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EFFECTIVENESS OF FOOD-BASED FORTIFICATION IN OLDER PEOPLE A SYSTEMATIC REVIEW AND META-ANALYSIS

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Abstract: *Background:* Early intervention with nutritional support has been found to stop weight loss in older people malnourished or at risk of malnutrition. Enriched food could be a more attractive alternative to improve meals, than conventional oral nutritional supplements. *Aims:* To determine the effectiveness of food-based fortification to prevent risk of malnutrition in elderly patients in community or institutionalized elderly patients. *Methods:* A systematic review was conducted of randomized controlled trials, quasi-experimental, and interrupted time series including a longitudinal analysis. *Participants:* Elderly patients who are institutionalized, hospitalized or community-dwelling, with a minimum average age of 65 years. All type of patient groups, with the exception of people in critical care, or those who were recovering from cancer treatment, were included. *Intervention:* Studies had to compare food-based fortification against alternatives. Studies that used oral nutritional supplementation such as commercial sip feeds, vitamin or mineral supplements were excluded. The search was conducted in Cochrane, CINAHL, PubMed, EMBASE, LILACS, and Cuiden. An independent peer review was carried out. *Results:* From 1011 studies obtained, 7 were included for the systematic review, with 588 participants. It was possible to perform meta-analysis of four studies that provided results on caloric and protein intake. Food-based fortification yielded positive results in the total amount of ingested calories and protein. Nevertheless, due to the small number of participants and the poor quality of some studies, further high quality studies are required to provide reliable evidence. *Implications for practice:* Despite the limited evidence, due to their simplicity, low cost, and positive results in protein and calories intake, simple dietary interventions based on the food-based fortification or densification with protein or energy of the standard diet could be considered in patients at risk of malnutrition.

Key words: Food, fortified, nutrition, older people, systematic review.

Introduction

Nutrition is one of the pillars of healthy aging (1). Thus, a combination of factors, including neuroendocrine deregulation, age-related anorexia, and energetic and metabolic imbalance leading to sarcopenia, interact to result in the so-called "cycle of frailty" in the elderly population (2). In this population, the problem of malnutrition appears related, among other factors, to the neglect of the first signs of malnutrition by both, the individual and the family, and health care professionals, who should focus on interventions to detect and treat risk of malnutrition (3, 4).

The prevalence of this problem in older people differs depending on the context. In community dwellings is nearly 24%, while among ambulatory patients, it is up to 45%. Malnutrition risk prevalence is also high for hospitalized and institutionalized patients, 46% and 51% respectively, and in the elderly with cognitive impairment, the prevalence is 44% (5).

Early intervention with nutritional support has been found to stop weight loss in older people malnourished or at risk of malnutrition, and is associated with improvements in the results of the most commonly used outcomes (5, 6). Enriched food could be a more attractive alternative to improve meals, than conventional oral nutritional supplements (7–10). This may include the addition of micronutrients to commonly eaten foods with (fortification), the addition of micronutrients in the form of pills, capsules or syrups (supplementation), the increase of volume of food especially rich in some micronutrients (enrichment) or increase of energy density in the meals (densification).

Although some studies on this topic have been published, no review has synthesized the answers to some questions about the different uses of enriched diets in diverse populations and environments.

The aim of this review is to determine the effectiveness of food-based fortification to prevent risk of malnutrition in elderly patients in community-dwelling, institutionalized, or hospitalized elderly patients, compared to other methods of nutritional support.

Methods

A systematic review was conducted to compare the different modalities of fortification in older people.

PICO question: In older people, the use of food-based

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fortification with macronutrients against other alternatives, which effects produces on any nutritional parameter, such as weight gain, protein or calories intake, or non-nutritional outcomes such as food consumption, functional status or quality of life.

Types of studies: The included studies were randomized controlled trials, quasi-experimental, and interrupted time series including a longitudinal analysis of the results with at least two observations, before and after the intervention.

Types of participants: The Patients include older people aged over 65 years receiving hospital services for acute or chronic conditions or as outpatients for diverse health problems, in home care programs, or in residential care in which food-based fortification was applied due to its condition of risk of malnutrition.

