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Original article

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SUMMARY

Background & aims: Malnutrition affects 5–10% of elderly people living in the community. A few studies suggest that nutritional intervention may reduce health care costs. The present study included malnourished elderly patients living at home. It aimed to compare health care costs between patients that were prescribed ONS by their general practitioner and those who were not, and to assess the effect of ONS prescription on the risk of hospitalisation.

Methods: This prospective multicentre observational study included malnourished patients ≥70 years old who lived at home. Patients were defined as malnourished if they presented with one or more of the following criteria: weight loss ≥5% in 1 month, weight loss ≥10% in 6 months, BMI <21 kg/m^2, albuminemia <35 g/L or Short-Form MNA ≤ 7. Their general practitioners prescribed an ONS, or not, according to their usual practice. Health care costs were recorded during a 6-month period. Other collected data were diseases, disability, self-perception of current health status, quality of life (QoL), nutritional status, appetite and compliance to ONS. A propensity score method was used to compare costs and risk of hospitalisation to adjust for potential confounding factors and control for selection bias.

Results: We analysed 191 patients. At baseline, the 133 patients (70%) who were prescribed ONS were more disabled ($p < 0.001$) and had poorer perception of their health ($p = 0.02$), lower QoL ($p = 0.04$) and lower appetite ($p < 0.001$) than the 58 patients (30%) who were not prescribed ONS. At 6 months, appetite had improved more in the ONS prescription group ($p = 0.001$). Weight change was not different between groups. Patients prescribed ONS were more frequently hospitalised (OR 2.518, 95% CI: [1.088; 5.829] hosp; $p = 0.03$). Analyses of adjusted populations revealed no differences in health care costs between groups. In the ONS prescription group, we identified that health care costs were lower ($p = 0.042$) in patients with an energy intake from ONS ≥ 500 kcal/d (1389 ± 264 €) *vs.* < 500 kcal/d (3502 ± 839 €). The risk of hospitalisation was reduced 3 and 5 times when the intake from ONS was ≥30 g of protein/day or ≥500 kcal/d, respectively.

Conclusions: ONS prescription in malnourished elderly patients generated no extra heath care cost. High energy and protein intake from ONS was associated with a reduced risk of hospitalisation and health care costs.

1. Introduction

Elderly people are at risk of malnutrition because of various pathological, social, economic or environmental conditions [1,2]. This population is prone to chronic diseases, cancer, dementia,

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Abbreviations

ADL	activities of daily living
BMI	body mass index
CCTIRS	French competent Authority (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la santé)
CI	confidence interval
CIRS-G	cumulative illness rating scale for geriatrics
CNIL	French competent Authority (Commission Nationale de l'Information et des Libertés)
EQ5D	EuroQol five dimensions questionnaire
GP	general practitioner
HAS	French Health Authority
MNA	Mini Nutritional Assessment
ONS	oral nutritional supplements
OR	odds ratio
PS	propensity score
Q1-Q3	quartiles
QoL	quality of life
SD	standard deviation
VAS	visual analogue scale

disability, poor appetite, chewing problems and polypharmacy. The prevalence of malnutrition in elderly people is estimated at 5–10% in the community, 15–30% in nursing homes and 40–50% in hospitals [3–5]. Malnutrition is associated with higher rates of hospitalisations, longer lengths of hospital stay, and higher morbidity and mortality. This leads to an economic burden [6].

The management of malnutrition is based on dietary counselling, technical or human assistance at mealtime, food fortification, texture adaptation, and prescriptions of energy- and protein-dense oral nutritional supplements (ONS) [3,7]. ONS are energy and nutrient dense products designed to increase dietary intake when diet alone is insufficient to meet daily nutritional requirements [8]. There are a wide range of ONS styles (milk, juice, yoghurt, savoury), formats (liquid, powder, pudding, prethickened), volumes, types (high protein, fibre containing), energy densities (1–3 kcal/ml) and flavours available to suit a wide range of needs and requirements. ONS are classified "high protein" when they provide >20% of energy from protein and "high energy" when they provide >1.5 kcal/ml or gram [9]. Systematic reviews and meta-analysis have shown that the treatment of malnutrition with ONS increases energy intake, protein intake and weight; in hospitalised patients, it reduces complications and readmissions to hospital and may reduce costs [9–11]. Effect on mortality and disability are controversial. In frail elderly people living at home, the weight gain was greater and the number of falls was lower in the group receiving a high energy ONS provided by a dietician than in the dietician visit only group [12]. Compared to snacks or dietary advice, ONS provided higher energy and protein intake and better quality of life in elderly people [13,14].

