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Do probiotics and fibre in milk powder have an effect on functional constipation and general wellbeing of Filipino mothers?

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ABSTRACT

Introduction: This study aimed to evaluate the effect of probiotics and fibre in milk powder on functional constipation and general well-being of a sample of Filipino mothers. **Methods:** The study employed a single group, controlled, before-after intervention design. Out of 115 females recruited from 7 military camps in Metro Manila aged 21-31 years, 85 mothers met the inclusion criteria namely, defecation frequency of <3 days/week or constipated for about 2-8 weeks, experienced bloating, flatulence, gurgling, feeling heavy after eating, and abdominal pain, willing to stop vitamin supplementation a week before the start of the study. Milk powder (40 g) in 200 ml of water was consumed twice a day for 28 days under supervision at the workplace. Digestive health, health and wellness, bowel habit and Bristol stool chart questionnaires, which were modified and pre-tested, were administered every 3-4 day visits. Constipation was defined as <3 days/week defecation frequency (Rome II). Appropriate statistical tests were employed in data analysis. **Results:** A total of 72 participants completed the study. At 4 weeks, a significant improvement in defecation frequency was reported. There was an increasing percentage of participants who were highly satisfied with their defecation frequency, stool characteristics, comfort during defecation and defecation duration as the number of intervention days increased. **Conclusion:** The consumption of a probiotic and fibre fortified milk powder might have contributed in alleviating functional constipation and the improvement in general health and wellbeing of the participants. Further studies should be conducted to confirm these results.

Keywords: Powder milk, probiotic, fibre, digestive health, constipation

INTRODUCTION

Functional constipation (FC) is a common functional bowel disorder in clinical practice, manifesting as straining during defecation, lumpy or hard stools and infrequent bowel movements, in the absence of evident organic or structural diseases (Xin *et al.,* 2014). Persistent constipation adversely affects the patients' mental state and their quality of life (Friedenberg, Dadabhai & Sankineni, 2012). Probiotics are live microorganisms that when administered in adequate amounts confer a health benefit on the host (Hill C *et al.*, 2014). Probiotics such as *Lactobacillus* and *Bifidobacterium* are producers of organic acids like lactic acid and acetic acid that can lower the pH of the colon, enhancing peristalsis and reducing colonic transit time

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(Walker *et al.*, 2011). Furthermore, lactic acid bacteria, including *Lactobacillus* species, which have been used for preservation of food by fermentation for thousands of years, serve a dual function by acting as agents for food fermentation in addition to imparting potential health benefits. Apart from these, some species of *Saccharomyces cerevisiae, E. coli* and *Bacillus* are also used as probiotics. The probiotic properties of genera, species, and strains may vary according to the indication (Agency for Healthcare Research and Quality, 2011).

Probiotics are intended to assist the body's naturally occurring gut microbiota. Some probiotic preparations have been used to prevent diarrhoea caused by antibiotics, or as part of the treatment for antibiotic-related dysbiosis. Studies have documented probiotic effects on a variety of gastrointestinal and extra-intestinal disorders, including inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and immune enhancement (Amara & Shibl, 2015; Kruis, 2004). In general, the strongest clinical evidence for probiotics is related to their use in improving gut health and stimulating immune function (Guarner *et al.*, 2008). Intake of probiotics majorly focuses on normalising the gastrointestinal flora and assisting normal digestive function. A systematic review and meta-analysis of 14 previous studies showed that probiotics indicated that overall, probiotics positively affected shortened regional gut transit time (GTT), increase stool frequency, and improve stool consistency. Several other cardinal symptoms of constipation also significantly improved, e.g. bloating, sensation of incomplete evacuation, occurrence of hard stools, ease of stool expulsion (Dimidi *et al.,* 2014).

