

DATOS GENERALES DEL ESTUDIO

Código del RPCEC	RPCEC00000406
Título abreviado del estudio	FiberHealth
Título completo del estudio	Efecto del consumo de fibra dietaria en la composición corporal, la microbiota intestinal y marcadores bioquímicos asociados a estado metabólico en personas con exceso de peso: estudio piloto
Descripción de las intervenciones	Fibra dietaria Administración, Oral

FLUJO DE PARTICIPANTES

Universo posible captado: 147 personas

Evaluados	58
Excluidos	18
No cumplieron con los criterios de inclusión	3
Declararon no tener disponibilidad para iniciar la intervención	5
Consumo de antibiótico menor a 3 meses	1
Valor de PCR muy alto (>20.90 mg/dL)	1
Presión arterial por fuera del límite admisible (>140/90 mm Hg)	5
Inicio de hipolipemiante menor a 1 mes	2
Retiro voluntario de la investigación por falta de tiempo para la realización de los exámenes (luego de iniciada la intervención)	1
Aleatorizados (<i>Para estudios donde no aplica se refiere a los incluidos</i>)	40

Características	Control	Konjac	Total
Aleatorizados	20	20	40
Interrumpieron	0	1	1
Falta de tiempo para realizar exámenes de seguimiento	0	1	1
No asistió a los exámenes de semana 12	1	0	1
Terminaron el estudio	19	19	38
Utilizados en el análisis	19	19	38

CARACTERÍSTICAS BASALES DE LOS SUJETOS

Características	Control (n)	Total	Konjac (n)	Total
Edad				
Media	36.5 (20)	20	37.3 (20)	20
Mínimo	23		25	
Máximo	50		50	
Sexo				
Femenino	11 (50%)	11	11 (50%)	11
Masculino	9 (45%)	9	9 (45%)	9

RESULTADOS PRIMARIOS Y SECUNDARIOS

Variable media (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
<i>Variable principal</i>				
Body weight (kg)	88.1 (11.7)	83.2 (13.3)	85.9 (11.8)	80.9 (13.2)
mediana [min-max]	87.8 [71.7, 116]	83.0 [62.2, 112]	86.4 [68.8, 113]	78.7 [62.2, 114]
N	20	20	19	19
<i>Variables secundarias</i>				
HDL (mg/dL) mean (SD)	46.7 (13.4)	44.9 (11.0)	42.7 (10.4)	44.5 (9.47)
mediana [min-max]	43.3 [28.4, 78.7]	44.4 [28.2, 72.9]	38.0 [29.2, 68.9]	43.0 [29.8, 59.5]
N	20	20	19	19
LDL (mg/dL)	130 (27.9)	135 (32.7)	129 (33.1)	125 (19.4)
mediana [min-max]	129 [74.6, 176]	129 [54.8, 195]	129 [69.3, 201]	121 [101, 169]
N	20	20	19	19
Total cholesterol (mg/dL)	188 (29.4)	194 (29.9)	181 (36.4)	180 (22.5)
mediana [min-max]	195 [136, 240]	189 [150, 258]	178 [119, 272]	177 [136, 226]
N	20	20	19	19
Atherogenic index	4.33 (1.40)	4.59 (1.46)	4.40 (1.13)	4.22 (1.11)
mediana [min-max]	3.76 [2.39, 7.85]	4.24 [2.36, 8.63]	4.52 [2.64, 6.88]	3.93 [3.03, 6.95]
N	20	20	19	19
Triglycerides (mg/dL)	144 (66.4)	146 (61.8)	113 (49.9)	142 (78.4)
mediana [min-max]	155 [59.8, 332]	139 [70.4, 330]	96.5 [41.6, 209]	119 [50.6, 375]
N	20	20	19	19
Fasting glycaemia (mg/dL)	89.7 (7.76)	85.8 (7.42)	89.8 (6.68)	87.2 (7.44)
mediana [min-max]	88.7 [75.9, 104]	84.4 [73.8, 107]	90.6 [79.5, 103]	88.2 [71.1, 107]
N	20	20	19	19
HbA1c (%)	5.47 (0.299)	5.48 (0.248)	5.44 (0.320)	5.44 (0.308)
mediana [min-max]	5.45 [4.60, 5.80]	5.40 [5.20, 6.40]	5.50 [4.50, 6.00]	5.40 [4.90, 6.40]