Economic studies address patients at risk of malnutrition or malnourished, with different surgical or medical diseases, in the hospital, post-discharge or in the community nursing home [6,15–18]. However, even if the prevalence of malnutrition is lower in the community than in nursing homes or in the hospital, the vast majority of elderly people are living in their own home and the number of malnourished older adults is higher in the community than in other settings. Studies including elderly people living in the community (own home and care home) suggest cost effectiveness but not cost savings [19–22]. However, to the best of our knowledge, there is no study on the clinical and economic consequences of ONS intake in elderly people living in their own home, where health care costs savings may be important.

We hypothesized that ONS would reduce hospitalisations and health care costs in patients living at home. The main objective of the present study was to compare the health care costs of malnourished elderly people living at home depending on ONS prescription status. It also aimed to assess the effect of ONS on the risk of hospitalisation and on nutritional parameters including appetite.

2. Materials and methods

2.1. Study design

We performed a prospective, comparative, multicentre, and non-interventional nutritional medico-economic study in France between March 2013 and January 2016.

2.2. Patients

Patients were eligible if they were aged 70 years and older, living at home, and diagnosed as malnourished by their general practitioner (GP) according to one or more of the following criteria: weight loss $\geq$ 5% in 1 month, weight loss $\geq$ 10% in 6 months, body mass index (BMI) < 21 kg/m^2, albuminemia <35 g/L or Mini Nutritional Assessment (MNA) Short-Form $\leq$ 7 [3].

Patients were not included if they used ONS in the previous month, received ongoing enteral or parenteral nutrition, or had a life expectancy shorter than 6 months.

The GP was free to prescribe ONS according to his/her usual practice. The final population consisted of patients with available data on compliance to ONS and 6-month health care costs record.

2.3. Ethics

Eligible patients were invited to participate, and written informed consent was obtained prior to any study procedure. GPs checked that enrolled patients were able to give a written consent, and to fill the compliance diary at home for those who were prescribed ONS. The protocol received approval from the competent national authority: CCTIRS (*Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé*) on 24 October 2012 (reference: 12.604) and CNIL (*Commission Nationale de l'Information et des Libertés*) on 26 November 2012 (reference: 912 527). This study was performed according to the protocol and ethical principles of the Declaration of Helsinki.

2.4. Data collection

Among the 100.000 GPs in France, we randomly sampled 5000 representative GPs. They were contacted by postal mail and phone for participation in the study, and 108 (8–10 GPs in each of the 12 regions of metropolitan France) agreed to participate. The GPs collected the following data from each patient at baseline and the 6-month follow-up: no family member at home (yes/no), assessed self-perception of current health status (visual analogue scale, (VAS), 1 to 10), quality of life (QoL) (EuroQol five dimensions questionnaire (EQ-5D)) scores, weight loss (yes/no), autonomy for activities of daily living (ADL) [23], actual weight, usual weight (kg), height, and appetite (VAS, 1 to 10). In order to describe the severity of illness, we used the comorbidities using the Cumulative Illness Rating Scale for Geriatrics (CIRS-G), that scores the severity of illness of 14 possible organs (heart, lung, kidney, etc …) from 0 to 4, with a maximum theoretical possible severity score of 64 [24]; in

addition, we recorded specifically whether or not the patient suffered from evolutive cancer.

When ONS was prescribed, the GP recorded the name of product, daily volume and duration. In France, when ONS are prescribed by a medical doctor in the indication of malnutrition, they are reimbursed by the health insurance system. During the first month of the study, patients recorded at home the name(s) of the ONS (thus indicating energy and protein content), the number of opened units and their daily volume intake as: no intake from the ONS, less than half, more than half or all. A visit to the GP was scheduled at 2 weeks and 1 month after inclusion that allowed to check compliance. Energy and protein intake from ONS calculation was based on the composition of the product, duration and compliance. Compliance was calculated as the percentage of prescribed amount consumed per day. Patients had on-line access to their own health care costs data from the health insurance system. At the 6-month follow-up, these economic data were collected by the GPs. The economic data were the direct health care costs: hospitalisations, visits, healthcare providers (nurses, physiotherapists), medications, laboratory tests, transport, medical devices, and ONS.

2.5. Statistical analysis

Descriptive statistics are presented as the number, missing values and frequency (excluding missing data) for qualitative data and the number, missing values, mean, standard deviation (SD), or median, quartiles [Q1; Q3] for quantitative data based on the distribution using the Shapiro–Wilk test.