Constipation is one of the most commonly experienced gastrointestinal symptoms and is not a disease (Ehrenpreis, 2006). It is defined as having bowel movement fewer than three times per week. Stools are usually hard, dry, small in size, and difficult to eliminate. People who experience constipation find it painful to have a bowel movement and often experience straining, bloating, and the sensation of a full bowel. Common causes of constipation are inadequate fibre in the diet, lack of physical activity, medications, irritable bowel syndrome (IBS), changes in life or routine, ignoring the urge to have a bowel movement, dehydration, specific diseases or conditions (such as stroke) and problems with the colon, rectum and intestinal function (Rome II Criteria). Prolonged constipation can lead to complications like haemorrhoids, anal fissures and rectal bleeding. Though chronic constipation is non-life threatening, it has significant impact on the quality of life and hence its management is important (Belsey *et al.,* 2010).

Constipation often affects adults, especially women; pregnant women suffer more from constipation and it is a common problem following childbirth or surgery (National Institute of Diabetes and Digestive and Kidney Disease, 2012). However, due to the sensitivity of the condition of pregnant women, the study opted to target women with children less than three years old.

The objective of this study was to evaluate the effect of probiotics (DR10™ Bifidus Lactis) and inulin fibre-fortified milk powder on functional constipation and general well-being of sample Filipino mothers.

MATERIALS AND METHODS

The study employed a single group, controlled, before-after intervention study design. About 115 mothers aged 21-35 years with a child aged 3 years old or above from seven military camps in Metro Manila were invited for screening.

Screening questionnaire, which indicated the screening criteria were administered face-to-face by trained research assistants. Inclusion criteria were mothers who had a defecation frequency of less than 3 days per week or constipated for about 2-8 weeks, experienced non-specific symptoms including bloating, flatulence, gurgling, feeling heavy after eating, and abdominal pain (Rome II criteria), willing to stop taking vitamin supplements a week before the start of the study. A total of 85 had passed the screening criteria and were recruited as participants in the study after having sought the signed informed consent. This study was approved by the FNRI Institutional Ethics Review Committee (FIERC) and was registered at ClinicalTrials.Gov (#NCT01862341).

Subjects took the probiotic – fibre-fortified milk powder twice a day for 28 days under supervised regimen. Table 1 indicates the nutrient profile of the investigational product. Each serving (40 g) of the product contains 3.2 x 10^7 cfu of DR10 Bifidus Lactis, fortified with 5 g of inulin fibre, and provides ~150kcal of energy. The product was packed in a single serving foil pack labelled with an expiry date and batch number.

Table 1. Nutrient profile of investigational product

Nutrient	*Per serve (40g)*
Energy (kcal)	~150
Protein (g)	10
Fat (g)	2.2g
Carbohydrate (g)	18
Fibre[1] (g)	5
DR10 Bifidus Lactis (cfu)	3.2 x 10^7
Calcium (mg)	500
Iron (mg)	5.4
Folate (ug)	120
Vitamin A (ugRE)	195
Vitamin C (mg)	22.5
Vitamin D (ug)	3.75
Vitamin E (mg)	4.5

[1] *Fiber used is Inulin*

One pack of the probiotic – fibre-fortified milk powder was directly administered by the research assistants (RA) in the morning (1000h) and one in the afternoon (1500h). Each milk pack was added to 200 ml of safe drinking water. Each RA has specific sites to cover. Compliance in this study which was recorded in the case report form (CRF) was indicated by the number of days the participants had consumed two packs of milk powder. Reported adverse events, which included complaints, related to the milk drinking like diarrhoea, bloating or flatulence after thorough investigation by a Physician were recorded daily in the Adverse Event Form.

All questionnaires used in this study were pre-tested, and modified prior to its use. These were administered face-to-face by trained RA. General profile, socio-economic and demographic data were collected at baseline. General Lifestyle Evaluation Form, Digestive Health Questionnaire (Bukovina, 2013) and Bristol Stool chart (Lewis & Heaton, 1997) were administered every 3-4 day visit while the Bowel Habit Questionnaire was administered only during the first and last day of the intervention.

