

Compliance with Standard care vs Ready to Eat Meals Prior to Bariatric Surgery - a Randomised Controlled Trial

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Background & Current Literature

- A 5-10% weight loss before Bariatric Surgery helps shrink liver volume → ↑ surgical visibility and access, optimising surgical outcomes [1]
- Very-low-calorie diets (VLCDs) ≤ 800 kcal/day are routinely prescribed to achieve this [2]
- However compliance to conventional liquid meal replacements VLCDs (Optifast™) is often suboptimal [1,3]
- Emerging evidence suggest that ready-to-eat (RTE) VLCD meals may ↑ compliance by ↑ palatability, variety and texture ➔ ↑ dietary adherence [4-6]



To investigate the effect of HealthFull™ versus Optifast™ on compliance, weight loss, metabolic parameters, and determinants of dietary adherence.



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[2] Van Nieuwenhove, Y. (2011). Archives of Surgery, 146(11), 1300. doi:10.1001/archsurg.2011.273

[3] Maston, G., Franklin, J., Gibson, A. A., Manson, E., Hocking, S., Sainsbury, A., & Markovic, T. P. (2020). Behavioral Sciences, 10(9), 136. https://doi.org/10.3390/bs10090136

[4] Erdem, N. Z., Ozelgun, D., Taskin, H. E., & Avsar, F. M. (2022). Scientific Reports, 12(1). doi:10.1038/s41598-022-24959-z

[5] Barrea, L., Verde, L., Schiavo, L., Sarno, G., Camajani, E., Iannelli, A., ... Muscogiuri, G. (2023). Nutrients, 15(8), 1907. doi:10.3390/nu15081907

[6] Carbajo, M. A., Castro, M. J., Kleinfinger, S., Gómez-Arenas, S., Ortiz-Solórzano, J., Wellman, R., García-Ianza, C., & Luque, E. (2010). Nutricion hospitalaria, 25(6), 939-948. PMID: 21519764.

Methods

Eligible Participants (n=68)
Recruitment: Jul 2024 to May 2026

Intervention Group (HealthFull™) (n=32)

Standard Care Group (Optifast™) (n=36)

Both group were also advised to:



1. Add on non-starchy vegetables



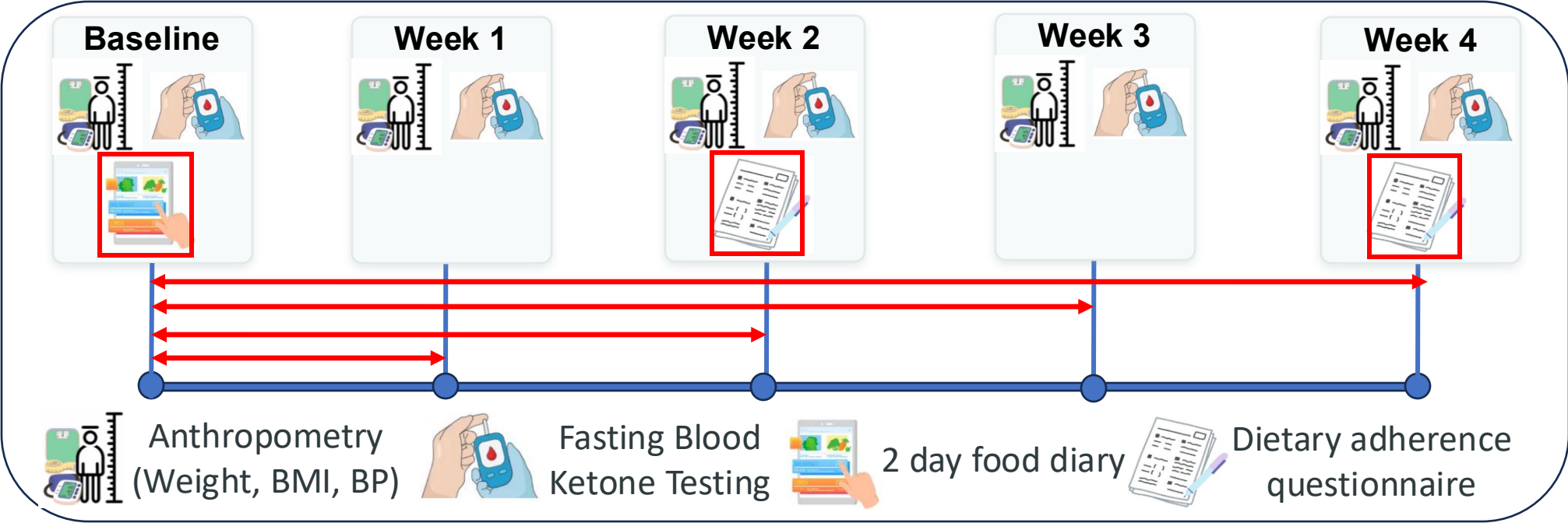
2. Keep to ≤ 800 kcal and ≤ 50 g net carbs a day