Types of interventions and outcome measures: The selected studies compared food-based fortification with macronutrients against other alternatives and assessed their effectiveness on any nutritional parameter, such as weight gain, protein or calories intake, or non-nutritional outcomes such as food consumption, functional status or quality of life. Interventions that investigated the use of oral nutritional supplementation such as commercial sip feeds, or vitamin and mineral supplements were excluded (Supplementary file 1). Studies were selected from the title and the abstracts, and the full text was obtained.

Search strategy: A search for published studies was carried out in the Cumulative Index to Nursing and Allied Health Literature, Cuiden Plus, EMBASE, LILACS, Cochrane, and Medline databases, with no time limits, and using the search strategies described in Supplementary file 2. A secondary search was also performed, analyzing the references included in the obtained articles. Unpublished studies were not included in the review.

Quality appraisal of studies: An independent peer review was implemented. In case of differences between the two reviewers' decisions, a third reviewer evaluated the concerns and determined its inclusion. The studies were evaluated with regards to the following issues: random sequence generation, allocation concealment, blinding of participants, personnel and outcome assessment, basal homogeneity of groups, precision of results (confidence intervals of the main outcomes), presence of co-interventions, and incomplete data reporting-intention to treat analysis.

Data extraction: The following information was extracted from each study: design, country, type of facility and participants, allocation concealment method, follow-up period, frequency of assessment, and enrichment intervention used. The following data were used to measure the clinical effectiveness of nutritional enrichment: weight difference, protein or calories intake, anthropometric changes, biochemical markers, changes in nutritional status evaluated with any instrument, and food consumption.

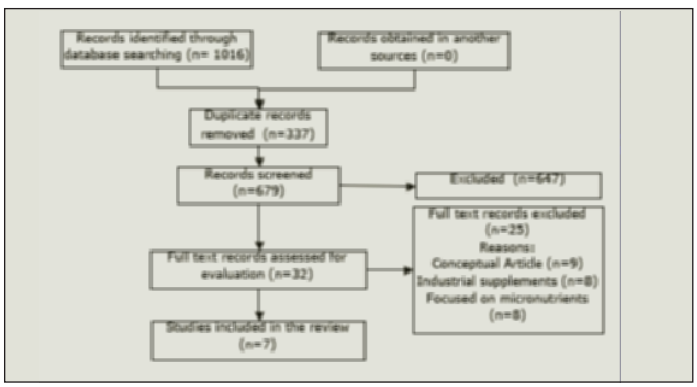
Data analysis

Data were extracted and pooled using the RevMan 5.0 software (11). A random effects model was used in all the comparisons, due to the heterogeneity detected among studies. Results on energy and protein intake were pooled through mean differences, as all studies reported the outcomes in the same scales. Heterogeneity was calculated with I2 (percentage of variation attributed to heterogeneity, evaluated with the Cochran's Q statistic). Sensitivity analyses were carried out taking into account the characteristics of the intervention in each study. For those outcomes where meta-analysis was not possible to be carried out, narrative synthesis was developed. Publication bias was estimated by funnel plots.

Results

After the analysis of 1011 studies, 7 were included for the systematic review. The 7 studies enrolled 588 participants (Figure 1). Table 1 summarizes the main characteristics of selected studies. The largest group of patients included (n = 276; 46,9%) came from two clinical trials of frail elders in community dwellings (12, 13). Another 30,4% of the subjects (n = 179) were identified in two clinical trials of hospitalized patients, and 22,6% (n = 133) were institutionalized subjects from three clinical trials (7, 9, 14–16).

Figure 1
Flow chart of studies



The alternative interventions found in this review were: administration of informative brochures, to compare against the usual diet, inclusion of controls in social programs, different standardized diets, or diets provided by the hospital.

Overall, the methodological quality was heterogeneous and in most of studies with limitations in randomization. The results of quality appraisal is represented in Figure 2.

Food-based fortification and quantification of the enrichment

To assure the extra amount of nutrients in a natural way, two strategies were found along the studies included in this review: enrichment (increase of volume) and densification.

