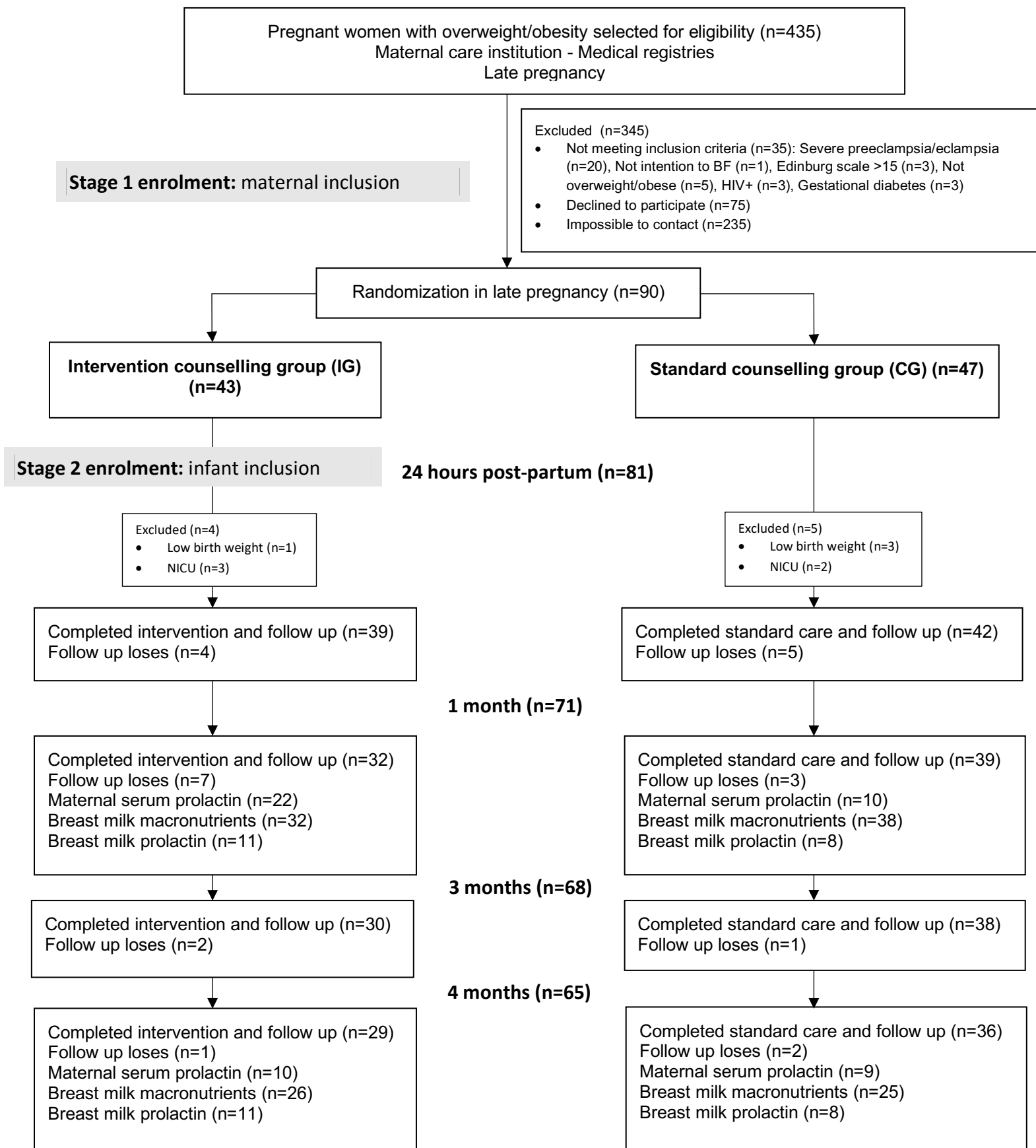


Participant flow



Maternal characteristics at late gestation

	Overall (n=90)	IG (n=43)	CG (n=47)	OR/difference	95% CI	p value
Maternal characteristics						
Maternal age (y)(mean,SD)	26.8 (±6.1)	26.1 (±4.5)	27.4 (±7.1)	-1.22	-3.7, 1.3	0.93
Nationality (n, %)						
Colombian	71 (78.9)	33 (76.7)	38 (80.9)	0.78	0.3, 2.1	0.63
Venezuelan	19 (21.1)	10 (23.3)	9 (19.1)			
Health care insurance (n, %)						
Transitory health insurance	20 (22.2)	10 (23.3)	10 (21.3)	1.12	0.4, 3.0	0.51
Subsided coverage	64 (71.1)	31 (72.1)	33 (70.2)	1.09	0.4, 2.7	0.52
Contributive health plan	6 (6.7)	2 (4.7)	4 (8.5)	0.52	0.1, 3.0	0.68
Years living in Bogotá (mean, SD)	13 (±11.8)	12.8 (±11.7)	13.2 (±12.0)	-0.36	-5.3, 4.6	0.99
Parity (n, %)						
Primiparous	38 (42.2)	18 (41.9)	20 (42.6)	1.01	0.4, 2.4	0.56
Multiparous	52 (57.8)	25 (58.1)	27 (57.4)			
Years of education (mean, SD)	11.7 (±3.2)	11.7 (±3.3)	11.7 (±3.2)	0.02	-1.3, 1.4	0.98
Mother lives with the partner (n, %)						
Yes	63 (70)	29 (67.4)	34 (72.3)	1.26	0.5, 3.1	0.65
No	27 (30)	14 (32.6)	13 (27.7)			
Maternal occupation (n, %)						
Employed/Independent/Student	23 (25.6)	12 (27.9)	11 (23.4)	1.27	0.5, 3.3	0.64
Unemployed	67 (74.4)	31 (72.1)	36 (76.6)			
Pregestational nutritional status (n, %)						
