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Effects of Black Bean Vinegar on Functional Constipation: A Randomised, Double-blind, Placebo-controlled Study

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ABSTRACT

Introduction: Functional constipation is a widespread gastrointestinal ailment associated with infrequent defecation, unfavorably affecting quality of life. However, it has not been well studied worldwide. This study aimed to investigate the effects of black bean vinegar (black bean and black bean yeast) consumption in alleviating functional constipation. **Methods:** A randomised, double-blind, placebo-controlled, parallel group study involving 70 adults with functional constipation was conducted in Peninsular Malaysia from May till July 2016. Subjects aged 18-60 years diagnosed with a score of more than 15 based on the Constipation Scoring System were included. A third-party-controller assigned black bean vinegar and placebo drinks to two groups with 1:1 ratio using randomisation software. Participants received once-daily doses of black bean vinegar (20 ml daily) or fruit-flavored squash placebo (20 ml daily) which contained vitamins, minerals, trace elements and carbohydrates, without black bean and black bean yeast, for four weeks. Analysis was conducted on an on-treatment basis (i.e., all randomised participants conformed to the study protocol by consuming 20 ml of drinks daily, with less than 10% leftover drinks at post-intervention assessment). Data were analysed using SPSS version 22. **Results:** Administration of black bean vinegar did not demonstrate statistically significant differences in any of the outcomes when compared with a placebo drink at α=5% level. However, black bean vinegar consumption significantly improved overall score at post-intervention assessment compared to placebo group (p<0.05). **Conclusion:** Since the present study was only able to demonstrate the beneficial effects of black bean vinegar consumption in improving overall score at post-intervention assessment compared to placebo group, further randomised, controlled intervention studies are warranted to confirm whether conventional dietary intervention may play a role in improving functional constipation among Malaysian adults.

Key words: Black bean vinegar, functional constipation, placebo-controlled, randomised

INTRODUCTION

Functional constipation is a widespread gastrointestinal ailment (Suares & Ford, 2011) associated with infrequent defecation (Drossman *et al*., 2000), unfavorably affecting quality of life (Belsey *et al*., 2010). However, it has not been well studied worldwide. Related principally with infrequent and difficult defecation of small amounts of hard, lumpy and dry stools in the absence of biochemical or structural abnormalities, functional constipation is frequently accompanied by an assortment of subjective symptoms such as bloating, sensation of incomplete evacuation or blockage, unsuccessful bowel movement attempts and excessive straining during evacuation (Longstreth *et al*., 2006). Some

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44.5% of the Malaysian population suffer from constipation for between 5 to 25 years, which confirms the chronic nature of the disorder. A substantial number of Malaysians (27.8%) are unaware of the fact that they have constipation, as they perceive their symptoms to be natural occurrences in the course of normal bowel movement. They therefore do not feel the need to seek medical attention for their condition (Mazlyn *et al*., 2013). While the affirmative causes of functional constipation are still vague, several factors may contribute to the occurrence of constipation including a low fibre diet, dehydration, sedentary lifestyle and stress (Leung *et al*., 2011). Increased dietary fibre and fluids intake has been demonstrated to be advantageous to individuals whose intake had been inadequate (Leung *et al*., 2011). In the case of low total caloric intake or lower frequency of meal intake, it has been suggested that a diminished gastrocolic reflex in response to eating may also be a contributory factor to constipation (Bouchoucha *et al*., 2006).

Presently, the standard therapy for managing functional constipation consists of a combination of fibre supplements, laxatives and dietary or lifestyle modification concentrated principally on increasing dietary fibre and fluid intake as well as becoming physically active where necessary (Tack & Muller-Lissner, 2009).

Standard therapies do not bring about satisfactory relief at all times (Tack & Muller-Lissner, 2009). Hence, there is a need to explore other methods that are safe and bring about long-term efficacy to manage this disorder (Pohl, Tutuian & Fried, 2008). Research studies observed that vinegar is useful in alleviating particular symptoms of constipation among adults by improving intestinal peristalsis (Stommel & Holschneider, 2006) albeit clinical application is still considered investigational. The aim of the present study was to investigate the beneficial effects of black bean vinegar consumption in alleviating constipation.