Categorical differences between the two groups were tested using the Chi-square test or Fisher's exact test when expected frequencies are less than 5 and quantitative variables were compared using Student's *t*-test for normally distributed data. The Wilcoxon rank sum test for between-group comparisons or the Wilcoxon signed-rank test for within-group comparisons were performed otherwise.

Data were analysed based on ONS prescription or non-prescription and, in the ONS prescription group, on the energy and protein daily intake from ONS. We analysed subgroups based on ONS energy ($\geq$400 Kcal/day) and protein ($\geq$30 g/day) intake, using the recommended thresholds by the French and European guidelines [3,8–10]. Considering that the above-mentioned thresholds might fail to demonstrate cost differences, we planned to determine a more relevant threshold by testing higher energy intakes (by steps of 100 kcal/d).

The propensity score (PS) method was used with inverse probability of treatment weighting, as described by Austin [25,26]. This method was used to compare health care costs and risk of hospitalisation in the predefined groups to adjust for potential confounding factors and control for selection bias. The following baseline variables were included in the propensity score model: age, sex, CIRS-G score, evolutive cancer, ADL score, no family at home, self-perception of health status, EQ5D score, BMI and appetite.

The likelihood for hospitalisation was estimated using a multiple logistic regression using the PS based on the abovementioned covariates, and the results are expressed for each patient group as an odds ratio (OR) and 95% confidence interval (CI). A bootstrapping generalised linear regression model was used to assess costs. The non-parametric bootstrap method was applied using the arithmetic mean, which is the most informative measure for cost data and avoids assumptions about the shape of the distribution [27].

All statistical tests were performed using a two-sided 5% level of significance. All analyses were performed using SAS® (version 9.3, SAS Institute, NC, Cary, USA).

3. Results

3.1. Population

One hundred eight GPs selected 467 patients. Nineteen patients did not fulfil the inclusion criteria, and data were missing for 7 patients. Therefore, the total baseline population included 441 patients. ONS was prescribed in 375 patients. At 6 months, data were complete for 191 patients (133 in the ONS prescription group and 58 in the no-ONS prescription group) (Fig. 1). Considering all baseline parameters and whether ONS was prescribed or not, the final population was not significantly different from the baseline population.

3.2. Baseline

The baseline population of 441 patients had a median age of 82.5 [77.6; 87.1] years, and 63.1% were female. The 375 patients in the ONS prescription group exhibited significantly lower autonomy and QoL. In the final population (n = 191), autonomy, self-perceived current health status, QoL and appetite were also lower in the ONS prescription group. Characteristics are described in Table 1.

3.3. ONS intake and compliance

Mean ONS compliance at 1 month was 83.5%. More precisely, 48.1% of the patients reported they took 100% of the ONS, 28.6% between 75 and 99%, and 12.8% between 50 and 74%. Only 10.5% of the patients group reported they took less than 50% of the ONS. ONS was prescribed for a total study period of 130 $\pm$ 59 days (median 178 days).

3.4. Clinical and economic data at 6 months

3.4.1. Non-adjusted analyses

Appetite improved within both groups between baseline and 6 months (from 2.9 [1.7; 4.5] to 6.0 [4.2; 7.7] in the ONS group, $p < 0.001$, and from 5.4 [3.5; 6.5] to 6.8 [5.2; 8.1] in the no-ONS group $p < 0.001$, Fig. 2). The absolute improvement in appetite

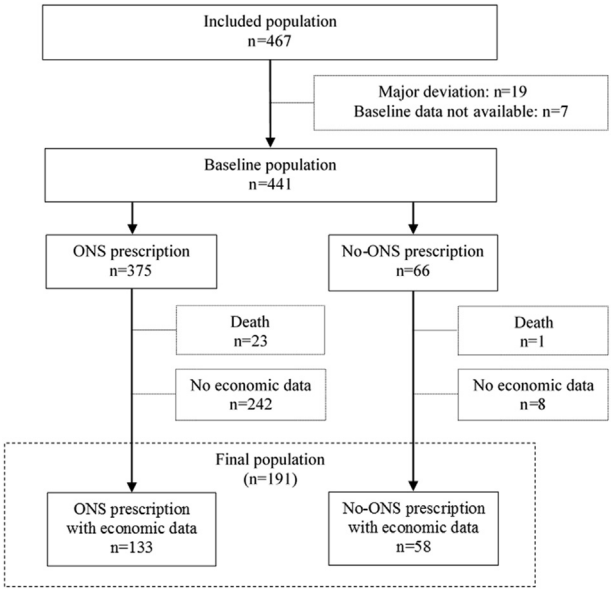

Fig. 1. Flow chart. n, Number of patients; ONS, Oral nutritional supplements.

