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Research Article

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Short-Chain Fructooligosaccharides Improve Gut Microbiota Composition in Patients with Type 2 Diabetes. A randomized, Open-Label, Controlled Pilot Clinical Trial

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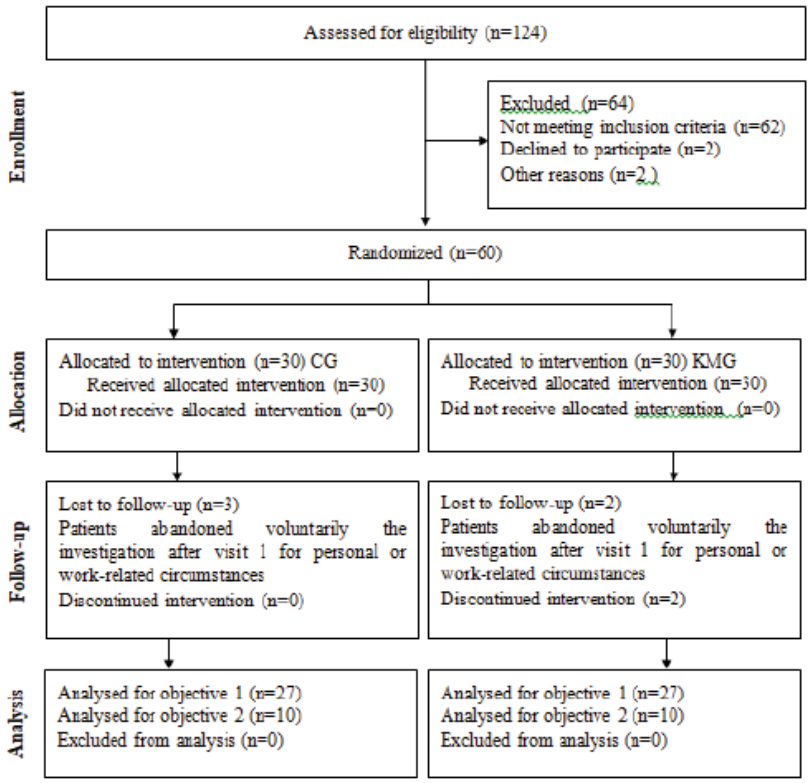

Figure 1: Figure 1 CONSORT Flow Diagram (Moher, Hopewell et al. 2012). Objective 1: Investigate if KestoMix improve or affect clinical parameters associated to T2DM like glicated hemoglobin A1c (HbA1c), fasting blood glucose (FBG), postprandial glucose – 2h (PPG), insulin; total cholesterol (Tc), triglycerides (TG), low-density lipoprotein cholesterol (LDL-c) and high-density lipoprotein cholesterol (HDL-c). Objective 2: Evaluate the effect of KestoMix, on the microbiome composition of patients diagnosed with T2DM

Table 1: Anthropometric and physiological data for the participants at baseline and the end of the KestoMix intervention.

