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Supplementation of psyllium husk and selected herb mixture improves cardiovascular disease risk factors in female adults

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ABSTRACT

This study aims to determine the effects of the psyllium husk and selected herbs mixture supplementation consisting of *Garcinia cambogia*, *Quercus infectoria*, *Pueraria mirifica*, *Piper betle*, *Labisia pumila*, astaxanthin, marine collagen, ginger, and honey on health indicators among the female adults. A total of 24 female subjects were included in this randomized controlled study. The dosage of the supplement was 25 g/day for the supplement group (n = 12), while no supplement was given to the control group (n = 12) for 1 month. There was a significant decrease in body mass index (BMI) and total cholesterol/high-density lipoprotein cholesterol ratio in the supplement group as compared to the control group ($p < 0.05$). A significant increase in aspartate aminotransferase and alanine aminotransferase was observed in the supplement group ($p < 0.05$); however, the increases were within the normal range. In conclusion, 25 g/day of psyllium husk and selected herb mixture supplementation were able to demonstrate a beneficial effect on BMI in female adults. However, there was an undesirable effect on liver function tests, indicating potential liver toxicity after long-term consumption. Further studies should be carried out to verify this effect.

INTRODUCTION

Data from the Department of Statistics and Health Ministry show that the main cause of death in Malaysia was ischemic heart disease, reaching 13.2% in 2016 and increasing to 13.9% in 2017 (Mahidin, 2018). Malaysia is ranked sixth in the Asia Pacific region and the top country within Southeast Asia for both obesity and diabetes (Malaysia-Nutritional and Food Supplements, 2019). It is a serious non-communicable disease (NCD) that may contribute to cardiovascular disease and other chronic diseases. Nowadays, dietary supplements are a choice for upper-middle and high-income families in Malaysia to take charge of their health as well as decrease the risk of NCD (Malaysia-Nutritional & Food Supplements, 2019). However, health indicators such as body mass index (BMI), blood pressure, blood glucose, lipid profile, liver function test, and health indicator parameters should be monitored to determine the effects after supplementation.

Masood and Miraftab (2010) stated that dietary complements derived from plants are becoming more popular in the industry. Scientists are continually trying to develop novel ways of alleviating ills and finding new treatments for chronic diseases. Therefore, the increasing use of herbal supplements by the Malaysian population has become a pressing issue in Malaysia (Malaysia-Nutritional & Food Supplements, 2019). The psyllium husk and selected herb mixture is a combination of dietary supplements that may bring a variety type of benefits to human. Psyllium husk is a dietary fiber used to help in weight reduction due to its satiety effect and promote natural bowel movement to prevent constipation (Hefny *et al*., 2018). Herbs are crude plant materials such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes, or other plant parts and can be used in natural product supplements (World Health Organization, 2000).

Globally, herb mixtures are a common dietary supplement product. According to World Health Organization (2019), approximately 68% of adults use dietary supplements in the United States. There was a 9.1% growth in the food supplement market in Asia and the Pacific, accounting for 31.2% of people in 2013

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(AlTamimi, 2019). It is a lucrative industry, and consumers tend to buy such products for their health claims. The Malaysian Adults Nutrition Survey 2014 found that 28% and 34% of Malaysian adults reported consuming vitamin/ mineral supplements and food supplements, respectively (Mohd Zaki *et al*., 2018). Since there are no regulations for supplements in Malaysia, they are available in numerous places and sold without a prescription (Sedek *et al*., 2018). Maughan *et al*. (2004) reported that supplement users typically do not get medical advice. While supplements have the potential to be beneficial to health, they also have risks. Hence, the US Food and Drug Administration (FDA) (2017) has stated that it is important to have a safety and effectiveness authority for dietary supplement products before they are marketed.

In the present study, it is believed that psyllium husk and selected herb mixture have brought beneficial effects for female adults. The supplement consists of *Garcinia cambogia*, *Quercus infectoria*, *Pueraria mirifica*, *Piper betle*, *Labisia pumila*, astaxanthin, marine collagen, ginger, and honey. Singh (2015) stated that the astringent action of *Q. infectoria* can be used to treat uterine prolapse, leucorrhoea, and excessive uterine bleeding. A study by Suwanvesh *et al*. (2017) has shown that *P. mirifica* improved the signs of vaginal atrophy and restoring vaginal epithelium in postmenopausal women. Additionally, Salehi *et al*. (2019) stated that *P. betle* can be used to promote vaginal health, as well as reduce itching of the vagina. Furthermore, *L. pumila* is widely used by Malay women in Malaysia to ease childbirth as well as to treat postpartum illnesses (Ezumi *et al*., 2007; Choi *et al*., 2010). Therefore, this study aims to determine the effects of the psyllium husk and selected herbs mixture supplementation consisting of *G. cambogia, Q. infectoria, P. mirifica, P. betle, L. pumila,* astaxanthin, marine collagen, ginger, and honey on health indicators (BMI, blood pressure, blood glucose, liver function, lipid profile, and quality of life) among the female adults with cardiovascular disease risk factors, including high BMI and elevated lipid profiles (total cholesterol, LDL-cholesterol).