Table 1
Characteristics of the selected studies

		Subjects	Sample size	Design	Intervention (i) Control (c)	Areas of evaluation	Main outcomes
COMMUNITY-DWELLING	Weekes et al. 2009.	Stable COPD patients in the community, at risk of malnutrition and over 18 years. EXCLUDED: individuals with unstable diabetes, determined malignancy, ICC, and untreated thyroid disease.	59	RCT	I: Dietary advice and counseling on food fortification. +600 Kcal/day (IP: 6 months) C: Informative brochure	a. Nutritional status b. Respiratory muscle strength c. Respiratory function d. Perceived dyspnea e. ADL f. Quality of life (FP: 6 months)	1. Caloric intake (kcal / day) 2. Protein intake (g / day) 3. Weight (Kg) 4. Dynamometry (labor force (Kg) 5. Spirometry (FEV1 and FVC) 6. Quality of Life (SGRQ and SF-36 short version) 7. Mid-arm circumference (cm) 8. Mid-arm muscle circumference (cm) 9. Four skinfolds: biceps, triceps, subscapular and suprailiac (mm)
	de Jong 2001	Frail community-dwelling elderly. Frailty selection criteria: health care requirements (e.g. home care), age same or higher than 70 years, that nowadays do not perform regular physical exercise, BMI less than or equal to 25 kg/m2, or recent weight loss.	217	RCT	Intervention: Condition «L» where enrichment food were consumed just at lunch and dinner. Condition «BL» where enrichment food were consumed just at breakfast and lunch. Control: Condition «C» or control without enrichment food. *the participants were used as their own controls, making them go through the three designed conditions along 56 days, and records were lost due to discontinuity points.	a. Consumed food weight (g) b. Kcalories (g) c. Protein d. Lower vs. Higher consumers.	1. Caloric intake (kcal / day) 2. Protein intake (g / day) 3. Ingested food weight (Gr.)
INSTITUTIONALISED	Castellanos et al. 2009	Subjects were admitted in two floors of a nursing care facility. EXCLUDED: Under 60 years, palliative patients, carriers of nasogastric tube, treated with renal diet, treated with crushed or thickeners diet, those who needed to eat in their rooms or required food assistance.	33	RCT	Intervention: Condition «L» where enrichment food were consumed just at lunch and dinner. Condition «BL» where enrichment food were consumed just at breakfast and lunch. Control: Condition «C» or control without enrichment food. *the participants were used as their own controls, making them go through the three designed conditions along 56 days, and records were lost due to discontinuity points.	a. Consumed food weight (g) b. Kcalories (g) c. Protein d. Lower vs. Higher consumers	1. Caloric intake (kcal / day) 2. Protein intake (g / day) 3. Ingested food weight (Gr.)
	Odlund Olin et al.2003.	Institutionalized in municipal nursing homes.	35	RCT	Intervention: Diet of 2100 kcal Intervention: Diet of 2100 kcal / day consisting of a standard enriched diet with natural ingredients: cream, oil or butter at lunch and dinner, and cream or hydrolyzate starch in desserts +500 Kcal / day Proteins. 0 (IP: 15 weeks) Control: Diet 1600 (kcal / day) as «Nordic Nutrition Recommendations"	a. Energy intake b. ADL (FP: 12 weeks)	1. Caloric intake (kcal/day) 2. Functionality (ADL) 3. Infections (no. Infections)

