

Effectiveness and safety of the intradialytic oral nutrition over nutritional markers and intradialytic hypotension in comparison with home complementation in patients undergoing hemodialysis.

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Brief report.

Flowchart diagram according to CONSORT 2010.

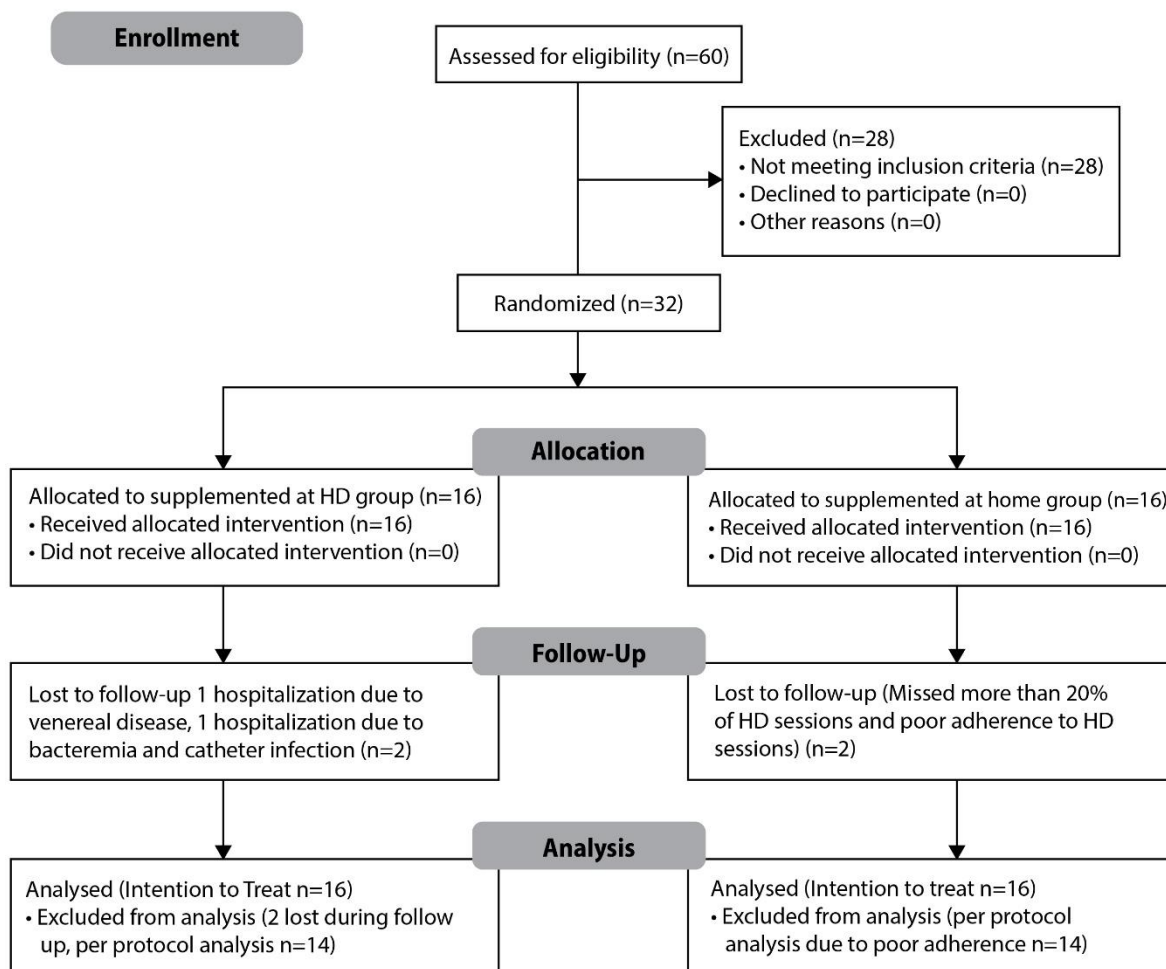


Figure 1. Flowchart of the study population

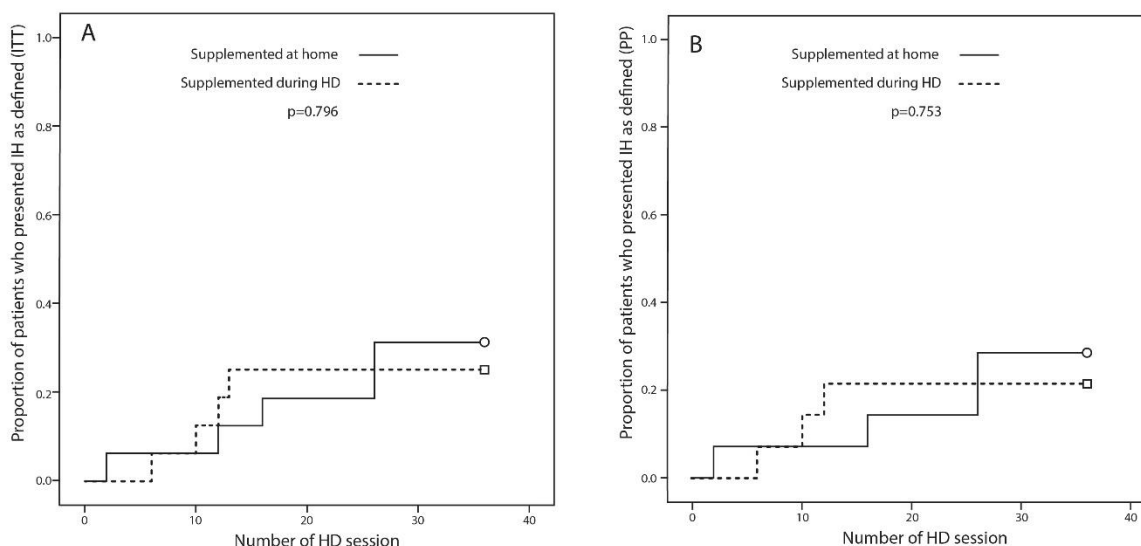
Baseline Characteristics. Table 1. Basal characteristics of patients.

Variable	All n=32	Supplemented during HD n=16	Supplemented at home n=16	P value
Age (years)	40.4±16.9	43.4±19.1	37.4±14.4	0.840
Sex (n/%Female)	17(53)	8(53)	7(43)	0.723
Dialysis vintage (months)	15.5 (8.5 - 35.5)	33 (10 – 38)	12 (7.5 – 25.5)	0.264
Hemodialysis characteristics				
Ultrafiltration Volume (L)	2.2 (1.8 – 2.7)	2.1 (1.6 – 2.6)	2.4 (1.9 – 2.7)	0.213
Time of treatment (minutes)	215±15	219±11	210±17	0.090
SAP (mm/Hg)	145 (132 – 163)	147 (131 – 161)	144 (132 – 170)	0.925
SAP 60 minutes (mm/Hg)	140 (123 – 155)	144 (124 -155)	136 (121 – 157)	0.611
Kt/V	1.9 (1.6 – 2.1)	1.9 (1.6 – 2.1)	1.9 (1.6 – 2.1)	0.522
URR (%)	79±6.6	78.3±6.2	79.5±7	0.612