MATERIALS AND METHODS

Research design

A simple randomized controlled study was carried out in Universiti Malaysia Terengganu. Subjects were screened and recruited between August and September 2019. Charan and Biswas (2013) were used for sample size calculation for confidence level of 95% and precision was assumed to be 0.5. Subject inclusion criteria were female adults between 30 and 50 years old and BMI range with 21–32 kg/m^2. The range of BMI was chosen based on the mid-point for normal BMI range and the mid-point for obese class I. The age range was taken based on the mid-career age of females which generally can be started at 20 and last at 60 years old. A total of 76 adults were screened and 24 adults were recruited, as shown in Figure 1. Subjects were randomized using permuted block four randomizations with an allocation ratio of 1:1.

Research instrument

Body weight, height, blood pressure, blood glucose, and blood samples were taken twice before starting the intervention and after the 1-month intervention period. The body weight of subjects was measured using a weight balance (CAMRY, China). Height was determined using a portable stadiometer (SECA, Germany).

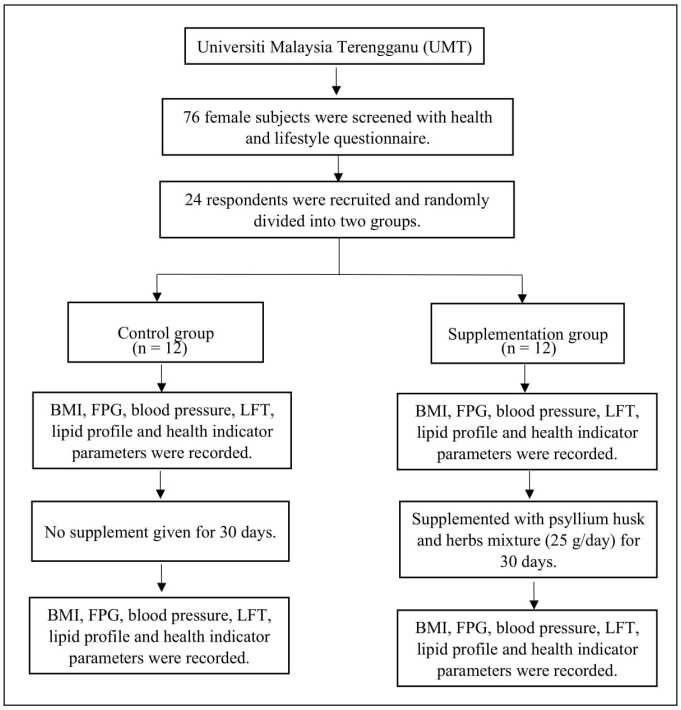

Figure 1. Sampling framework.

Systolic and diastolic blood pressure in mmHg were measured using automatic blood pressure monitors (Omron, Japan). Fasting blood glucose in mmol/l was measured using glucometer (Accu-Chek, Indiana). A 5-7 ml blood sample was taken from the subjects after 8–12 hours' fasting by medical personnel at the Universiti Malaysia Terengganu Health Centre. The blood was sent to an accredited lab to determine the results of the liver function test and lipid profile. A self-administered questionnaire was used in the present study. The three sections of the bilingual Malay and English questionnaire were used to obtain personal information, physical measurement, and health indicator parameters. Part A included personal information such as name, age, race, and origin state. Part B included physical measurements such as body weight, height, BMI, blood glucose, and blood pressure. Part C included health indicator parameters and physical and mental symptoms ranked from 1 to 5.

Statistical analysis

The data were analyzed using Statistical Package for Social Science version 23.0. The statistical analysis was performed by using the independent *t*-test and paired *t*-test (normal distribution) or Mann-Whitney *U* test and Wilcoxon's signed-rank test (nonnormally distribution). A 95% confidence interval was used in all analyses to indicate significant outcomes. The normality test was tested by the Shapiro-Wilk test, since the sample size was smaller than 50 (Shapiro and Wilk, 1965).

