

# Effect of Cultured Milk (Yakult) Versus Yogurt on Relief of Constipation Among Undergraduate Medical Student-Randomized Control Trial

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## Abstract

Constipation is one of the most common digestive complaints, with a prevalence of 5–20% in the general population and is defined by infrequent passage of hard stools usually 3 times or less in a week with complaint of straining, sensation of incomplete evacuation, perianal or abdominal discomfort. Many research has been done on the effect of probiotics on constipation, yet the research done is limited when comparing both yakult and yogurt together. Our research is to determine the effect of cultured milk (Yakult) in increasing stool frequency, improve stool consistency and relieving constipation compared to yogurt. A randomized controlled trial was conducted from May 2019 to June 2019 in private medical college, Malaysia. The sampling method done in our study was convenience sampling. A total of 30 students from 3<sup>rd</sup> and 4<sup>th</sup> year of the private medical college, Malaysia had voluntarily participated in this study. Block randomization was used to randomly assign the participants into 2 groups which were the intervention group and the control group where each group had 15 students. 80ml of cultured milk (yakult) was given to the participants in the intervention group and 125g of plain yogurt was given to the participants in the control group for 3 days continuously after their lunch. We followed up the participants for 3 days and asked if they were experiencing any side effects like nausea, abdominal cramp, bloating and flatulence during the study. After 3 days, any changes in the bowel habits according to the Bristol stool chart were noted. Our result showed that there was no significant difference between cultured milk (yakult) and the control group on relieving constipation at day-1 ( $P=0.361$ ), day-2 ( $P=0.999$ ) and day-3 ( $P=0.999$ ). However, there is a significant difference of Bristol score between before (mean 2.13, SD 0.52) and after (mean 3.81, SD 0.80) providing cultured milk (intervention group) ( $P<0.001$ ). Similarly there is a significant difference of Bristol score between before (mean 2.21, SD 0.56) and after providing yogurt (control group) (mean 3.56, SD 1.02) ( $P<0.001$ ). We can conclude that consuming probiotics does relieve constipation and it brought significant effect among the undergraduate medical students.

## Keywords

Cultured Milk, Yogurt, Constipation, Medical Students, Experiment

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## 1. Introduction

Constipation is the most common digestive complaint in the modern days which is also affected by the environment,

lifestyle, diet and medication with increasing prevalence of 5–20% in the general population representing a huge health care burden. [1, 2] Constipation is defined as infrequent passage of hard stools usually 3 times or less in a week,

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despite its frequency, it usually remains asymptomatic until the patients develop sequelae like straining, sensation of incomplete evacuation, perianal or abdominal discomfort. [3] Chronic complication does affects quality of life, with a significant impairment in both mental and physical aspect. It causes complications such as hemorrhoids, anal fissure, fecal impaction and rectal prolapsed. [4]

According to the Rome III criteria for constipation, a patient must have experienced at least 2 of the following symptoms over the preceding 3 months-Fewer than 3 bowel movements per week, straining, lumpy or hard stools, sensation of anorectal obstruction, sensation of incomplete defecation and manual maneuvering required to defecate. [5] There are many different causes of chronic constipation such as structural lesions of the colon (colon cancer, colon stricture or narrowing), medical conditions such as diabetes, hypertension, thyroid disorders, Parkinson's disease, or pregnancy. Medication is also one of the major causes of chronic constipation such as pain medications (narcotics), blood pressure medications (calcium channel blockers), anti-seizure medication, antispasmodics and calcium. [6] The management of functional constipation remains challenging.