METHODS

Study design

A randomised, double-blind, placebo-controlled, parallel group study involving 70 adults with functional constipation was conducted in the Perak state of Peninsular Malaysia between May 2016 and July 2016. A third-party-controller assigned black bean vinegar and placebo drinks to two groups with 1:1 ratio using randomisation software. Both researchers and participants were blind to the allocation.

A conscientious and stringent selection process was conducted in the recruitment of participants. Potential participants were broadly screened via surveys at public events to identify eligible participants. Only those who met the strict eligibility criteria were invited to participate in the intervention study.

Participants received once-daily doses of black bean vinegar or fruit-flavoured squash placebo for four weeks. Participants reported information regarding their bowel movements. Participants were asked to maintain their usual diet and lifestyle throughout the intervention study.

Ethical consideration

The study was conducted in accordance with Malaysian Guidelines for Good Clinical Practice and the Declaration of Helsinki. The protocol was approved by the University Tunku Abdul Rahman Scientific and Ethical Review Committee (Research Project Identification No. U/SERC/29/2016). All participants gave written informed consent.

Safety considerations

Adverse outcomes that happened during the study were recorded. Participants were not obliged to avoid administering oral or rectal lactulose if they had constipation in

the event of absence of bowel movement for four consecutive days.

Study agents

The test beverages consisted of black bean vinegar (intervention group) and fruit-flavored squash (placebo group). The beverages were packaged in unmarked individual bottles of 600 ml. The ingredients were vitamins, minerals, trace elements, and carbohydrates. The black bean vinegar contained black bean and black bean yeast, while the placebo did not contain black bean and black bean yeast. The placebo did not contain traces of soluble fibre.

Eligibility

Participants were of either gender, aged between 18 and 60 years diagnosed as suffering from constipation using the Constipation Scoring System (Agachan *et al*., 1996); those with a score of more than 15, satisfied the cut-off point for constipation. Participants were otherwise-healthy, free of cardiovascular-related diseases, cancer, diabetes, neurological diseases, or other serious degenerative illnesses and not physically or mentally handicapped. Participants lived in Perak, with no predetermined plans to move to other states during the intervention study. Participants were excluded if they (i) were pregnant, (ii) regularly used laxatives (more than once per week), anti-diarrheals, anti-cholinergics, or antibiotics in the month prior to screening or at any point during intervention; (iii) had gastritis; (iv) had constipation of organic or neurological origin; (v) failed to confirm consumption of study drink; (v) experienced adverse events that required discontinuation of intervention.

Efficacy measurements

The Constipation Scoring System is an 8-item questionnaire with items on frequency of bowel movement, difficult evacuation, feeling of incomplete evacuation, abdominal pain, length of time in lavatory per attempt, assistance to evacuate, number of unsuccessful attempts within 24 hours and the history of constipation. The maximum score is 30, with a higher score signifying increased severity. The Constipation Scoring System was selected as the primary outcome measure, as this was believed to be the most appropriate measurement for use in this group of participants at that time. A scoring range of 0 to 4 (with the exception of "assistance for defecation", which is 0 to 2) was derived. The total score was obtained by adding each individual score. A score of more than 15 was defined as having "constipation".

Stool consistency was also assessed using a seven-scale Bristol Stool Chart (Type 1: separate hard lumps; Type 2: lumpy and sausage like; Type 3: a sausage shape with cracks in the surface; Type 4: like a smooth, soft sausage or snake; Type 5: Soft blobs with clear-cut edges; Type 6: mushy consistency with ragged edges; Type 7: liquid consistency with non solid pieces)(Agachan *et al.,* 1996). In addition, all the attributes of black bean vinegar were evaluated on a 5-point rating scale. Participants in the intervention and placebo groups rated the colour, smell, taste and overall attributes of black bean vinegar based on five scales. "Hate" was denoted as 1, "don't like" as 2, "don't mind" as 3, "like" as 4 and "love" as 5 (Figure 1).