RESULTS

Baseline characteristics

A total of 24 female subjects were recruited and randomly allocated into two groups, with 12 subjects in the control group and 12 subjects in the supplement group. Subjects recruited

in this study were not diagnosed with any diseases and did not take any medication or supplementation. The median BMI was 27.7 and 27.3 for the control and supplementation groups, respectively, which were considered overweight. There were no significant differences in all the baseline parameters between the supplement group and control group although the subjects were randomly assigned into two groups (Table 1). Overall, the compliance was 100% and thus all subjects were included in the final analysis.

Anthropometric measurement

The present study found that there was a significant difference ($p < 0.050$) in BMI between baseline and after a 1-month intervention period in both groups as shown in Table 2. However, there was a significant increase ($p = 0.002$) in the BMI in the control group and a significant decrease ($p = 0.002$) in the BMI in the supplement group after the 1-month intervention period, respectively, as compared between the two groups (Table 3).

Blood pressure and blood glucose

The present study found no significant changes ($p > 0.05$) in systolic blood pressure (SBP) and diastolic blood pressure (DBP) in both groups at the end of the study (Tables 2 and 3).

It was found that there were no significant differences ($p > 0.05$) in fasting blood glucose (FPG) in both groups after the 1-month intervention period, as shown in Tables 2 and 3.

Liver function test and lipid profile

There were no significant differences ($p > 0.05$) in all the indicators in the liver function tests in both groups (Table 2). There was a significant increase in the absolute change of the AST ($p = 0.039$) and ALT ($p = 0.041$) in the supplement group (Table 3).

There were no significant differences ($p > 0.05$) in lipid profile in the supplement group, apart from high-density lipoprotein cholesterol (HDL-c) and TC/HDL-c ratio ($p < 0.05$) (Table 2). On the other hand, there were no significant differences ($p > 0.05$) in lipid profile in the control group, except for TC and HDL-c, as shown in Table 2. In addition, there was a significant decrease in absolute change ($p = 0.033$) and percentage change ($p = 0.039$) in TC/HDL-c ratio as compared between groups (Table 3).

Health indicator parameter

The present study found no significant changes to any health indicator parameters in both groups after the 1-month intervention, as shown in Table 4.

DISCUSSION

This study found a significant difference in BMI whereby there was an increase in absolute change by 0.32 kg/m^2 (+1.09%) in the control group and a decrease by 0.25 kg/m^2 (−-1.04%) in the supplement group. A study by Cicero *et al.* (2007) also demonstrated that the psyllium powder decreased BMI significantly (−0.8 ± 0.2) in 96 hypertensive overweight individuals after 4 months of supplementation. If the present study data is extrapolated for 4 months, BMI decreases by ≈−0.8 kg/m^2, similar to a previous study.

Although all respondents from the supplement group reported that the supplement gave them a satiety effect through an open-ended general comment section, a significant difference in the satiety score compared to the control group was not observed. This fiber-rich psyllium husk will slow down gastric emptying, decrease the speed of intestinal passage rates, and increase nutrient absorption in the small intestine (Wanders *et al*., 2011; Pal and Radavelli-Bagatini, 2012). Hence, the respondents might reduce their food intake portion size. Furthermore, all respondents from the supplement group also stated that their bowel movement improved after consuming the supplement based on open-ended general comments. Three respondents said that their stool excretion increased from once to twice daily as stated in the detailed information checklist and the other six respondents claimed that time spent for defecation was shortened. The improvement in the stool excretion process will increase the bile acid excretion and this will stimulate the liver to increase bile acid production instead of decreasing the fat absorption by body tissues (Romero *et al*., 2002).

Trippi (2017) reported that the hydroxycitric acid in *G. cambogia* will interrupt lipogenesis which prevents carbohydrates converted to fatty acids. Hence, it will reduce body fat accumulation and induced weight loss in human models (Kothadia *et al*., 2018). In summary, apart from the reduction of food intake portion size, an increase of the stool excretion as well as decrease of fat absorption in the body will induce to decrease in BMI.

The present study shows no effect of supplementation on SBP and DBP in both groups after a 1-month intervention period. Previous study reported no improvements in blood pressure in overweight and obese individuals after 12-week psyllium fiber supplementation with the dosage of 21 g/day (Pal *et al*., 2011b). The change in blood pressure may not be related to an increase in fibre, but the healthy diet intake may be a factor in affecting this parameter (Pal *et al*., 2011b).