3. Drink 2L of unsweetened fluids a day



4. Nutritionist Buddy (nBuddy) Keto App food logging



Results – Meal compliance

Table 1: Meal compliance (%) via Nutritionist Buddy App logging

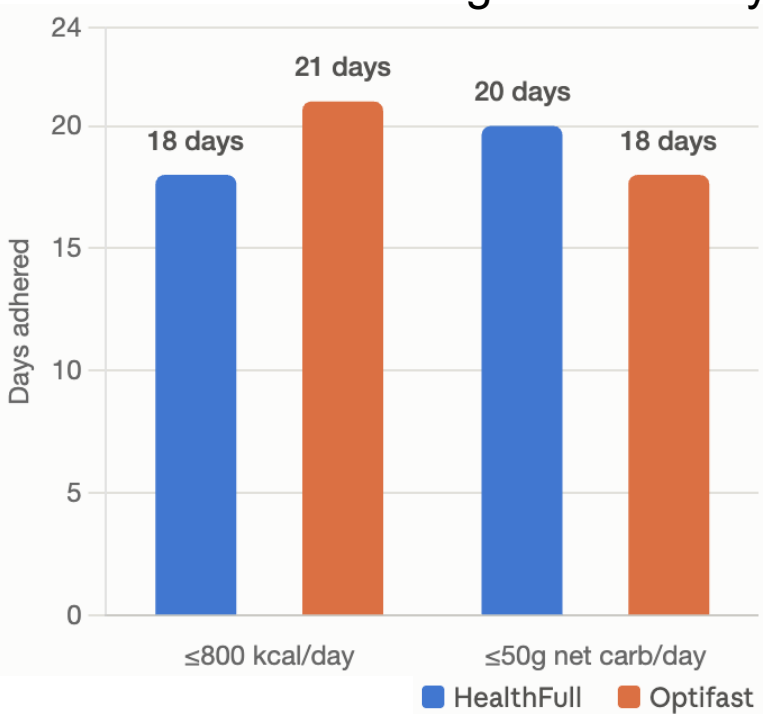
	HealthFull™ (n = 32)	Optifast™ (n = 36)		
Study Week	Median (IQR)	Median (IQR)	Effect Size (r)	P value
Week 1	85.7 (75.0-96.5)	66.7 (57.1-90.5)	0.28	0.030
Week 2	78.6 (64.3-92.9)	71.4 (38.1-90.5)	0.15	0.235
Week 3	78.6 (64.3-92.9)	76.2 (52.4-95.2)	0.14	0.301
Week 4	71.4 (53.6-92.9)	69.1 (52.5-100)	0.03	0.833
Across 2-weeks	82.1 (71.4-89.3)	64.3 (50.0-90.5)	0.21	0.109
Across 4-weeks	76.8 (62.5-87.5)	67.3 (47.6-90.5)	0.16	0.226

Table 2: Participants achieving nutritional ketosis (0.5–3.0 mmol/L)

Group	Blood Ketones <0.5	Blood Ketones ≥0.5	Adjusted ^a		Group	Blood Ketones <0.5	Blood Ketones ≥0.5	Adjusted ^a	
			OR (95% CI)	p-value				OR (95% CI)	p-value
Week 1					Week 3				
HealthFull™	26 (96.3%)	1 (3.7%)	1.0		HealthFull™	24 (96.0%)	1 (4.0%)	1.2 (0.1 – 14.3)	0.875
Optifast™	29 (90.6%)	3 (9.4%)	1.4 (0.2 – 13.0)	0.751	Optifast™	29 (96.7%)	1 (3.3%)	1.0	
Week 2					Week 4				
HealthFull™	26 (100.0%)	0 (0.0%)	1.0		HealthFull™	22 (95.7%)	1 (4.3%)	1.04 (0.09 – 12.35)	0.978
Optifast™	32 (97.0%)	1 (3.0%)	1.7 (0.1 - 29.3)	0.698	Optifast™	28 (96.6%)	1 (3.4%)	1.0	

