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Article

A dietary Intervention with a Synbiotic Beverage on Women with Type 2 Diabetes, Overweight and Obesity

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Abstract: *Introduction:* Non committable chronic diseases such as overweight and obesity are considered in high risk for type 2 diabetes. Around the world, there are 536.6 million people with diabetes. Mexico represents a high prevalence of these diseases. *Objective:* Evaluate the effect of a synbiotic beverage and a 12-week dietary intervention on body composition and biochemical parameters in women with T2D, overweight or obesity, to obtain an additional strategy as treatment. *Methods:* A double-blinded, randomized and experimental in a 12 week dietary intervention with a synbiotic fermented beverage with a $n=51$ women divided in 4 groups: G1 followed a moderate calorie-restricted diet, G2 did the same moderate calorie-restricted diet and a synbiotic, G3 took only the synbiotic and G4 consumed a placebo beverage. *Results:* The total mean of ages of the 4 groups was 42.90 ± 10.6 . The significant changes were in BMI ($P<0.001$), fat mass ($P<0.001$), HOMA-index ($P<0.001$) and serum insulin serum ($P<0.001$), after the 12 week dietary intervention, proving the effect of the synbiotic. *Conclusion:* Significant decreases in different body composition and biochemical profiles were proved showing the benefits of the beverage. Further research is needed in gut microbiota profile in this kind of participants.

Keywords: Synbiotic; fermented beverage; diabetes; overweight; obesity

1. Introduction

Nowadays, overweight and obesity are considered detonating risk factors for type 2 diabetes (T2D) (1). The global prevalence, in 2021, of T2D in adults is around 536.6 million people. It is estimated that the amount of this patients will increase up to 783.2 million in 2045 (2). Mexico is not the exception, since it is ranked in the 7th position around the world with T2D. According to the National Survey of Health and Nutrition (ENSANUT), that represents 12.4 million people with diabetes (3).

As it is known, there are proved ways to treat T2D, overweight and obesity. However, in recent years, emerged new alternatives to complete these treatments. The nutritional aspects of diets have revealed important premises by improving human's health, for example the intake of probiotics,

prebiotics and synbiotics. It is associated with weight loss, low glycemic index, low cholesterol levels; among others (4).

Probiotics are lived beneficial microorganisms, and prebiotics are non-digestible food ingredients that stimulate the growth and activity of bacteria in gut (5, 6). In this study a synbiotic was developed by using a Mexican fermented traditional beverage called “aguamiel”, proved in a previous study (7). It is defined as fresh drink from various species of Agave and it was used to decrease biochemical profiles and improve body composition. It is noted that dysbiosis is an alteration of gut microbiota homeostasis associated with chronic diseases (8, 9). Aguamiel works by reducing the concentration of soluble carbohydrates participating in the decrease of glycemic index by delaying gastric emptying and reducing starch availability (10).

Since the early stage of life, synbiotics (combination of prebiotics and probiotics), have shown a healthy influence and beneficial effects on obesity and T2D and several other metabolic diseases (11). Therefore, recent studies have proved that by giving certain doses of them have promising results specially when they are taken in T2D and obesity subjects (12-34). Even if, probiotics and synbiotics have showed positive effects on glycemic control and other metabolic parameters. Some studies have failed to prove these effects. Therefore, there is a need for a study to provide a comprehensive conclusion on these effects (35). Due to, the aim of this study is to evaluate the effect of a synbiotic beverage and a 12-week dietary intervention on body composition and biochemical parameters in women with T2D, overweight or obesity, to obtain an additional strategy as treatment.

2. Materials and Methods

The design of this study was longitudinal, prospective, double-blinded, randomized and experimental clinical trial. The sample was randomized by identifying similar factors between the groups, that gave them equally representation. Thereby, we intentionally generated a homogenous groups. This dietary intervention was approved by the ethical committee of the University [CEIUPAEP18/2021], Declaration of Helsinki and by The Mexican Health Law (36). The protocol was approved with the next ID code CON-BIOETICA21CEI00620131021. All the participants signed an informed consent. The inclusion criteria was; women between 30 and 50 years old, with overweight (BMI>25), obesity (BMI>30) and T2D, for about three years diagnosed according to the American Diabetes Association (ADA) criteria. They were under their own prescribed medical treatment. Participants that did not fulfill these were excluded. The first sample was 62 women having an attrition of 11 women ($n= 51$). The women that did not complete the dietary intervention were excluded due to the lack of participation, blood samples, interest and others. The study flowchart and enrollment are illustrated in Figure 1.