Smoliner et al. 2008	Institutionalized elderly with malnutrition or risk of malnutrition (MNA) <23.5 points) EXCLUDED: • Good nutritional status (MNA> 23.5) • Severe cognitive impairment	65	RCT	Intervention: standard diet of 2000 kcal according to German nutritional benchmarks values of energetic and protein enrichment. +300 Kcal / day +5 G ml protein/100	a. Mini Nutritional Assessment b. Impedance c. Hand dynamometer d. Barthel index e. The physical functioning component of the SF- 36	1. Caloric intake (kcal/day) 2. Protein intake (g/day) 3. Functionality (Barthel) 4. BMI (kg/m2) 5. Dynamometry (labor force) 6. Weight (Kg) 7. MNA
	(assessed subjectively by the nursing home staff on their knowledge of the resident's cognitive ability) • Enteral feeding • Hospitalization> 6 days during the study • Pacemaker implantation (unable to use impedance in these patients) • Hemiplegic or severe arthritis			Control: standard diet of 2000 kcal nutritional values under benchmark German (IT: 12 weeks)		8. Lean mass (lean mass) 9. Spirometry (Maximum flow (L/min) * 10. Quality of Life (SF-36)
Gall et al. 1998	Subjects admitted in three different hospital services, medical service (men and women), orthopedic service (men and women) and a living room for the elderly (women only). EXCLUDED: • Not being able to eat without help for at least three days. • Being hospitalized for less than 3 days. • To have prescribed a specific diet (excluding hiperprotein or hipercaloric diets) • Incomplete records • Refuse informed consent.	144	RCT	Intervention: standard hospital diet chosen by patients through the usual procedure, which was enriched by 50cc cream for dessert, derived from skimmed milk powder to enhance lunch and dinner food. Between meals, a piece of pie and a sandwich with cheese was provided in the afternoon and before bed (alternating). +966 Kcal / day Proteins: + 22.2 g Control: standard hospital diet chosen by the subjects in the usual way (IP 3 days)	1. Caloric intake (FP 3 days)	1. Caloric intake (kcal/day) 2. Protein intake (g/day)
Barton et al, 2000	Elderly admitted to a rehabilitation hospital	35	RCT	Intervention: 1. Enriched Menu (F): density increased (enrichment based primarily on fat derivatives: butter, cream, cheese and carbohydrates) of food in order to achieve a daily energy increase of 200 kcal/day along with a decrease in size of the supplied rations (approximately 20%) with a drop of 5 g protein/day. 2. Cooked breakfast menu (CB) was the same menu as the control group (standard hospital menu) that was enriched by offering a complimentary cooked tomato with bacon, eggs, beans from which the subject could choose , instead of the usual breakfast (cereal or similar). In this case, in addition to securing an energetic increase of 200 kcal / day, proteins were also increased up to 12 g protein/day. (14 days cycles in each modality (56 days in total)) Control: usual menu service provided by the hospital (N)	Wasted food weight (FP: 56 days)	1. Caloric intake (kcal/day) 2. Consumed food weight (Gr)

Four studies (7, 13, 15, 16) reported the quantity of enrichment used to increase the supplied caloric intake. Weekes et al. (13), Odlund et al. (16), and Gall et al. (15) opted for a strategy of enrichment without paying attention to the portion size. Two studies used densification to increase the caloric intake while maintaining the ration volume, including the study by Castellanos et al. (14) that allowed the participants in the intervention group to choose from among several densified foods with different tastes. For detailed information of each intervention, see Table 1.

The duration of follow up was highly variable between studies. The most extended study had an intervention duration of 6 months and another 6 months of follow-up after the intervention (13). Most of the studies had no follow-up after the intervention (Table 1).

Figure 2
Methodological quality of included studies.

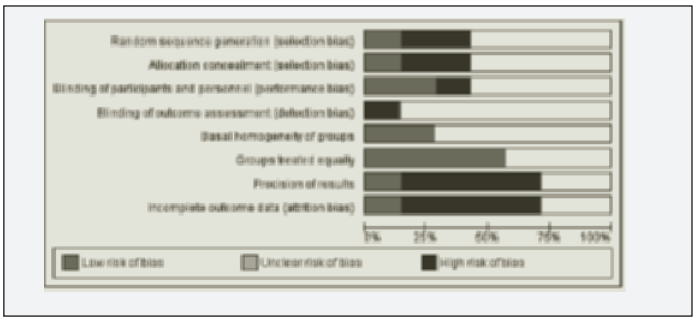
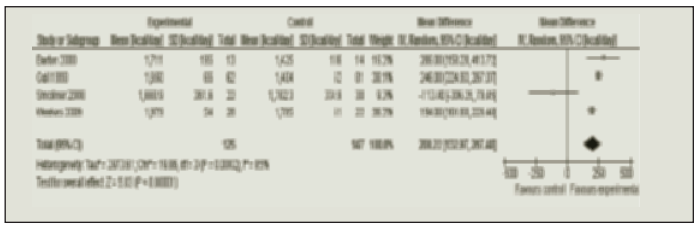