	CG		KMG					
	Day 1	Day 84	Day 1	Day 84	p^1	p^2	p^3	p^4
	n = 27		n = 28		-			
T2DM Medication								
M	10		12					
Insulin	2		7					
M + Insulin	7		1					
G + I/M	6		3					
No Medication	2		5					
Metric								
Sex (m/f)	13/14		14/14		-	-	-	-
Age (years)	56.4 (54.1-58.7)		58.0 (56.0-59.9)		0.29	-	-	-
High (m)	1.66 (1.62-1.70)		1.67 (1.63-1.71)		0.89	-	-	-
Weight (kg)	85.1 (79.1-92.7)	83.0 (77.3-89.1)	83.0 (77.0-89.5)	82.9 (77.3-89.0)	0.55	0.98	0.00	0.93
BMI	30.8 (28.7-33.1)	29.8 (28.0-31.8)	29.7 (27.7-31.9)	29.6 (27.6-31.9)	0.45	0.89	0.00	0.91
FBG	7.4 (6.6-8.3)	7.9 (7.2-8.7)	7.0 (6.0-8.1)	7.2 (6.4-8.0)	0.6	0.08	0.12	0.71
PPG	10.6 (9.3-12.1)	11.1 (9.5-13.0)	10.7 (8.7-13.1)	10.1 (8.8-12.4)	0.92	0.45	0.48	0.4
HbA1c	7.2 (6.6-7.8)	7.1 (6.4-7.9)	6.9 (6.2-7.8)	7.1 (6.4-7.9)	0.74	0.44	0.92	0.67
Insulin	16.4 (12.0-22.6)	18.0 (14.3-22.5)	19.2 (14.0-26.4)	15.8 (11.8-21.3)	0.39	0.79	0.33	0.19
HOMA-IR	4.2 (2.9-6.1)	5.3 (3.9-7.0)	3.7 (2.7-5.2)	3.6 (2.6-5.0)	0.54	0.91	0.09	0.72
LPS	0.42 (0.29-0.54)	0.30 (0.21-0.40)	0.36 (0.30-0.41)	0.39 (0.33-0.46)	0.29	0.10	0.02	0.33
Tc	4.4 (4.1-4.6)	5.1 (4.7-5.4)	4.8 (4.4-5.2)	4.7 (4.3-5.2)	0.09	0.25	0.00	0.76
LDL-c	2.7 (2.5-3.0)	3.4 (3.1-3.8)	3.2 (2.8-3.7)	2.6 (2.2-3.0)	0.10	0.00	0.00	0.00
HDL-c	1.1 (1.0-1.2)	1.1 (1.0-1.2)	1.1 (1.0-1.2)	1.0 (0.9-1.1)	0.56	0.53	0.21	0.12
TG	1.9 (1.6-2.2)	1.1 (1.0-1.3)	1.5 (1.2-1.9)	1.3 (1.0-1.7)	0.04	0.42	0.00	0.31

Values represent Mean (95% confidence interval); M, Metformin; M + Insulin, combination of Metformin and Insulin; G + I/M, combinations of Glibencamine and Metformin or Insulin. (m/f) male/female; BMI, body mass index (kg/m²); HbA1c (kg/m²); FBG (mmol/L); PPG (mmol/L); Insulin (µU/mL); LPS (EU/mL); Tc (mmol/L); LDL-c (mmol/L); HDL-c (mmol/L); TG (mmol/L). Values are mean ± SD. p^1 Unpaired t-tests comparison between KMG and CG Day 1; p^2 Unpaired t-tests comparison between KMG and CG day 84; p^3 Paired t-tests comparison between day 1 and 84 of CG and p^4 Paired t-tests comparison between day 1 and 84 of KMG; Significance difference $p \leq 0.05$.

FBG and PPG were also measured at day 1, 28, 56 and 84 (Figure 2) and they were analyzed with the two-way Repeated Measure ANOVA. The Mauchly's test of Sphericity was not significant neither for FBG (p=0.142) nor PPG (p=0.481). The comparison between the intra-subject factor (time) with sphericity assumed showed no difference for FBG (p=0.081) or PPG (p=0.937). The Box's M test for inter-group comparison showed homogeneity of covariance matrices, p=0.079 and p=0.172 for FBG and PPG, respectively. Then, comparison between CG and KMG showed not significant differences for FBG (p=0.338) nor PPG (p=0.764).

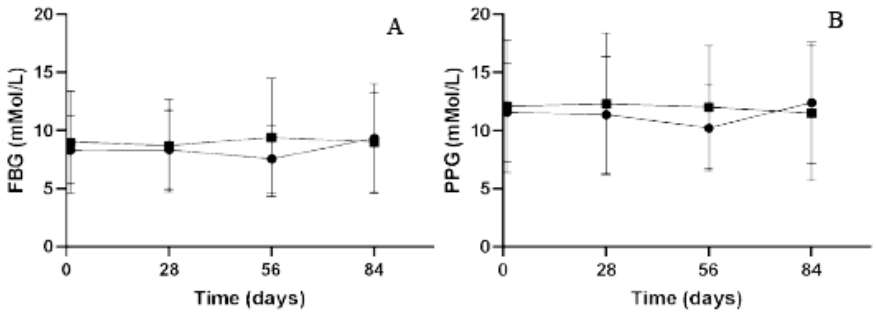

Figure 2: Variation of FBG (A) and PPG (B) in type 2 diabetic patients during 84 days of trial. Values represent mean ± standard deviation of CG (●) and KMG (■).The comparison between the intra-subject factor (time) showed no difference for FBG (p=0.081) nor PPG (p=0.937). The comparison between CG and KMG showed not significant differences for FBG (p=0.338) nor PPG (p=0.764). Two-way Repeated Measure ANOVA.