Table 1
Demographic and clinical characteristics of patients based on ONS prescription status at baseline.

	Baseline population n = 441			Final population n = 191		
	ONS prescription n = 375	No-ONS prescription n = 66	p-value	ONS prescription n = 133	No-ONS prescription n = 58	p-value
Age (years)	82.6 [77.6; 87.3] (116)	80.1 [77.5; 86.9] (3)	0.543[c]	84.2 [76.9; 88.5] (26)	79.8 [77.5; 86.5] (1)	0.119[c]
Female	232 (62.2%) (2)	45 (68.2%) (0)	0.353[d]	83 (62.4%) (0)	40 (69.0%) (0)	0.384[d]
CIRS-G score	8.0 [5.0; 12.0] (18)	8.0 [5.0; 13.0] (2)	0.741[c]	8.0 [5.0; 12.0] (4)	9.0 [6.0; 13.0] (2)	0.678[c]
Evolutive cancer[a]	33 (9.9%) (40)	5 (7.9%) (3)	0.635[d]	11 (8.7%) (6)	5 (9.1%) (3)	0.925[d]
ADL score	5.5 [4.0; 6.0] (4)	6.0 [5.5; 6.0] (0)	<0.001[c]	5.5 [4.0; 6.0] (0)	6.0 [5.5; 6.0] (0)	<0.001[c]
No family member at home	72 (19.3%) (2)	10 (15.2%) (0)	0.425[c]	25 (18.8%) (0)	7 (12.1%) (0)	0.252[d]
Health status (VAS)	3.8 [2.6; 5.1] (111)	4.5 [2.8; 6.0] (8)	0.053[c]	3.6 [2.4; 5.0] (10)	4.5 [2.8; 6.2] (3)	0.018[c]
EQ5D score (utility)	0.4 [0.1; 0.6] (107)	0.5 [0.3; 0.8] (8)	0.031[c]	0.4 [0.1; 0.6] (7)	0.5 [0.2; 0.8] (3)	0.040[c]
Weight (kg)	56.5 [49.0; 64.3] (3)	59.0 [49.0; 66.5] (0)	0.186[c]	57.0 [49.0: 66.0] (0)	58.8 [49.0; 68.0] (0)	0.297[c]
BMI (kgm^2)	21.0 [19.4; 23.5] (6)	22.8 [18.8; 25.1] (0)	0.149[c]	21.1 [19.4; 24.0] (0)	22.9 [19.1; 25.3] (0)	0.155[c]
Usual weight (kg)	64.0 [55.5; 72.0] (2)	65.0 [55.0; 76.0] (0)	0.582[c]	63.0 [55.0; 72.0] (0)	64.5 [55.0; 77.0] (0)	0.389[c]
Weight loss[b]	349 (93.8%) (3)	57 (86.4%) (0)	0.068[e]	124 (93.2%) (0)	50 (86.2%) (0)	0.268[e]
Weight loss (% of USB)	−10.3 [−14.6; −6.7] (3)	−8.8 [−12.9; −4.9] (0)	0.034[c]	−10.0 [−13.9;−6.9] (0)	−9.0 [−12.7; −5.0] (0)	0.151[c]
Appetite (VAS)	3.0 [2.0; 4.6] (117)	5.1 [3.5; 6.5] (12)	<0.001[c]	2.9 [1.7; 4.5] (8)	5.4 [3.5; 6.5] (8)	<0.001[c]

Non-normal variables expressed as median [Q1-Q3] (n missing), Q1 is the first quartile, Q3 is the third quartile. Categorical variables expressed as n (%) (n missing).
Abbreviation: ADL, activities of daily living; BMI, body mass index; CIRS-G, cumulative illness rating scale for geriatrics; EQ5D, EuroQol five dimensions questionnaire; ONS, oral nutritional supplements; USB, usual body weight; VAS, visual analogue scale.
[a] Yes: Cancer with ongoing treatment.
[b] Number (proportion) of patients with weight loss at baseline relative to usual weight.
[c] Wilcoxon rank sum test.
[d] Chi-square test.
[e] Fisher's exact test.

