

Supplementary Material.

Results

In the recruitment and allocation of the 193 eligible participants, 05 were excluded before randomization for not meeting the inclusion criteria, 11 refused to participate and 02 had severe anemia. Accordingly, 175 pregnant women were randomized and randomly allocated into 3 groups, preliminarily divided into placebo group (n=59), calcium group 500mg/day (n=58) and calcium group 1,500mg/day (n=58).

At the follow-up after 6 weeks, there were 44 losses, 12 in the placebo group, 15 in the calcium group 500mg/day and 17 in calcium group 1,500mg/day. In the analysis of the total number of pregnant women who started the research protocol, 83 completed all stages. Supplementary Material displays the flow chart of study participants according to CONSORT 2010. For patients who did not attend reassessments, data from the last assessment were repeated to perform the intention-to-treat analysis.

Clinical characteristics, demographic information and laboratory characteristics before the start of the trial (baseline) were statistically similar for the study sample and are shown in Table 1. The results suggest the homogeneity between the groups and that randomization was not compromised by discrepancies among the groups. At the end of the study, after 8 weeks, low treatment adherence and loss with regard to follow-up were significant for the group with maximal supplementation.

Flow diagram of the study design and participant allocation.

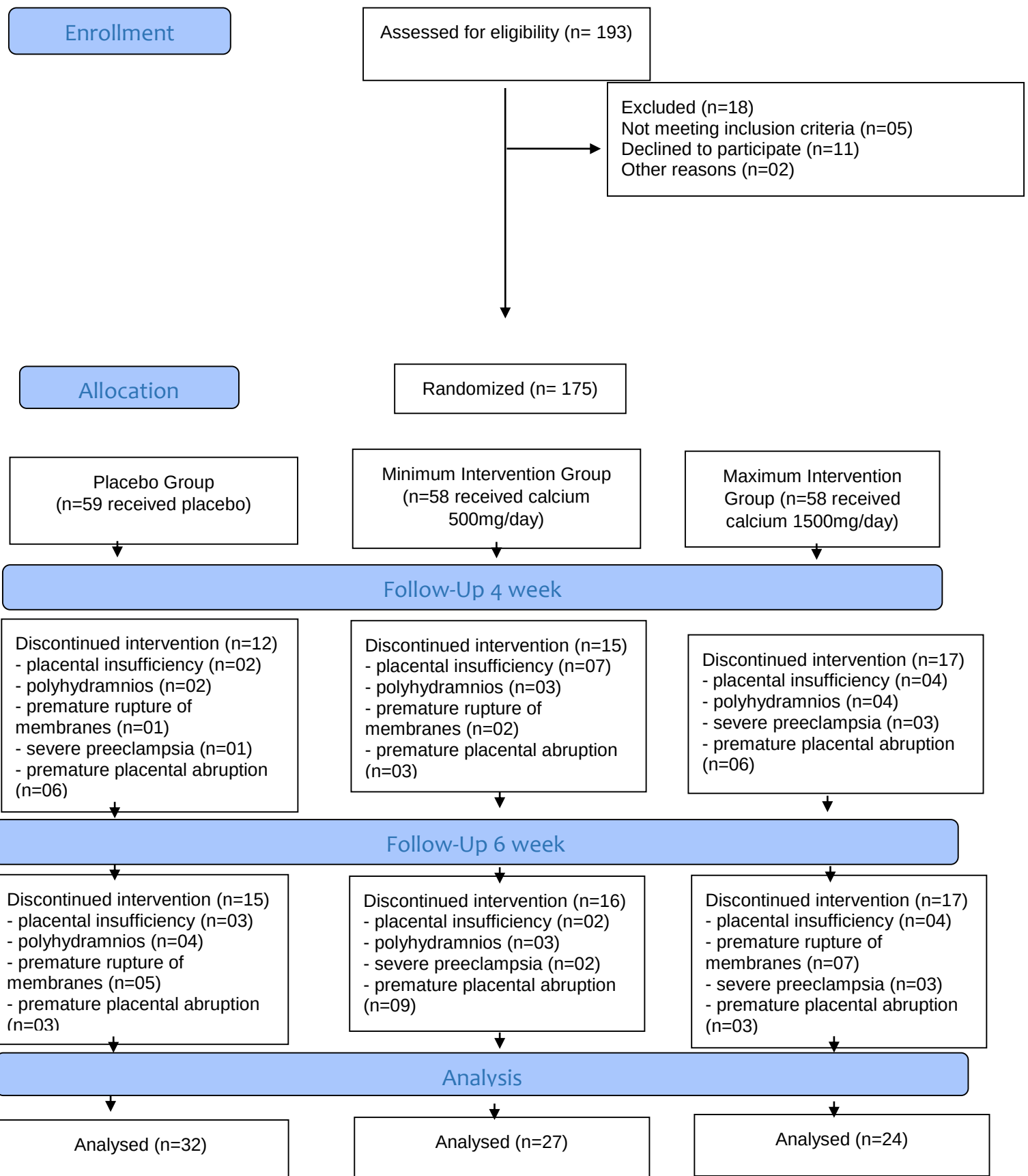


Table 1. Clinical characteristics, demographic information before the start of the trial (baseline) according to the groups.

Variable	Calcium group 500mg/day (n=58)	Calcium group 1,500mg/day (n=58)	Placebo Group (n=59)	p-value
	Mean (SD)	Mean (SD)	Mean (SD)	
Age (years)	30.2 (5.1)	30.4 (5.1)	28.6 (4.7)	0.327
Education (years of study)	12.4 (5.5)	12.4 (4.6)	13.9 (5.3)	0.427
Gestational age (weeks)	26.9 (4.0)	26.3 (4.7)	28.2 (5.0)	0.299
Initial weight (Kg)	94.2 (17.3)	86.5 (16.3)	87.7 (17.9)	0.227
Initial BMI (Kg/m ²)	35.7 (5.9)	32.6 (7.1)	32.7 (6.2)	0.161
Dietary calcium (g)	531.5 (315.7)	731.5 (477.0)	569.7 (310.1)	0.135
Initial SBP (mmHg)	131.6 (13.8)	131.5 (11.2)	127.8 (12.6)	0.416
Initial DBP (mmHg)	84.2 (9.3)	83.8 (13.2)	81.3 (8.9)	0.531
Triglyceride, mg/dl	224.9 (18.1)	211.2 (15.1)	137.8 (8.9)	0.075
Cholesterol, mg/dl	201.0 (6.9)	235.8 (8.0)	227.1 (6.9)	0.195
LDL-c, mg/dl	101.7 (5.7)	123.8 (6.9)	116.3 (5.8)	0.063
HDL-c, mg/dl	62.8 (3.4)	65.6 (3.5)	76.6 (3.7)	0.393
Hs-CRP, mg/dl	14.3 (1.8)	10.5 (1.3)	3.3 (0.3)	0.268
Ionized calcium, mg/dl	9.1 (0.2)	9.1 (0.2)	9.4(0.2)	0.832
After 8 weeks	n (%)	n (%)	n (%)	
Low treatment adherence	4 (2.2)	14 (8) [#]	3 (1.7)	0.026[#]
Follow-up loss	31 (17.7)	34 (19.4)	27 (15.4)	0.890

ANOVA – independent samples / [#] Chi-square. SBP, systolic blood pressure; DBP, diastolic blood pressure; BMI, body mass index; LDL-c, low-density lipoprotein cholesterol; HDL-c, high-density lipoprotein cholesterol; hs-CRP, ultrasensitive C-reactive protein.