Sample size

The minimum sample size for the study was calculated using a formula by Daniel (1999):

$n = z^2p(1-p)/d^2$

where

n = estimated sample size

z = standard value of confidence level at 95% = 1.96

p = estimated prevalence of constipation among Malaysian (Mazlyn Mena *et al.,* 2013).

d= margin of error set at 20% = 0.20

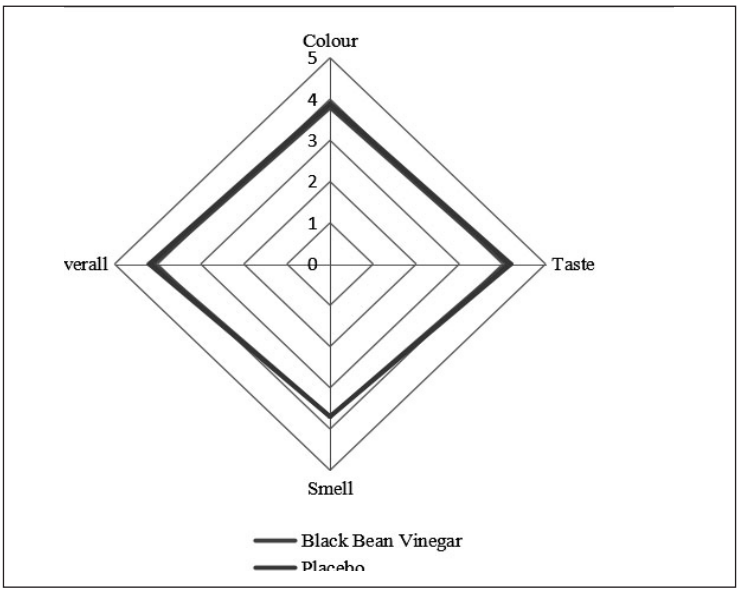

Figure 1. Sensory evaluation for black bean vinegar and fruit-flavored squash (Placebo)

Hence, the minimum sample size required would be 35 participants per group to accommodate for a 30% dropout rate. A minimum of 30 to 40 participants per group was needed, as suggested by Hertzog(2008).

Statistical analysis

Analysis was conducted on an on-treatment basis (i.e.: all randomised participants conformed to the study protocol by consuming 20 ml of drink daily, with less than 10% leftover drinks at post-intervention assessment). Participants were suggested to dilute the 20 ml of drink with one glass of water (approximately 300 ml) for consumption. Chi-square analysis was used to examine the association between categorical variables. An independent *t*-test was used to determine if any significant differences in the mean of the continuous variables existed between those participants in intervention and placebo group. Data were analysed using SPSS version 22. A statistical probability level of $p<0.05$ (two-sided) was considered significant.

RESULTS

Table 1 describes the socio-demographic characteristics and constipation scores of participants during the screening phase (n=238). A total of 70 constipated participants (29.4%) were invited to participate in a four-week randomised, double-blind, placebo-controlled study (Table 2). A total of 10 participants in the four-week randomised, double-blind, placebo-controlled study were excluded due to pregnancy (n=1) or failed to conform to the study protocol (n=9) (Figure 2).

Table 3 demonstrates the comparison between intervention and placebo groups at pre-intervention assessment. No significant difference in distribution across different categories was found between intervention and placebo groups for all the items in Constipation Scoring System and Bristol Stool Chart. No significant difference in the distributions across different categories was found between intervention and placebo groups for all the items in the Constipation Scoring System and Bristol Stool Chart. However, black

Table 1. Socio-demographic characteristics and constipation scores of participants during screening phase (n=238)