General Lifestyle Evaluation Form

The General Lifestyle Evaluation Form included 12 items that assessed changes in the participants' attitude to health and well-being. Each item was rated on a 5-point Likert scale ranging from 0 (never) to 4 (all the time).

Digestive Health Questionnaire

Participants also answered questions regarding intestinal health which include defecation frequency, difficulty of bowel motion, defecation duration and self-assessed bowel habits. For the first part of the Digestive Health Questionnaire, four questions relating to the participants' satisfaction with their bowel habit were asked. Each

item was rated on a 4-point Likert scale ranging from 0 (highly satisfied) to 3 (not satisfied). An 11-item self-assessment of whether the participants perceived improvements in their digestive system was also included in the questionnaire. Each item was rated on a 4-point Likert scale ranging from 0 (never) to 3 (always).

Bristol Stool Chart

Stool consistency was assessed by a 6-point scale using the Bristol Stool chart: Type 1 (separate hard lumps, like nuts), Type 2 (sausage-shaped but lumpy), Type 3 (like a sausage but with cracks on its surface), Type 4 (like a sausage or snake, smooth and soft), Type 5 (soft blobs with clear-cut edges), Type 6 (fluffy pieces with ragged edges, a mushy stool), Type 7 (watery, no solid pieces, entirely liquid) .The responses of the participants for the Bristol Stool Chart were also re-categorised into the following 1) constipation, 2) normal stool, 3) diarrhoea and urgency (Lewis & Heaton, 1997).

Anthropometry

Weight and height were measured to compute for body mass index (BMI) at baseline. Subjects were weighed using a calibrated Detecto weighing scale (Webb City, Mo. U.S.A.) while height was taken using a calibrated Microtoise (Depose, France). Participants were weighed in official uniform without shoes, belts and other accessories. Weight was recorded to the nearest 0.1 kg while height was recorded to the nearest 0.1 cm. Two readings for weight and height were recorded per measurement; based on the means of the two readings BMI was calculated.

Statistical analysis

A per-protocol analysis of the effects of milk powder with probiotics and fibre on the digestive habits and general well-being of selected Filipino mothers with less than three times per week defecation was done. Frequencies and descriptive statistical measures were calculated for baseline characteristics using statistical software SPSS (Statistical Package for the Social Sciences) version 12. For the Bowel Habit Evaluation Form, the non-parametric Wilcoxon Signed Rank test was used to compare the change in Intestinal Health of mothers at baseline and week 4 (28 days). For changes in eating habit, the McNemar Change and the Wilcoxon Signed Rank test was used whenever applicable. A p-value of <0.05 was considered statistically significant. To illustrate the differences of responses in each item in the Digestive Health Questionnaire, all items were subdivided in a component bar graph in every visit. To calculate the statistically significant difference on each item throughout the study period, the Friedman Test was used.

RESULTS

A total of 85 military female participants were enrolled in the study, however, only 72 had completed the study. Thirteen (13) participants were dropped from the study because they were transferred to another office outside Metro Manila (Figure 1). Analysis of all baseline characteristics of drop-outs like mean age, weight, height, education, and income showed no significant difference between that of the remaining subjects.

The mean age of the participants was 29.8 (*SD*=3.7) years, 87.5% were college graduates, and 45.8% were professionals. The mean monthly income was PhP 33,222.22 (*SD*=16,999.77) (US$664.44±340.00) with an average food expenditure of PhP 405.8 (*SD*=203.5) (US$ 8.12±4.07) per day. The participants mostly belonged to a nuclear family (54.2%) and 25.0% had an average household size of three (Table 2).