Variable media (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
N	20	20	19	19
Fasting insulin (uUI/dL)	13.4 (9.54)	10.1 (4.95)	11.7 (6.06)	10.2 (3.92)
mediana [min-max]	9.85 [3.70, 42.8]	9.30 [4.80, 25.9]	10.2 [3.50, 24.3]	10.1 [5.00, 17.3]
N	20	20	19	19
HOMA-IR	2.95 (2.00)	2.16 (1.05)	2.60 (1.39)	2.20 (0.944)
mediana [min-max]	2.27 [0.778, 8.86]	2.05 [1.00, 5.39]	2.18 [0.783, 5.47]	2.14 [1.11, 4.35]
N	20	20	19	19
hsCRP (mg/L)	3.42 (3.79)	4.01 (3.14)	2.88 (2.32)	2.95 (2.10)
mediana [min-max]	1.63 [0.720, 13.6]	3.57 [0.630, 14.7]	2.31 [0.400, 8.81]	2.40 [0.540, 6.88]
N	20	20	19	19
Systolic blood pressure (mm Hg)	122 (14.2)	125 (9.69)	114 (13.3)	122 (6.98)
mediana [min-max]	125 [88.0, 139]	129 [110, 139]	116 [87.0, 140]	122 [105, 129]
N	20	20	19	19
Diastolic blood pressure (mm Hg)	78.8 (9.12)	83.5 (7.63)	76.4 (9.41)	77.5 (6.41)
mediana [min-max]	80.5 [55.0, 94.0]	83.0 [70.0, 98.0]	77.0 [53.0, 90.0]	78.0 [67.0, 87.0]
N	20	20	19	19
Mean arterial pressure (mm Hg)	100 (10.9)	104 (7.58)	95.3 (11.0)	99.7 (5.87)
mediana [min-max]	101 [71.5, 114]	105 [90.5, 118]	96.0 [70.0, 115]	100 [88.5, 108]
N	20	20	19	19
BMI (kg/m²)	30.7 (1.67)	30.9 (2.26)	29.9 (1.90)	29.9 (2.76)
mediana [min-max]	30.6 [28.6, 34.8]	30.4 [27.6, 35.5]	30.3 [26.1, 33.8]	29.8 [25.9, 35.8]
N	20	20	19	19
Waist circumference (cm)	94.6 (7.44)	93.7 (10.8)	92.5 (6.94)	91.0 (10.3)
mediana [min-max]	93.9 [83.4, 107]	90.3 [77.8, 114]	91.2 [80.9, 104]	86.9 [75.5, 107]
N	20	20	19	19
DEXA total muscular mass (kg)	53.7 (11.0)	50.3 (11.4)	53.7 (11.0)	50.8 (10.5)
mediana [min-max]	52.2 [37.8, 71.5]	48.1 [34.3, 69.8]	51.3 [40.0, 70.5]	49.8 [36.9, 68.4]
N	20	19	18	16
DEXA body fat (%)	38.8 (6.57)	38.9 (7.27)	37.2 (6.61)	36.5 (7.81)
mediana [min-max]	39.9 [29.4, 48.8]	41.1 [23.0, 47.8]	37.1 [26.9, 45.7]	39.1 [20.8, 45.3]
N	20	19	18	16
DEXA Fat Mass Index (kg/m²)	11.8 (2.24)	11.9 (2.57)	10.9 (2.14)	10.9 (2.97)
mediana [min-max]	11.7 [8.79, 15.7]	12.2 [6.60, 16.2]	10.5 [6.94, 14.7]	11.2 [5.73, 15.9]
N	20	19	18	16
DEXA Free Fat Mass Index (kg/m²)	17.6 (1.95)	17.7 (2.20)	17.5 (2.08)	17.6 (1.66)
mediana [min-max]	17.3 [15.2, 20.6]	16.9 [14.4, 21.8]	17.4 [14.7, 20.7]	17.5 [15.3, 21.0]
N	20	19	18	16
DEXA Android/Gynoid	1.11 (0.190)	1.08 (0.166)	1.11 (0.187)	1.04 (0.170)
mediana [min-max]	1.07 [0.850, 1.48]	1.11 [0.830, 1.44]	1.09 [0.870, 1.44]	1.06 [0.790, 1.35]
N	20	19	18	16
DEXA Appendicular skeletal mass index (kg/m²)	8.07 (1.33)	7.82 (1.31)	8.03 (1.38)	7.79 (1.06)

