



Oral nutrition supplements compared with between-meal snacks for nutritional therapy in patients with COPD identified as at nutritional risk: A randomized controlled feasibility trial

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Background

- Malnutrition is common in patients with chronic obstructive pulmonary disease (COPD)
 - ↑ complications, ↑ hospital stay and ↑ mortality
 - leading to an increased economic and operational burden for health services
- Many randomized trials have investigated nutritional interventions to treat malnutrition in stable COPD patients
 - positive impact on survival, rate of complications, length of stay (LOS) and hospital readmissions as well as some nutritional and patient-centered outcomes
- Most of the studies focused on oral nutritional supplements (ONS)
 - often comparing ONS to control group receiving no nutritional intervention



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Collins PF, Elia M, Stratton RJ. Nutritional support and functional capacity in chronic obstructive pulmonary disease: a systematic review and meta-analysis. *Respirology*. 2013;18(4):616-29.

Collins PF, Stratton RJ, Elia M. Nutritional support in chronic obstructive pulmonary disease: a systematic review and meta-analysis. *Am J Clin Nutr*. 2012;95(6):1385-95.

Ferreira IM, Brooks D, White J, Goldstein R. Nutritional supplementation for stable chronic obstructive pulmonary disease. *Cochrane Database Syst Rev*. 2012;12:CD000998.



Background

- Few clinical studies and none in COPD patients evaluating the use of energy and protein dense in-between meal snacks alone
 - relatively cheaper approach than ONS
 - increases the variety of options for the patient
- Studies have mainly focused on weight change, mortality, LOS and hospital readmissions as outcomes
- Few have assessed the effect of nutritional support on quality of life
 - outcome particularly relevant to the patient



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Collins PF, Elia M, Stratton RJ. Nutritional support and functional capacity in chronic obstructive pulmonary disease: a systematic review and meta-analysis. *Respirology*. 2013;18(4):616-29.

Weekes CE, Emery PW, Elia M. Dietary counselling and food fortification in stable COPD: a randomised trial. *Thorax*. 2009;64(4):326-31.

Collins PF, Stratton RJ, Elia M. PP122-SUN: Outstanding abstract: Nutritional support in Chronic Obstructive Pulmonary Disease (COPD): A Randomised Trial. *Clinical Nutrition*.33:S65.



Aim

The aim of this 12-month randomized intervention trial were:

- 1) To study the feasibility of the recruitment, retention and provision of each intervention
- 2) To study the potential impact of the provision of Snacks compared with ONS on body weight and QoL in patients with COPD.



Methods

- Randomized controlled trial
- COPD patients at nutritional risk
≥4 score using a validated screening tool
- Two study groups:
 - ONS or Snacks
- The intervention started in hospital and was continued for 12 months after discharge from the hospital
- Assessments were undertaken in at hospital discharge (baseline) and then at 3, 6, 9 and 12 months post discharge



Outcomes

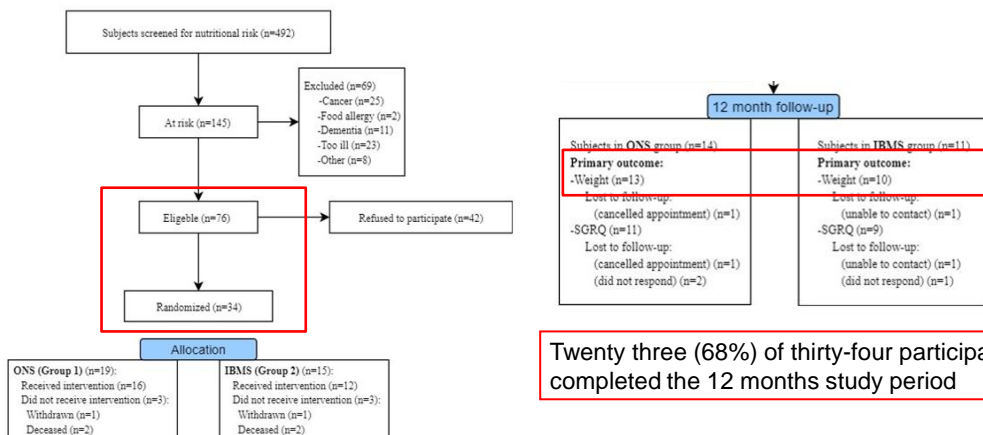
- Feasibility outcomes:
 - percentage of eligible subjects that accepted participation
 - percentage of included subjects that finished the 12 months intervention period
 - use of ONS/Snacks according to 24 hour recalls
- Primary outcome:
 - weight change to one year from admission to the hospital
 - bioelectrical impedance analysis (BIA)
- Secondary outcomes:
 - quality of life
 - St George's Respiratory Questionnaire (SGRQ)
 - energy- and protein intake during hospital stay and at home
 - plate diagram sheet and 24 hour recalls
 - lung function (FEV₁ and FVC)
 - spirometry
 - functional performance:
 - six-minute walk distance (6MWD)
 - timed up and go (TUG)
 - 30 second chair stand
 - hand-grip strength (HGS)