As compared to four- and 6-month randomized psyllium fibre (10.5 g/day) supplementation study by Cicero *et al*. (2007), their results significantly reduced the SBP of 96 hypertensive overweight individuals by −3.1 ± 0.9 and −5.2 ± 1.3 mmHg, respectively. DBP was also significantly reduced by 2.2 ± 0.8 mmHg after 6 months of psyllium fibre supplementation (Cicero *et al*., 2007). In another study, Nurhaedar *et al*. (2017) reported that there was a significant reduction in SBP by 4.1% and in DBP by 9.1% after 4 weeks of honey supplementation in healthy individuals. If the present data are extrapolated for 4 months, the decrease in SBP is expected to be about −4 mmHg, which is similar to a previous study.

Based on the detailed information collected, 41.7% (five respondents) from the supplement group stated that they increased their physical activity during the intervention period. The increase in physical activity would bring the beneficial effect of reduction on SBP (Morgenstern *et al*., 2016). In summary, the blood pressure of the respondents in both groups was in a normal range; therefore, no lowering effect or undesirable effects were found in the 1-month study.

This study shows no effect of supplementation on the fasting blood glucose (FPG) levels in both groups after 1-month intervention period. In Pal *et al*.'s (2011a) study, glucose and insulin of psyllium group did not show significant change after 12 weeks supplementation (21 g/day) as compared to baseline (p-value > 0.05). Changes in insulin sensitivity would require a longer term and also the additional physiological properties of

Table 1. Subjects characteristics at baseline.

Measurement	Parameters	Control (n = 12)	Supplement (n = 12)	p value
Anthropometric	BMI (kg/m^2)	27.73 ± 3.76	27.29 ± 4.09	0.790*
Blood pressure	SBP (mmHg)	115.50 ± 14.06	119.25 ± 13.86	0.517*
	DBP (mmHg)	73.92 ± 7.90	76.75 ± 6.84	0.358*
Blood glucose	FBG (mmol/l)	4.90 (0.40)	5.03 ± 0.44	0.794**
Liver function test	Total protein (g/l)	79.67 ± 3.55	77.67 ± 5.03	0.273*
	Albumin (g/l)	45.17 ± 3.01	44.08 ± 1.68	0.288*
	Globulin (g/l)	34.50 ± 2.75	33.50 ± 3.94	0.479*
	A/G ratio	1.33 ± 0.15	1.33 ± 0.14	0.892*
	Total bilirubin (umol/l)	8.55 (6.10)	10.69 ± 4.21	0.632**
	SGOT/ AST (U/l)	16.50 (11.00)	18.50 (26.00)	0.163**
	SGPT/ ALT (U/l)	15.50 (34.00)	18.00 (65.00)	0.750**
	GGT (U/l)	48.50 (75.00)	28.50 (33.00)	0.298**
	ALP (U/l)	72.25 ± 14.49	67.75 ± 16.27	0.545*
Lipid profile	TC (mmol/l)	5.78 ± 0.94	5.56 ± 0.80	0.532*
	TG (mmol/l)	1.20 (1.48)	1.22 ± 0.42	0.544**
	HDL-c (mmol/l)	1.34 ± 0.35	1.22 ± 0.27	0.333*
	LDL-c (mmol/l)	3.73 ± 0.67	3.79 ± 0.60	0.824*
	TC/ HDL-c	4.58 ± 1.34	4.68 ± 1.03	0.826*
	Non-HDL-c (mmol/l)	4.44 ± 0.91	4.28 ± 0.77	0.648*
Health indicator parameters (Scale[a])	Weight loss	2.33 ± 1.15	2.00 (1.00)	0.854**
	Tired eye	2.00 (2.00)	2.75 ± 1.06	0.107**
	Early satiety	2.00 (1.00)	3.00 (1.00)	0.747**
	Diarrhea	2.00 (1.00)	2.00 (0.00)	0.278**
	Constipation	2.00 (1.00)	2.00 (1.00)	0.559**
	Headache	2.42 ± 1.08	2.67 ± 0.89	0.543*
	Joint pain	2.33 ± 0.98	2.58 ± 1.08	0.560*
	Gastric pain	2.00 (2.00)	2.00 (2.00)	0.854**
	Menstrual pain	2.00 (1.00)	2.00 (2.00)	0.321**
	A feeling of uselessness	1.00 (1.00)	1.00 (2.00)	0.253**
	Energetic	2.83 ± 1.19	3.42 ± 1.24	0.253*
	Difficulty of falling asleep	2.17 ± 1.03	2.58 ± 1.00	0.325*
	Lapse of memory	2.00 (2.00)	2.33 ± 0.98	0.502**
	Ability to concentrate	2.42 ± 1.00	2.25 ± 0.97	0.681*