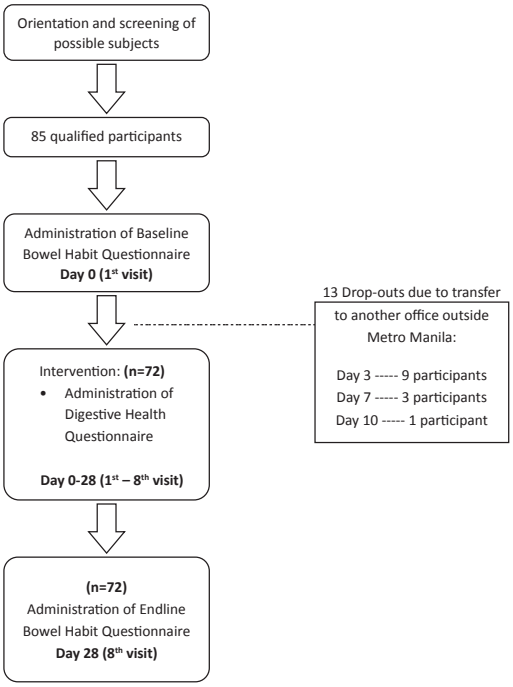

Figure 1. Operational flow of the study

Intestinal Health at Baseline and at Week 4

All participants who were enrolled in the study were categorized as constipated at baseline. At endline, a significant improvement in the frequency of defaecation wherein 71 (98.6%) participants had defecated more than 5 times a week and 1 (1.4) had it for 3-5 times a week.

During baseline, about 33.3% had spent about ¼ of their time having a difficulty in bowel motion, 37.5% had 1/3 and 29.2% had spent about ½ of their time. Majority had spent more than 5-10 minutes (83.3%) while 13.9 had spent 15-30 minutes defecating. At end line, 100% did not experience any difficulty in defecation and the defecation duration was ≤5 minutes. Self-assessment of their bowel habit showed that before the start of the study, 40.3% had some pushing down and discomfort, 56.9% had strong pushing down and discomfort with small/hard defecation, and 2.8% often have constipated feeling and painful bowel motion. After the intervention, 71 (98.6%) had assessed themselves as having normal bowel habit.

At week 4, about 98.6% of the participants were able to defecate more

Table 2. Demographic and anthropometric data of participants at baseline

Anthropometric Measurement	*Mean*	*SD*	*Min, Max*
Age	29.83	3.68	23,35
Height (cm)	156.8	7.4	151.2, 169.9
Weight (kg)	61.7	9.6	43.0, 87.8
Hip (cm)	95.3	7.5	69.4, 113.2
Waist (cm)	83.8	8.3	69.7, 108.0
BMI (kg/)	25.0	3.6	18, 34
Monthly Income (PhP)	33,222.22	16,999.77	4,000.00, 100,000.00
Average Food Expenditure per day (PhP)	405.8	203.5	120, 1000

The anthropometric data obtained at baseline showed that the mean height was 156.8 (*SD*=7.4) cm and the mean weight was 61.7 (*SD*=9.6) kg. Mean hip and waist measurement was 95.3 (*SD*=7.5) cm and 83.8 (*SD*=8.3) cm, respectively. The mean calculated BMI of the participants was 25.0 (*SD*=3.6) kg/m^2.

Table 3. Distribution of participants by defecation frequency, difficulty of bowel motion, defecation duration and self-assessed bowel habit at baseline and week 4

Item	*Baseline (n=72)*		*Week 4 (n=72)*		*Wilcoxon Signed Rank test*	
	Frequency	*Percentage (%)*	*Frequency*	*Percentage (%)*	*z*	*p*
Defecation Frequency						
More than 5 times (0)	-	-	71	98.6	-7.997	<0.0001*
3-5 times (1)			1	1.4		
1-<3 times (2)	72	100.0	-	-		
Total	72	100.0	72	100.0		
Difficulty of Bowel Motion						
No difficulty (0)	-	-	72	100.0	-7.479	<0.0001*
Difficulty 1/4 of the time (1)	24	33.3	-	-		
Difficulty 1/3 of the time (2)	27	37.5	-	-		
Difficulty more than 1/2 of the time (3)	21	29.2	-	-		
Total	72	100.0	72	100.0		
Defecation Duration						
≤5 min (0)	1	1.4	71	98.6	-7.874	<0.0001*
>5-10 min (1)	60	83.3	1	1.4		
>10-30 min (2)	10	13.9	-	-		
More than 30 min (3)	1	1.4	-	-		
Total	72	100.0	72	100.0		
Self-assessed bowel habit						
Normal (0)	-	-	71	98.6	-7.561	<0.0001*
Some pushing down and discomfort only (1)	29	40.3	1	1.4		
Strong pushing down and discomfort, difficult or small/hard defecation (2)	41	56.9	-	-		
Often have constipated feeling and painful bowel motion (3)	2	2.8	-	-		
Total	72	100.0	72	100.0		