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Results

feasibility outcomes



Twenty three (68%) of thirty-four participants completed the 12 months study period

Thirty four (45%) of the 76 eligible patients consented to take part in the study

Mean weight change (%) from baseline

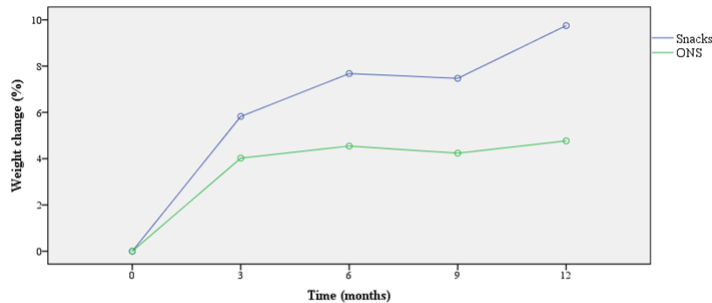


Figure 2 Mean weight change (%) from baseline. Intention-to-treat analysis. Groups: ONS=oral nutritional supplements (n=16), Snacks (n=13).



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Body composition

Table 3 Mean change (SD) (kg) in body composition from baseline to each follow up.

	ONS				Snacks			
	3 months	6 months	9 months	12 months	3 months	6 months	9 months	12 months
Weight (kg)	2.1 (4.3)	2.2 (4.7)	2.1 (4.5)	2.3 (4.6)	2.7 (4.4) ¹	3.6 (5.3) ¹	3.4 (6.4)	4.4 (6.4) ¹
Fat mass (kg)	4.4 (6.4) ¹	3.9 (5.4) ¹	4.0 (5.0) ¹	3.7 (4.9) ¹	3.2 (4.5) ¹	2.8 (3.7) ¹	3.1 (4.8) ¹	2.9 (4.8)
Fat free mass (kg)	-2.3 (5.4)	-1.7 (5.5)	-1.9 (6.0)	-1.3 (5.8)	-0.1 (3.3)	2.0 (6.0)	0.8 (6.3)	1.8 (6.1)
Fat free mass index (kg/m ²)	-0.7 (1.6)	-0.5 (1.7)	-0.6 (1.8)	-0.4 (1.7)	0.0 (0.9)	0.5 (1.6)	0.1 (1.8)	0.5 (1.7)

Data shown as mean (SD). Intention-to-treat analysis. Groups: ONS=oral nutritional supplements (n=16), Snacks (n=13).

¹ Significantly different from baseline, p<0.05.



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Quality of life

Table 4 Quality of life (SGRQ)

	ONS			Snacks		
	Baseline	3 months	12 months	Baseline	3 months	12 months
Activity score	75.0 (30.5)	71.4 (30.2)	78.3 (21.3)	71.5 (16.8)	68.8 (18.8)	68.1 (15.9)
Impact score	52.8 (23.6)	44.2 (29.3)	48.5 (25.2)	45.7 (19.8)	35.9 (24.2)	35.5 (24.9)
Symptoms score	66.7 (16.9)	45.9 (19.4) ¹	51.1 (19.3) ¹	64.3 (20.7)	39.5 (23.0) ¹	49.0 (26.8) ¹
Total score	62.0 (22.1)	52.9 (26.8)¹	58.1 (21.1)	56.7 (17.0)	46.6 (20.4)¹	47.7 (20.7)¹

Intention-to-treat analysis. Groups: ONS=oral nutritional supplements. (n=16), Snacks (n=13).
Data shown as mean (SD).

