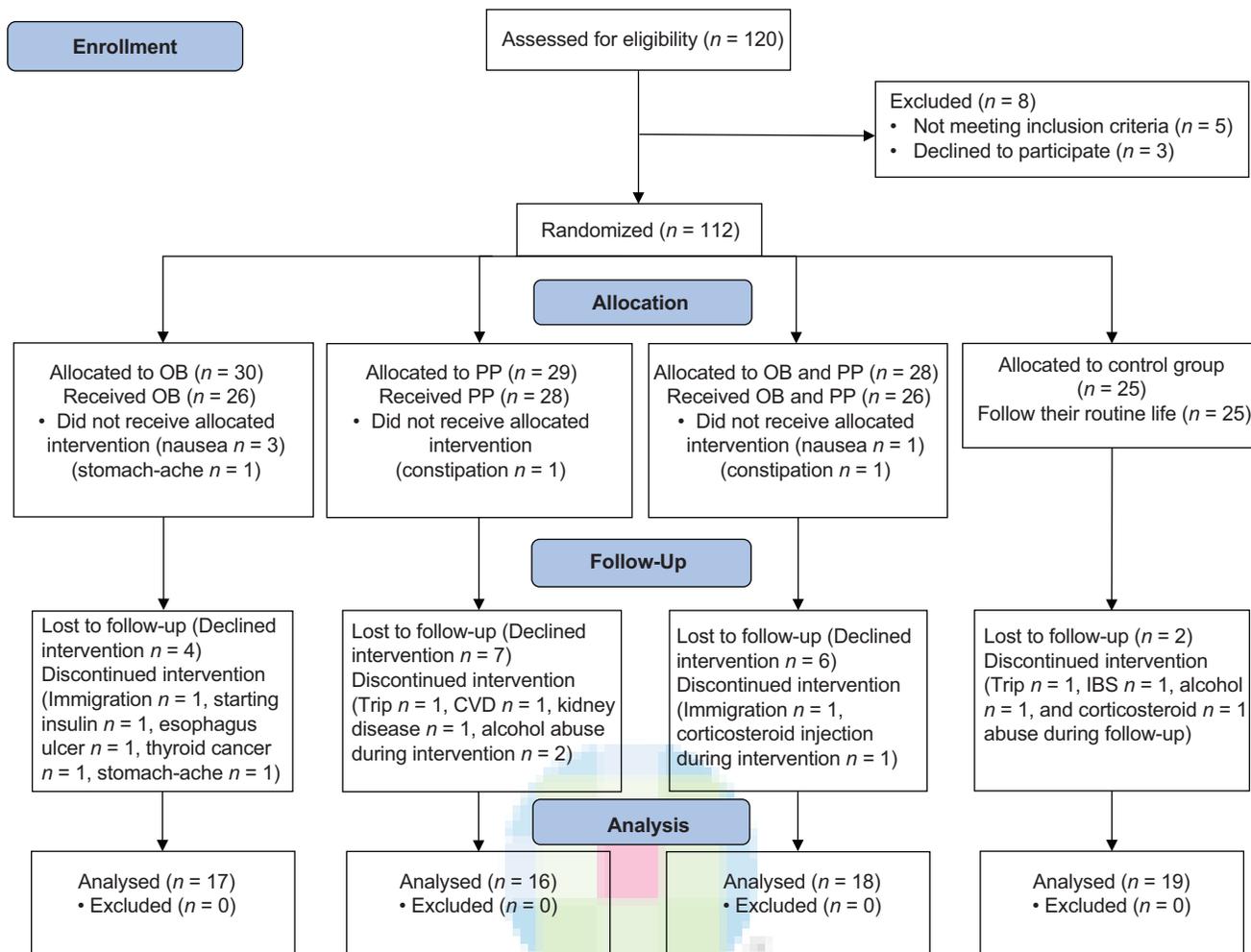


Figure 1: Flow diagram of the progress through the phases of study

## RESULTS

Eight participants could not tolerate PP and OB because of constipation, nausea or stomach-ache and were excluded from our study. Moreover, 42 patients that were involved to exclusion criteria during the study or they did not want to continue were eliminated. There were no significant differences regarding sex distribution, smoking condition, education status, and body weight in four groups at baseline. However, age was the only factor that was significantly different among groups which was adjusted in our analysis. No significant difference of receiving pill was observed among groups. Table 1 is showing all participants demographic information.