Data are presented as mean ± SD or median (IQR) and p value > 0.05 indicates no significant difference by independent t-test* or Mann Whitney U test**.
If either one of the groups shows median value, non-parametric test was done instead.
[a] Scale: 1 = No symptoms occur; 2 = Symptom rarely present, 3 = Symptom sometimes present; 4 = Symptom often present; 5 = Symptom almost always present.

psyllium, such as the production of short-chain fatty acids (de Bock *et al*., 2012). Poor fermentation of psyllium in the production short-chain fatty acids as compared to other sources of dietary fiber will not improve insulin sensitivity, and this would not allow cells to use blood glucose more effectively (de Bock *et al*., 2012).

Arablou *et al*. (2014) stated that 12 weeks of ginger supplementation (1,600 mg/day) reduced blood glucose through blockage of serotonin receptors and inhibition of intestinal glucosidase and amylase enzyme activity. In addition, the regulation of serotonin levels by hydroxycitric acid from *G. cambogia* will decrease plasma insulin levels and generate a satiety effect in the brain, as well as suppress the appetite (Hayamizu *et al*., 2003; Ohia *et al*., 2001; Wielinga *et al*., 2005; Chuah *et al*., 2012).

The blood glucose of the respondents in the supplement group was in a normal range; therefore, the lowering effect or undesirable effect of the supplement in a 1-month study cannot be anticipated. In summary, 1-month supplementation is not enough to improve the blood glucose of the respondents and the beneficial effect will be shown if the subjects are diabetic rather than normal respondents.

Based on the absolute change in liver function test, supplementation significantly increased AST and ALT, both at absolute and percentage change, respectively as compared to the control group. Even though some respondents showed an increase in AST and ALT, but it is still in the normal reference range. High levels of the enzymes AST (>34 U/l) and ALT (>55 U/l) are

Table 2. Comparison between baseline and after 1 month within group.

Measurement	Parameters		Baseline	After	*p* value
Anthropometric	BMI	Control	27.73 ± 3.76	28.04 ± 3.97	*0.040[a]
		Supplement	27.29 ± 4.09	27.04 ± 4.29	*0.022[a]
Blood pressure	SBP	Control	115.50 ± 14.06	116.17 ± 16.74	0.788[a]
		Supplement	119.23 ± 13.86	118.00 ± 11.64	0.639[a]
	DBP	Control	73.92 ± 7.90	75.25 ± 9.20	0.634[a]
		Supplement	76.75 ± 6.84	77.67 ± 8.29	0.575[a]
Blood glucose	FPG	Control	4.90 (0.40)	4.85 (0.50)	0.269[b]
		Supplement	5.03 ± 0.44	4.95 ± 0.35	0.218[a]
Liver function test	Total protein	Control	79.67 ± 3.55	79.42 ± 4.06	0.793[a]
		Supplement	77.67 ± 5.03	78.67 ± 6.83	0.493[a]
	Albumin	Control	45.17 ± 3.01	44.25 ± 2.49	0.152[a]
		Supplement	44.08 ± 1.68	44.08 ± 2.58	1.000[a]
	Globulin	Control	34.50 ± 2.75	35.17 ± 3.30	0.331[a]
		Supplement	33.50 ± 3.94	34.58 ± 4.62	0.350[a]
	A/G ratio	Control	1.33 ± 0.15	1.28 ± 0.14	0.210[a]
		Supplement	1.33 ± 0.14	1.29 ± 0.12	0.295[a]
	Total bilirubin	Control	8.55 (6.10)	9.56 ± 5.18	0.859[b]
		Supplement	10.69 ± 4.21	8.70 ± 2.60	0.079[a]
	AST	Control	16.50 (11.00)	18.00 (10.00)	0.324[b]
		Supplement	18.50 (26.00)	23.00 (48.00)	0.105[b]
	ALT	Control	15.50 (34.00)	16.00 (14.00)	0.954[b]
		Supplement	18.00 (65.00)	28.50 (65.00)	0.285[b]
	GGT	Control	48.50 (75.00)	47.00 (52.00)	0.525[b]
		Supplement	28.50 (33.00)	33.00 (41.00)	0.931[b]
	ALP	Control	72.25 ± 19.49	67.00 ± 15.06	0.093[a]
		Supplement	67.75 ± 16.27	64.92 ± 19.09	0.126[a]
Lipid profile	TC	Control	5.78 ± 0.94	6.04 ± 0.96	*0.022[a]
		Supplement	5.56 ± 0.80	5.57 ± 0.89	0.927[a]
	TG	Control	1.20 (1.48)	1.53 ± 0.57	0.644[b]
		Supplement	1.22 ± 0.42	1.10 ± 0.44	0.226[a]
	HDL-c	Control	1.34 ± 0.35	1.48 ± 0.40	*0.033[a]
		Supplement	1.22 ± 0.27	1.48 ± 0.34	*0.001[a]
	LDL-c	Control	3.73 ± 0.67	3.88 ± 0.75	0.273[a]
		Supplement	3.79 ± 0.60	3.62 ± 0.72	0.288[a]
	TC/HDL-c	Control	4.58 ± 1.34	4.33 ± 1.29	0.127[a]
		Supplement	4.68 ± 1.03	3.92 ± 0.79	*0.001[a]
	Non-HDL-c	Control	4.44 ± 0.91	4.57 ± 0.90	0.307[a]
		Supplement	4.28 ± 0.77	4.10 ± 0.79	0.287[a]