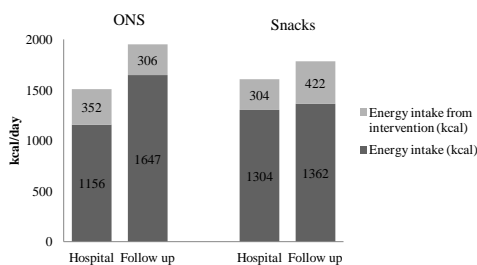
¹ Significantly different from baseline, $p < 0.05$.



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Energy- and protein intake/day during hospitalization and in follow up

Energy (kcal/day)



Protein (g/day)

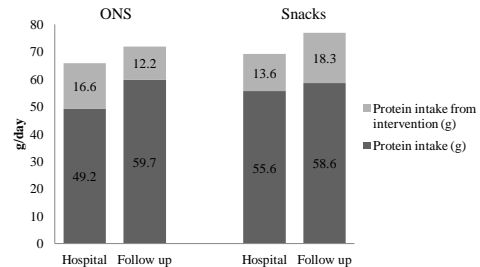


Figure 3 a) Energy- and b) protein intake/day during hospitalization and in follow up. Total energy- and protein intake per kg actual body weight at baseline, during hospitalization vs. follow up. ONS 28 kcal vs. 39 kcal, $p=0.002$ and 1.2 g vs. 1.4 g, $p=0.213$. Snacks 32 kcal vs. 40 kcal, $p=0.009$ and 1.4 g vs. 1.8 g, $p=0.048$.

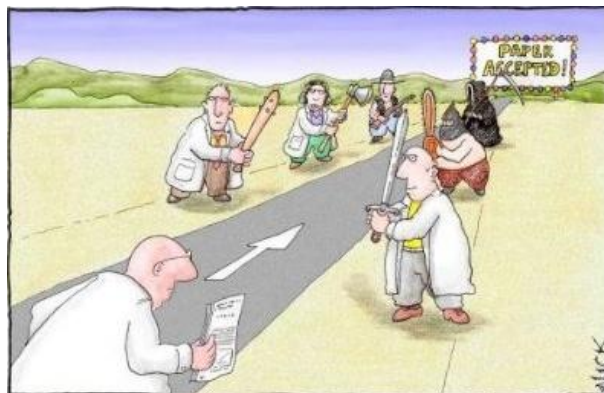


Conclusion

- Results from this feasibility study suggest that the provision of Snacks are at least as feasible and effective as ONS to patients with COPD who are at nutritional risk
- Adequately powered RCTs are required to confirm this effect
- Future RCTs should be informed by the recruitment and retention issues that have been raised



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Supplemental table 5 Measures of lung function, functional measures and muscle strength in follow up (3 and 12 months).

	ONS				IBMS			
	n	Baseline	3 months	12 months	n	Baseline	3 months	12 months
Lung function								
FEV ₁ (%)	14	36.3 (14.0)	39.0 (12.6)	36.6 (14.9)	12	39.9 (8.1)	41.8 (6.1)	37.3 (6.9)
FVC (%)	14	63.3 (12.7)	73.4 (16.3) ¹	66.7 (13.2)	12	69.3 (23.0)	71.3 (18.4)	68.2 (15.2)
Functional measures and muscle strength								
6 MWD (m)	13	236 (132)	266 (157)	258 (173)	9	212 (88)	257 (119)	259 (112)
TUG (sec)	15	15.4 (7.7)	12.9 (5.7) ¹	13.8 (7.4)	11	14.3 (3.9)	12.5 (3.0) ¹	13.7 (5.8)
30sec chair stand (n)	15	4.2 (4.3)	5.5 (5.4)	5.4 (5.0)	12	5.7 (3.3)	5.8 (2.9)	6.0 (2.5)
HGS (kg)	16	15.0 (9.0)	15.4 (10.2)	12.4 (9.2)	13	14.3 (6.9)	13.6 (5.8)	13.9 (5.6)

Intention-to-treat analysis. Data shown as mean (SD). ONS=oral nutritional supplements. IBMS=In-between meals snack. FEV₁=forced expiratory volume in 1 s. FVC=forced vital capacity. 6MWD=six minute walking distance. TUG=time up and go. HGS=hand grip strength.

¹ Significantly different from baseline, p<0.05.



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