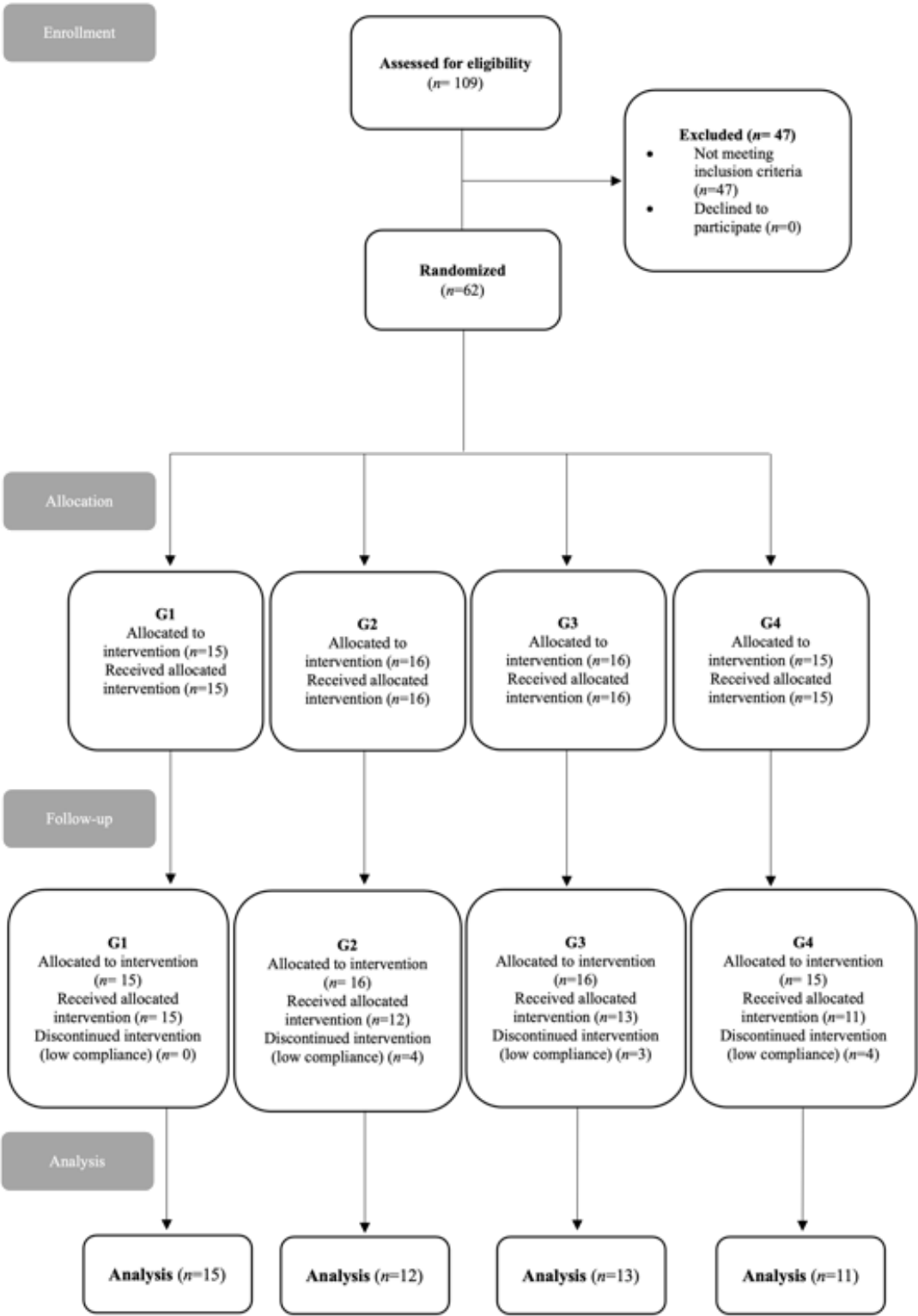


Figure 1. The study flow chart and enrollment.

In this dietary intervention a synbiotic Mexican fermented beverage was developed by diluted aguamiel (1:1 with water). It was pasteurized at 80°C for 30 minutes in a 30 L fermenter (Grainfather G30v3®), and inoculated with 0.5% of *L. plantarum* and *L. paracasei* with an optical density (OD) between 0.6 and 0.8. The mixture was incubated at 37°C for 48 hours. At the end of the incubation period, the concentration of bacteria in the synbiotic beverage was measured yielding 1×10^{10} CFU/mL \pm 130. This synbiotic beverage was used by a previous study by the same University (patent No. 371480) (7). A placebo beverage was also developed using rice water, acid citric and sweetener

fermented using Grainfather G30v3® pasteurized at 80°C for 30 minutes; bottling and letting them to cool off, after the process the bottles were kept in refrigeration (41°C).

The measurements were taken in two different times, at the beginning of the study and then 12-weeks after. Body composition parameters were measured; weight, height, BMI, waist-hip ratio and bioimpedance (TANITA BC-418). Also, biochemical profiles were tested; total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), triglycerides (TG), glucose, glycosylated hemoglobin (HbA1c), serum insulin and Homeostatic Model Assessment (HOMA) index.

The dietary intervention was done as it follows: The participants were assigned in four different groups, three experimental groups and a control group. Group one (G1) ($n=15$) followed a moderate calorie-restricted diet of 1500 kcal with a distribution of 50% of carbohydrates 30% of lipids and 20% of proteins. Group two (G2) ($n=12$) did the same moderate calorie-restricted diet and consumed 120 ml of a synbiotic Mexican fermented beverage, group three (G3) ($n=13$) took 120 ml of the synbiotic Mexican fermented beverage without a restricted diet or any other dietary intervention. Finally, group four (G4) ($n=11$) consumed 120 ml of the placebo beverage with the same organoleptic characteristics without a restricted diet or any other dietary intervention, being this the control one. All of the groups followed the same instructions for 12-weeks.

For this study statistical inference was performed using Software SPSS® and MINITAB®. $p < 0.05$ was considered statistically significant. The results were statistically evaluated by means of Pearson correlation tests (r^2), t test and average tests (ANOVA).

3. Results

From a total of 62 women, 11 were excluded from the research for reasons including; 5 did not complete the treatment, 2 did not get the fermented beverage on time, 4 did not get on time for the blood test. Therefore, 51 women (G1=15, G2=12, G3=13, G4=11) completed the study.

The following results were divided in the four different groups showing the beginning and the last measurements of body composition and biochemical profiles.

In table 1 the body composition parameters before and after the 12-week dietary intervention are shown as follows: For G1 there were some changes in the waist circumference ($M = 92.6$, $SD = 10.6$), $P=0.017$ and hip circumference ($M = 105.5$, $SD = 9.6$), $P=0.029$. For the BMI the results were ($M = 29.1$, $SD = 4.8$), $P=0.044$ and for fat mass ($M = 27.5$, $SD = 9.4$), $P=0.058$. These results showed the effectiveness of only the moderate calorie-restricted diet. For G2, as predicted, women got ($M = 76.3$, $SD = 12.2$), $P=0.015$ as significant loss of weight, reported perceiving a moderate calorie-restricted diet and consumed 120 ml of a synbiotic Mexican fermented beverage significantly more than the rest of the groups. The fat mass of G2 was the most statistical significance ($M = 39.1$, $SD = 5.5$), $P= 0.003$ of the four groups. The BMI of G2 reported statically greater significance ($M = 30.8$, $SD = 3.8$), $P < 0.001$ compared to G1 ($M = 29.1$, $SD = 4.8$), $P=0.044$. The waist circumference of G2 was found more statistical significance ($M = 97$, $SD = 10$), $P=0.006$ than G1 ($M = 92.6$, $SD = 10.6$), $P=0.017$. For G3, the only change was related to the hip circumference ($M = 104.3$, $SD = 12.2$), $P=0.051$ due that they only took the synbiotic Mexican fermented beverage. Nevertheless, for G4, there were not statistical significance changes.

Table 1. Body composition parameters before and after the 12-week intervention in the different groups.

