

# Compliance with an energy-dense low-volume oral nutritional supplement versus a standard high-energy supplement: a non-inferiority randomized crossover trial

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## INTRODUCTION

Several studies have highlighted the benefits associated with the use of oral nutritional supplements (ONS) in different conditions<sup>1,2</sup>. However, it should be noted that compliance with ONS is key to improving patient nutritional status, especially in disease-related malnutrition (DRM)<sup>3</sup>.

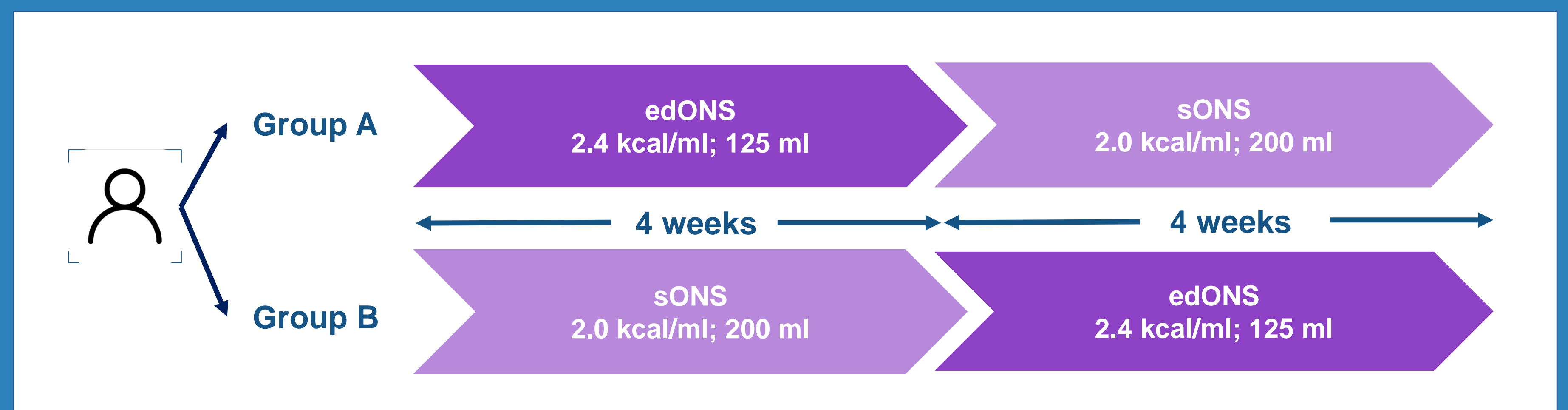
Compliance can be influenced by the energy density and volume of the ONS<sup>3</sup>.

## AIM

We aimed to evaluate compliance (defined as the percentage of consumed energy out of prescribed) with an energy-dense ONS (edONS) versus a high-energy standard ONS (sONS).

## METHODS

A randomized, crossover trial was conducted in adult patients with DRM from 2 Spanish hospitals. Patients were randomly assigned to take 2 bottles daily of an ONS for 4 weeks and then switched to the other ONS.



Nutritional status (SGA) and body mass index (BMI) were recorded at baseline, weeks 4 and 8. Patients daily recorded the wasted ONS volume. Based on wasted ONS recorded and energy prescribed, compliance was estimated for each group period. Statistical analysis considered a non-inferiority margin of 5% and a significance p-value <0.05. The analysis was performed using Stata v.14.

## RESULTS

A total of 73 patients were recruited (63% male; mean age 55.7±13.9). At baseline, the mean BMI was 22, 49% of patients were suspected malnourished or moderately malnourished and 51% were severely malnourished. The baseline characteristics of both groups are shown in **Table 1**. In both groups, mean BMI slightly increased with edONS; at the last visit, 9.5% in Group A and 12.9% in Group B were well-nourished (**Table 2**).