Many researchers and health care centers have been working on the management of functional constipation, yet it remains challenging. Many intervention and medication such as bulking agents, osmotic laxatives, stimulant laxatives, and stool softeners has been used. [7, 8] However, it is reported that up to 47% of patients are not satisfied and compliance with such treatments, due to inconsistent symptom response and concerns regarding the safety, adverse effects, taste, inconvenience, and cost. [9]

Gut microbiota are important because it provides protective mechanism, however, it is responsible for certain pathologic disorders, such as colon cancer, multisystem organ failure, and inflammatory bowel diseases. [10, 11] A recent study also shows that intestinal microbiota may have impact against appetite-regulating peptide hormones and neuropeptides by producing autoantibodies. [12] Probiotics are food containing beneficial living microorganisms that are either the same or very similar to the bacteria that are already in our body. We consume to benefit our health by improving the balance of our intestinal flora. Any disruption and imbalance in the gut flora can caused constipation because it influences the peristalsis of the colon, similarly constipation can be improved by favorable modulation of the gut flora, therefore, probiotics is a safe and effective therapeutic option when it is administered in satisfactory amounts with patient suffering from constipation. [13-15]

A strict probiotic must meet the following requirements, such as, it is proven to be safe for human consumption, able to live

and multiply in our intestine, resistant to gastric and bile juice to reach the intestine alive, scientifically proven to have beneficial effects on our health, has optimum shelf life which able to remain alive in sufficient numbers throughout storage, remain to have correct concentration by the time of consumption and is affordable and easy to consume. [16-17] The majority of probiotic bacteria used in food production as functional ingredients are 'Lactic Acid Bacteria' such as species of *Lactobacillus* and *Bifidobacteria*. They are the most studied probiotics. [18] The Shirota strain has been specially selected for its strength as it has the ability to survive through our stomach and bile acids to reach the intestines alive to deliver its health benefits. Beneficial effects of *Lactobacilli* has been seen in constipation-related conditions. [19-21] Previous systemic review had found 14 studies that have met their criteria for a well-done study. It was a clinical trials where people with constipation was randomly assigned to consume either a placebo or probiotics. Based on the findings of their trials, researchers had establish that "gut transit time" was slowed down by probiotics on an average of 12.4 hours, the number of weekly bowel movements had increased by 1.3 times, stool was soften which makes them to pass easily. *Bifidobacterium* containing probiotics revealed to be the most efficacious.

The numbers of Malaysian who are taking Yakult were 22,000 on year 2004 according to the Yakult Annual Report. [23] Research has been done on the effect of probiotics on constipation yet the research done is limited when comparing both yakult and yogurt together. Both Yakult and yogurt helps to relieve constipation, therefore, the aim of our research is to determine the efficacy of cultured milk (Yakult) in increasing stool frequency, improve stool consistency and relieving constipation compared to yogurt.

## 2. Methodology

### 2.1. Study Design, Time, Setting and Population

A randomized controlled trial was conducted from May 2019 to June 2019 in a private medical college, Malaysia. The study was focused on semester 6 and semester 7 students which is around 300.

### 2.2. Sample Size

Quantitative outcome between the group given cultured milk (intervention group) and the group given yogurt (control group) was compared. The below formula was used to calculate sample size.

$$n \geq \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2/r)}{(\mu_1 - \mu_2)^2}$$

Alpha ( $\alpha$ )-0.05.

Beta ( $\beta$ )-0.2.

Mean of stool frequency in Group 1 ( $\mu_1$ )-4.1 [24].

Standard deviation in Group 1 ( $\sigma_1$ ) -1.7 [24].

Mean of stool frequency in Group 2 ( $\mu_2$ )-2.6 [24].

Standard deviation in Group 2 ( $\sigma_2$ )-1 [24].

Ratio (Group2/1)-1.

According to sample size calculator, minimum total sample size needed is 28.

Therefore our intervention group and control group both include 15 participants each.

A formula was also used to apply adjustments against the rate of attrition:

Attrition:

$$\begin{aligned} n_{final} &= \frac{n_{calculated}}{1 - attrition (\%)} \\ &= \frac{14}{1 - 0.9} \\ &= 15.56 (16) \end{aligned}$$

### 2.3. Sampling Method and Randomization

The sampling method done in our study was convenience sampling. It is a non-probability sampling method. A total of 30 students from 3<sup>rd</sup> and 4<sup>th</sup> year in the private medical college, Malaysia had voluntarily participated in this study.