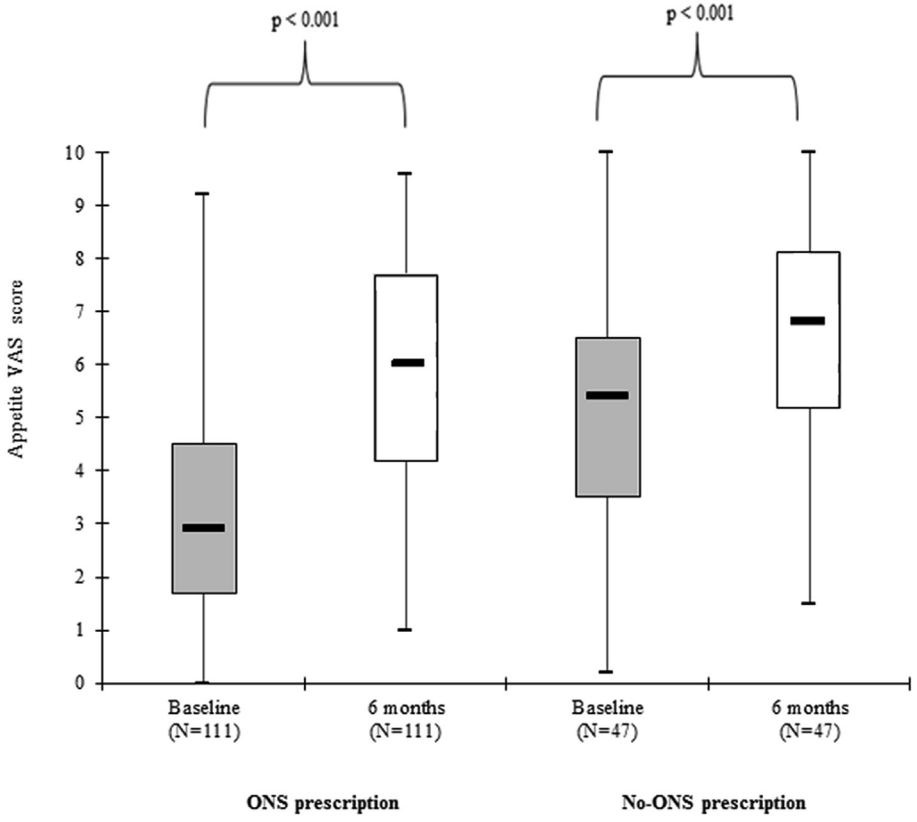

Fig. 2. Change in median appetite VAS scores between baseline and 6 months based on ONS prescription status (Wilcoxon signed-rank test). ONS, oral nutritional supplements; p, p-value; Q1, first quartile; Q3, third quartile; VAS, visual analogue scale; vs., versus. Median [Q1; Q3] change in appetite VAS score at 6 months from baseline: 2.5 [1.2; 4.4] in the ONS-prescription group vs. 1.1 [-0.7; 3.2] in the no-ONS prescription group (p = 0.0092; Wilcoxon rank sum test).

was greater in the ONS group than in the no-ONS group (2.5 [1.2; 4.4] vs. 1.1 [−0.7; 3.2], p = 0.0092) (Fig. 2).

Median change in weight from baseline to 6 months was not statistically different in the ONS prescription and no-ONS prescription groups (2.0 *vs.* 1.0 kg, respectively; p = 0.826). Also, weight change was not different between ONS and no-ONS groups when considering only patients with ONS intake ≥30 g/d of protein or ≥500 kcal/d. However, in the ONS prescription group, weight improved significantly from baseline to 6 months when ONS protein intake was ≥30 g/d (1.0 [0; 3.8] kg, p = 0.0017) or when ONS energy intake was ≥500 kcal/d (2.0 [0; 5.0] kg, p = 0.0001). There was no statistically significant difference between baseline and 6-

month values between ONS and no-ONS groups for all other clinical parameters.

The mean health care costs were not different between the two groups (2732 € in the ONS prescription group and 2345 € in the no-ONS prescription group). The detailed costs are presented in Table 2.

3.4.2. Adjusted analyses

We observed no differences in health care costs between the ONS and no-ONS prescription groups (3034 ± 700 [1812; 4496] € in the ONS prescription group and 2131 ± 609 [1127; 3548] € in the no-ONS prescription group, p = 0.48). In the ONS prescription group, no difference in costs was shown with the 400 kcal/d and 30 g of protein/d energy intake cut-offs. We then identified that a cut-off of 500 kcal/d (bringing a median protein intake of 38 g/d) was the most relevant.