Characteristic	G1			G2			G3			G4		
	Before	After	<i>p</i>	Before	After	<i>p</i>	Before	After	<i>p</i>	Before	After	<i>p</i>
Number	15			12			13			11		
Weight (kg)	74.5 (13.3)	73.6 (12.5)	0.105	77.7 (11.9)	76.3 (12.2)	0.015*	74.4 (13.2)	73.7 (13.1)	0.28	72.3 (10.9)	73.3 (12.0)	0.102
Waist circumference (cm)	95.2 (10.5)	92.6 (10.6)	0.017*	99.8 (11.3)	97 (10)	0.006*	97.5 (9.2)	94.9 (9.1)	0.099	92.7 (6.0)	92.8 (7.2)	0.475
Hip circumference (cm)	107.3 (11.3)	105.5 (9.6)	0.029*	110.1 (7.7)	108.8 (11.2)	0.183	107.9 (12.3)	104.3 (12.2)	0.051*	104.7 (8.4)	105.2 (6.4)	0.403
Waist-hip ratio	0.89 (0.06)	0.87 (0.05)	0.141	0.90 (0.07)	0.8 (0.06)	0.169	0.90 (0.07)	0.9 (0.08)	0.27	0.8 (0.06)	0.8 (0.06)	0.411
BMI	29.6 (5.1)	29.1 (4.8)	0.044*	31.7 (3.8)	30.8 (3.9)	<.001*	30.7 (4.5)	30.4 (4.7)	0.281	29.7 (2.4)	29.9 (3.1)	0.215
Fat mass (%)	39.5 (4.9)	38.7 (5.1)	0.074	41.6 (4.8)	39.1 (5.5)	0.003*	40.8 (4.8)	40.3 (4.7)	0.301	37.5 (4.2)	38.4 (3.7)	0.070
Fat mass (kg)	29.9 (8.5)	27.5 (9.4)	0.058*	32.7 (8.1)	30.9 (8.1)	<.001*	30.9 (9.1)	30.2 (9.0)	0.262	27.4 (6.6)	28.4 (7.1)	0.063
Fat free mass (%)	44.5 (5.7)	44.6 (5.7)	0.386	44.9 (4.6)	45.4 (4.6)	0.177	43.5 (4.6)	43.4 (5.0)	0.424	44.9 (5.4)	44.7 (5.3)	0.373
Total Body Water (%)	32.6 (4.1)	32.6 (4.2)	0.424	32.9 (3.4)	32.4 (4.1)	0.292	31.8 (3.4)	31.8 (3.6)	0.448	32.8 (4.0)	32.7 (3.9)	0.369

Note. N= 51. G= Group; BMI, Body Mass Index.; Results expressed as mean (SD: Standard Deviation); * $p<0.05$

For the biochemical profiles the following were reported (table 2); TC had a statistically significant ($M = 185.4$, $SD = 24.3$), $P < 0.006$ of the groups. LDL-C reported, the greatest statistically significant ($M = 94.2$, $SD = 19$), $P = 0.054$ compared to G1, G3 and G4.

Table 2. Biochemical profiles before and after the 12-week dietary intervention in the different groups.

Characteristic	G1			G2			G3			G4		
	Before	After	<i>p</i>	Before	After	<i>p</i>	Before	After	<i>p</i>	Before	After	<i>P</i>
Number	15			12			13			11		
TC (mg/dL)	202.5 (47.0)	198.4 (44.2)	0.548	197.2 (30.5)	185.4 (24.3)	0.006*	200.9 (33.2)	200.6 (32.5)	0.467	206.7 (72.0)	206.3 (64.4)	0.479
HDL-C (mg/dL)	38.2 (12.3)	35.8 (8.3)	0.251	38.13 (10.0)	33.8 (8.1)	0.01*	37.8 (10.0)	36.9 (7.0)	0.322	41.0 (9.4)	39.1 (9.9)	0.184
LDL-C (mg/dL)	95.5 (41.5)	110.4 (38.9)	0.012*	101.3 (22.3)	94.2 (19.0)	0.054*	97.6 (23.3)	112.4 (23.8)	0.034*	114.0 (60.0)	117.8 (55.1)	0.302
TG (mg/dL)	144.9 (131.6)	140.5 (73.4)	0.846	125.7 (62.3)	158.4 (75.0)	0.006*	149.2 (98.9)	149.1 (55.9)	0.498	118.3 (51.9)	125.7 (67.6)	0.338
Glucose (mg/dL)	77.3 (25.2)	109.6 (58.1)	0.021*	77.9 (33.7)	88.6 (13.1)	0.091	91.8 (26.2)	102.4 (55.3)	0.157	71.9 (10.8)	87.3 (11.3)	0.001*
HbA1C (mmol/mol)	48.3 (15.9)	48.6 (17.9)	0.438	46.5 (15.6)	46.7 (10.4)	0.479	48.0 (16.5)	48.7 (19.5)	0.271	41.7 (3.6)	40.8 (5.4)	0.31
Serum insulin (µIU/mL)	22.8 (21.4)	31.4 (22.3)	0.004*	14.2 (5.1)	14.2 (6.9)	0.489	24.7 (17.9)	17.3 (8.7)	0.093	12.5 (5.1)	13.9 (8.8)	0.312
HOMA index	4.0 (3.7)	9.1 (10.6)	0.033*	2.6 (0.98)	3.1 (1.8)	0.155	5.9 (5.4)	4.1 (2.5)	0.15	2.2 (1.1)	2.9 (1.9)	0.129

Note. N= 51. G= Group; TC, Total Cholesterol; HDL-C, High Density Lipoprotein Cholesterol, LDL-C, Low Density Lipoprotein Cholesterol; TG, Triglyceride; HbA1c, Glycosylated Hemoglobin; HOMA index, Homeostatic Model Assessment index.

Results expressed as mean (SD: Standard Deviation)

* p<0.05

For table 3 the correlation between the first weight measurement and the 12-weeks after measure was significant ($P < 0.005$). The table represents how several variables had a significant impact BMI ($P < 0.001$), fat mass (%) ($P < 0.001$), fat mass (kg) ($P < 0.001$). For the biochemical profiles it was found that the serum insulin showed statistically significant with the 12-weeks after measure weight ($P < 0.003$) and for the fat mass (kg) too ($P < 0.017$). HbA1C ($P < 0.008$) and serum glucose ($P < 0.049$) were statistically significant compare to waist-hip ratio.

Table 3. Pearson Correlation Coefficients (r²) for the relation of body composition parameters and biochemical profiles before and after the 12-week dietary intervention.