nPNA (g/kg)	0.96±0.2	0.92±0.2	0.99±0.2	0.290
Biochemical parameters				
Hemoglobin (mg/dL)	9.4±1.9	9.6±1.9	9.2±1.8	0.582
Glucose (mg/dL)	113.5 (98-150)	119 (99 – 167)	113 (94 -147)	0.584
Creatinine (mg/dL)	11.5±3.2	11.5±3.6	11.5±2.9	0.998
Sodium (mEq/L)	138±2.5	138.3±2.7	138.5±2.4	0.891
Albumin (mg/dL)	3.6 (3.3 – 4.1)	3.5 (3.1 – 3.7)	3.9 (3.5 – 4.4)	0.073
Nutritional and body composition indicators				
BMI Kg/m ²	22.5 (20 – 27)	22.8 (20.3 -27)	22.5 (19.6 – 27.1)	0.734
Fat mass (%)	26.2±8.7	28±8.7	24.2±8.5	0.225
Lean mass (%)	73.8±8.7	71.9±8.7	75.8±8.4	0.208
MAC (cm)	26.4 (24.1-31.3)	26.5 (24.7 – 33.4)	26.2 (23.6 – 29.3)	0.485
Phase angle (°)	5.8 (5.3 -6.7)	6 (4.6 – 6.9)	5.6 (5.3-6.4)	0.821
Dry weight (Kg)	62.1 (47.8 – 73.6)	62.9 (46.2 – 74.2)	58 (50.9 – 70.9)	0.970
MIS (Score)	6 (5-8)	6.5 (5.3 – 8)	6 (5 – 7.8)	0.503
Functionality test				
Gait speed (seconds)	4.4 (3.9 – 5.5)	4.6(4.1 – 6.2)	4.4 (3.5-4.9)	0.221
Student-T test for independent groups				
U-Mann Whitney Test , SAP, systolic arterial pressure; URR, urea reduction rate; nPNA, Normalized protein nitrogen appearance; BMI, body mass index; MAC, Mid arm circumference; MIS, Malnutrition Inflammation Score.				
Chi² Pearson				