We identified that for energy intake ≥500 kcal/d, the health care costs were statistically lower compared to energy intake <500 kcal/d (Table 3).

The risk of hospitalisation (hosp) within the 6-month study period was 2.5 times higher in the ONS prescription group than in the no-ONS prescription group (OR: 2.52, 95% CI: [1.088; 5.829] hosp; p = 0.03). In the ONS prescription group, the risk of hospitalisation was approximately 2.5 times lower when ONS energy intake was ≥400 kcal/d (OR: 0.393, 95% CI: [0.167; 0.925] hosp; p = 0.03), 3 times lower when ONS protein intake was ≥30 g/d (OR: 0.320, 95% CI: [0.121; 0.845] hosp; p = 0.02), and 5 times lower when ONS energy intake was ≥500 kcal/d (OR: 0.185, 95% CI: [0.063; 0.547] hosp; p = 0.002) (Fig. 3).

4. Discussion

Our results show that ONS prescription for malnourished older patients who lived at home induced no extra health care cost and improved appetite. In the ONS prescription group, when energy intake ≥500 kcal/d *vs.* <500 kcal/d, health care costs were significantly lower. Furthermore, when intake from ONS was ≥30 g of protein/d or ≥400 kcal/d (or ≥500 kcal/d), the risk of hospitalisation during the 6-month observation period was significantly reduced.

To our knowledge, this report is the first study performed in elderly people living in their own homes (*e.g.* not institutionalised), and exclusively in malnourished (*e.g.* not at risk of malnutrition) patients.

Arnaud-Battandier et al. performed a medico-economic study in elderly people living at home (n = 311), but it included home and home care subjects and malnourished or at risk patients according to the MNA [19]. The authors reported that in a district where GPs prescribed ONS often (in 70% of patients), the health care costs were lower than in districts where GPs rarely prescribed ONS (in 10% of patients) [19]. However, energy and protein intake from ONS was not recorded. In a systematic review, Elia et al. analysed 19 studies that combined surgery and medicine, post-discharge and community and in adult and older patients [21]. The results of the included studies that addressed patients ≥65 years in heterogeneous settings suggested that ONS use in the community produced an overall cost advantage or near neutral balance. A subsequent study suggested that use of ONS in care homes are cost-effective relative to dietary advice [22]. Our results demonstrated no difference in health care costs between the ONS prescription group and the no-ONS group. In France, when ONS are prescribed by a medical doctor, they are reimbursed by the health insurance system: ONS prescription induces health care costs. In the ONS group, ONS increased costs, but this was levelled by the reduction of other health care costs. It is important to stress that the ONS prescription group exhibited lower baseline health indicators, which might have caused higher costs during the study without nutritional support.

In our study, hospitalisation was approximately 40% of health care costs, and we hypothesised that reducing the risk of hospitalisation would be associated with lower costs. Firstly, we analysed our results using suggested thresholds [3,8–10]. Energy intake ≥400 kcal/d and protein intake ≥30 g protein/d in the ONS prescription group were significantly associated with a reduced risk of hospitalisation, but the effect on costs was neutral. Secondly, we identified that ONS intake ≥500 kcal/d (with a median protein intake of 38 g/d) further reduced hospitalisation risk and significantly reduced health care costs. Reducing health care costs in community malnourished elderly patients may require higher energy and protein levels from ONS than the recommended levels to achieve a clinical benefit.

Compliance to ONS was 83.5% in the present study, which is consistent with previously published results in adults in the community [27]. The fact that, in France, ONS prescribed to malnourished elderly patients living at home are reimbursed by the health insurance system (but not freely provided) may have contributed to such compliance. It may also have increased the sample of patients that were prescribed ONS. Additionally, in France, dietary counselling from dieticians are not provided freely nor reimbursed by the health insurance system. In our observational study, patients

Table 2
Six-month health care costs (€) based on ONS prescription status (n = 191).