		Weight -B	Wc -B	Hc -B	WH-ratio -B	BMI-B	FTM (%) -B	FM (kg) -B	TC -B	HDL-C -B	LDL-C -B	Glucose -B	TG -B	HbA1C -B	SI -B	HOMA-I -B
Weight -A	r ²	0.971**	0.733**	0.853**	-0.096	0.834**	0.705**	0.913**	0.04	-0.072	0.154	-.319*	-0.126	-0.268	0.169	0.045
	p	<.001	<.001	<.001	0.504	<.001	<.001	<.001	0.778	0.616	0.282	0.023	0.379	0.057	0.237	0.754
Wc -A	r ²	0.688**	0.861**	0.632**	0.347*	0.730**	0.639**	0.708**	0.099	-0.049	0.153	-0.145	-0.006	-0.057	0.071	0.04
	p	<.001	<.001	<.001	0.013	<.001	<.001	<.001	0.488	0.731	0.283	0.31	0.965	0.693	0.622	0.78
Hc -A	r ²	0.798**	0.641**	0.852**	-0.212	0.822**	0.704**	0.801**	-0.032	0.015	0.005	-.343*	-0.066	-.319*	0.192	0.089
	p	<.001	<.001	<.001	0.135	<.001	<.001	<.001	0.823	0.919	0.973	0.014	0.645	0.023	0.176	0.535
WH-ratio -A	r ²	-0.107	0.324*	-0.24	0.727**	-0.072	-0.04	-0.079	0.181	-0.093	0.198	0.278*	0.093	0.366**	-0.152	-0.056
	p	0.456	0.02	0.089	<.001	0.617	0.781	0.582	0.204	0.514	0.164	0.049	0.514	0.008	0.286	0.694
BMI-A	r ²	0.787**	0.718**	0.808**	-0.051	0.958**	0.668**	0.785**	-0.031	-0.089	0.026	-0.216	-0.015	-.297*	0.078	0.022
	p	<.001	<.001	<.001	0.724	<.001	<.001	<.001	0.827	0.536	0.858	0.127	0.917	0.034	0.584	0.879
FTM (%) -A	r ²	0.703**	0.623**	0.729**	-0.073	0.698**	0.850**	0.806**	0.116	0.089	0.167	-0.196	-0.057	-0.183	0.209	0.179
	p	<.001	<.001	<.001	0.611	<.001	<.001	<.001	0.419	0.534	0.242	0.169	0.691	0.2	0.141	0.208
FM (kg) -A	r ²	0.881**	0.749**	0.839**	-0.053	0.848**	0.771**	0.892**	-0.015	-0.027	0.051	-0.229	-0.035	-0.188	0.209	0.122
	p	<.001	<.001	<.001	0.714	<.001	<.001	<.001	0.918	0.85	0.723	0.107	0.805	0.186	0.141	0.392
TC -A	r ²	-0.034	-0.074	-0.025	-0.043	-0.088	-0.029	-0.032	0.900**	0.227	0.754**	0.006	0.143	0.06	0.012	0.022
	p	0.815	0.605	0.861	0.763	0.539	0.842	0.822	<.001	0.109	<.001	0.965	0.318	0.674	0.932	0.879
HDL-C -A	r ²	-0.026	-0.084	0.03	-0.147	0.004	-0.014	-0.008	0.216	0.776**	0.197	0.012	-0.259	0.02	-0.004	0.036
	p	0.857	0.559	0.834	0.303	0.975	0.922	0.956	0.127	<.001	0.165	0.935	0.066	0.891	0.979	0.801
LDL-C -A	r ²	0.059	-0.032	0.053	-0.079	-0.032	0.015	0.043	0.841**	0.209	0.818**	-0.079	-0.07	-0.006	0.022	0.015
	p	0.68	0.823	0.71	0.579	0.823	0.918	0.764	<.001	0.142	<.001	0.579	0.626	0.968	0.878	0.914
TG -A	r ²	-0.146	0.084	-0.126	0.272	-0.011	-0.076	-0.129	0.202	-.308*	-0.104	0.244	0.679**	0.176	-0.066	-0.041
	p	0.308	0.56	0.377	0.054	0.938	0.596	0.367	0.156	0.028	0.466	0.085	<.001	0.216	0.645	0.774
Glucose -A	r ²	-0.117	0.089	-0.148	0.306*	-0.211	-0.112	-0.115	-0.016	-0.043	-0.053	0.465**	0.005	0.835**	0.109	0.119
	p	0.413	0.535	0.299	0.029	0.138	0.432	0.422	0.909	0.762	0.712	<.001	0.974	<.001	0.448	0.404
HbA1C -A	r ²	-0.136	0.095	-0.144	0.305*	-0.187	-0.055	-0.097	-0.036	-0.009	-0.035	0.540**	-0.074	0.870**	0.094	0.125
	p	0.34	0.506	0.313	0.03	0.189	0.702	0.497	0.802	0.947	0.808	<.001	0.604	<.001	0.512	0.381
SI -A	r ²	0.409**	0.234	0.337*	-0.114	0.271	0.215	0.333*	-0.009	0.016	-0.09	-0.227	0.037	0.003	0.639**	0.383**
	p	0.003	0.098	0.016	0.428	0.054	0.129	0.017	0.952	0.909	0.53	0.11	0.799	0.985	<.001	0.006
HOMA-I -A	r ²	0.283*	0.252	0.226	0.046	0.102	0.174	0.243	-0.001	-0.046	-0.068	-0.121	-0.006	0.350*	0.478**	0.246
	p	0.044	0.075	0.112	0.749	0.475	0.223	0.085	0.993	0.747	0.636	0.396	0.965	0.012	<.001	0.082

The Figure 2 showed that for serum insulin outcomes, G1 had a significantly higher mean than the other three groups. G1 box is in a higher range, indicating that both its median and quartiles are higher compared to the other groups.