Reporte Resumido de los Resultados del Ensayo Clínico

Variable media (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
mediana [min-max]	7.91 [6.11, 10.1]	7.37 [5.79, 9.84]	7.72 [5.96, 10.1]	7.82 [6.07, 9.71]
N	20	19	18	16
DEXA Visceral Fat Area (cm²)	143 (42.0)	143 (44.0)	132 (40.1)	120 (44.4)
mediana [min-max]	135 [105, 282]	138 [67.4, 234]	120 [83.5, 228]	106 [68.1, 211]
N	20	19	18	16
BIA free fat mass (%)	63.1 (7.94)	61.7 (8.21)	64.2 (7.15)	61.9 (7.67)
mediana [min-max]	62.9 [49.0, 77.1]	59.3 [51.9, 78.2]	63.6 [51.7, 75.4]	60.5 [52.7, 76.3]
N	20	20	19	19
BIA fat mass (%)	36.9 (7.94)	38.3 (8.21)	33.5 (8.03)	34.7 (9.47)
mediana [min-max]	37.1 [22.9, 51.0]	40.7 [21.8, 48.1]	35.0 [15.8, 52.4]	36.1 [17.9, 46.1]
N	20	20	19	19
BIA musculoskeletal mass (%)	35.3 (5.01)	34.4 (5.17)	36.0 (4.55)	34.5 (4.76)
mediana [min-max]	34.6 [26.6, 44.4]	32.8 [28.6, 44.5]	35.6 [28.0, 43.1]	33.5 [28.6, 43.2]
N	20	20	19	19
BIA Fat Mass Index (kg/m²)	11.2 (2.66)	11.8 (2.95)	10.1 (2.62)	11.4 (4.45)
mediana [min-max]	10.6 [6.60, 16.1]	12.1 [6.30, 16.1]	9.70 [4.50, 16.5]	10.7 [5.10, 23.6]
N	20	20	19	19
BIA Free Fat Mass Index (kg/m²)	19.1 (2.36)	18.9 (2.34)	19.4 (2.23)	19.0 (2.18)
mediana [min-max]	19.0 [15.5, 22.7]	18.5 [15.0, 22.9]	18.8 [16.3, 22.3]	18.7 [14.9, 22.7]
N	20	20	19	19
BIA Visceral Fat Area (cm²)	151 (35.7)	151 (40.2)	136 (33.6)	136 (45.6)
mediana [min-max]	151 [88.4, 215]	153 [75.0, 234]	138 [59.1, 191]	136 [62.0, 243]
N	20	20	19	19
AgRP/ART (pg/mL)	42.6 (12.7)	35.7 (8.20)	41.4 (11.7)	39.1 (9.58)
mediana [min-max]	39.9 [24.9, 67.5]	33.0 [25.4, 57.2]	39.2 [25.9, 68.3]	39.5 [26.6, 55.3]
N	19	19	19	19
IL-18 (pg/mL)	127 (116)	102 (43.9)	114 (68.9)	97.1 (29.8)
mediana [min-max]	91.6 [53.3, 575]	102 [39.3, 220]	87.7 [48.0, 358]	91.3 [57.0, 160]
N	19	19	19	19
Leptin (ng/mL)	15.9 (10.1)	16.6 (12.6)	14.3 (7.81)	14.5 (11.7)
mediana [min-max]	15.1 [3.83, 38.9]	14.4 [1.15, 57.3]	14.3 [3.76, 28.5]	13.6 [1.20, 53.1]
N	19	19	19	19
Chemerin (ng/mL)	5.99 (4.38)	4.51 (2.23)	5.50 (3.67)	5.10 (2.05)
mediana [min-max]	4.78 [1.94, 22.7]	4.06 [1.20, 11.3]	4.90 [2.58, 19.8]	4.89 [1.14, 9.41]
N	19	19	19	19
Adiponectin (ng/mL)	8.57 (2.08)	7.93 (2.00)	8.24 (2.64)	8.15 (1.82)
mediana [min-max]	8.15 [5.36, 12.7]	7.76 [4.77, 12.5]	7.60 [5.82, 16.0]	7.59 [5.43, 12.1]
N	19	19	19	19
Leptin/Adiponectin	1.89 (1.19)	2.13 (1.96)	1.82 (1.11)	1.83 (1.62)
mediana [min-max]	1.50 [0.391, 4.39]	1.81 [0.182, 9.57]	1.66 [0.510, 4.07]	1.75 [0.146, 7.71]
N	19	19	19	19
LBP (ug/mL)	8.23 (4.45)	8.95 (3.15)	7.93 (2.78)	8.63 (2.53)