Normal (BMI 20.0 - 25.0 kg/m ²)	19 (21.1)	11 (29.7)	8 (18.6)	1		
Overweight (BMI 25.1 - 30.0 kg/m ²)	40 (44.4)	15 (40.5)	25 (58.1)	2.29	0.7, 6.9	0.23
Obesity (BMI >30.1 kg/m ²)	21 (23.3)	10 (23.3)	11 (29.7)	1.51	0.4, 5.3	0.74
Maternal weight gain during pregnancy (kg)(mean, SD)	12.4 (±5.8)	12.4 (±5.2)	12.4 (±6.3)	0.04	-2.5, 2.6	0.97
Gestational BMI (kg/m ²)(mean, SD)	33.4 (±3.4)	33.6 (±3.7)	33.2 (±3.1)	0.40	-1.0, 1.8	0.71
Physical activity during gestation						
Sedentary (<1.49 MET/h/d)	43 (47.8)	23 (53.5)	20 (42.6)	0.41	0.1, 1.2	0.16
Light (1.5-2.9 MET/h/d)	25 (27.8)	13 (30.2)	12 (25.5)	0.43	0.1, 1.4	0.3
Moderate/Vigorous (>3.0 MET/h/d)	16 (17.8)	7 (16.3)	15 (21.9)	1		
Screen time (h) (TV and cellular phone)	6.8 (±3.9)	6.9 (±3.9)	6.6 (±3.8)	0.31	-1.3, 1.9	0.62
Breastfeeding support and expertise						
Family and/or friends support (n, %)						
Yes	85 (94.4)	41 (48.2)	44 (51.8)	0.71	0.4, 1.8	0.54
No	5 (5.6)	2 (51.8)	3 (48.2)			
Breast-fed a previous infant (n, %)						
Yes	48 (53.3)	21 (48.8)	27 (57.4)	1.4	0.6, 3.2	0.54
No	42 (46.7)	22 (51.2)	20 (42.6)			
Breast and nipple problems (self-reported)						
Normal form of the breast (n, %)						
Yes	87 (96.7)	42 (97.7)	45 (95.7)	nd	nd	nd
No	3 (3.3)	1 (2.3)	2 (4.3)			
Large breast (n, %)						