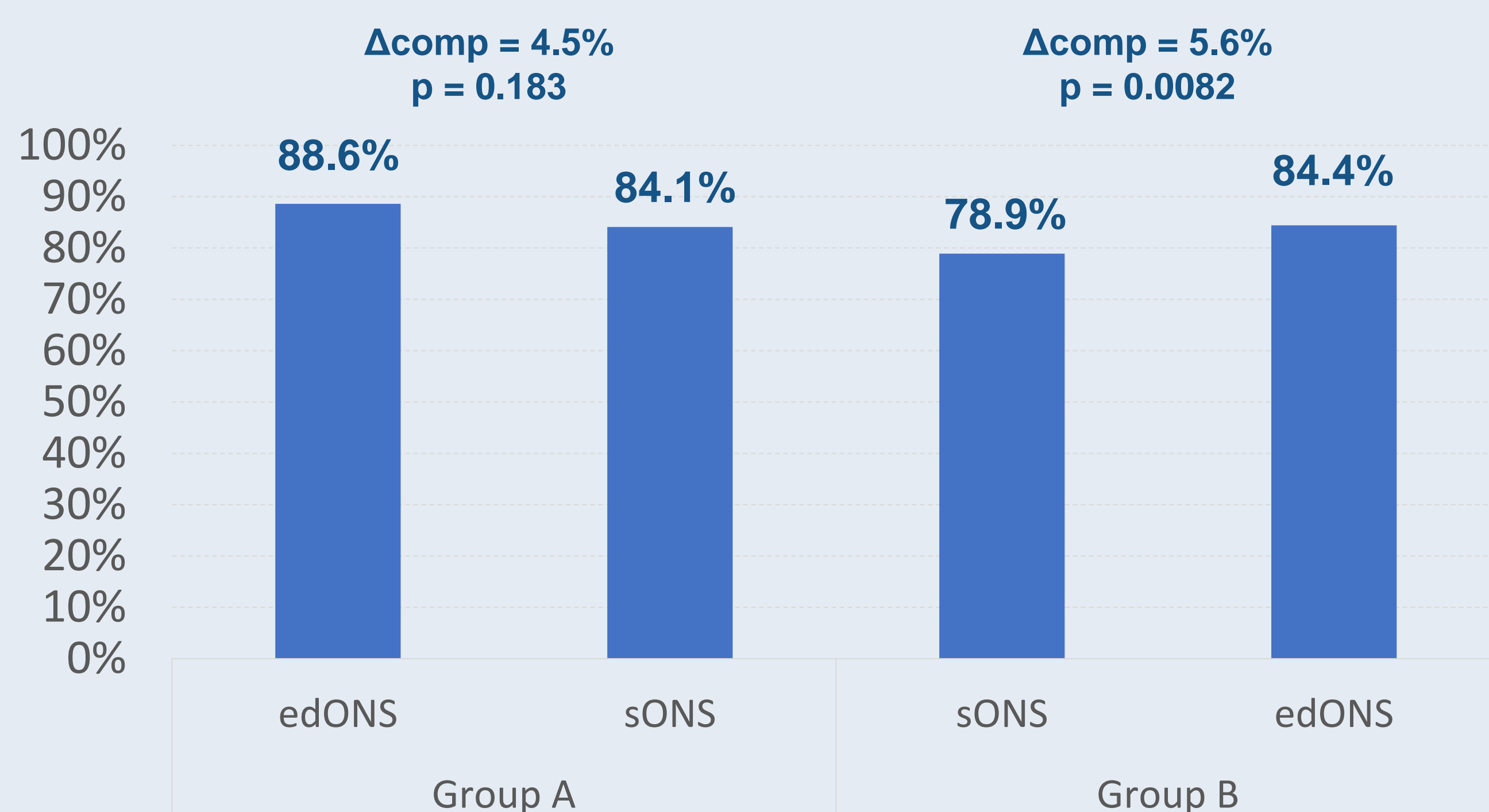
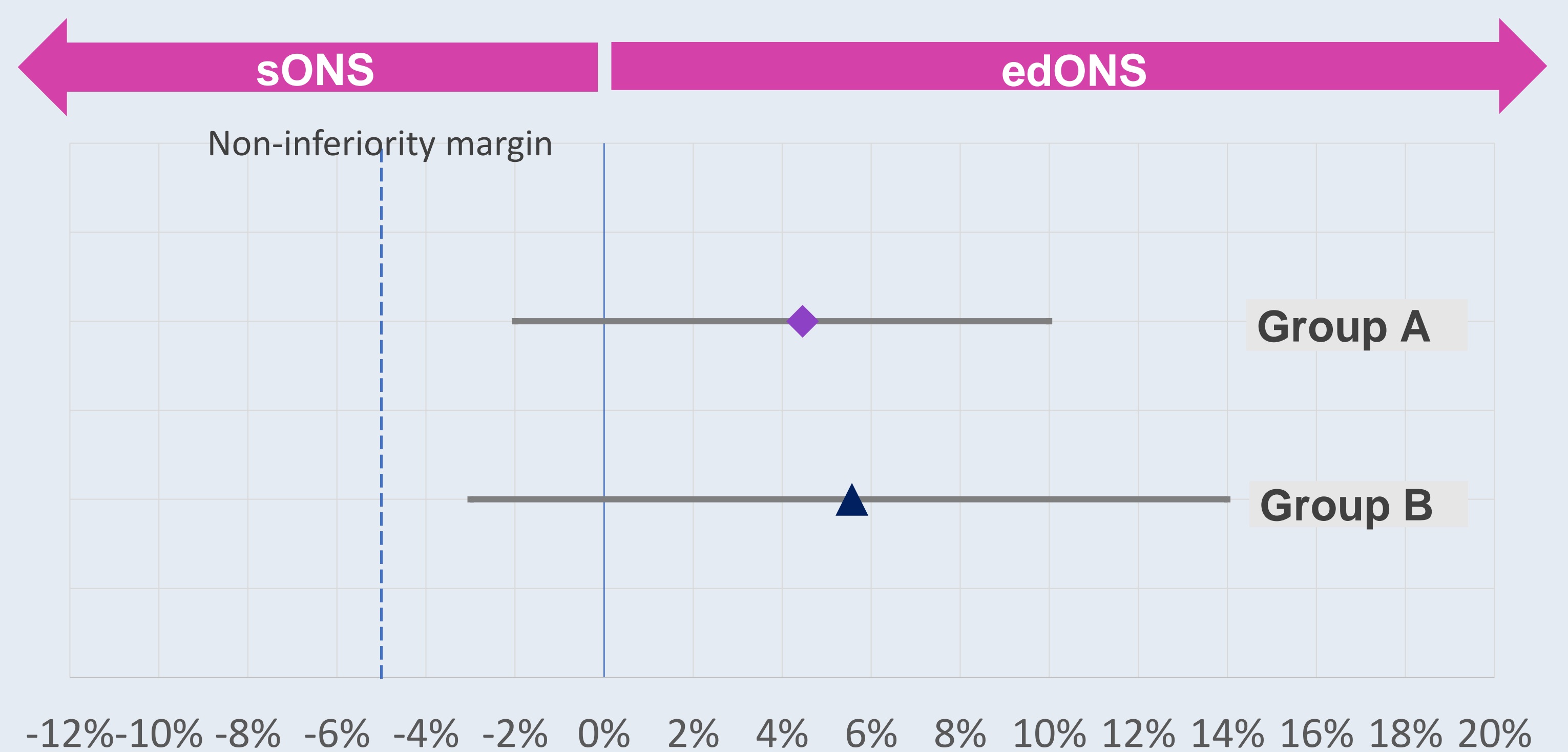
**Table 1. Patient baseline characteristics.**