The inclusion criteria for this study are the students who were having constipation problems. Constipation is defined as infrequent passage of hard stools usually 3 times or less in a week, despite its frequency, it usually remains asymptomatic until the patients develop sequelae like straining, sensation of incomplete evacuation, perianal or abdominal discomfort.

The exclusion criteria for this study were the students who smokes, consume alcohol, taking medications which can lead to constipation such as non-steroidal anti-inflammatory drugs (NSAIDs), iron and calcium supplements, tricyclic antidepressants (TCAs) and antidiarrheal drug like loperamide and those who had systemic diseases like hypertension, diabetes mellitus and others.

The method of randomization done in this study was the block randomization. The participants were randomly assigned into 2 groups which were the intervention group and the control group. Each group had 15 students. The

intervention group were given cultured milk (yakult) and the control group were given yogurt. Randomization was done using randomizer.org.

### 2.4. Intervention Procedure

We assembled 30 participants after the exclusion criteria and collected the participants demographic data like their age, gender and ethnicity. The participants were assigned into two groups according to the blocked randomization after explaining the procedure. One bottle of yakult (80ml) was given to each participant in the intervention group and one cup of plain yogurt (125gram) was given to each participant in the control group for 3 days continuously. We distributed the yakult and yogurt to the participants after their lunch for 3 days. We called every participant for 3 days continuously and asked if they were experiencing any side effects like nausea, abdominal cramp, bloating and flatulence during the study. After 3 days, any changes in the bowel habits according to the Bristol stool chart were noted to study the effect of yakult and yogurt on their constipation.

### Bristol Stool Chart








Type 1		Separate hard lumps, like nuts (hard to pass)
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 (passed easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces. Entirely Liquid

Figure 1. Bristol Stool Chart.

### 2.5. Data Collection

A total number of 30 students had participated in this study. The participants were assigned into 2 groups which were the intervention group and the control group by block randomization where each group consists of 15 students.

Each participant in the intervention group were given 1 bottle of yakult (80ml) and each participants in control group were given one cup of yogurt (125grams) to consume for 3 days consecutively. Then, participants were called individually for 3 days to find out if they were experiencing any side effects due to the yakult and yogurt during the study and also to check the progression of bowel habit after the consumption of yakult and yogurt.

The 2 groups in this study were Group 1 (Intervention group)-those who consume yakult for 3 consecutive days and Group 2 (Control group)-those who consume yogurt for 3 consecutive days.

As a first step in our study, a form was rotated among the students of 3<sup>rd</sup> and 4<sup>th</sup> year to find out the students who were suffering from constipation. Based on that form, 30 students who were suffering from constipation were chosen after the exclusion criteria. To start our intervention, the chosen 30 students as our sample size were assembled in a classroom in our campus and briefed shortly about our intervention study. As the participants participated on our study, each of the individual were given a set of questionnaire prepared by us after obtaining their consent and demographic data such as age, gender, and ethnicity were asked. Our questionnaire consisted of 3 parts. The first part is before we start the study to see if the participants are fit into our study. The second part is during the study for 3 days to find out if there were any side effect due to consumptions of yakult and yogurt and also to note the progression of bowel habit. The third part is after the study to find out the progression of bowel habit after the consumption of yakult and yogurt.

The dependent variables of our study were to measure the effect of yakult and yogurt on constipation. We focused on

assessing the overall improvement of the constipation. We explored the adverse effect, incidence and duration of any possible side effect of our intervention. The satisfaction of the participants is taken into consideration in our study.

## 2.6. Data Processing and Analysis

Data was entered using Microsoft Excel while Epi info Software (7<sup>th</sup> version) was used for the data analysis. Categorical variables was calculated using frequency and percentage while quantitative variables was measured using mean and standard deviation (SD). Mean and standard deviation (SD) were used to analyse age, fluid intake, coffee intake and hour of exercise. Frequency and percentage was calculated for categorical data which includes gender, ethnicity, family history of constipation and previous history of IBS. The p value and 95% confidential interval were calculated to locate any significance result. The level of significance,  $\alpha$  was set at 0.05. Unpaired T-test was used to analyse stool frequency and Chi-square test was used to analyse the overall improvement of yakult and yogurt on constipation, stool consistency and adverse effect experienced by the participants.