Characteristics	*n (%)*	*Mean±S.D.*
Gender		
Male	105 (44.1)	
Female	133 (55.9)	
Ethnicity		
Malay	9 (3.8)	
Chinese	216 (90.8)	
Indian	13 (5.5)	
Age (years)		30.50±5.66
Frequency of bowel movements		
1 to 2 times per 1 to 2 days	55 (23.1)	
2 times per week	77 (32.4)	
Once per week	71 (29.8)	
Less than once per week	25 (10.5)	
Less than once per month	10 (4.2)	
Difficult or painful evacuation		
Never	51 (21.4)	
Rarely	85 (35.7)	
Sometimes	74 (31.1)	
Usually	13 (5.5)	
Always	15 (6.3)	
Feeling incomplete evacuation		
Never	41 (17.2)	
Rarely	57 (23.9)	
Sometimes	54 (22.7)	
Usually	40 (16.8)	
Always	46 (19.3)	
Abdominal pain		
Never	33 (13.9)	
Rarely	63 (26.5)	
Sometimes	57 (23.9)	
Usually	45 (18.9)	
Always	40 (16.8)	
Minutes in lavatory per attempt		
Less than 5	60 (25.2)	
5 to 10	82 (34.5)	
10 to 20	70 (29.4)	
20 to 30	14 (5.9)	
More than 30	12 (5.0)	
Assistance to evacuate		
Without assistance	61 (25.6)	
Laxative use	102 (42.9)	
Digital assistance or enema	75 (31.5)	

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Table 1. Continued

Characteristics	*n (%)*	*Mean±S.D.*
Unsuccessful attempts of evacuation within 24 hours		
Never	36 (15.1)	
1 to 3	50 (21.0)	
3 to 6	58 (24.4)	
6 to 9	51 (21.4)	
More than 9	43 (18.1)	
History of constipation (duration)		
0 years	44 (18.5)	
1 to 5 years	61 (25.6)	
5 to 10 years	47 (19.7)	
10 to 20 years	49 (20.6)	
More than 20 years	37 (15.5)	
Total Score		
Normal	168 (70.6)	
Constipation	70 (29.4)	
Bristol Stool Chart Score		
Type 2	70 (29.4)	
Type 3	168 (70.6)	

Table 2. Socio-demographic data of participants in intervention study (n=60)\

Parameter	*Intervention n (%)*	*Control n (%)*	*p-value*
Total number of participants	30	30	
Gender			
Male	7 (23.3)	5 (16.7)	0.748
Female	23 (76.7)	25 (83.3)	
Age (Years)	29.03±5.857	30.77±4.840	0.217
Ethnicity			
Malay	0 (0)	0 (0)	0.554
Chinese	28 (93.3)	29 (96.7)	
Indian	2 (6.7)	1 (3.3)	

bean vinegar consumption significantly improved overall score at post-intervention assessment compared to placebo group (p<0.05) (Table 4).

DISCUSSION

Administration of black bean vinegar did not demonstrate statistically significant difference in any of the outcomes when compared with a placebo drink at α=5% level, which is conservatively used for clinical trials of medical prescriptions. However, it should be emphasised that the black bean vinegar significantly improved overall score compared to the placebo group.

These findings offer a suggestion that time could have been a limiting feature in