Variable media (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
mediana [min-max]	7.46 [3.19, 21.3]	8.17 [4.45, 18.4]	8.28 [2.92, 14.8]	8.67 [3.94, 14.5]
N	19	19	19	19
8-isoprostane (ng/mg urine creatinine)	0.861 (0.596)	0.478 (0.234)	0.449 (0.285)	0.534 (0.301)
mediana [min-max]	0.612 [0.251, 2.43]	0.533 [0.0990, 0.819]	0.391 [0.127, 1.23]	0.503 [0.112, 1.34]
N	19	19	19	19
Basal metabolic rate (kcal/day)	1580 (274)	1490 (266)	1600 (269)	1500 (259)
mediana [min-max]	1500 [1140, 2100]	1440 [1100, 1960]	1490 [1180, 2140]	1470 [1100, 1940]
N	20	20	19	19
Energy intake (kcal/day)	1260 (345)	1410 (362)	1390 (360)	1380 (414)
mediana [min-max]	1240 [695, 2080]	1350 [681, 2200]	1330 [930, 2130]	1350 [728, 2340]
N	20	20	20	19
Protein intake (g/day)	76.8 (19.7)	87.3 (24.2)	87.6 (19.9)	80.5 (20.8)
mediana [min-max]	78.9 [48.3, 117]	88.2 [47.2, 132]	87.7 [38.4, 135]	79.2 [48.4, 120]
N	20	20	20	19
Carbohydrate intake (g/day)	133 (51.1)	140 (49.8)	136 (45.2)	132 (44.7)
mediana [min-max]	130 [46.8, 285]	136 [57.7, 263]	116 [81.2, 256]	126 [53.8, 238]
N	20	20	20	19
Sugar intake (g/day)	43.1 (35.3)	46.8 (21.7)	44.9 (21.1)	44.0 (25.1)
mediana [min-max]	35.3 [5.70, 171]	42.3 [17.8, 103]	44.2 [13.6, 100]	38.5 [12.5, 116]
N	20	20	20	19
Fiber intake (g/day)	12.9 (6.55)	12.7 (6.05)	12.1 (6.50)	11.7 (4.53)
mediana [min-max]	12.7 [4.30, 28.3]	11.1 [4.70, 27.2]	11.1 [2.60, 30.1]	11.2 [5.00, 19.2]
N	20	20	20	19
total fat intake (g/day)	46.7 (19.8)	56.3 (22.5)	55.6 (20.3)	56.4 (21.6)
mediana [min-max]	38.1 [24.2, 97.5]	49.7 [18.9, 108]	54.7 [23.9, 102]	50.3 [30.6, 100]
N	20	20	20	19
Gut microbiota alpha div: OTU richness	217 (82.9)	216 (70.8)	227 (49.3)	226 (56.5)
mediana [min-max]	204 [73.0, 439]	224 [120, 403]	227 [135, 331]	215 [149, 354]
N	18	18	18	18
Gut microbiota alpha div: Shannon index	3.47 (0.585)	3.37 (0.530)	3.35 (0.552)	3.34 (0.486)
mediana [min-max]	3.51 [2.02, 4.56]	3.38 [2.48, 4.52]	3.29 [2.62, 4.12]	3.36 [2.45, 3.97]
N	18	18	18	18
Gut microbiota alpha div: Pielou's index	0.651 (0.0776)	0.630 (0.0736)	0.617 (0.0828)	0.618 (0.0796)
mediana [min-max]	0.663 [0.471, 0.750]	0.642 [0.480, 0.753]	0.603 [0.510, 0.732]	0.612 [0.488, 0.726]
N	18	18	18	18
Beta diversity (Aitchison distances)	28.59 (3.59)	28.19 (4.06)		