## 2.7. Ethical Consideration

All the participants were thoroughly instructed about the objective and procedure prior to the onset of the study. An informed consent sheet was provided to all the participants where they had to sign to confirm their voluntary participation. The participants were assured that the data collected will be kept confidential and used only for purpose of the study by the analyzers. The study was approved by the Research Ethics Committee, Faculty of Medicine, Melaka Manipal Medical College, Malaysia.

## 3. Results

**Table 1.** Baseline characteristics of the participant.

Variables	Yakult (n=15) Frequency (%)	Control (n=15) Frequency (%)	Total Frequency (%)
Age (years)			
Mean (SD)	22.00 (1.41)	22.40 (0.99)	23.44 (1.07)
Gender			
Male	8 (53.33)	6 (40.00)	15 (100)
Female	7 (46.67)	9 (60.00)	15 (100)
Ethnicity			
Malay	0 (0.00)	1 (6.67)	1 (3.33)
Chinese	2 (13.33)	8 (53.33)	10 (33.33)
Indian	8 (53.33)	4 (26.67)	12 (40.00)
Others	5 (33.33)	2 (13.33)	7 (23.33)
Exercise			
<30mins	1 (6.67)	1 (6.67)	2 (6.67)
30-1hr	4 (26.67)	5 (33.33)	9 (30.00)
1-2hrs	3 (20.00)	2 (13.33)	5 (16.67)
>2hrs	6 (40.00)	1 (6.67)	7 (23.33)
Daily fluid intake			
500ml-1L	5 (33.33)	8 (53.33)	13 (43.33)
1L-2L	9 (60.00)	7 (46.67)	16 (53.33)

Variables	Yakult (n=15) Frequency (%)	Control (n=15) Frequency (%)	Total Frequency (%)
>2L	1 (6.67)	0 (0.00)	1 (3.33)
Coffee (cups)			
No	8 (53.33)	9 (60.00)	17 (56.67)
1cup	6 (40.00)	4 (26.67)	10 (33.33)
2-3cups	1 (6.67)	2 (13.33)	3 (10.00)
Family history of constipation			
Yes	2 (13.33)	3 (20.00)	5 (16.67)
No	8 (6.67)	12 (80.00)	25 (83.33)
Previous history of IBS			
Yes	0 (0.00)	3 (20.00)	3 (10.00)
No	15 (100.00)	12 (80.00)	27 (90.00)

**Table 2.** Relieve of constipation and constipation assessed by Constipation Risk Assessment Scale.

Outcome Variables	Yakult (n=15) Frequency (%)	Control (n=15) Frequency (%)	Relative Risk (95%CI)	X <sup>2</sup>	P value
Day1 Constipation relieved					
Yes	11 (73.33)	13 (86.67)	0.85 (0.58 1.21)	0.83	0.361
No	4 (26.67)	2 (13.33)			
Day2 Constipation relieved					
Yes	13 (86.67)	13 (86.67)	1.00 (0.75 1.32)	0.00	0.999
No	2 (13.33)	2 (13.33)			
Day3 Constipation relieved					
Yes	14 (93.33)	14 (93.33)	1.00 (0.83 1.21)	0.00	0.999
No	1 (6.67)	1 (6.67)			
Constipation Risk Assessment Scale					
Experienced straining during at least 25% of defecations in the past 24 hours					
Yes	2 (13.33)	5 (66.67)	0.40 (0.02 1.75)	1.67	0.195
No	13 (86.67)	10 (33.33)			
Lumpy or hard stools in at least 25% of defecation in the past 24 hours					
Yes	4 (26.67)	3 (20.00)	1.33 (0.36 5.00)	0.19	0.666
No	11 (73.33)	12 (80.00)			
Sensation of incomplete evacuation for at least 25% of defecation in the past 24 hours					
Yes	4 (26.67)	2 (13.33)	2.00 (0.43 9.32)	0.83	0.361
No	11 (73.33)	13 (86.67)			
Sensation of anorectal obstruction/blockage for at least 25% of defecation in the past 24 hours					
Yes	0 (0.00)	0 (0.00)	-	-	-
No	15 (100.00)	15 (100.00)			
Manual maneuvers to facilitate at least 25% of defecation (eg digital evacuation, support of pelvic floor) in the past 24 hours					
Yes	4 (26.67)	3 (20.00)	1.33 (0.36 4.96)	0.1863	0.666
No	11 (73.33)	12 (80.00)			

