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## Research paper

# Solid oral supplementation: Economic assessment. Economic impact of the introduction of a solid oral nutritional supplement adapted to malnourished older adults with poor dental health



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## ARTICLE INFO

### Article history:

Received 24 February 2017

Accepted 28 April 2017

Available online 24 May 2017

### Keywords:

Cost analysis

Diarrhea

Dietary supplements

Accidental falls

Protein-energy malnutrition

Frail elderly

## ABSTRACT

**Background:** In a study involving 175 malnourished frail older adults, a solid oral supplement (ONS) adapted to people with poor dental status allowed an increase of weight and appetite (Protibis<sup>®</sup> cookies, France). There was a decrease of bedsores and diarrhea and a trend of a decrease of falls and infections (Pouysségur et al., 2015).

**Objectives:** To use the database of this randomized controlled trial for an economic assessment a posteriori.

**Methods:** 1) Estimation of the medical cost of bedsores, diarrhea, falls and infections (Delphi method). 2) Comparison of the average cost per participant of the Control group (no cookies) vs. Intervention group (cookies). 3) Sensitivity analysis (Monte Carlo simulations, Tornado diagrams).

**Results:** For an 18-week period of observation, the consumption of cookies during 6 weeks generated a cost minimization for Health Insurance. For 18 weeks, the cost cutting was confirmed, mainly in the treatment of falls, with savings due to the reduction of hospital stays (83.44 €) and medical consultations (85.37 €), and in the treatment of infections, with savings due to the reduction of hospital stays (58.90 €). Savings ranged from 1.52 to 2.48 € daily and per malnourished resident, in the case of standard or full protection, respectively. For the institution, it also reduced the working time of the nursing staff by 30 min daily and per malnourished resident.

**Conclusion:** The additional cost generated by this new solid ONS in the usual care was compensated with savings generated thanks to the improvement of the nutritional status of the residents.

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## 1. Introduction

The consumption of oral nutritional supplements (ONS) decreases length of hospital stay, episode cost, and 30-day readmission risk in hospitalized adult population [1,2]. Most ONS are in the form of beverages or cream [3,4]. However, many frail older adults are edentulous and they frequently complain about the monotony of a

soft-texture diet [5,6]. A solid ONS has been developed with a crunchy texture adapted to people with masticatory impairment (Protibis<sup>®</sup> cookies, France) [7]. Briefly, Protibis<sup>®</sup> cookies are small high protein and high energy butter cookies. Ingredients are wheat flour, fresh butter, milk protein (casein), sugar, vanilla aroma, baking powder and salt. There is no palm oil or other vegetable oil. Each cookie weights 6.5 g and contains 22% of weight in proteins. The serving size is 8 cookies daily, usually distributed in the breakfast and/or in the snack (total 52 g of cookies: 11.5 g of protein and 244 kcal as daily supplementation) [8]. Nutritional analysis is detailed in [Supplementary material A](#). In a randomized controlled trial, cookies consumption was followed by an increase of weight and appetite [8]. The present work aimed to assess the economic impact of the introduction of these cookies in patients' care.

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## 2. Methods

### 2.1. Data source and patients

The population studied was the same of the pivotal study, involving 175 malnourished older adults aged  $86 \pm 8$  years and living in seven institutions [8]. Briefly, residents who had a current prescription of home-made sweets enriched with milk proteins and/or liquid or creamy ONSs ('dairy supplements'), but who were diagnosed as malnourished anyway, were also included. In order to avoid a bias due to this supplementation, there was a 4-week observation period before cookies consumption ( $w - 4$  to  $w_0$ ), to confirm weight loss. All participants received the standard institutional diet. In addition, Intervention group participants received eight cookies daily for 6 weeks ( $w_0$ – $w_6$ ). The cookies consumption was followed by an 18-week observation period. There was five visits ( $w - 4$ ,  $w_0$ ,  $w_6$ ,  $w_{10}$  and  $w_{18}$ ) and the main outcome was the percentage of weight gain from  $w_0$  to  $w_6$  (body mass in kg). Secondary outcomes were appetite, rated using a numerical scale (0: no appetite to 10: extremely good appetite), current episodes of pressure ulcers and diarrhea. According to Pouysségur et al. [8], the main result consisted in a significant weight gain in Intervention group ( $n = 88$ ) compared with Control group ( $n = 87$ ) without cookies supplementation (+1.6 versus  $-0.7\%$ ,  $P = 0.038$ ). Weight gain persisted 1 month (+3.0 versus  $-0.2\%$ ,  $P = 0.025$ ) and 3 months after the end of cookies consumption (+3.9 versus  $-0.9\%$ ,  $P = 0.003$ ), with diarrhea reduction ( $P = 0.027$ ). There was a synergistic effect with liquid/creamy dietary supplements. Subgroup analysis confirmed the positive impact of cookies supplementation alone on weight increase ( $P = 0.024$ ), appetite increase ( $P = 0.009$ ) and pressure ulcers reduction ( $P = 0.031$ ) [8].