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Variable media (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
mediana [min-max]	28.75 [21.86, 33.98]	28.62 [19.23, 36.35]		
N	18	18		
Actinobacteriota	4.16 (1.38)	3.84 (0.92)	3.63 (1.34)	3.47 (1.34)
mediana [min-max]	4.51 [1.77, 6.31]	4.12 [2.05, 5.37]	3.68 [1.23, 5.95]	3.23 [1.64, 6.41]
N	18	18	18	18
Unkown bacteria	-1.54 (1.61)	-1.05 (1.74)	-1.14 (1.73)	-0.33 (1.45)
mediana [min-max]	-2.09 [-3.57, 1.59]	-0.79 [-3.9, 2.33]	-1 [-3.41, 1.7]	0.02 [-3.55, 1.64]
N	18	18	18	18
Bacteroidota	6.97 (1.24)	6.96 (0.96)	7.35 (1.26)	7.25 (1.02)
mediana [min-max]	6.96 [5.04, 9.4]	7.04 [5.38, 8.55]	7.58 [4.42, 9.09]	6.84 [5.62, 9.06]
N	18	18	18	18
Campylobacterota	-5.58 (1.91)	-6.16 (1.23)	-5.72 (1.95)	-6.54 (0.88)
mediana [min-max]	-6.15 [-7.28, 0.22]	-6.3 [-7.6, -2.25]	-6.53 [-7.49, 0.37]	-6.61 [-8.41, -4.77]
N	18	18	18	18
Cyanobacteria	-1.08 (1.71)	-1.11 (2.05)	-0.65 (1.82)	-0.36 (2.23)
mediana [min-max]	-1.69 [-2.78, 3.12]	-2.13 [-3.36, 3.31]	-1.32 [-2.41, 4.28]	-1.37 [-2.77, 3.7]
N	18	18	18	18
Desulfobacterota_I	1.32 (2.25)	1.54 (1.29)	2.05 (2.07)	2.01 (1.59)
mediana [min-max]	1.76 [-2.24, 4.39]	1.67 [-0.87, 4.07]	2.23 [-2.39, 4.9]	2.28 [-1.69, 5.28]
N	18	18	18	18
Elusimicrobiota	-3.31 (1.22)	-3.7 (0.77)	-3.69 (0.74)	-3.5 (1.71)
mediana [min-max]	-3.52 [-4.63, 0.58]	-3.62 [-4.95, -2.04]	-3.92 [-4.84, -2.26]	-3.88 [-5.76, 2.36]
N	18	18	18	18
Firmicutes	4.42 (1.38)	3.95 (0.83)	4.44 (1.26)	3.9 (0.98)
mediana [min-max]	4.37 [1.9, 6.73]	3.75 [2.18, 5.47]	4.51 [2.25, 7.43]	3.65 [2.28, 5.96]
N	18	18	18	18
Firmicutes_A	7.42 (1.02)	7.03 (0.91)	7.41 (1.01)	7.11 (0.76)
mediana [min-max]	7.56 [5.58, 8.95]	6.82 [5.98, 9.29]	7.53 [5.36, 9.07]	7.04 [5.89, 8.42]
N	18	18	18	18
Firmicutes_B	-3.08 (1.61)	-2.06 (1.62)	-3.01 (1.68)	-2.83 (1.97)
mediana [min-max]	-3.81 [-5.11, -0.11]	-1.8 [-4.58, 0.58]	-3.28 [-4.95, -0.18]	-2.57 [-5.33, 0.69]
N	18	18	18	18
Firmicutes_C	5.82 (1.39)	5.52 (1.03)	5.87 (1.1)	5.44 (0.92)
mediana [min-max]	5.58 [3.31, 8.12]	5.54 [3.81, 7.78]	5.84 [3.4, 7.42]	5.41 [3.88, 6.82]
N	18	18	18	18
Fusobacteriota	-3.03 (1.96)	-3.12 (1.88)	-3.85 (1.37)	-3.82 (2.16)
mediana [min-max]	-3.84 [-5.3, 0.6]	-3.73 [-5.64, 0.51]	-4.5 [-5.15, -0.62]	-4.45 [-6.44, 3.06]
N	18	18	18	18
Methanobacteriota	-0.04 (2.37)	0.94 (2.32)	-0.36 (1.84)	0.7 (2.21)