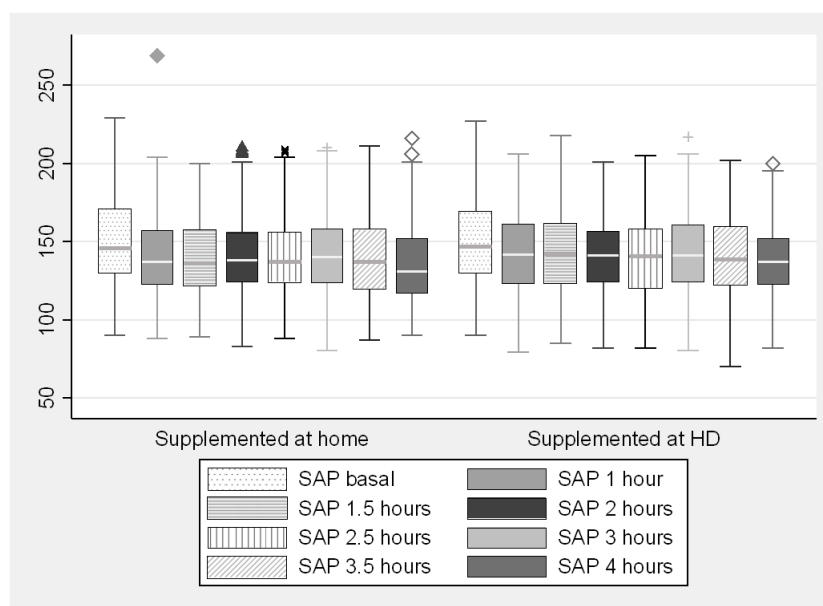
1) Nutritional outcomes. Table 2. Nutritional and clinical parameters before and after the study protocol.

Variable	Supplemented during HD (n=16) Baseline	Final	p *	Supplemented at home (n=16) Baseline	Final	p *	p +
Hemodialysis characteristics							
Kt/V	1.9 (1.6 – 2.1)	1.8(1.5-2.1)	0.570	1.9 (1.6 – 2.1)	1.8(1.7 –2.0)	0.162	0.940
URR (%)	78.3±6.2	81.4±4.2	0.036	79.5±7	78.4±7.7	0.329	0.174
nPNA (g/kg/day)	0.92±0.2	1.06±0.23	0.059	0.99±0.2	1.08±0.17	0.056	0.802
Biochemical paramaters							
Hemoglobin mg/dL	9.6±1.9	9.7±2.1	0.689	9.2±1.8	10.3	0.010	0.518
Glucose mg/dL	119 (99 – 167)	120 (91-170)	0.877	113 (94 -147)	110(94-151)	0.641	0.850
Creatinine mg/dL	11.5±3.6	10.8±3.9	0.139	11.5±2.9	11.3±2.9	0.672	0.655
Albumin mg/dL	3.5 (3.1 – 3.7)	3.5(3.4-4.1)	0.046	3.9 (3.5 – 4.4)	3.8 (3.5 –4.3)	0.722	0.307
Nutritional and body composition indicators							
BMI (Kg/m ²)	22.8 (20.3 -27)	23.6(21.4-27.2)	0.001	22.5 (19.6 – 27.1)	22(19.8 – 28.2)	0.167	0.327
Fat mass (%)	28±8.7	27.7±9	0.632	24.2±8.5	24.8±8.4	0.312	0.350
Lean mass (%)	71.9±8.7	72.2±9	0.663	75.8±8.4	75.1±8.4	0.239	0.349
MAC (cm)	26.5 (24.7 – 33.4)	26.7(25.1-32)	0.460	26.2 (23.6 – 29.3)	26(23.3-32.6)	0.550	0.451
Phase angle (°)	6 (4.6 – 6.9)	6.2(5 – 6.7)	0.347	5.6 (5.3-6.4)	5.9(5.5-6.9)	0.977	0.865
Dry weight (Kg)	62.9 (46.2 – 74.2)	65.2(47.6 – 75.1)	0.001	58 (50.9 – 70.9)	58 (50.9 – 72.9)	0.285	0.624
MIS (Score)	6.5 (5.3 – 8)	4 (3 -4.8)	0.001	6 (5 – 7.8)	3 (2-5)	0.001	0.418
Functionality							
Gait speed (seconds)	4.6(4.1 – 6.2)	3.9 (3.4 – 4.7)	0.000	4.4 (3.5-4.9)	3.5(2.9 – 4.2)	0.000	0.235
*Baseline vs Final +Final vs Final Paired test (Paired T-Test or Wilcoxon) Independent groups (T-Student for independent groups or Mann-Whitney) Chi² (Pearson or Fisher)							

2) Safety outcome. Figure 1. Kaplan-Meier analysis for Intradialytic hypotension (ITT: Intention to treat; PP: Per protocol).



3) Safety outcome. Figure 2. Systolic arterial pressure (SAP) during 36 sessions.



No statistical differences were shown in repeated measures modelling.

4) Adverse events. There were no adverse events associated with this trial.