First of all, we compared before and after anthropometric measurements in different groups separately that some of them had been significantly decreased. Weight ( $P = 0.02$ ), BMI ( $P = 0.01$ ), and MBF ( $P = 0.04$ ) in OB group were significantly reduced. Moreover, weight ( $P = 0.00$ ), BMI, SLM, and lean body mass (LBM) ( $P = 0.01$ ) were lowered in PP group. In PP

Table 1: Baseline demographic information of participants

Variables	OB	PP	PP and OB	Control	P
Age (years)	55.5±2.2	45.7±3.2	53.5±1.8	49.2±2.3	0.03
Sex					
Women/men (n)	11/6	11/5	14/4	16/3	0.53
Weight (kg)	79.5±3.6	81±2.9	85.5±4.4	76.2±2.4	0.48
Educational level (n)					
Illiterate	3	1	1	3	0.8
Elementary	5	8	9	10	
Diploma	6	3	5	4	
University education	3	4	3	2	
Smoking (n)	0	3	1	0	0.06
Physical activity (MET-min/d)	33.1±0.9	35.2±5.5	35.6±0.7	35.2±0.6	0.1

OB=*Ocimum basilicum*, PP=*Plantago psyllium*

and OB mixed group, we saw a similar result to the last group. Weight, BMI, SLM, and LBM were significantly different while, SLM of trunk was marginally significant. Similarly, control group data showed considerable

**Table 2: Result of within group and between groups comparison**

Variables	OB group		PP group		PP and OB group		Control group		P <sup>a</sup>	P <sup>b</sup>
	Before	After	Before	After	Before	After	Before	After		
<b>Weight</b>										
Mean±SE	79.5±3.6	78.1±3.5	80.4±2.4	78.5±2.3	84.7±4.9	82.7±4.6	75.3±2.7	73.7±2.8	0	0.89
Median (IQR)	79.8 (70.5-83.6)	78.2 (69.7-83.1)	78.7 (73.3-88.9)	77.6 (70.5-82.6)	78.4 (75-94.7)	76.5 (74-87.4)	73.8 (68.5-83.6)	69.6 (66-82.7)		
<b>BMI</b>										
Mean±SE	30.1±1.1	29.5±1.1	29.9±0.8	29.2±0.8	34.6±1.8	33.6±1.7	31.2±1.1	30.6±1.1	0	0.92
Median (IQR)	30.1 (27.1-32.1)	29.1 (25.7-30.7)	29.7 (27.4-32.6)	29.2 (27-32.1)	31.4 (28.3-39)	31 (27.7-37.9)	29.9 (28.1-33)	30.2 (27.7-33.1)		
<b>PBF</b>										
Mean±SE	34.8±1.5	33.6±1.9	33.4±2.1	33.4±2.0	38.7±1.6	39.1±1.5	38.2±1.4	37.5±1.4	0.47	0.43
Median (IQR)	34.7 (28.6-39.7)	34.1 (27.8-39.3)	36.4 (27.4-39.0)	36.9 (26.3-40)	39.1 (30.1-44.1)	40.4 (33.1-44.1)	39.3 (35-41.1)	38.8 (35.1-41.3)		
<b>MBF</b>										
Mean±SE	27.8±2.0	26.5±2.3	26.6±1.7	25.9±1.7	33.8±3.2	33.2±2.9	29.2±2.0	28.0±2.0	0.24	0.73
Median (IQR)	27.4 (22.7-29.9)	27.3 (20.4-31.0)	26.8 (21.1-31.5)	27.3 (23.0-30.9)	29.5 (23.3-40.4)	30.1 (22.9-38.1)	27.8 (22.3-33.9)	26.9 (21.1-34.4)		
<b>MBF trunk</b>										
Mean±SE	14.3±1.0	13.6±1.2	13.6±0.9	13.3±0.8	17.4±1.6	17.1±1.5	14.9±1.0	14.3±1.0	0.31	0.68
Median (IQR)	14.0 (11.6-15.5)	14.4 (10.4-15.9)	13.7 (10.8-16.2)	14.0 (11.8-15.8)	15.1 (11.9-20.8)	15.4 (11.8-19.5)	14.2 (11.4-17.4)	13.7 (10.8-17.6)		
<b>SLM</b>										
Mean±SE	47.2±2.3	47.1±2.2	48.5±2.4	47.2±2.2	46.7±2.0	45.4±2.0	41.8±0.9	41.5±1.1	0.01	0.45
Median (IQR)	44.8 (39.2-55.1)	44.1 (40.1-53.4)	47 (42.7-52.9)	45.2 (41.2-51.4)	47.8 (41.5-51)	42.6 (40.3-48.1)	41.8 (40-45)	41 (37.1-45.9)		
<b>SLM trunk</b>										
Mean±SE	23.6±1.0	23.6±1.0	23.9±1.2	23.5±1.0	22.8±0.8	22.4±0.8	20.9±0.4	20.8±0.5	0.05	0.65
Median (IQR)	22.6 (19.7-27.0)	22.1 (19.9-27.2)	22.9 (21.1-26.6)	22.3 (20.5-26.1)	23.5 (20.2-25.4)	21 (20-23.9)	20.6 (19.9-22.7)	20.7 (18.6-23)		
<b>LBM</b>										
Mean±SE	51.7±2.4	51.5±2.4	53.0±2.5	51.6±2.3	51.49±2.3	50.1±2.3	46.0±1.0	45.6±1.2	0	0.53
Median (IQR)	49.2 (43.1-60.1)	48.6 (44.1-58.9)	51.6 (47.1-57.1)	49.4 (45.4-55.8)	52.1 (45.6-56)	47.1 (44.4-52.4)	45.8 (43.6-49.8)	44.8 (40.9-50.5)		

<sup>a</sup>Resulted from paired sample t-test, <sup>b</sup>Resulted from ANCOVA; adjustment was made for baseline values, energy intake and age. BMI=Body mass index, PBF=Percent body fat, MBF=Mass body fat, SLM=Soft lean mass, LBM=Lean body mass, ANCOVA=Analysis of covariance, SE=Standard error, IQR=Interquartile range, OB=Ocimum basilicum, PP=Plantago psyllium

reduction in weight and BMI  $P = 0.00$  and  $0.02$ , respectively, we examined among group changes as more important aim in order to reach reliable consequences of our intervention that we did not see any significant effects among groups [Table 2].