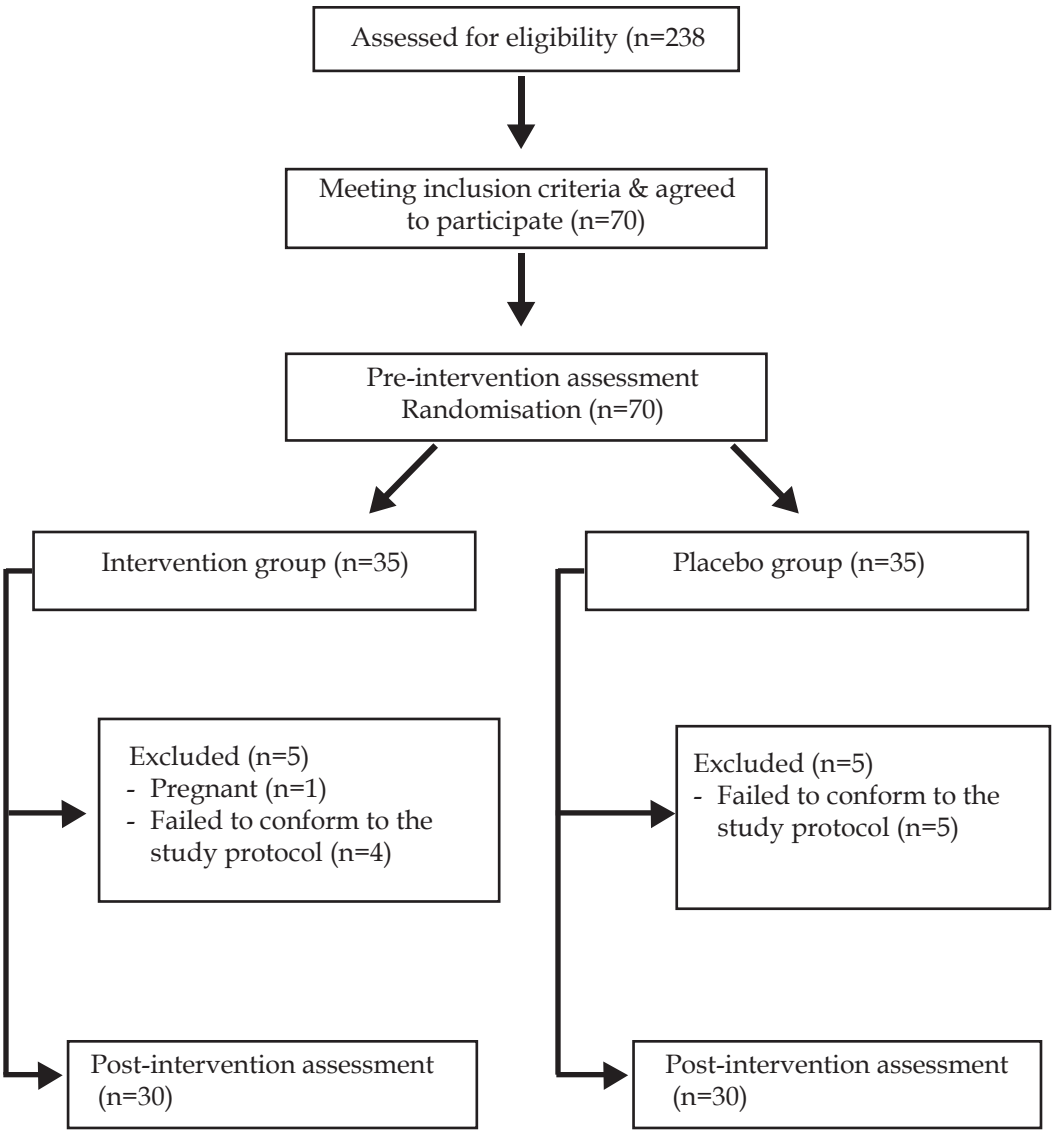

Figure 2. Recruitment and progress of participants through the study

Table 3. Comparisons between intervention and placebo groups (Pre-intervention)

Parameters	*Intervention* *n (%)*	*Control* *n (%)*	*P-value*
Frequency of bowel movements			0.558
1 to 2 times per 1 to 2 days	1 (3.3)	0 (0)	
2 times per week	5 (16.7)	4 (13.3)	
Once per week	8 (26.7)	6 (20.0)	
Less than once per week	3 (10.0)	7 (23.3)	
Less than once per month	13 (43.3)	13 (43.3)	
Difficult or painful evacuation		0.402	
Never	0 (0.0)	0 (0)	
Rarely	6 (20.0)	8 (26.7)	
Sometimes	9 (30.0)	7 (23.3)	
Usually	7 (23.3)	3 (10.0)	
Always	8 (26.7)	12 (40.0)	
Feeling incomplete evacuation		0.770	
Never	0 (0)	0 (0)	
Rarely	6 (20.0)	4 (13.3)	
Sometimes	8 (26.7)	6 (20.0)	
Usually	8 (26.7)	10 (33.3)	
Always	8 (26.7)	10 (33.3)	
Abdominal pain		0.996	
Never	0 (0)	0 (0)	
Rarely	7 (23.3)	8 (26.7)	
Sometimes	8 (26.7)	7 (23.3)	
Usually	8 (26.7)	7 (23.3)	
Always	7 (23.3)	8 (26.7)	
Duration in toilet per attempt (mins)		0.405	
Less than 5	0 (0.0)	0 (0.0)	
5 to 10	11 (36.7)	6 (20.0)	
10 to 20	9 (30.0)	8 (26.7)	
20 to 30	5 (16.7)	8 (26.7)	
More than 30	5 (16.7)	8 (26.7)	
Assistance to evacuate		0.121	
Without assistance	0 (0)	0 (0)	
Laxative use	11 (36.7)	17 (56.7)	
Digital assistance or enema	19 (63.3)	13 (21.7)	
Unsuccessful attempts of evacuation within 24 hours			
Never		0.693	
1 to 3	3 (10.0)	5 (16.7)	
3 to 6	6 (20.0)	8 (26.7)	
6 to 9	14 (46.7)	10 (33.3)	
More than 9	7 (23.3)	7 (23.3)	