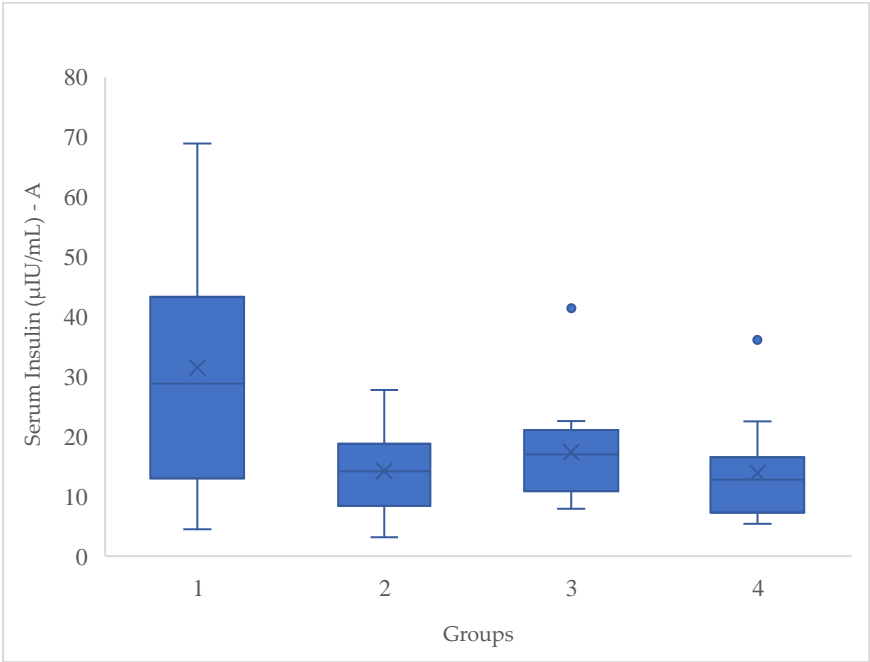


Figure 2. Post- Serum Insulin (µIU/mL) box and whisker plot.

The Figure 3 demonstrated, the post-HOMA index, G1 had a higher mean and median than the others. This group had a wider interquartile range, suggesting greater variability in results. G2 and G4 had ranges and distributions that were more similar to each other, both with lower means and medians than G1.

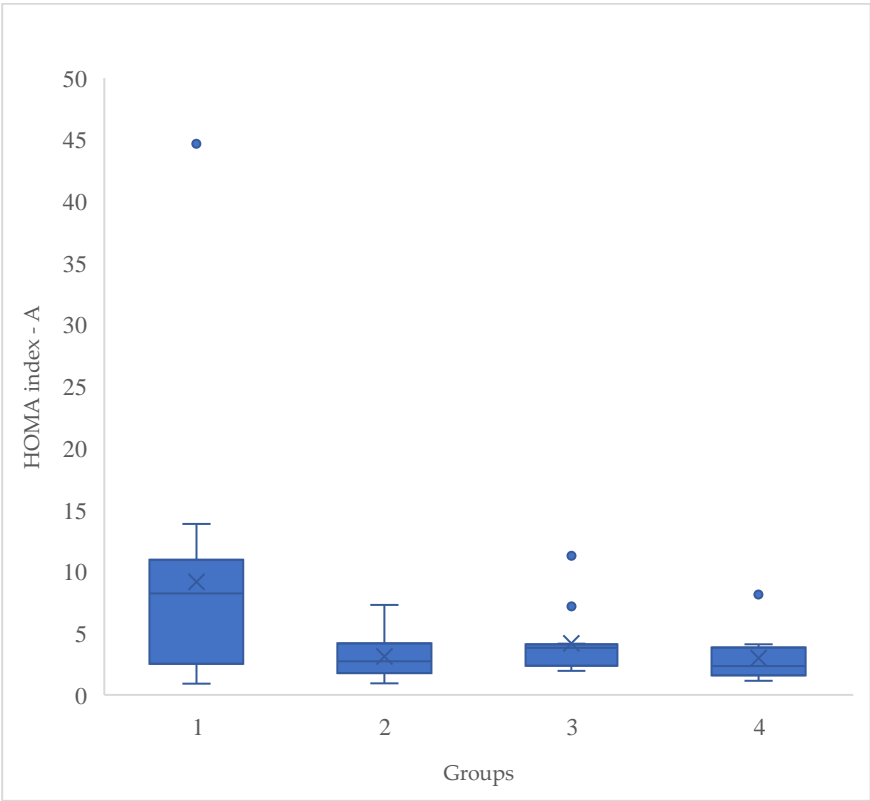


Figure 3. Post-HOMA index serum box and whisker plot. Note. HOMA index, Homeostatic Model Assessment index.

4. Discussion

The application of a synbiotic Mexican fermented beverage has proved its effects on body composition parameters and biochemical profiles which had been proved by several authors (37-43). In previous studies synbiotic fermented beverages were used as a supplementation to assess body composition, glycemic indices and lipid profiles which was the same in (40, 44). The duration of the dietary intervention in this study was 12 weeks likewise (39, 40, 43, 45, 46), this differs with Darvishi et al., (2020) that their dietary intervention was done in 8 weeks (47).

In our study, we found significant weight loss in only one group (G2) that was on moderate calorie-restricted diet and a synbiotic Mexican fermented beverage. Although, in G1 there were significant changes related to body composition such as; waist circumference, hip circumference, BMI and fat mass due to the moderate calorie-restricted diet. For G3 the only change was related to the hip circumference and the last group (G4) there were not changes. These findings suggested that moderate calorie-restricted diet and a synbiotic Mexican fermented beverage together have a synergistic effects (47, 48) among overweight, obesity and T2D individuals compared with moderate calorie-restricted diet without a synbiotic Mexican fermented beverage. One of the interesting points of our study was the impact in body composition trend between the G2 and the rest of the groups (G1 and G3).

According to findings of present trial, there were significant differences in weight loss which was different than Rabiei et al., (2019) and Othman et al., (2022). However, in several studies they got no significant differences (45-47, 49). Our results are in accordance with the findings reported by Jamshidi et al., (2022), Rabiei et al., (2019), Chaiyasut et al., (2021) and Darvishi et al., (2020) which showed significant differences changes in the BMI (45, 47, 50). For fat mass significant changes were reported on the contrary from different previous studies.

On the other hand, the findings on biochemical profile reported significant changes on HOMA-index and serum insulin only in one group in accordance with Othman et al., (2022) and Darvishi et al., (2020) that reported significant distinctions. However, this group was not the one on the synbiotic beverage. Thus, anthropometric variables were not significant differences in every group. Moreover, BMI, fat mass, HOMA-index and the serum insulin revealed significant distinctions due to the conditions how the study was done.