Variable media (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
mediana [min-max]	-0.91 [-2.78, 4.2]	1.7 [-2.55, 3.71]	-0.94 [-2.41, 3.37]	0.38 [-2.74, 4.02]
N	18	18	18	18
Patescibacteria	-7.76 (1.86)	-8.3 (0.76)	-8.32 (0.73)	-8.47 (0.88)
mediana [min-max]	-8.15 [-9.21, -0.86]	-8.23 [-9.54, -6.86]	-8.5 [-9.43, -6.86]	-8.54 [-10.34, -6.71]
N	18	18	18	18
Proteobacteria	3.66 (1.79)	3.66 (0.92)	4.29 (1.46)	4.01 (1.44)
mediana [min-max]	3.64 [1.02, 7.62]	3.65 [1.88, 4.91]	3.98 [1.44, 7.12]	3.91 [1.6, 6.43]
N	18	18	18	18
Synergistota	-3.79 (1.43)	-3.49 (1.58)	-4.18 (1.23)	-3.73 (1.84)
mediana [min-max]	-4.2 [-5.33, -0.16]	-4 [-5.6, -0.12]	-4.62 [-5.55, -0.21]	-4.14 [-6.46, 0.37]
N	18	18	18	18
Thermoplasmatota	-5.33 (1.28)	-5.82 (0.76)	-5.6 (1.25)	-5.99 (0.88)
mediana [min-max]	-5.6 [-6.73, -1.01]	-5.75 [-7.06, -4.38]	-6.02 [-6.95, -1.56]	-6.06 [-7.86, -4.23]
N	18	18	18	18
Verrucomicrobiota	0.75 (2.58)	1.36 (2.39)	1.48 (2.56)	1.69 (2.26)
mediana [min-max]	0.48 [-2.79, 6.03]	1.23 [-3.26, 4.76]	0.88 [-2.42, 6.03]	1.25 [-2.23, 4.76]
N	18	18	18	18

EVENTOS ADVERSOS

Los eventos adversos reportados, estuvieron asociados con el disconfort gastrointestinal asociado a la incorporación de fibra dietaria en personas que manifestaban tener una dieta pobre en frutas y verduras al inicio de la intervención. Las manifestaciones de disconfort desaparecieron luego de habituarse a su consumo a los dos o tres días de reportados los síntomas.

Presencia de eventos adversos por grupo.

Presencia de EA	Control		Konjac		Total	
	N	%	N	%	N	%
Sí	1	5	4	20	5	12
No	20	95	16	80	36	88
Total	21	100	20	100	41	100