^aadjusted for gender, age and baseline value of the outcome

Figure 1: Dietary adherence to ≤800kcal and ≤50g net carb/day



Results – Metabolic parameters and determinants of dietary adherence

Table 3: Secondary outcomes at Week 1, 2, 3, 4 post-enrollment

Outcomes	n	Mean Change from Baseline		Between-group differences ^a			Outcomes	n	Mean Change from Baseline		Between-group differences ^a		
		HealthFull™ (n = 32)	Optifast™ (n = 36)	Mean difference (95% CI)	P value	Cohen d			HealthFull™ (n = 32)	Optifast™ (n = 36)	Mean difference (95% CI)	P value	Cohen d
Δ Weight, kg							Total Score						
Week 1	59	-2.3 ±1.8	-2.4 ±2.0	-0.2 (-1.1- 0.7)	0.679	0.05	Week 2	59	86 ±15	91 ±13	-6 (-14- 1) ^b	0.109 ^b	0.21 ^b
Week 2	59	-3.1 ±2.3	-3.2 ±3.0	-0.4 (-1.6- 0.8)	0.519	0.09	Week 4	54	90 ±10	94 ±14	-4 (-11- 3) ^b	0.211 ^b	0.17 ^b
Week 3	55	-4.5 ±3.0	-4.4 ±2.9	-0.3 (-1.8- 1.0)	0.600	0.07	Self-efficacy						
Week 4	54	-5.1 ±3.4	-5.7 ±3.4	-0.0 (-1.7- 1.6)	0.985	0.003	Week 2	59	20 ±5	22 ±5	-2 (-4- 0.8) ^b	0.186 ^b	0.17 ^b
Δ Weight,%							Week 4	55	22 ±4	23 ±5	-2 (-4- 0.9) ^b	0.189 ^b	0.18 ^b
Week 1	59	-1.8 ±1.3	-1.9 ±1.5	-0.1 (-0.8- 0.6) ^b	0.753 ^b	0.04 ^b	Social Influence						
Week 2	59	-2.6 ±1.7	-2.6 ±2.2	-0.3 (-1.2- 0.6) ^b	0.498 ^b	0.09 ^b	Week 2	59	26 ±5	26 ±5	0 (-3- 2) ^b	0.732 ^b	0.05 ^b
Week 3	55	-3.6 ±2.2	-3.5 ±2.1	-0.3 (-1.3- 0.7) ^b	0.555 ^b	0.08 ^b	Week 4	54	27 ±4	28 ±5	-1 (-3- 2) ^b	0.655 ^b	0.06 ^b
Week 4	54	-4.1 ±2.4	-4.4 ±2.3	0.0 (-1.1- 1.1) ^b	0.990 ^b	0.002 ^b	Intention						
Δ Systolic blood pressure, mmHg							Week 2	59	17 ±4	18 ±3	-2 (-3- 0) ^b	0.079 ^b	0.23 ^b
Week 1	59	1.9 ±13.4	-1.9 ±12.4	0.8 (-6.0- 7.6)	0.809	0.03	Week 4	55	18 ±2	18 ±3	-0 (-2- 1) ^b	0.617 ^b	0.07 ^b
Week 2	59	-4.8 ±12.7	-4.5 ±16.9	-3.3 (-11.9- 5.3)	0.446	0.10	Attitude						
Week 3	55	-3.3 ±12.4	-8.7 ±11.0	2.9 (-3.7- 9.6)	0.379	0.12	Week 2	59	23 ±4	25 ±4	-2 (-5- 0) ^b	0.032 ^b	0.29 ^b
Week 4	54	1.2 ±11.1	-3.1 ±16.2	1.7 (-7.0- 10.4)	0.695	0.05	Week 4	55	24 ±3	25 ±3	-2 (-4- 0) ^b	0.123 ^b	0.21 ^b
Δ Diastolic blood pressure, mmHg							^a adjusted for gender, race, age and baseline value of the outcome						
Week 1	59	-0.9 ±9.2	0.8 ±9.5	-2.0 (-6.7- 2.7)	0.387	0.11	^b adjusted for gender , race and age						
Week 2	59	-3.7 ±7.9	-1.3 ±10.3	-2.5 (-7.3- 2.3)	0.297	0.14	No significant p-value after Benjamini-Hochberg correction with false discovery rate at 0.20 and n=56						
Week 3	55	-4.2 ±8.8	-3.2 ±10.5	-1.6 (-6.2- 3.0)	0.481	0.10							
Week 4	54	-9.3 ±10.9	-6.6 ±14.7	-3.0 (-9.7- 3.7)	0.376	0.12							

Conclusion



Extending VLCD slightly beyond 4 weeks may help achieve $\geq 5\%$ weight loss.



Optifast™ remains an effective option for preoperative VLCDs



HealthFull™ meals are a viable alternative