In addition, we averaged out a 3-day food and a 2-day record in order to controlled confounding such as a total dietary, total fiber, insoluble fiber, and soluble fiber intake [Table 3] and also, physical activity [Table 1]. None of the mean dietary confounding factors and mean of physical activity was significantly different among four groups.

## DISCUSSION

This study illustrates a 10 g increasing of PP, OB, or mix of them have no effects on weight, BMI, % PBF, or SLM during 12 weeks. Previous studies have recommended that increased fiber intake up to Recommended Dietary Allowance (RDA) amount (38 for men and 25 g for women<sup>[17]</sup> leads to increased postmeal satiety.<sup>[18]</sup> Moreover, the gut hormone, ghrelin, gastrointestinal peptide, and glucagon-like peptide (GLP-1) were increased. Ghrelin can suppress appetite and GLP-1 can enhance postprandial satiety time.<sup>[19]</sup>

However, the effects of fiber on weight loss are controversial. Similar to our study, no protective effect of PP on weight change did not observed in 36 diabetic patients.<sup>[20]</sup> Likewise, when soluble fiber was compared against insoluble fiber neither of them have cause reduction in weight.<sup>[21]</sup>

In contrast, some documents showed positive outcomes of soluble fiber in anthropometric characters. High dose of PP (36 g daily) demonstrated considerable decrease in weight, BMI, and, especially % body fat either with a diet modification or without that.<sup>[22]</sup> Similarly, both soluble (24 g PP) and insoluble (28 g wheat bran) elucidated a significantly weight loss after 6 weeks, while the participants had gone on a modified diet.<sup>[23]</sup>

As other studies, our study includes some limitations inevitably. Some used drugs by patients to improve liver status, might fade the effects of PP and OB

on anthropometric measures. Our participants were new cases of NAFLD who may have gone on a diet unconsciously.

The aim of present study was to demonstrate protective effect of PP and OB mixture on weight reduction but it was not observed which can be due to the low-dose of soluble fiber used in present study.

In a similar meta-analysis, the effect of guar gum on body weight was evaluated rigorously. As a consequence, when 11 randomized controlled trials were put together, no significant robust effect of guar gum consumption on weight loss was observed.<sup>[24]</sup> Although most animal studies showed a significant effect of fiber on weight reduction,<sup>[25]</sup> human studies have yielded inconsistent inferences.<sup>[20,21]</sup> Likewise, it is shown in another systematic review that soluble fiber has no effect on weight loss.<sup>[26]</sup> However, it should be noted in our study and other similar studies, participant's baseline weight was normal or overweight which may have precluded the expected results. This study has been registered both in Iranian registry clinical trial (IRCT2014101811763N17) and Isfahan University of Medical Sciences (393583).

## CONCLUSIONS

This study indicated that supplementation with 10 mg/day PP, 10 mg/day OB, and 10 mg/day PP and OB mixed for 12 weeks did not improve weight, BMI, SLM, LBM, MBF, and PBF significantly. Further trials should be done in this area with higher dose of PP and OB and also, in bigger population which draw a clear link between anthropometric measures and fiber supplementation.

This study was funded by Isfahan University of Medical Sciences and Sedigheh Tahereh, Isfahan Endocrine and Metabolism Research Center was involved in data collection.

**Financial support and sponsorship**  
Nil.

## Conflicts of interest

There are no conflicts of interest.

**Table 3: Baseline dietary intakes**

Macronutrient intake	OB	PP	PP and OB	Control	P
Dietary fiber	14.9±1.1	14.3±1.5	18.0±1.4	15.0±1.2	0.16
Insoluble fiber	3.3±0.4	3.1±0.5	3.8±0.4	3.1±0.5	0.74
Soluble fiber	0.5±0.0	0.5±0.0	0.6±0.0	0.5±0.0	0.98
Crude fiber	4.6±0.4	4.5±0.5	6±0.4	4.9±0.4	0.08
Carbohydrate	270.4±19.5	265.8±16.7	327.5±15.6	298.4±18.0	0.06
Fat	54.4±4.1	53.1±5.5	65.6±4.8	61.7±6.2	0.30
Calorie	1844.3±116.9	1794.2±116	2215.1±85.6	2010.8±131.4	0.047
Protein	72.3±3.7	69.6±6.3	84.5±3.1	74.5±4.6	0.11

OB=*Ocimum basilicum*, PP=*Plantago psyllium*

Received: 10 Aug 16 Accepted: 23 Aug 16

Published: 10 Oct 6

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