**Significant difference*

than five times in a week, took less than 5 minutes to defecate and described their bowel habits as normal (Table 3). Only one participant (1.4%) had the defecation frequency of 3-5 times, defecated for 5-10 minutes and said that her bowel habit was "Some pushing down and discomfort only".

Using the Wilcoxon Signed Rank test, it was found that all 72 participants had defecated more frequently at week 4 than at baseline and none of the participants had difficulty in bowel motion at week 4. It further showed that a 4-week,

twice daily intake of fortified milk powder elicited a statistically significant improvement in defecation frequency of the participants constipation (z=-7.997, p<0.0001) and in defecation of all participants (z=-7.479, p<0.0001).

The defecation duration of the 70 participants was decreased at week 4 though only two participants had unchanged bowel movement duration. Furthermore, it was found that 71 participants had assessed their defecation to be better at week 4 than at baseline and only one participant said there was no change. The 4-week, twice daily intake of fortified milk powder elicited a statistically significant change in defecation duration of the participants with mild to moderate constipation (z=-7.874, p<0.0001) and participants' self-assessed bowel habits (z=-7.561, p<0.0001) (Table 3).

Eating Habits at baseline and at week 4

At baseline, about 93.1% of participants preferred white bread and rice followed by fish (91.7%), fried food (86.1%) and chicken and beef (86.1%). Only 16.7% of the participants preferred eating brown rice and entire-wheat bread. On the contrary, majority (81.9%) of the participants preferred water to other types of beverages at baseline. At week 4, the participants were again asked about the food they prefer and showed that 70 participants (97.2%) preferred white rice or white bread, followed by fish (95.8%), fruit and vegetables (91.7%), and chicken

Table 4. Distribution of participants by food and drink preferences at baseline and week 4[a]

Preferences	*Baseline (n=41)*		*Week 4 (n=41)*		*p-value*
	Frequency	*Percentage (%)*	*Frequency*	*Percentage (%)*	
Food preference					
Fruit and vegetable	59	81.9	66	91.7	0.118
Fish	66	91.7	69	95.8	0.453
Chicken and beef	62	86.1	66	91.7	0.344
White rice or white bread	67	93.1	70	97.2	0.375
Brown rice/Entire-wheat bread	12	16.7	9	12.5	0.581
Fried food	62	86.1	60	83.3	0.727
Dairy products	26	36.1	34	47.2	0.200
Bean products	22	30.6	32	44.4	0.087
Potato chips/snack	35	48.6	33	45.8	0.845
Dessert	35	48.6	33	45.8	0.845
Drink preference					
Tea	21	29.2	13	18.1	0.152
Water	59	81.9	70	97.2	0.001
Coffee	45	62.5	47	65.3	0.824
Carbonated drinks	40	55.6	35	48.6	0.332
Milk (fresh liquid or UHT)	23	31.9	18	25.0	0.458
Milk (as milk powder)	20	27.8	57	79.2	<0.0001
Fruit juice	40	55.6	34	47.2	0.307
Others	7	9. 8	2	2.8	NA

[a] multiple responses

and beef (91.7%). Using the McNemar Change test, it was found that the food preference of the participants at baseline is not statistically and significantly different from week 4 (Table 4).