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Table 3. Continued

Parameters	*Intervention* n (%)	*Control* n (%)	*P-value*
History of constipation (duration)			0.887
0 years	5 (16.7)	5 (16.7)	
1 to 5 years	7 (23.3)	9 (30.0)	
5 to 10 years	7 (23.3)	4 (13.3)	
10 to 20 years	6 (20.0)	7 (23.3)	
More than 20 years	5 (16.7)	5 (16.7)	
Total Score		-	
Normal	0 (0)	0 (0)	
Constipation	30 (100)	30 (100)	
Bristol Stool Chart Score			
Type 2	30 (100)	30 (100)	-

Table 4. Comparisons between intervention and placebo groups (Post-intervention)

Parameters	*Intervention* n (%)	*Control* n (%)	*p-value*
Frequency of bowel movements			0.752
1 to 2 times per 1 to 2 days	7 (23.3)	6 (20.0)	
2 times per week	8 (26.7)	6 (20.0)	
Once per week	4 (13.3)	7 (23.3)	
Less than once per week	7 (23.3)	5 (16.7)	
Less than once per month	4 (13.3)	6 (20.0)	
Difficult or painful evacuation			0.987
Never	7 (23.3)	8 (26.7)	
Rarely	8 (26.7)	7 (23.3)	
Sometimes	5 (16.7)	5 (16.7)	
Usually	5 (16.7)	4 (13.3)	
Always	5 (16.7)	6 (20.0)	
Feeling incomplete evacuation			0.171
Never	7 (23.3)	3 (10.0)	
Rarely	7 (23.3)	2 (6.7)	
Sometimes	5 (16.7)	7 (23.3)	
Usually	3 (10.0)	5 (16.7)	
Always	8 (26.7)	13 (43.3)	
Abdominal pain			0.614
Never	7 (23.3)	4 (6.7)	
Rarely	5 (16.7)	4 (13.3)	
Sometimes	7 (23.3)	6 (20.0)	
Usually	6 (20.0)	6 (20.0)	
Always			
5 (16.7)	10 (33.3)		

Continued on next page

Table 4. Continued

Parameters	Intervention n (%)	Control n (%)	*p*-value
Duration in toilet per attempt (mins)			0.373
Less than 5	5 (16.7)	2 (6.7)	
5 to 10	10 (33.3)	6 (20.0)	
10 to 20	3 (10.0)	7 (23.3)	
20 to 30	6 (20.0)	8 (26.7)	
More than 30	6 (20.0)	7 (23.3)	
Assistance to evacuate			0.950
Without assistance	11 (36.7)	12 (40.0)	
Laxative use	10 (33.3)	10 (33.3)	
Digital assistance or enema	9 (30.0)	8 (26.7)	
Unsuccessful attempts of evacuation within 24 hours			0.163
Never	5 (16.7)	5 (16.7)	
1 to 3	10 (33.3)	5 (33.3)	
3 to 6	3 (10.0)	7 (23.3)	
6 to 9	4 (13.3)	9 (30.0)	
More than 9	8 (26.7)	4 (13.3)	
History of constipation (duration)			0.887
0 years	5 (16.7)	5 (16.7)	
1 to 5 years	7 (23.3)	9 (30.0)	
5 to 10 years	7 (23.3)	4 (13.3)	
10 to 20 years	6 (20.0)	7 (23.3)	
More than 20 years	5 (16.7)	5 (16.7)	
Total score			0.035
Normal	16 (53.3)	8 (26.7)	
Constipation	14 (46.7)	22 (73.3)	
Bristol Stool Chart Score			0.035
Type 3	14 (46.7)	16 (53.3)	
Type 4	22 (73.3)	8 (26.7)	

