

GENERAL INFORMATION OF THE CLINICAL TRIAL

RPCEC code	RPCEC00000406
Public title	FiberHealth
Scientific title	Effect of dietary fiber consumption on body composition, gut microbiota and biochemical markers associated with metabolic state in overweight people: a pilot study
Intervention description	Dietary Fiber Administration, Oral

FLUJO DE PARTICIPANTES

Universo posible captado: 147 personas

Evaluated	58
Excluded	18
Did not meet the inclusion criteria	3
They stated they were unavailable to begin the intervention	5
Antibiotic use within the past 3 months.	1
Very high CRP value (>20.90 mg/dL)	1
Blood pressure outside the acceptable range (>140/90 mm Hg)	5
Start of lipid-lowering therapy less than 1 month	2
Voluntary withdrawal from the study due to lack of time to complete the tests (after starting the intervention)	1
Randomized (For studies where it does not apply, it refers to those included)	40

Characteristics	Control	Konjac	Total
Randomized	20	20	40
Interrupt	0	1	1
Lack of time to perform follow-up exams	0	1	1
Did not attend week 12 exams	1	0	1
Finished the study	19	19	38
Used in analysis	19	19	38

BASELINE CHARACTERISTICS

Características	Control (n)	Total	Konjac (n)	Total
Edad				
Media	36.5 (20)	20	37.3 (20)	20
Minimum	23		25	
Maximum	50		50	
Sexo				
Female	11 (50%)	11	11 (50%)	11
Male	9 (45%)	9	9 (45%)	9

OUTCOME MEASURES

Variable M (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)

Variable M (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
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]
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

Variable M (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
DEXA Appendicular skeletal mass index (kg/m²)	8.07 (1.33)	7.82 (1.31)	8.03 (1.38)	7.79 (1.06)
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]

Variable M (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
N	19	19	19	19
LBP (ug/mL)	8.23 (4.45)	8.95 (3.15)	7.93 (2.78)	8.63 (2.53)
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]

Variable M (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
N	18	18	18	18
Beta diversity (Aitchison distances)	28.59 (3.59)	28.19 (4.06)		
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]

Variable M (SD)	Control Basal	Konjac Basal	Control Final	Konjac Final
N	18	18	18	18
Methanobacteriota	-0.04 (2.37)	0.94 (2.32)	-0.36 (1.84)	0.7 (2.21)
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

ADVERSE EVENTS

The reported adverse events were related to gastrointestinal discomfort caused by the introduction of dietary fiber in individuals who initially had a diet low in fruits and vegetables. The discomfort symptoms resolved after participants adapted to its consumption, typically within two to three days of symptom onset.

Presence of AE	Control		Konjac		Total	
	N	%	N	%	N	%
Yes	1	5	4	20	5	12
No	20	95	16	80	36	88
Total	21	100	20	100	41	100