### 2.2. Study type

The clinical endpoint in the pivotal study was intermediate criteria (not directly linked to life expectancy). The economic study was proposed after the end of the pivotal study, which showed relevant results. Therefore, a cost minimization study was proposed. The incremental cost effectiveness was not possible due to the intermediate clinical criteria. But the intermediate criteria can be linked to mortality rate and can help as a decision tool.

Some useful data for economic objectives were not collected in the pivotal study so an adapted methodology was proposed. The economic analysis adopted the health-care payer's perspective and took into account all direct medical costs (i.e. health care resource consumption). Indirect costs (e.g. sick leave) and intangible costs (e.g. pain and suffering) were not assessed. The direct costs included the price of cookies, ONS and the care of four adverse effects:

- bedsores;
- diarrhea;
- falls;
- infections.

The point of view of the institution (Assisted Living Accommodation) was also considered by assessing the time spent by nurses and nursing auxiliary.

The time horizon of this study was defined from  $w_0$  to  $w_{18}$ .

### 2.3. Identifying patients' trajectories

Available information was not sufficient to assess the global cost of the care of these four adverse events, since according to their characteristics (e.g. stage of severity), the care was different.

Therefore, a panel of experts was constituted according to the Delphi method in order to identify the classification of each event. The care resources needed for each event were also recorded, including the number of consultations, the types and frequencies of medical procedures and the details of prescriptions.

Experts were selected according to the following criteria:

- to have at least 10 years of experience in geriatrics (nursing home or other institution);
- to have not participated to the pivotal study.

Finally, 13 experts from various regions of France participated to the survey.

### 2.4. Pricing patients' trajectories

Medical procedures requiring hospitalization were assigned values using the French Diagnosed Related Groups, with the *Groupe homogène de séjour* (GHS) corresponding to inpatient care. The *Groupe homogène de malades* (GHMs) corresponding to each hospitalization, as well as whether or not they occurred in the public or private sector, were identified from the French national discharge database ("Anonymous Discharge Record" database).

The cost of outpatient care, i.e. care not requiring hospitalization, was valued according to French Public Health Insurance (*l'Assurance maladie*) rates at the time. It included the cost of drugs and medical devices, medical transports, radiology and biology analyses, physiotherapist consultations and other care. Prices were valued as € 2014.

The present results are presented in the case of standard (partial) social coverage by the French Public Health Insurance and full coverage (long-term illness). In France, this status is defined by the clinicians and the cost difference between a full or a partial coverage is paid by the patient himself or by his private health insurance.

### 2.5. Economic analysis

The decision tree methodology was used to perform the economic analysis. Decision tree is a decision support tool that uses a tree-like graph or model of decisions and their possible consequences, including chance event outcomes and/or resource costs. Each node of the tree is associated to a probability and each trajectory is associated to a leaf and a cost. A stochastic analysis was performed. All probabilities were associated to a beta distribution. 10,000 Monte Carlo simulations were performed to estimate the mean cost and the associated confidence interval of each group (without vs. with cookies). The stochastic analysis enables to estimate the standard deviation of the mean cost which does not depend on the number of simulations (as in determinist analysis).

The robustness of the results was checked with the sensibility analysis. Variability was applied to probabilities (minimum and maximum declared by the panel experts) and according to the literature review. The Tornado diagram was proposed to evaluate the most sensitive parameter.

Finally, the working time of the nursing staff required was presented and compared in each group.

Tree Age pro 2008 Healthcare Release 1.6 software was used.

## 3. Results

### 3.1. Medical events

The panel of experts defined four adverse events. Bedsores were qualified according to four severity stages:

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