Data are presented as mean ± SD or median (IQR).
[*] *p* value < 0.05 indicates significant difference by paired *t*-test[a] or Wilcoxon Signed Rank test[b].
If either one of the groups shows median value, non-parametric test was done instead.

present in the liver, and it could lead to liver damage, which this condition might cause by several factors such as infective agents, autoimmune disorders, and toxins (Blann, 2014).

The *G. cambogia* present in this supplement is a type of Hydroxycut product marketed for weight loss. Hydroxycut products have been associated with liver damage and one reported death, but reports on the liver toxicity of *G. cambogia* supplement are limited (Corey *et al*., 2016; Zheng and Navarro, 2015). It is an idiosyncratic form of injury, as high doses of hydroxycitric acid may be toxic to the liver. The possibility of mislabelling or adulteration with hepatotoxic herbal products is an issue in herbal-related injuries. Semwal *et al*. (2015) stated that regular use of *G. cambogia*

Table 3. Comparison between absolute change and percentage change between groups.

Measurement	Parameters		Control	Supplement	*p* value
Anthropometric	BMI	Absolute change	0.32 ± 0.47	−0.25 ± 0.33	*0.002[a]
		Percentage change	1.09 ± 1.60	−1.04 ± 1.44	*0.002[a]
Blood pressure	SBP	Absolute change	0.67 ± 8.37	−1.25 ± 8.98	0.594[a]
		Percentage change	0.54 ± 7.62	−0.66 ± 7.49	0.701[a]
	DBP	Absolute change	1.33 ± 9.44	0.92 ± 5.50	0.896[a]
		Percentage change	0.65 (8.72)	1.27 ± 7.43	0.840[b]
Blood glucose	FPG	Absolute change	−0.14 ± 0.24	−0.08 ± 0.22	0.538[a]
		Percentage change	−2.61 ± 4.38	−1.44 ± 4.27	0.516[a]
Liver function test	Total protein	Absolute change	−0.25 ± 3.22	−0.50 (5.75)	0.816[b]
		Percentage change	−0.27 ± 4.03	−0.66 (7.37)	0.908[b]
	Albumin	Absolute change	−0.92 ± 2.07	−0.50 (1.75)	0.518[b]
		Percentage change	−1.88 ± 4.43	−0.01 ± 4.17	0.298[a]
	Globulin	Absolute change	0.67 ± 2.27	0.50 (4.50)	0.907[b]
		Percentage change	2.01 ± 6.65	1.62 (14.27)	0.977[b]
	A/G ratio	Absolute change	−0.04 ± 0.11	−0.04 ± 0.13	1.000[a]
		Percentage change	−2.78 ± 7.84	−2.48 ± 9.87	0.936[a]
	Total bilirubin	Absolute change	−0.83 ± 2.69	−1.99 ± 3.57	0.379[a]
		Percentage change	−7.71 ± 34.06	−11.41 ± 32.45	0.788[a]
	AST	Absolute change	0.42 ± 5.07	4.50 (7.50)	*0.039[b]
		Percentage change	8.60 ± 19.97	26.58 ± 27.98	0.084[a]
	ALT	Absolute change	−0.50 (14.25)	5.50 ± 18.72	*0.041[b]
		Percentage change	−2.13 (27.43)	19.38 (77.40)	*0.024[b]
	GGT	Absolute change	−1.00 (24.50)	2.00 ± 10.14	0.236[b]
		Percentage change	−10.82 ± 22.20	5.12 ± 29.51	0.149[a]
	ALP	Absolute change	−5.50 (8.25)	−2.83 ± 5.92	0.505[b]
		Percentage change	−5.63 ± 11.83	−5.03 ± 8.89	0.890[a]
Lipid profile	TC	Absolute change	0.26 ± 0.33	0.02 ± 0.62	0.251[a]
		Percentage change	4.55 ± 6.11	0.63 ± 11.29	0.301[a]
	TG	Absolute change	−0.04 ± 0.49	−0.13 ± 0.34	0.621[a]
		Percentage change	5.98 ± 29.74	−8.34 ± 22.79	0.199[a]
	HDL-c	Absolute change	0.14 ± 0.20	0.27 ± 0.21	0.148[a]
		Percentage change	11.02 ± 14.94	22.70 ± 17.35	0.091[a]
	LDL-c	Absolute change	0.15 ± 0.45	−0.18 ± 0.54	0.125[a]
		Percentage change	4.28 ± 12.59	−4.73 ± 13.77	0.129[a]
	TC/HDL-c	Absolute change	−0.25 ± 0.52	−0.77 ± 0.59	*0.033[a]
		Percentage change	−4.58 ± 13.54	−15.51 ± 10.63	*0.039[a]
	Non-HDL-c	Absolute change	0.12 ± 0.40	−0.19 ± 0.58	0.141[a]
		Percentage change	3.18 ± 10.22	−3.54 ± 14.43	0.201[a]