	Group A (n=42)	Group B (n=31)
Age, years (mean [SD])	56.2 (13.1)	55.1 (15.1)
Gender, n (%)		
Male	25 (59.5%)	21 (67.7%)
Female	17 (40.5%)	10 (32.3%)

**Table 2. Evolution of the nutritional status.**

	Baseline		Week 8	
	Group A	Group B	Group A	Group B
Body mass index (BMI)	22.1 (3.5)	21.9 (4.1)	22.3 (3.3)	22.0 (3.9)
Nutritional Status, SGA (%)				
Well-nourished	-	-	4 (9.5)	4 (12.9)
suspected malnourished/moderate malnourished	20 (47.6)	16 (51.6)	19 (45.2)	16 (51.6)
Severe malnourished	22 (52.4)	15 (48.4)	18 (42.9)	11 (35.5)

Compliance with the study ONS is shown in **Figure 1**. Compliance with edONS was higher than with sONS, with significant differences observed in group B. In both groups, the lower range of the confidence interval for compliance with edONS was greater than the non-inferiority margin, therefore, compliance with edONS was non-inferior to compliance with sONS (**Figure 2**).

**Figure 1. Compliance with ONS in each group.****Figure 2. Non-inferiority analysis of edONS versus sONS.**

## CONCLUSIONS

Compliance with edONS is higher than sONS, achieving similar nutritional results with less wasted product.

## REFERENCES

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