Results also showed that by the end of week 4, 97.2% of the participants drank water, followed by milk as milk powder (79.2%) and coffee (65.3%). The number of participants drinking water increased from 59 (81.9%) at baseline to 70 (97.2%) at week 4. This change is found to be statistically significant (p=0.001). In addition, the number of participants who drink powdered milk also increased from 20 (27.8%) to 57 (79.2%) from baseline to end line, respectively and this is statistically significant (p<0.001).

Digestive Health Questionnaire

The improvement of the participants' digestive system was assessed using the Digestive Health Questionnaire. The 72 participants were visited eight times during the 4-week duration of the study.

A. Bowel Habit

An increasing percentage of participants stated they were highly satisfied with their defecation frequency, stool characteristic, comfort during defecation and defecation duration as the number of days increased. There was a significant change over time in satisfaction with defecation frequency (χ^2=314.06, p<0.0001), stool characteristic (χ^2=329.26, p<0.0001), comfort during defecation (χ^2=307.30, p<0.0001) and defecation duration (χ^2=302.25, p<0.0001), on every visit. It was interesting to note that by day 10 of the intervention program, the percentage of participants who were jointly satisfied and highly satisfied with their defecation frequency, stool characteristics and defecation duration rose to 87%, 75% and 80%, respectively. There was a statistically significant improvement in satisfaction with bowel function; nearly 80% of women reported a noticeable improvement.

B. Improvement of Digestive System

Over the study course, a steady decline on the prevalence of abdominal bloating or distention (χ^2=143.31, p<0.0001), abdominal pain (χ^2=149.54, p<0.0001), heaviness in mid-abdomen (χ^2=143.25, p<0.0001), weighing down around the abdominal area (χ^2=147.30, p<0.0001) (Figure 3A), constipation (χ^2=219.86, p<0.0001), presence of gas or wind (χ^2=110.39, p<0.0001), pain or discomfort felt during a bowel motion (χ^2=180.74, p<0.0001), straining when passing a bowel motion (χ^2=197.53, p<0.0001), intestinal gurgling (xχ^2=138.17, p<0.0001), presence of poor appetite (χ^2=57.12, p<0.0001), and mid-abdominal discomfort (χ^2=153.42, p<0.0001) was observed. There was a statistically significant reduction with feeling constipated; over 50% felt less constipated within seven days of taking fortified milk powder. Moreover, by day 10, over 45% never felt strained when passing a bowel motion and over 40% never felt pain or discomfort during the bowel motion.

General Lifestyle Evaluation Form

During the whole study period, a significant improvement in the following items from the general lifestyle evaluation form were observed: feeling good in shape (χ^2=120.10, p<0.0001), feeling positive in physical wellbeing (χ^2=104.42, p<0.0001), feeling positive in emotional wellbeing (χ^2=93.19, p<0.0001), feeling positive about one's self (χ^2=70.52, p<0.0001), feeling in control of one's life (χ^2=79.69, p<0.0001), feeling confident in day to day activities (χ^2=70.65, p<0.0001), feeling that life as a mother is enjoyable (χ^2=19.08, p=0.008), feeling happy as a mother (χ^2=21.69, p=0.003),

feeling energized (χ^2=62.34, p<0.0001), feeling in shape to be the best mother one can be (χ^2=53.04, p<0.0001) and reduction in worrying about one's looks (χ^2=107.16, p<0.0001) and feelings of tiredness (χ^2=177.09, p<0.0001). There was a statistically significant change in self-rated feelings of good health and of feeling positive about themselves and their mental wellbeing, and about being in control of their lives. Around 40% of participants felt more positive about their health than at baseline (four separate measures all agreed). Nearly half of subjects were less worried about how they looked after only seven days and this was statistically significant and over a third of women felt less tired after seven days (statistically significant). By day 7 of taking the fortified milk powder, about 28% of the participants felt positive about their physical well-being all the time, and about 30% each felt positive about their emotional wellbeing and felt positive about themselves.