**Table 3.** Stool frequency and consistency (Bristol score) between Intervention and Control.

Outcome Variables	Intervention (n=15) Mean (SD)	Control (n=15) Mean (SD)	Mean difference (95%CI)	t (df)	P value
Day 1 Stool frequency	1.18 (0.40)	1.77 (1.01)	-1.26 0.09	-1.80 (22)	0.085
Day 2 Stool frequency	1.15 (0.38)	1.69 (1.03)	-1.17 0.09	-1.77 (24)	0.090
Day 3 Stool frequency	1.21 (0.43)	1.64 (0.84)	-0.95 0.09	-1.70 (26)	0.101
Day1 Stool consistency (Bristol score)	3.18 (0.98)	3.54 (1.20)	-1.30 0.58	-0.79 (22)	0.439
Day2 Stool consistency (Bristol score)	3.85 (1.28)	3.38 (1.12)	-0.51 1.44	0.98 (24)	0.338
Day3 Stool consistency (Bristol score)	4.29 (1.07)	3.57 (0.94)	-0.07 1.50	1.88 (26)	0.071

**Table 4.** Adverse effect between intervention and control.

Adverse effect	Intervention (n=15) Frequency (%)	Control (n=15) Frequency (%)
Day 1		
Abdominal cramps (Yes)	1 (6.67)	2 (13.33)
Bloating (Yes)	0 (0.00)	6 (20.00)
Diarrhea (Yes)	2 (13.33)	3 (20.00)
Skin rashes (Yes)	0 (0.00)	0 (0.00)
Nausea/ Vomiting (Yes)	0 (0.00)	2 (13.33)
Flatulence (Yes)	2 (13.33)	4 (26.67)
Others (Yes)	0 (0.00)	0 (0.00)
Day 2		
Abdominal cramps (Yes)	1 (6.67)	2 (13.33)
Bloating (Yes)	1 (6.67)	2 (13.33)
Diarrhea (Yes)	0 (0.00)	3 (20.00)
Skin rashes (Yes)	0 (0.00)	0 (0.00)

Adverse effect	Intervention (n=15) Frequency (%)	Control (n=15) Frequency (%)
Nausea/ Vomiting (Yes)	2 (13.33)	1 (6.67)
Flatulence (Yes)	3 (20.00)	2 (13.33)
Others (Yes)	0 (0.00)	0 (0.00)
Day 3		
Abdominal cramps (Yes)	3 (20.00)	2 (13.33)
Bloating (Yes)	3 (20.00)	1 (6.67)
Diarrhea (Yes)	0 (0.00)	1 (6.67)
Skin rashes (Yes)	0 (0.00)	0 (0.00)
Nausea/ Vomiting (Yes)	0 (0.00)	1 (6.67)
Flatulence (Yes)	3 (20.00)	3 (20.00)
Others (Yes)	0 (0.00)	0 (0.00)

**Table 5.** At least one adverse effect on participants between Intervention and Control group.

Outcome Variables	Yakult (n=15) Frequency (%)	Control (n=15) Frequency (%)	Relative Risk (95%CI)	X <sup>2</sup>	P value
At least one adverse effect					
Yes	5 (35.71)	9 (60.00)	0.60 (0.26 1.35)	1.71	0.191
No	9 (64.29)	6 (40.00)			

## 4. Discussion

We carried out a Randomised Control Trial to find out the effect of cultured milk (Yakult) versus yogurt in relieving constipation among undergraduate students in a private medical college, Malaysia. There were total 30 participants, 15 participants were divided into intervention group (cultured milk-Yakult) and another 15 participants into control group (yogurt). The objectives of our study are to determine the efficacy of cultured milk (Yakult) in increasing stool frequency, improve stool consistency and relieving constipation compared to yogurt. From our hypothesis, cultured milk (Yakult) which is the intervention group has a higher efficacy in relieving constipation compared to control group (yogurt).