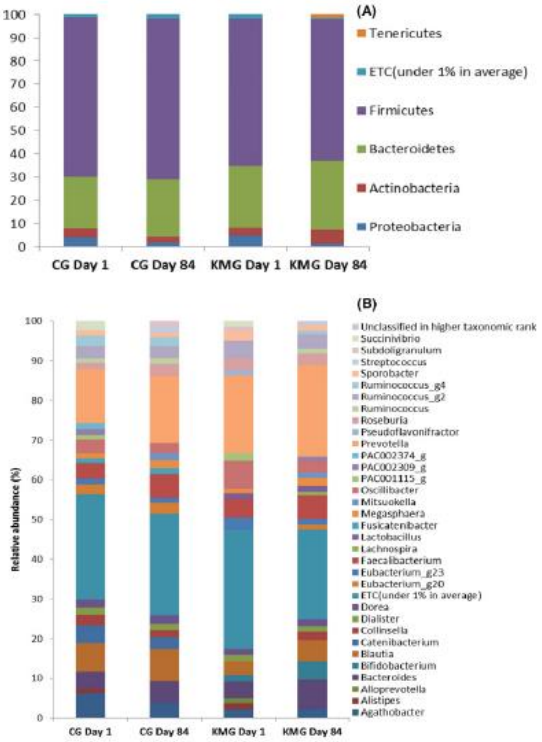

Figure 3: The relative abundance of gut bacteria found within metagenome datasets by phenotype. The relative abundance of major phyla (A) and genera (B).

Citation: Gissel García, Duniesky Martínez, Josanne Soto, Lays Rodríguez, Maricela Nuez, Noraika Domínguez, Emilio F. Buchaca, Carlos Hernández, Alina Sobrino, Enrique R. Pérez, Raúl J. Cano. Short-Chain Fructooligosaccharides Improve Gut Microbiota Composition in Patients with Type 2 Diabetes. A randomized, Open-Label, Controlled Pilot Clinical Trial. Journal of Biotechnology and Biomedicine. 6 (2023): 244-258.

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Metabolic Shifting Probiotic in Type 2 Diabetes Mellitus Management: Randomized Clinical Trial

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Table 1: Distribution of Patients according to Demographic Characteristic (sex and age), Nutritional Assessment and Kind of Treatment.

Demographic Variables		SS cohort (n = 30)		Placebo (n = 27)		P Value
		No.	%	No.	%	
Sex	Female	18	60	14	51.9	0.725a
	Male	12	40	13	48.1	
Age	Media ± SD	56.3 ± 6.7		53.2 ± 7.6		0.120b
Nutritional Assessment	Normal weight	3	10	5	18.5	0.722a
	Overweight	16	53.3	8	29.6	
	Obesity	11	36.7	14	51.9	
Kind of Treatment	Diet	3	10	2	7.4	0.549a
	Diet plus oral hypoglycemic agents	19	63.3	15	55.6	
	Insulin	0	0	2	7.4	
	Combined treatment	8	26.7	8	29.6	