Yes	35 (38.9)	19 (44.2)	16 (34)	0.65	0.3, 1.5	0.32
No	55 (61.1)	24 (55.8)	31 (66)			
Normal nipple (n, %)						
Yes	77 (85.6)	37 (86)	40 (85.1)	0.92	0.3, 3.0	0.88
No	13 (14.4)	6 (14)	7 (14.9)			
Maternal feeding practices						
Food intolerances during gestation (n, %)						
Yes	52 (57.8)	25 (58.1)	27 (57.4)	0.97	0.4, 2.2	0.55
No	38 (42.2)	18 (41.9)	20 (42.6)			
Alcohol consumption (n, %)						
Yes	5 (5.6)	3 (7)	2 (4.3)	nd	nd	nd
No	85 (94.4)	40 (93)	45 (95.7)			
Smoking (n, %)						
Yes	0	0	0	nd	nd	nd
No	90 (100)	43 (100)	47 (100)			
Second hand smoking (n, %)						
Yes	24 (26.7)	13 (30.2)	11 (23.4)	0.71	0.3, 1.8	0.46
No	66 (73.3)	30 (69.8)	36 (76.6)			
Monthly food expenditure (US\$)(mean, SD)	27.88 (±14.88)	29.61 (±15.39)	26.37 (±14.4)	3.3	-3.1, 9.6	0.26
Minerals supplementation (Calcium, Iron, Folate) (n, %)						
Yes	71 (78.8)	34 (79.1)	37 (78.7)	0.97	0.3, 2.7	0.97
No	19 (21.2)	9 (20.9)	10 (21.3)			
Other medications (n, %) ^a						
Yes	33 (36.7)	15 (34.9)	18 (38.3)	1.15	0.7, 1.6	0.74
No	57 (63.3)	28 (65.1)	29 (61.7)			
Maternal intake (kcal)(mean, SD)	2053.7 (±501.3)	2132 (±521.4)	1981 (±476.3)	151.4	-57.5, 360.4	0.22

Abbreviations: IG, intervention group; CG, control group; y, years; wk, weeks; BMI, body mass index; nd, no data; h, hour; d, day; SD, standard deviation; nd, no data; MET, metabolic equivalent; OR, Odds Ratio; CI, confidence interval

Group comparisons were performed with Chi2-test for categorical variables and for continuous variables with U-Mann Whitney test and *t* test (gestational weight gain)

^a acetaminophen, simethyl, topic antibiotics, thyroid hormones and misoprostol

Primary outcomes comparisons between IC and CG

Variables	Overall (n=65)	IG (n=29)	CG (n=36)	PR/difference	95% CI	p value
EBF prevalence at 4 months (n, %)						
Yes	35 (53.8)	24 (82.8)	11 (30.6)	2.7	1.6, 4.5	<0.001**
No	30 (46.2)	5 (17.2)	25 (69.4)			
Infant change in WLZ (mean, SD)						
Change in WLZ from 0 to 4mo	0.69 (±0.7)	0.75 (±1.3)	0.65 (±1.7)	0.1	-0.6, 0.8	0.76
Change in LAZ from 0 to 4mo	0.25 (±0.9)	0.4 (±0.9)	0.1 (±1.0)	0.22	-0.3, 0.7	0.36
Maternal weight loss						
1st wk pp to 4 months (mean, SD)	3.1 (±5.0)	1.9 (±4.7)	4.2 (±5.1)	-2.2	-0.2, 4.8	0.07
1st wk pp to 4 months (n, %)	4.03 (±6.6)	2.5 (±6.4)	5.4 (±6.5)	-2.9	-0.38, 6.2	0.08

Abbreviations: IG, intervention group; CG, control group; EBF, exclusive breastfeeding; WLZ, weight for length Z-Score; LAZ, length for age Z-Score; PR, prevalence ratio

* Statistical significance at the level of <0.05

Group comparisons were performed with Chi2-test for categorical variables and for continuous variables with *t* test as all continuous variables were normally distributed