In our study, it was found that there was a overall relief of constipation in both groups, however there is no significant difference between the intervention (yakult) group and the control (yogurt) group in relieving constipation on all 3 days. Previous study about the effect of probiotic yogurt on constipation in pregnant women shown that constipation symptoms including straining, anorectal obstruction, manipulation to facilitate defecation, consistency of stool and colour of stool were improved significantly after receiving 300g of yogurt for four weeks. In addition, the amount of defecation was significantly increased in both groups, while incomplete evacuation was significantly reduced in the treatment group. [24]

This study showed that there were no significant difference between intervention (yakult) and control (yogurt) groups on stool frequency and consistency. Previous study done regarding Probiotic beverage containing *Lactobacillus casei* Shirota improves gastrointestinal symptoms in patients with chronic constipation, where 65mL of probiotic beverage containing *Lactobacillus casei* Shirota (LcS) was given over

a four-week period in patients with symptoms of chronic constipation. It was found that there was a significant improvement in constipation and stool consistency, starting in the second week of the intervention phase. [25]

We also compared the Bristol score before and after the intervention as well as control. It showed that the Bristol score were significantly higher in both the intervention (yakult) and control (yogurt) groups. Similar to our finding, previous study done on Fermented milk containing *Lactobacillus casei* strain Shirota reduces incidence of hard or lumpy stools in healthy population where 39 subjects with Bristol Stool Form Scale (BS) score <3.0 were randomized to fermented milk treatment for 3 weeks. The BS score was significantly improved after the treatment. [26]

We also found that there was no significant difference between cultured milk (Yakult) and yogurt in at least one adverse effect experienced by the participants. However, participants in intervention group (Yakult) experienced less adverse effect compared to the control group (yogurt). Previous studies on Probiotics Ameliorate Stool Consistency in Patients with Chronic Constipation measured the safety analysis in their participants had shown no harmful effect that could led to the termination of their trial. Tolerability was excellent in their study. [27]

Throughout the study, we have come across certain strengths and limitations on our research. The beneficial effects of this study were the constipation of the participants were relieved and there was an overall improvement in the stool consistency and stool frequency. Besides that, we also included caffeine intake, water intake, physical exercise, family history of constipation and previous history of Irritable Bowel Syndrome (IBS) which are affecting constipation in our study. We were not able to control the possible effect of other food intake that might cause constipation during our research. Moreover, due to time

limitation, only small number of the participants were recruited. Therefore, we recommend future researchers should devote attention to recruit a larger sample size and more diverse population. In our Randomised Control Trial (RCT), we were only able to follow the participant for 3 days due to time limitation where we would like to recommend the future researchers to conduct the study for a longer period of time so that they can further advance the results on the effect of probiotics on constipation. Our study only confined to the younger age group of participants so we recommend the future study should include an older age group of participants to address the knowledge of the population regarding the effect and benefits of probiotics on constipation can be improved.

## 5. Conclusion

As demonstrated in the study, both cultured milk and yogurt have an effect on relieving constipation. It was shown that both cultured milk and yogurt increase the frequency of evacuation and also improve the stool consistency according to the Bristol stool chart. They also felt less symptoms of constipation such as straining and sensation of incomplete evacuation after consuming cultured milk and yogurt. However there's no significant difference between the cultured milk group (Intervention) and yogurt (control) group on relieving constipation, but constipation was relieved significantly after the consumption of cultured milk and yogurt.

Hence, we can conclude that both cultured milk and yogurt have a significant effect on relieving constipation and improving bowel habits although there's no significant difference between cultured milk and yogurt.

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