	ONS prescription	No-ONS prescription	p-value[a]
	n = 133	n = 58	
Total Costs	2732 ± 4569 [2017; 3603] €	2345 ± 5136 [1281; 3849] €	0.707
Hospitalisations	1135 ± 2946 [686; 1698] €	677 ± 2564 [138; 1420] €	0.443
Costs *(excluding hospitalisations)*	1597 ± 2736 [1185; 2098] €	1669 ± 4507 [873; 3015] €	0.987
Visits	158 ± 232 [120; 200] €	266 ± 328 [188; 353] €	0.08
Nurses	123 ± 560 [44; 227] €	105 ± 406 [18; 223] €	0.859
Physiotherapists	69 ± 273 [29; 118] €	50 ± 118 [22; 81] €	0.663
Medications	664 ± 2122 [398; 1080] €	836 ± 3305 [315; 1837] €	0.755
Laboratory tests	15 ± 78 [5; 30] €	12 ± 43 [4; 25] €	0.816
Transport	26 ± 155 [4; 57] €	13 ± 60 [0; 31] €	0.521
Medical Devices	195 ± 561 [111; 296] €	278 ± 893 [82; 541] €	0.652
ONS	240 ± 363 [183; 308] €	0 [0; 0] €	
Other	108 ± 566 [36; 223] €	110 ± 340 [40; 215] €	0.985

Variable expressed as means ± standard deviation [95% CI bootstrap] in Euros.
Abbreviation: CI, confidence interval; ONS, oral nutritional supplements.
[a] Bootstrap p-value.

Table 3
Six-month health care costs (€) after propensity score adjustment based on the level of daily ONS intake (n = 82).

ONS intake		p-value[a]
≥30 g of protein/d	<30 g of protein/d	
1505 ± 315 [955; 2201] €	3255 ± 752 [1916; 4916] €	0.084
≥400 kcal/d	<400 kcal/d	
2331 ± 717 [1236; 3947] €	2883 ± 797 [1490; 4620] €	0.688
≥500 kcal/d	<500 kcal/d	
1389 ± 264 [922; 1951] €	3502 ± 839 [2018; 5353] €	0.042

Variables expressed as means ± standard deviation [95% CI bootstrap] in Euros.
Abbreviation: CI, Confidence interval; ONS, oral nutritional supplements; SD, standard deviation; SEM, standard error of the mean.
After applying propensity score adjustment for the 133 patients in the ONS prescription group, 82 subjects had all available covariates (age, sex, CIRS-G score, evolutive cancer, ADL score, no family at home, self-perception of health status, EQ5D score, weight, BMI, usual weight, weight loss, and appetite).
[a] Bootstrap p-value.

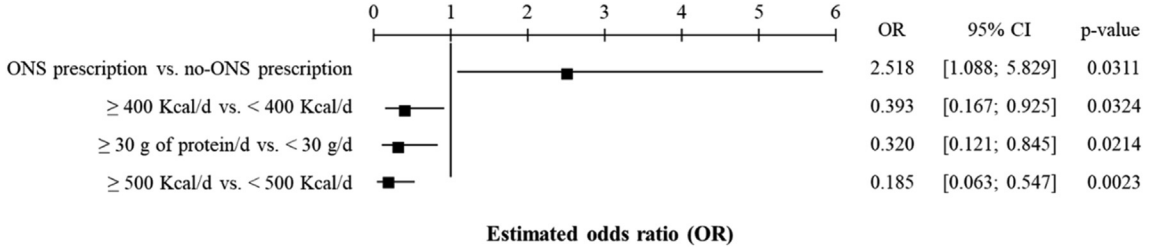

Fig. 3. Likelihood of hospitalisation after propensity score adjustment based on ONS prescription status and the level of daily ONS intake. CI, confidence interval; d, day; OR, odds ratio; vs., versus.

did not benefit from dietary counselling. This may limit the generalizability of the findings of the present study to other countries.

Our study demonstrated that high compliance to ONS reduced the risk of hospitalisation in home-living elderly people older subjects. Thus, our results extend previous studies that demonstrated that ONS reduced readmissions in hospitalised elderly patients [10,11]. The latest ESPEN recommendations stipulate that ONS offered to a malnourished older person should provide at least 400 Kcal/day including 30 g or more of protein/d [8]. In accordance, these thresholds were significantly associated with a reduced risk of hospitalisation in our study. However, the ESPEN thresholds appeared insufficient to reduce health care costs which we observed with an intake ≥500 kcal/d from ONS corresponding to a median protein intake of 38 g/d.

Appetite improved within both groups between baseline and 6 months, but it improved significantly more in the ONS prescription group, which had lower appetite and health status at baseline. ONS consistently improves total nutritional intake. There is a strong positive correlation between compliance and total energy intake (energy intake from food plus ONS energy intake), suggesting that ONS consumption has little effect on usual food intake [28]. However, the effect of ONS on appetite has been poorly studied in malnourished elderly patients. Our results support the hypothesis that appetite loss should not be feared as a side effect of nutritional supplementation.