Two items on the General Lifestyle Evaluation Form specifically asked whether the participants felt trimmer and slimmer (a) or whether they felt lighter (b) around the middle of their abdomen since the study start. There was a statistically significant increase over time whether the participants felt trimmer and slimmer (χ^2=325.49, p<0.0001) and whether they felt lighter (χ^2=328.87, p<0.0001).

Bristol Stool Chart

Most of the participants started from a Type 2 (sausage-like but lumpy) Bristol stool category, and then at Day 3, the stool category became a Type 5 (soft blobs with clear-cut edges). It can also be noticed in the figure below that starting Day 3, participants with a Type 4 (like a sausage or snake, smooth and soft) stool increase gradually until Day 28. There was a statistically significantly different median assessment of the stool of the participants on every visit (χ^2=182.39, p<0.0001).

The responses of the participants for the Bristol Stool Chart was re-categorised into 1 (constipation), 2 (normal stool) and 3 (diarrhoea and urgency). At Day 0, although most of the participants are constipated, there are still some with stool categorized as normal. In Day 3, a high proportion of the participants had diarrhoea which slowly decreased until Day 24. At the end of the study, all the participants had normal bowel movement.

DISCUSSION

Constipation targets the population regardless of age group and gender. It is related to increasing age, female gender, lower socioeconomic status, low consumption of fibre and the western lifestyle (Mugie *et al.,* 2011). It is also associated with physical activity, limited education, a history of sexual abuse and symptoms of depression (Lembo *et al.*, 2003).

Several studies have shown that some probiotics are effective therapeutic agents in many different gastrointestinal disorders. Though the exact mechanism of how a probiotic helps in constipation is not clearly known, several hypotheses have been proposed. Firstly, a dysbiosis in the gut flora in constipated patients has been suggested to improve after the administration of probiotic bacteria (Picard *et al.*, 2005; Szajewska *et al.*, 2006). Furthermore, probiotics can lower the pH of the colon by producing lactic, acetic and other short chain fatty acids. A lower pH enhances colonic peristalsis and subsequently decreases colonic transit time (Picard *et al.*, 2005; Szajewska *et al.*, 2006).

In this study, at baseline majority of the participants (83.3%) constipation, and had difficulty in passing bowel motions wherein 83.3% took 5-10

minutes with strong pushing down and discomfort, difficult or small/hard defecation (56.9%). These symptoms affect the general health of the participants and can lead to intestinal obstruction, stercoral ulceration, mental disturbances, urinary retention, overflow diarrhoea and can result in megacolon leading to sigmoid volvulus, ischemic colitis, cecal perforation, rectal prolapse and even haemorrhoids (Toney *et al.*, 2008). This condition might have been aggravated by sedentary lifestyle (70.8%), and low consumption of high fibre foods as evidenced by the results of the food preferences of participants: white rice, fried foods, fish and meat, coffee and carbonated drinks. Coffee and carbonated drinks mostly have caffeine and contribute to constipation due to the diuretic effects of caffeine. Diuretics cause excretion of fluid through the kidneys, and can lead to dehydration, which may produce hard stools that are difficult to pass leading to constipation (Ignatavicius & Workman, 2013).