Our data confirmed that several other authors found before, where there is a promising associations with body composition. In present study, as described in results section the fermented beverage with synbiotics have contributed to considerable changes. It was also proved that the dose and duration of these beverage was adequate to positively change the body composition in our trial. As mentioned previously, Othman et al., (2022), the anthropometric variables did not have any significant distinctions (48). Our study also showed that when a weight-loss diet is accompanied with a synbiotic fermented beverage the decreases of several biochemical profiles such as HOMA-index and serum insulin will be significantly more than when a weight-loss diet is used alone. This could imply that the synbiotic beverage and associated serum insulin levels could be linked to maintaining a normal blood glucose levels in obesity (44).

There are controversial results on the efficacy of prebiotics/synbiotics in glucose levels some studies could not find these favorable effects likewise our results (35). They showed no significant effects on glycemic and lipid profiles such as (51-53). These controversial results might be a result of different probiotic strains and prebiotic types, clinical characteristics of the participants, the lack of appropriate instructions among others (35, 54, 55).

No other study is available about possible significant changes in Mexican population, proving that effect of these kind of beverages should be explored more in Latin population attributable to the high prevalence of non-committable diseases (56-58). There is a considerable call of clinical trials studies proving the efficacy of these Mexican fermented beverages due to the low price and accessible that these are in our country (56, 59).

5. Conclusions

The present study revealed that the use of Mexican fermented beverage in decreasing the BMI, fat mass, HOMA-index and serum insulin in women with overweight, obesity and T2D could be effective. In consideration of, these disorders have significant decrease by using a fermented beverage proving that symbiotics are suitable tools for chronic diseases.

It should be also considered that gut microbiota was not analyzed in our study and further researched must be done to analyze these. It is recommended that follow-up should be consider for participants in order keep them motivated to continue with the treatment. Further studies are needed to be conducted in the future to keep proving the benefits of synbiotic fermented beverages. In conclusion, there is still a need to prove the effects on the use of moderate calorie-restricted diet and a synbiotic Mexican fermented beverage in longer duration to decrease the biochemical profiles caused by the life styles, adherence to medical treatment, dietary habits, stress, physical activity, hormones among others. Using a synbiotic Mexican fermented beverage and a moderate calorie-restricted diet assessed significant potential benefits for these participants proving that it is an additional treatment for diabetes, overweight and obesity could be a possibility for future alternative treatments for non-committable diseases representing a low cost opportunity for health professionals in Mexico.

6. Patents

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Consent to participate statement: For this study an informed consent was obtained and signed by all the women. The final data and this consents are kept save by the main author.

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References

- Nianogo RA, Arah OA. Forecasting Obesity and Type 2 Diabetes Incidence and Burden: The ViLA-Obesity Simulation Model. *Front Public Health*. 2022;10:818816.
- Sun H, Saeedi P, Karuranga S, Pinkepank M, Ogurtsova K, Duncan BB, et al. IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. *Diabetes Research and Clinical Practice*. 2022;183.
- Shamah-Levy T R-MM, Barrientos-Gutiérrez T, Cuevas-Nasu L, Bautista-Arredondo S, Colchero MA, Gaona-Pineda EB, Lazcano-Ponce E, Martínez-Barnetche J, Alpuche-Arana C, Rivera-Dommarco J. . Encuesta Nacional de Salud y Nutrición 2021 sobre Covid-19. Resultados nacionales. 2021.
- Sáez-Lara MJ, Robles-Sanchez C, Ruiz-Ojeda FJ, Plaza-Diaz J, Gil A. Effects of Probiotics and Synbiotics on Obesity, Insulin Resistance Syndrome, Type 2 Diabetes and Non-Alcoholic Fatty Liver Disease: A Review of Human Clinical Trials. *Int J Mol Sci*. 2016;17(6).

- Cuamatzin-García L, Rodríguez-Rugarcía P, El-Kassis EG, Galicia G, Meza-Jiménez MdL, Baños-Lara MdR, et al. Traditional Fermented Foods and Beverages from around the World and Their Health Benefits. *Microorganisms*. 2022;10(6):1151.
- Probiotics in food : health and nutritional properties and guidelines for evaluation : Report of a Joint FAO/WHO Expert Consultation on Evaluation of Health and Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid Bacteria, Cordoba, Argentina, 1-4 October 2001 [and] Report of a Joint FAO/WHO Working Group on Drafting Guidelines for the Evaluation of Probiotics in Food, London, Ontario, Canada, 30 April -1 May 2002. Food, Agriculture Organization of the United N, World Health O, Joint FAOWHOECOEoH, Nutritional Properties of Probiotics in Food including Powder Milk with Live Lactic Acid B, Joint FAOWHOWGoDGftEoPiF, editors. Rome [Italy]: Food and Agriculture Organization of the United Nations, World Health Organization; 2006.
- Marquez Morales L, El Kassis E, Cavazos-Arroyo J, Rocha Rocha V, Martínez-Gutiérrez F, Pérez-Armendáriz B. Effect of the Intake of a Traditional Mexican Beverage Fermented with Lactic Acid Bacteria on Academic Stress in Medical Students. *Nutrients*. 2021;13.
- Devotee D, Contreras-Esquivel J. Aguamiel and its fermentation: Science beyond tradition. *Mexican Journal of Biotechnology*. 2018;3:1-22.
- Díez-Sainz E, Milagro FI, Riezu-Boj JI, Lorente-Cebrián S. Effects of gut microbiota-derived extracellular vesicles on obesity and diabetes and their potential modulation through diet. *J Physiol Biochem*. 2022;78(2):485-99.
- Negrete-Romero B, Valencia-Olivares C, Baños-Dossetti GA, Pérez-Armendáriz B, Cardoso-Ugarte GA. Nutritional Contributions and Health Associations of Traditional Fermented Foods. *Fermentation*. 2021;7(4):289.
- Li HY, Zhou DD, Gan RY, Huang SY, Zhao CN, Shang A, et al. Effects and Mechanisms of Probiotics, Prebiotics, Synbiotics, and Postbiotics on Metabolic Diseases Targeting Gut Microbiota: A Narrative Review. *Nutrients*. 2021;13(9).
- Salazar J, Angarita L, Morillo V, Navarro C, Martínez MS, Chacín M, et al. Microbiota and Diabetes Mellitus: Role of Lipid Mediators. *Nutrients*. 2020;12(10).
- Ortega MA, Fraile-Martínez O, Naya I, García-Honduvilla N, Álvarez-Mon M, Buján J, et al. Type 2 Diabetes Mellitus Associated with Obesity (Diabesity). The Central Role of Gut Microbiota and Its Translational Applications. *Nutrients*. 2020;12(9).
- Boscaiini S, Leigh SJ, Lavelle A, García-Cabrerizo R, Lipuma T, Clarke G, et al. Microbiota and body weight control: Weight watchers within? *Mol Metab*. 2022;57:101427.
- Wang D, Liu J, Zhou L, Zhang Q, Li M, Xiao X. Effects of Oral Glucose-Lowering Agents on Gut Microbiota and Microbial Metabolites. *Front Endocrinol (Lausanne)*. 2022;13:905171.
- Zhou Z, Sun B, Yu D, Zhu C. Gut Microbiota: An Important Player in Type 2 Diabetes Mellitus. *Front Cell Infect Microbiol*. 2022;12:834485.
- Craciun CI, Neag MA, Catinean A, Mitre AO, Rusu A, Bala C, et al. The Relationships between Gut Microbiota and Diabetes Mellitus, and Treatments for Diabetes Mellitus. *Biomedicines*. 2022;10(2).
- Wu D, Wang H, Xie L, Hu F. Cross-Talk Between Gut Microbiota and Adipose Tissues in Obesity and Related Metabolic Diseases. *Front Endocrinol (Lausanne)*. 2022;13:908868.
- Saleem A, Ikram A, Dikareva E, Lahtinen E, Matharu D, Pajari AM, et al. Unique Pakistani gut microbiota highlights population-specific microbiota signatures of type 2 diabetes mellitus. *Gut Microbes*. 2022;14(1):2142009.
- Liu W, Luo Z, Zhou J, Sun B. Gut Microbiota and Antidiabetic Drugs: Perspectives of Personalized Treatment in Type 2 Diabetes Mellitus. *Front Cell Infect Microbiol*. 2022;12:853771.
- Huda MN, Kim M, Bennett BJ. Modulating the Microbiota as a Therapeutic Intervention for Type 2 Diabetes. *Front Endocrinol (Lausanne)*. 2021;12:632335.
- Lazar V, Ditu L-M, Pircalabioru GG, Picu A, Petcu L, Cucu N, et al. Gut Microbiota, Host Organism, and Diet Trialogue in Diabetes and Obesity. *Frontiers in Nutrition*. 2019;6.
- New Insights on Obesity and Diabetes from Gut Microbiome Alterations in Egyptian Adults. *OMICS: A Journal of Integrative Biology*. 2019;23(10):477-85.