Data are presented as mean ± SD or median (IQR) and *p value < 0.05 indicates significant difference by Independent t-test[a] or Mann Whitney U test[b].
If either one of the groups shows median value, non-parametric test was done instead. .

supplementation is associated with possible liver toxicity; however, the doses that cause hepatotoxicity is still unclear.

Besides, long-term intake and high doses usage of hydrolyzable tannins from *Q. infectoria* may cause negative health effects (Sariozlu and Kivanc, 2011). In addition, multi-ingredients formulation products are associated with more possible negative effects as compared to a specific ingredient (Semwal *et al*., 2015). Thus, in formulating a mixture of herb supplement, the dosage is a very important element to be considered. It can be concluded that there is an undesirable effect of this supplement on liver function, even though the increases were still in the normal reference range.

Both groups showed significantly increased HDL-c, with higher percentage (23% *vs.* 11%) in supplement group than in the control group. Therefore, it can be concluded that there is a benefit

Table 4. Comparison of health indicator parameters between baseline and after 1 month.

		Baseline	After	*p* value
Weight loss	Control	2.33 ± 1.15	2.00 (1.00)	0.758[b]
	Supplement	2.00 (1.00)	2.00 (1.00)	0.216[b]
Tired eye	Control	2.00 (2.00)	2.33 ± 1.30	0.762[b]
	Supplement	2.75 ± 1.06	2.42 ± 1.08	0.220[a]
Early satiety	Control	2.00 (1.00)	2.58 ± 1.24	0.688[b]
	Supplement	3.00 (1.00)	3.00 (1.00)	0.278[b]
Diarrhea	Control	2.00 (1.00)	2.00 (1.00)	1.000[b]
	Supplement	2.00 (0.00)	2.42 ± 1.17	0.419[b]
Constipation	Control	2.00 (1.00)	2.00 (0.00)	0.534[b]
	Supplement	2.00 (1.00)	2.33 ± 1.23	0.554[b]
Headache	Control	2.42 ± 1.08	2.50 ± 1.09	0.674[a]
	Supplement	2.67 ± 0.89	3.00 (1.00)	1.000[b]
Joint pain	Control	2.33 ± 0.98	3.00 (2.00)	0.950[b]
	Supplement	2.58 ± 1.08	2.17 ± 1.03	0.241[a]
Gastric pain	Control	2.00 (2.00)	2.08 ± 1.00	0.739[b]
	Supplement	2.00 (2.00)	1.00 (2.00)	0.389[b]
Menstrual pain	Control	2.00 (1.00)	2.08 ± 0.90	0.243[b]
	Supplement	2.00 (2.00)	1.00 (2.00)	0.387[b]
A feeling of uselessness	Control	1.00 (1.00)	1.00 (1.00)	1.000[b]
	Supplement	1.00 (2.00)	1.00 (1.00)	0.332[b]
Energetic	Control	2.83 ± 1.19	4.00 (1.00)	0.059[b]
	Supplement	3.42 ± 1.24	3.08 ± 1.08	0.417[a]
Difficulty of falling asleep	Control	2.17 ± 1.03	2.00 (2.00)	0.715[b]
	Supplement	2.58 ± 1.00	2.00 (1.00)	0.159[b]
Lapse of memory	Control	2.00 (2.00)	2.00 (2.00)	0.443[b]
	Supplement	2.33 ± 0.98	2.50 (1.00)	1.000[b]
Ability to concentrate	Control	2.42 ± 1.00	3.17 ± 1.19	0.069[a]
	Supplement	2.25 ± 0.97	2.33 ± 0.89	0.723[a]