The administration of the probiotic – fibre-fortified milk powder reflected several positive effects that have been reported by the participants. There was a statistically significant improvement in satisfaction with bowel function; nearly 80% of women recorded a noticeable improvement. Moreover, at day 10, the percentage of participants who were satisfied to highly satisfied in terms of their defecation frequency, stool characteristics and defecation duration were 87%, 75% and 80%, respectively. Furthermore, based on the analysis of the digestive system questionnaire, there was a statistically significant reduction with feeling constipated with over 50% of the participants feeling less constipated within seven days of taking the fortified milk powder. Additionally, by day 10, over 45% never felt strained when passing a bowel motion and over 40% never felt pain or discomfort during the bowel motion. This is consistent with the results of a systematic review and meta-analysis of 14 studies with 1182 patients. It was revealed that overall, probiotics significantly reduced whole gut transit time by 12.4 h (95% CI: 222.3, 22.5 h) and increased stool frequency by 1.3 bowel movements/week (95% CI: 0.7, 1.9 bowel movements/week), Probiotics improved stool consistency (SMD: +0.55; 95% CI: 0.27, 0.82) (Dimidi, 2014). The addition of fibre in the milk might also have contributed to the significant improvement in gut health. Dietary fibre is commonly used in the treatment of patients with IBS. The proposed mechanism of action of fibre, in the treatment of IBS and constipation, is the acceleration of oroanal transit and a decrease in the intra-colon pressures (Camilleri *et al.*, 2002). The inulin fibre added in the milk is a natural fibre from plant. Inulin resist digestion in the upper gastrointestinal tract but are fermented in the colon. By increasing faecal biomass and water content of the stools, they improve bowel habits. (Roberfroid, 1993). Amongst others, one of the most promising effects is modulation of the activity of the colon which is more and more recognized to play an essential role in maintaining health and well-being as well as reducing the risk of diseases (Gibson & Roberfroid, 1995; Cummings, 1997).

Furthermore, there was a statistically significant change in self-rated feelings of good health and of feeling positive about themselves, mental, emotional wellbeing, and about being in control of their lives at endpoint: e.g. felt more positive about their health (40%) than at baseline; less worried about how they looked and felt less tired after seven days. Based on the analysis of the general lifestyle evaluation forms, women felt lighter, trimmer and slimmer most of the time just 10 days after taking the fortified milk powder. These results is in congruent with the

study in Canada where a combination of *Lactobacillus rhamnosus* CGMCC1.3724 (LPR), inulin and oligofructose helped to further reduce weight (2.7 kg) and total body fat mass (1.8%) during a weight-loss and weight maintenance period in women (Sanchez *et al.,* 2014). This improved well-being might have been due to the improvement in the function of the colon and significant reduction in experiencing the symptoms of functional constipation. It has been postulated that disturbances of the colon's functions may lead to dysfunction not only in the gut but also in the whole body. The colon has a major role in digestion (as achieved by the microbial fermentation) through the salvage of energy, and possibly nitrogen, from carbohydrate and protein not digested in the upper gut. But it also plays important roles in (Rowland, 1988; Berg, 1996; Cummings, 1997; Cummings & Macfarlane, 1997) the absorption of minerals and vitamins; the protection of the body against translocation of bacteria; the protection of the body against the *in situ* proliferation of pathogens; the regulation of intestinal epithelial cell growth and proliferation; the immune function (Roberfroid, 2005).

Based on the Bristol Stool Chart Analysis, a normalised bowel movement was reported at the end (28th day) of the study. Also, participants with ideal stools (Type 4, like a sausage or snake, smooth and soft) according to the Bristol Stool Chart increased gradually from baseline to the end of the study. This is in conformity with the previous findings from Sakai *et al.* (2011), who reported that three weeks treatment of fermented milk reduces incidence of hard lumpy stools among healthy subjects. Furthermore, it has been reported that probiotics soften the stools by increasing the secretion of water and electrolytes (Tabbers *et al.*, 2011). The fermentation process by probiotics in the intestine produces short-chain fatty acids that promote osmotic stimulation (Ribeiro *et al.,* 2012). Moreover, studies on healthy adults have also shown an increase in short-chain fatty acids and improvement in defecation conditions after the probiotic intake (Sanmugapriya *et al.,* 2013; Riezzo G *et al.,* 2012). So, softer stools along with improved intestinal peristalsis will probably relieve the symptoms of constipation. Again, the addition of fibre in the milk might have acted with the improvement in the defecation conditions.

CONCLUSION

The consumption of a probiotic and fibre-fortified milk powder might have contributed in alleviating functional constipation and the improvement in general health and wellbeing of the participants. Further studies should be conducted to confirm these results with better design by employing a randomised double blind trial.

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