- Li WZ, Stirling K, Yang JJ, Zhang L. Gut microbiota and diabetes: From correlation to causality and mechanism. *World J Diabetes*. 2020;11(7):293-308.
- Pai C-S, Wang C-Y, Hung W-W, Hung W-C, Tsai H-J, Chang C-C, et al. Interrelationship of Gut Microbiota, Obesity, Body Composition and Insulin Resistance in Asians with Type 2 Diabetes Mellitus. *Journal of Personalized Medicine*. 2022;12(4):617.
- Megur A, Daliri EB-M, Baltriukienė D, Burokas A. Prebiotics as a Tool for the Prevention and Treatment of Obesity and Diabetes: Classification and Ability to Modulate the Gut Microbiota. *International Journal of Molecular Sciences*. 2022;23(11):6097.
- Włodarczyk M, Śliżewska K. Obesity as the 21st Century's major disease: The role of probiotics and prebiotics in prevention and treatment. *Food Bioscience*. 2021;42:101115.
- Gomes AC, de Sousa RG, Botelho PB, Gomes TL, Prada PO, Mota JF. The additional effects of a probiotic mix on abdominal adiposity and antioxidant Status: A double-blind, randomized trial. *Obesity (Silver Spring)*. 2017;25(1):30-8.
- Kim J, Yun JM, Kim MK, Kwon O, Cho B. Lactobacillus gasseri BNR17 Supplementation Reduces the Visceral Fat Accumulation and Waist Circumference in Obese Adults: A Randomized, Double-Blind, Placebo-Controlled Trial. *J Med Food*. 2018;21(5):454-61.
- Thiennimitr P, Yasom S, Tunapong W, Chunchai T, Wanchai K, Pongchaidecha A, et al. Lactobacillus paracasei HII01, xylooligosaccharides, and synbiotics reduce gut disturbance in obese rats. *Nutrition*. 2018;54:40-7.
- Farhangi MA, Javid AZ, Dehghan P. The effect of enriched chicory inulin on liver enzymes, calcium homeostasis and hematological parameters in patients with type 2 diabetes mellitus: A randomized placebo-controlled trial. *Primary Care Diabetes*. 2016;10(4):265-71.
- Razmpoosh E, Javadi A, Ejtahed HS, Mirmiran P, Javadi M, Yousefinejad A. The effect of probiotic supplementation on glycemic control and lipid profile in patients with type 2 diabetes: A randomized placebo controlled trial. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*. 2019;13(1):175-82.
- Kobyliak N, Falalyeyeva T, Mykhalchyshyn G, Kyriienko D, Komissarenko I. Effect of alive probiotic on insulin resistance in type 2 diabetes patients: Randomized clinical trial. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*. 2018;12(5):617-24.
- Ebrahimi Zs, Nasli-Esfahani E, Nadjarzade A, Mozaffari-khosravi H. Effect of symbiotic supplementation on glycemic control, lipid profiles and microalbuminuria in patients with non-obese type 2 diabetes: a randomized, double-blind, clinical trial. *Journal of Diabetes & Metabolic Disorders*. 2017;16(1):23.
- Mahboobi S, Rahimi F, Jafarnejad S. Effects of Prebiotic and Synbiotic Supplementation on Glycaemia and Lipid Profile in Type 2 Diabetes: A Meta-Analysis of Randomized Controlled Trials. *Adv Pharm Bull*. 2018;8(4):565-74.
- Salud Sd. Ley General de Salud. Artículo 54. "Reglamento Interno de Investigación en Salud". Consultado en: https://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf. 2014.
- Cuamatzin-García L, Rodríguez-Rugarcía P, El-Kassis EG, Galicia G, Meza-Jiménez ML, Baños-Lara MDR, et al. Traditional Fermented Foods and Beverages from around the World and Their Health Benefits. *Microorganisms*. 2022;10(6).
- Dimidi E, Cox SR, Rossi M, Whelan K. Fermented Foods: Definitions and Characteristics, Impact on the Gut Microbiota and Effects on Gastrointestinal Health and Disease. *Nutrients*. 2019;11(8).
- Zeinali F, Aghaei Zarch SM, Vahidi Mehrjardi MY, Kalantar SM, Jahan-Mihan A, Karimi-Nazari E, et al. Effects of synbiotic supplementation on gut microbiome, serum level of TNF- α , and expression of microRNA-126 and microRNA-146a in patients with type 2 diabetes mellitus: study protocol for a double-blind controlled randomized clinical trial. *Trials*. 2020;21(1):324.
- Karimi E, Heshmati J, Shirzad N, Vesali S, Hosseinzadeh-Attar MJ, Moini A, et al. The effect of synbiotics supplementation on anthropometric indicators and lipid profiles in women with polycystic ovary syndrome: a randomized controlled trial. *Lipids Health Dis*. 2020;19(1):60.
- Rasaei N, Heidari M, Esmaeili F, Khosravi S, Baeeri M, Tabatabaei-Malazy O, et al. The effects of prebiotic, probiotic or synbiotic supplementation on overweight/obesity indicators: an umbrella review of the trials' meta-analyses. *Front Endocrinol (Lausanne)*. 2024;15:1277921.