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

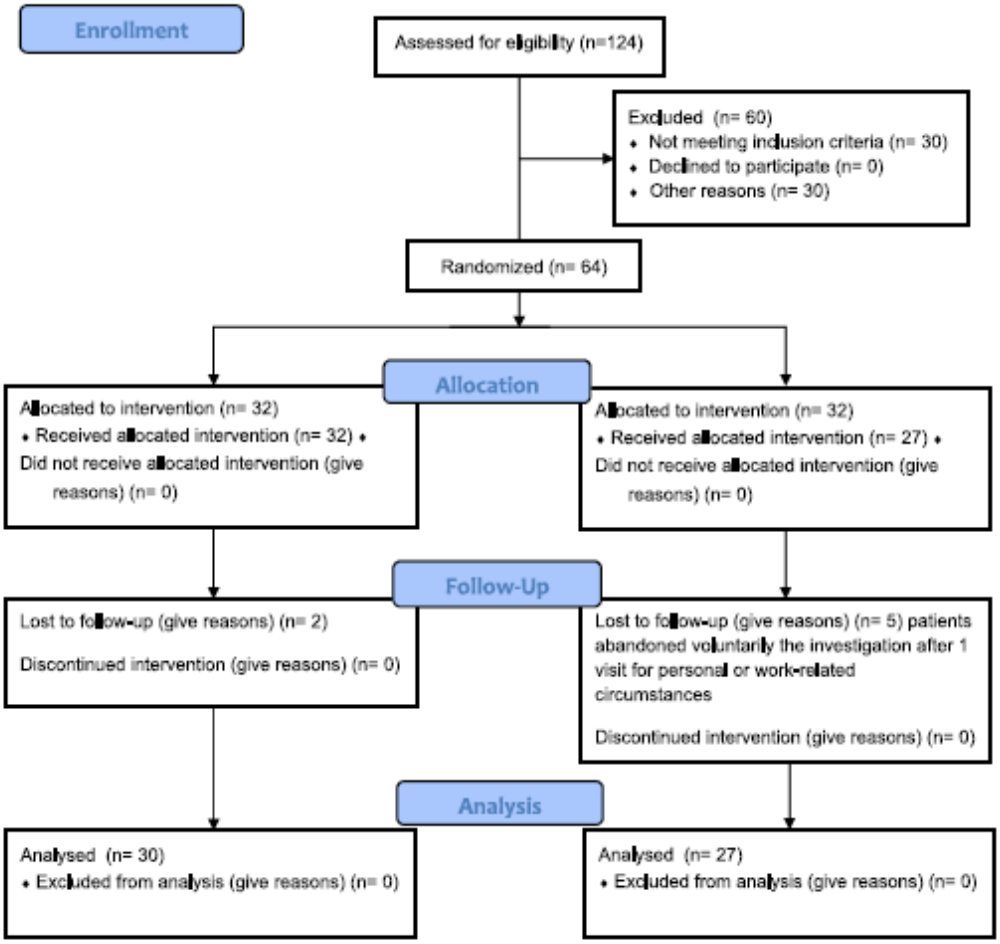

Figure 1: CONSORT Diagram of Recruitment and Retention Throughout the Study.

Table 2: Base line and End-of-Study Outcomes of the Study.

Variables	Cohort	Study Days				p value
		Day 1	Day 28	Day 56	Day 84	
(Range of Quality Control Standard)[1]		Descriptive Statistics (mean ± SD)				
Primary Outcome						
HbA1c(≤ 6%)	SS cohort	7.2 ± 1.1	ND	ND	7.2 ± 1.1	0.262[b]
	Placebo	7.3 ± 1.6	ND	ND	7.4 ± 1.9	0.387[b]
Secondary Outcomes						
FBG (4.2 - 7 mmol/L)	SS* Group	8.4 ± 2.7	8.7 ± 4.2	8.5 ± 3.4	8.4 ± 3.0	0.942[a]
	Placebo	8.3 ± 2.9	8.9 ± 4.5	8.2 ± 4.4	9.4 ± 4.8	0.001[a]
vPost Prandial-2h (≤ 10 mmol/L)	SS cohort	11.8 ± 4.5	11.4 ± 4.1	11.2 ± 4.6	11.6 ± 4.0	0. 646[a]
	Placebo	11.6 ± 4.2	11.4 ± 5.1	10.2 ± 3.7	12.4 ± 5.3	0.013[a]
Cholesterol (3.6 – 5.2 mmol/L)	SS cohort	4.3 ± 0.8	ND	ND	4.4 ± 0.8	0.181[b]
	Placebo	4.4 ± 0.6	ND	ND	5.1 ± 1.3	< 0.001[b]
HDL-c (≥ 0.9 mmol/L)	SS cohort	1.2 ± 0.4	ND	ND	1.1 ± 0.3	0.008[b]
	Placebo	1.2 ± 0.3	ND	ND	1.1 ± 0.3	0.416[b]
LDL-c (2.6–3.35 mmol/L)	SS cohort	2.9 ± 0.8	ND	ND	3.2 ± 0.9	0.001[b]
	Placebo	2.8 ± 0.6	ND	ND	3.5 ± 1.1	< 0.001[b]
Triglycerides (0.5–1.85 mmol/L)	SS cohort	2.1 ± 0.8	ND	ND	1.7 ± 0.6	0.005[b]
	Placebo	2.4 ± 1.2	ND	ND	1.6 ± 1.4	0.002[b]
Insulin (2.6–24.9) mUI/mL	SS cohort	23.8 ± 22.0	ND	ND	19.8 ± 13.1	0.0496[c]
	Placebo	26.4 ± 20.5	ND	ND	26.5 ± 19.6	0.4897[c]
Serum LPS	SS cohort	0.45 ± 0.13	ND	ND	0.30 ± 0.04	0.0009[c]
	Placebo	0.42 ± 0.16	ND	ND	0.36 ± 0.14	0.0681[c]
HOMA-IR Index	SS cohort	8.85 ± 9.87	ND	ND	7.32 ± 5.36	0.0007[a]
	Placebo	11.26 ± 11.48	ND	ND	12.34 ± 13.14	0.2472[a]
Creatinine (65.4-119.3 µmol/L)	SS cohort	83.6 ± 21.50	ND	ND	77.17 ± 17.96	0.1745[c]
	Placebo	77.17 ± 18.48	ND	ND	80.29 ± 15.51	0.2099[c]