Data are presented as mean ± SD or median (IQR) and p value > 0.05 indicates no significant difference by Paired t-test[a] or Wilcoxon Signed Rank test[b].
If either one of the groups shows median value, non-parametric test was done instead. .
Scale: 1 = No symptoms occur; 2 = Symptom rarely present, 3 = Symptom sometimes present; 4 = Symptom often present; 5 = Symptom almost always present.

of supplement in increasing the HDL-c with 25 g/day dosage of this supplement. A study of Ziai *et al*. (2005) reported that 10.2 g/day of psyllium supplementation among 57 patients with T2D showed significantly increased HDL-c (from 0.94 to 1.10 mmol/l) after 2 months of supplementation. Weight change significantly affects HDL-c concentrations, as HDL-c will increase with concurrent weight decreases (Dansinger *et al*., 2018). Additionally, astaxanthin can increase serum HDL-c in subjects with mild hyperlipidemia (Yoshida *et al*., 2010). In the present study, there was a significant reduction in BMI; this reduction in weight will significantly increase with HDL-c, and the presence of astaxanthin in the supplement may be a factor in increasing the HDL-c.

There was a significant decrease in absolute change and percentage change of TC/HDL-c ratio in both groups by 0.25 (–4.58%) and 0.77 (–15.51%), respectively. In a study by Soltanian *et al*. (2018), TC levels were significantly reduced by 0.56 mmol/l and HDL-c levels significantly increased by 0.10 mmol/l in T2D patients after 3 months of taking psyllium (10 g premixed in cookies twice per day) supplementation as compared to the baseline. If the present data are extrapolated for 3 months, the HDL-c can be increased by 0.65 mmol/l, which is higher than the previous study. Since there were changes in TC and HDL-c level in the present data, this result indicates a significant change on TC/HDL-c ratio. The TC/HDL-c ratio in both groups was shown at risk in the baseline data.

TC/HDL-c ratio was significantly reduced to the normal reference range (<4.50) in both groups (–16% *vs*. –5%). The intake of plant-based diets and Mediterranean-type diets may lead to a significant decrease in TC and LDL-c since the diet is a major contributor to reducing cholesterol (Heidemann *et al*., 2008; Capewell and Ford, 2011). In summary, the supplement still has the potential to control the increase in TC level and demonstrated an effect in lowering the TC/HDL-c ratio.

The respondents in the supplement group have shown improvement in "tired eye" (–6% *vs.* +21%), "joint pain" (–6% *vs.* 0%), and "menstrual pain" (–17% *vs.* 0%) as compared to the control group. Although there was little change in health indicator parameters during the 1-month period, positive changes were observed among respondents in the supplement group, who described their condition as improved. There is a significant deficit in health indicator parameters that persisted over time. White *et al.* (2016) stated that it is not enough to observe a change in a 6–month intervention period when the majority of patients are not newly diagnosed with Amyloid light-chain amyloidosis, particularly in a given sample. Hence, it can be concluded that a 1-month study duration is not enough to observe the change in health indicator parameters among the respondents in the supplement group.

CONCLUSION

It can be concluded that there are beneficial effects in reducing BMI and TC/HDL-c, along with an undesirable effect on liver function tests, especially in the AST and ALT levels, which might indicate potential liver toxicity after 1-month supplementation of 25 g/day of psyllium husk and mixed herb. Future studies should increase the duration of the intervention period to seek the optimum beneficial effects of the supplement.

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All authors made a substantial contribution to the conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit it to the current journal; gave final approval of the version to be published; and agreed to be accountable for all aspects of the work. All the authors are eligible as per the International Committee of Medical Journal Editors (ICMJE) requirements/guidelines.

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The authors report no financial or any other conflicts of interest in this work.

ETHICAL APPROVALS

The present study was approved by RMIC Human Ethics Committee, Universiti Malaysia Terengganu with reference number of UMT/JKEPHMK/2020/43. Consent forms were signed and collected from all study participants.

DATA AVAILABILITY

All data generated and analysed are included within this research article.

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