- Álvarez-Arraño V, Martín-Peláez S. Effects of Probiotics and Synbiotics on Weight Loss in Subjects with Overweight or Obesity: A Systematic Review. *Nutrients*. 2021;13(10).
- Chaiyasut C, Sivamaruthi BS, Kesika P, Khongtan S, Khampithum N, Thangaleela S, et al. Synbiotic Supplementation Improves Obesity Index and Metabolic Biomarkers in Thai Obese Adults: A Randomized Clinical Trial. *Foods*. 2021;10(7):1580.
- Rahimi F, Pasdar Y, Kaviani M, Abbasi S, Fry H, Hekmatdoost A, et al. Efficacy of the Synbiotic Supplementation on the Metabolic Factors in Patients with Metabolic Syndrome: A Randomized, Triple-Blind, Placebo-Controlled Trial. *Int J Clin Pract*. 2022;2022:2967977.
- Rabiei S, Hedayati M, Rashidkhani B, Saadat N, Shakerhossini R. The Effects of Synbiotic Supplementation on Body Mass Index, Metabolic and Inflammatory Biomarkers, and Appetite in Patients with Metabolic Syndrome: A Triple-Blind Randomized Controlled Trial. *J Diet Suppl*. 2019;16(3):294-306.
- Batu Z, Gök Balcı U, Akal Yıldız E. The Effect of Using Synbiotic on Weight Loss, Body Fat Percentage and Anthropometric Measures in Obese Women. *Progress in Nutrition*. 2021;23(2):e2021116.
- Darvishi S, Raftaf M, Asghari-Jafarabadi M, Farzadi L. Synbiotic Supplementation Improves Metabolic Factors and Obesity Values in Women with Polycystic Ovary Syndrome Independent of Affecting Apelin Levels: A Randomized Double-Blind Placebo - Controlled Clinical Trial. *Int J Fertil Steril*. 2021;15(1):51-9.
- Ben Othman R, Ben Amor N, Mahjoub F, Berriche O, El Ghali C, Gamoudi A, et al. A clinical trial about effects of prebiotic and probiotic supplementation on weight loss, psychological profile and metabolic parameters in obese subjects. *Endocrinol Diabetes Metab*. 2023;6(2):e402.
- Sergeev IN, Aljutaily T, Walton G, Huarte E. Effects of Synbiotic Supplement on Human Gut Microbiota, Body Composition and Weight Loss in Obesity. *Nutrients*. 2020;12(1).
- Jamshidi S, Masoumi SJ, Abiri B, Vafa M. The effects of synbiotic and/or vitamin D supplementation on gut-muscle axis in overweight and obese women: a study protocol for a double-blind, randomized, placebo-controlled trial. *Trials*. 2022;23(1):631.
- Greany KA, Bonorden MJ, Hamilton-Reeves JM, McMullen MH, Wangen KE, Phipps WR, et al. Probiotic capsules do not lower plasma lipids in young women and men. *Eur J Clin Nutr*. 2008;62(2):232-7.
- Sun L, Xie C, Wang G, Wu Y, Wu Q, Wang X, et al. Gut microbiota and intestinal FXR mediate the clinical benefits of metformin. *Nature Medicine*. 2018;24(12):1919-29.
- Tenorio-Jiménez C, Martínez-Ramírez MJ, Gil Á, Gómez-Llorente C. Effects of Probiotics on Metabolic Syndrome: A Systematic Review of Randomized Clinical Trials. *Nutrients*. 2020;12(1):124.
- Megur A, Daliri EB, Baltriukienė D, Burokas A. Prebiotics as a Tool for the Prevention and Treatment of Obesity and Diabetes: Classification and Ability to Modulate the Gut Microbiota. *Int J Mol Sci*. 2022;23(11).
- Ooi LG, Liong MT. Cholesterol-lowering effects of probiotics and prebiotics: a review of in vivo and in vitro findings. *Int J Mol Sci*. 2010;11(6):2499-522.
- Ojeda-Linares C, Álvarez-Ríos GD, Figueredo-Urbina CJ, Islas LA, Lappe-Oliveras P, Nabhan GP, et al. Traditional Fermented Beverages of Mexico: A Biocultural Unseen Foodscape. *Foods*. 2021;10(10).
- Márquez-Morales L, El-Kassis EG, Cavazos-Arroyo J, Rocha-Rocha V, Martínez-Gutiérrez F, Pérez-Armendáriz B. Effect of the Intake of a Traditional Mexican Beverage Fermented with Lactic Acid Bacteria on Academic Stress in Medical Students. *Nutrients*. 2021;13(5).
- García-Arce ZP, Castro-Muñoz R. Exploring the potentialities of the Mexican fermented beverage: Pulque. *Journal of Ethnic Foods*. 2021;8(1):35.
- Romero-Luna HE, Hernández-Sánchez H, Dávila-Ortiz G. Traditional fermented beverages from Mexico as a potential probiotic source. *Annals of Microbiology*. 2017;67(9):577-86.

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