1Values in parenthesis represent thew Quality Standards used with the Immunochemical Autoanalyzer Cobas 6000.
*SS = Sugar Shift treated cohort (n=30); Placebo cohort (n=27), ND = measurement was not done; aFriedman Test. bWilcoxon signed rank test, ct-Test: Paired Two Samples for Means
†Multiply the value in mmol/L by 18 to obtain values in mg/dL. Day 1 is a baseline value

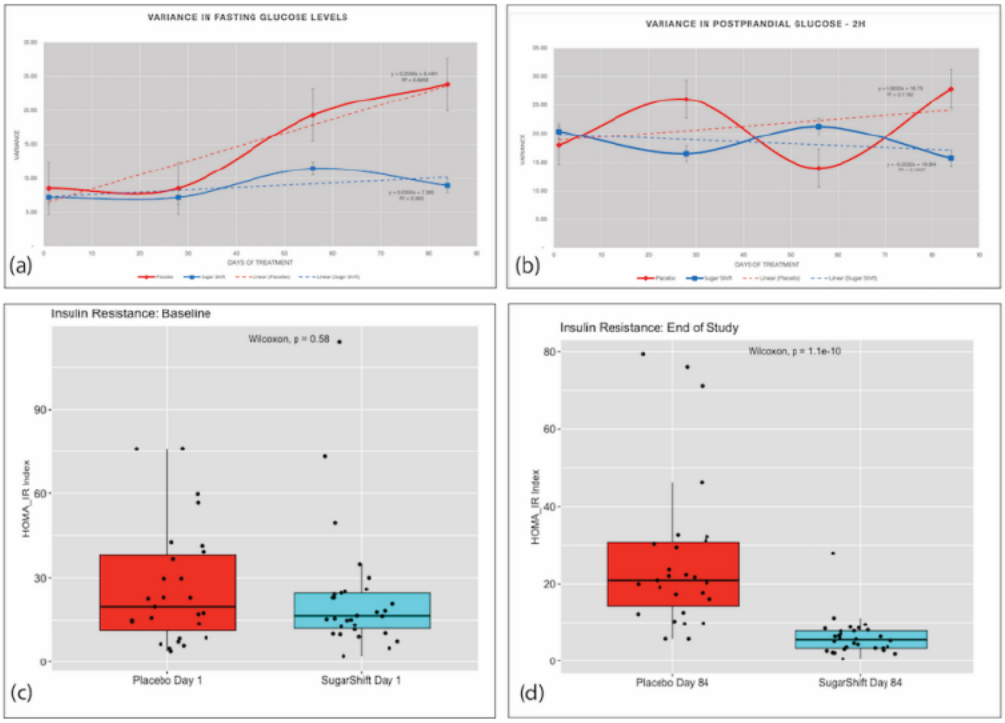

Figure 2: Dynamics of Serum Glucose and Insulin Resistance Measurements and Variances Throughout the 84-day Study. (a) Variance in Fasting Glucose of Placebo and Treatment (SS) groups showing trends over the 84-day study. (b) Variance in 2-hour Post Prandial glucose of Placebo and Treatment (SS) groups showing trends over the 84-day study. (c) Baseline boxplots with jitter showing distribution and medians in HOMA-IR indices with statistical significance (Wilcoxon) for Placebo and Treatment groups. (d) End of Study (84 days) boxplots with jitter showing distribution and medians in HOMA-IR indices with statistical significance (Wilcoxon) for Placebo and Treatment groups.