the observation of the full effects of black bean vinegar on the earlier individual mentioned parameters of the Constipation Scoring System (Table 4). Further investigation with a longer duration of intervention between six and eight weeks is warranted in order to acquire conclusive findings with the incorporation of Food Frequency Questionnaire or 24-hour dietary recall.

In addition to the duration of intervention, the positive response towards the fruit-flavoured squash in the placebo group was another limitation of the intervention study. Compared to baseline values, the placebo group demonstrated improvement in terms of Constipation Scoring System. Whether this observation was due to day-to-day diet variations, a laxative effect of the fruit-flavored squash itself or a placebo effect, is unknown. Malaysians characteristically consume spicy food with capsaicin regularly that may irritate the digestive system, eventually resulting in a laxative effect. Nonetheless, the placebo effect has been demonstrated to be specifically strong in gut-related disorders (De Filipino *et al.,* 2010) and can sometimes persevere for the first two to three weeks of intervention (Koebnick *et*

al., 2003). This offers an ongoing challenge to researchers in assessing therapies in functional gut disorders.

Although participants were asked to maintain their usual dietary intake and lifestyle throughout the intervention study, the aggressive sour taste of black bean vinegar made consuming black bean vinegar arduous. This led to participants in the intervention group consuming approximately extra two glasses of water a day to further dilute the prescribed black bean vinegar, which may enhance the effect of black bean vinegar on functional constipation. The black bean vinegar had been aged for 6 months after the manufacture date before being distributed to participants. It is very difficult to establish the exact concentration of the black bean vinegar in view of participants diluting it according to taste, though the suggestion provided was to dilute the 20 ml of drink with one glass of water for consumption.

While the changes in bowel movements could be due partly to possible changes in dietary intake, it was unlikely in this study as an attempt had been made to control for this factor. Participants were informed to maintain their usual diets.

It is unclear whether the enormously dissimilar diets of South East Asians compared with Japanese or Europeans would have any bearing on the effects of the black bean vinegar in functional constipation, although diet has been demonstrated to affect gut microflora composition that may be part of the procedures through which black bean vinegar exerted its effects.

Participants in the present study were not actively looking for treatment for their constipation, and hence, could be regarded as having fairly mild constipation. This is further confirmed and revealed by their relatively low scores for Constipation Scoring System and Bristol Stool Chart at pre-intervention assessment. The relatively low scores may have also contributed partly to the failure to achieve statistical significance.

The participants were homogenous in ethnicity as a majority of the participants were Chinese. Hence, the findings from this study cannot be generalised to other populations.

There is a paucity of published randomised controlled trials regarding the beneficial effects of black bean vinegar on functional constipation. However, vinegar consumption has demonstrated its benefits in improving appetite (Mahin *et al.,* 2016), relieving colonic spasms (Abdullah *et al.,* 2015) in addition to alleviating constipation (Madhulika, 2016). Further randomised, controlled intervention studies are warranted to confirm whether conventional dietary intervention such as consuming black bean vinegar may play a role in improving functional constipation among Malaysian adults. However, the overall findings of the present intervention study seem to support the continued use of dietary alterations, when appropriate, as part of standard care for individuals with functional constipation in Malaysia; dietary alterations need to be seem as an adjunct to treatment with fibre supplements and laxatives pending further investigation.

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