There was no significant change in weight in patients in the ONS prescription group (+2 kg) and the no-ONS prescription (+1 kg) group over the 6-month study period. The fact the ONS prescription group exhibited lower baseline health indicators may explain this result. However, the cessation of weight loss in patients who previously lost approximately 10% of their body weight may be considered a successful achievement in malnourished elderly patients. Furthermore, in the ONS prescription group, weight increased significantly in patients that took ≥500 kcal/d or ≥30 g protein/d from ONS, as can be expected.

Our study presents some limitations. Only 108 GPs agreed to participate in the study among a French representative sample of 5,000, which may have selected the GPs that are more aware of malnutrition, and those who prescribe more ONS in their usual practice. However, approximatively one out of three of the investigators had not prescribed an ONS to their malnourished patients, thus allowing comparisons in health care costs. The reasons for ONS prescriptions were not recorded. However, the ONS prescription group exhibited lower appetite, more disability, poorer QoL and lower self-perceived health status, which may have prompted the GPs to implement ONS. In the no-ONS prescription group, it cannot be excluded that GPs provided dietary counselling and food fortification. Furthermore, the inclusion in the study may have had a positive impact on the behaviour of GPs and patients on food management in both groups. In this open and non-randomised prospective study, the GPs might have been influenced to prescribe more ONS than his/her usual practice, and thus potentially increasing the number of subjects receiving ONS, which could lead to a potential bias. *De facto*, in this observational study, the ONS prescription and no-ONS group exhibited different characteristics and sizes at baseline. However, it would not have been ethical to conduct an interventional randomised study that included a no-ONS prescription group in malnourished elderly patients. This study presents a real-life scenario of ONS prescriptions and intake by elderly people living at home.

All patients were malnourished according to the French Health Authority criteria, which GPs were using in France at the time of the study. If we were to consider the GLIM criteria for the diagnosis of malnutrition in our final population (n = 191) [29], 88% presented with at least one phenotypic criterion (weight loss > 5% or BMI < 22), 94% presented with at least one etiologic criterion (reduction in food intake as defined by appetite ≤ 7/10 points on the visual analogic scale, chronic disease as defined by at least one disease having an impact on activities of daily living and altering prognosis on the CIRS-G scale, or presence of evolutive cancer) and 83% would be diagnosed malnutrition with at least one phenotypic and one etiologic criterion present (data not shown). It is important to underline that it was not possible to assess muscle mass (phenotypic criterion) in our observational study, which may have increased the prevalence of malnutrition. To this day, there is no

gold standard definition of malnutrition, and we feel that the nutritional characteristics of our population described in Table 2 indicate moderate to severe malnutrition in these older patients.

We encountered some difficulties in the collection of economic data. It was not possible to obtain economic data directly from French health insurance companies, which protect personal data. With the patients' agreement, the GP was allowed to collect their health care costs records. However, because the patients did not allow the GPs to look into their health records, or because the GPs didn't have the time to do it, this generated more than 40% of missing economic data. This reduced our population to 191 patients (43% of the baseline population) for economic analysis. It is thus important to underline that the characteristics of our final population, with no missing data for costs (n = 191), did not statistically differ from the baseline population (n = 441).

Compliance to the ONS was self-reported. For financial and practical reasons, and in order to favour participation of elderly people in the study, it was chosen not to collect ONS containers at their homes to measure compliance. However, the reported compliance was similar to that reported in other clinical studies [28], and we feel that the self-reported compliance, like other self-reported clinical parameters such as appetite, may be used to interpret our results. Also, total dietary intake and spontaneous food intake were not recorded in the present study, because we hypothesized elderly people would have been reluctant to record their daily food intake at home and this would have produced inaccurate data. However, median weight did not change, which suggests total energy intake met energy expenditure.

In conclusion, this study demonstrated that the prescribing of ONS to malnourished elderly outpatients did not increase health care costs. Patients who were highly compliant to the high protein and had high energy intake from ONS exhibited a reduced risk of hospitalisations and health care cost.

Statement of authorship

All authors contributed to the manuscript writing and read and approved the final manuscript.

Conflicts of interest

The authors have received research funding from Alliance 7 (French professional federation including ONSs producers) (Paris, France). Companies are part of Alliance 7. The recruitment of GPs was done by a contract research organisation financed by Alliance 7. They were no direct contact between Alliance 7 or authors and GPs. The recruitment of patients was only performed by GPs.

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