Secondary outcomes comparisons between IC and CG

	Overall	IG	CG	Difference	95% CI	p value
1 months						
Human milk energy and macronutrient composition (mean, SD)(n=66; IG=36; CG=30)						
Energy (kcal/100mL)	73.2 (±14.6)	70.9 (±11.9)	74.8 (±16.7)	3.9	-3.3, 11.2	0.28
Protein (g/100mL)	1.07 (±0.19)	1.09 (±0.20)	1.06 (±0.19)			0.64
Fat (g/100mL)	3.69 (±1.55)	3.4 (±1.2)	3.9 (±1.8)	0.49	-0.27, 1.26	0.2
Lactose (g/100mL)	8.27 (±0.67)	8.36 (±0.74)	8.21 (±0.62)			0.45
Maternal intake at 1 month (mean, SD)(n=68; IG=31; CG=37)						
Energy (kcal/d)	1,956 (±507.8)	2,008 (±510.1)	1,800 (±499)	-168	-413, 77	0.18
Protein (g/d)	74.5 (±24.4)	75.3 (±28.1)	67.6 (±20.4)	-8.8	-20, 2.9	0.14
Fat (g/d)	63.1 (±25.2)	61.3 (±27.6)	63.8 (±23.3)	-0.73	-13, 11	0.9
Carbohydrate (g/d)	270.4 (±84.9)	283.5 (±88.5)	254.9 (±81.6)	-22.17	-63, 19	0.29
Maternal serum prolactin (median, IQR)(n=32; IG=20; CG=12)	70.6 (380.08)	65.4 (380.0)	74 (223.4)			0.72
Human milk prolactin (mean, SD)(n=19; IG=11; CG=8)	2.15 (±1.49)	1.72 (±1.4)	2.75 (±1.48)	1.03	-0.38, 2.43	0.14
Breast milk volume estimation (g/d)(n=78; IG=37; CG=41)	564.8 (±3.02)	563.6 (±2.7)	565.9 (±2.89)	-2.3	0.9, 3.7	0.001**
4 months						
Human milk energy and macronutrient composition (mean, SD)(n=52; IG=26; CG=26)						
Energy (kcal/100mL)	69.9 (±18.17)	69.86 (±19.81)	70.09 (±16.77)	0.23	-9.99, 10.45	0.96
Protein (g/100mL)	0.87 (±0.13)	0.86 (±0.15)	0.88 (±0.11)	0.02	-0.58, 0.09	0.62
Fat (g/100mL)	3.42 (±1.95)	3.48 (±2.18)	3.37 (±1.73)	-0.11	-1.20, 0.98	0.85
Lactose (g/100mL)	8.4 (±0.72)	8.27 (±0.76)	8.52 (±0.67)	0.25	-0.15, 0.64	0.22
Maternal intake at 4 months (mean, SD)(n=49; IG=22; CG=27)						
Energy (kcal/d)	1876 (±486.7)	2,039 (±423)	1,923 (±534)	-116	-398, 166	0.41
Protein (g/d)	74.4 (±20.2)	78.3 (±19.3)	71.6 (±20.9)	-6.69	-18.39, 4.99	0.25
Fat (g/d)	62.9 (±21.6)	67.0 (±19.3)	68.3 (±23.7)	1.28	-11, 13	0.84
Carbohydrate (g/d)	256.7 (±80.2)	289.7 (±81.0)	253.1 (±77.2)	-36.62	-82.2, 8.95	0.11
Maternal serum prolactin (median, IQR)(n=19; IG=10; CG=9)	37.5 (75.77)	24 (73.27)	39.6 (55)			0.18
Human milk prolactin (mean, SD)(n=19; IG=11; CG=8)	1.29 (±0.73)	1.27 (±0.70)	1.33 (±0.83)	0.06	-0.679, 0.81	0.855

Breast milk volume estimation (g/d)(mean, SD)(n=65; IG=29; CG=36)	719.1 (±65.03)	738.2 (±56.7)	704.7 (±67.8)	33.5	2.05, 64.9	0.04*
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Abbreviations: IG, intervention group; CG, control group; SD, standard deviation; d, day

Group comparisons were performed with *t* test, U-Mann Whitney test (energy and fat at 1 month, breast milk volumen at 1 and 4 months) or independent samples median test (maternal serum prolactin at 1 and 4 months)

*Statistical significance at the level of $p<0.005$

**Statistical significance at the level of $p<0.001$

Adverse events

Date of SAE onset	SAE info	Related	Expected	Reported as RUSAE
None reported*	Non applicable	Not applicable	Not applicable	Not applicable

*The intervention evaluated breastfeeding counselling support to obese pregnant and lactating women, as so, we did not found physical or emotional adverse events and those adverse effects of breastfeeding counselling are not reported in scientific literature.