Figure 3
Forest plot of calories intake

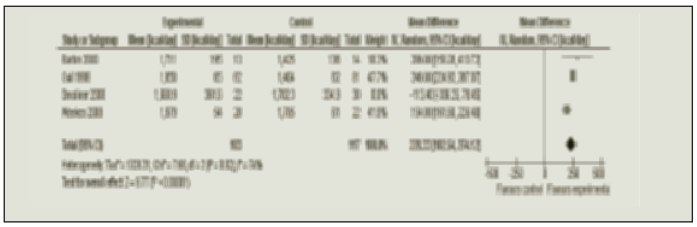


Enrichment

Enrichment strategies have shown to be effective to achieve caloric increases, excepting one (9) which, nevertheless, is difficult to be classified under this section. This study used a combination of both strategies, where the intervention group received the same diet than the control group, but was densified with protein, soups and sauces with high caloric value, and enriched by two additional snacks with high values of protein and energy that were served between meals. As a result, the volume of food was increased, so we decided to classify as an enrichment study although some subjects did not received those snacks.

Different modalities of enrichment were deployed along studies: enriched breakfast (7), or enriched foods and snacks (15), which produced significant increments in daily energy and proteins intake. Unfortunately, one study (12) did not express the changes in the caloric intake, nor in the proteins.

Figure 4
Forest plot of calories intake with sensitivity analysis

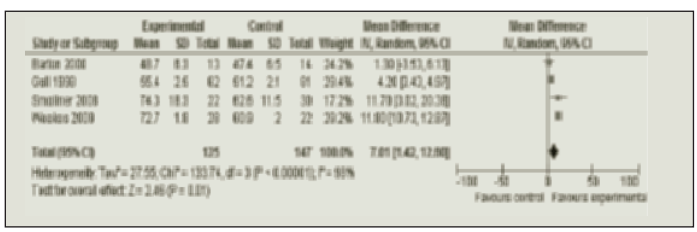


Densification

The modality of densified menu of the previously mentioned Barton`s study (7) implemented at lunch and supper, achieved a caloric increase of 25% higher (1,111 kcal), compared with the usual menu (825 kcal) (P<0.001). The mean total daily energy intake was 1,711 kcal per day on the densified menu, compared with 1425 kcal on the usual menu. Nevertheless, this strategy did not significantly increase the protein intake.

Castellanos et al. (14) also found significant differences in the densification strategies. Nevertheless, they describe different behaviors between subjects classified as "smaller and bigger eaters", depending on if their caloric intake were higher or less than mean group intake (1,150 Kcal) in a prior analysis. When comparing lunch-enhanced vs control conditions, the average three-meal energy intake was significantly greater or smaller eaters (199 kcal; P:0.05), but not the bigger eaters (67 kcal). However, when comparing breakfast and lunch-enhanced vs control, the average three-meal increase was significant for both smaller and bigger eaters (increase of 214 kcal and 289 kcal, respectively). Nevertheless, it was not obtain a statistical significant increase in the protein intake in the three meals.

Figure 5
Forest plot of protein intake

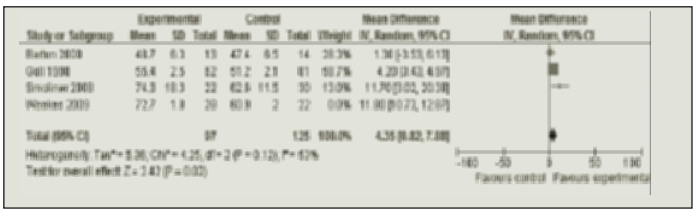


Odlund et al. (16), obtained significant results by increasing the energetic intake from 1,437 Kcal/day to 1,840 Kcal/day. They also obtained a discrete but significant increase in protein intake (54.7 grs (47.0–59.9) versus 57.9 grs (46.2–61.2), P<0.001).

Weekes et al. (13), as in the previous ones, detected significant improvements in the caloric intake/day of 194 Kcal/day (31 -357) and in the protein intake: 11.8 g/day (6.3-17.3);

72.7 (SD: 1.8), versus 60.9 (DS: 2.0) g/day.

Figure 6
Forest plot of protein intake with sensitivity analysis



Four studies shared variables that allowed the development of a meta-analysis of the caloric and protein intake (7, 9, 13, 15). Mean difference in favor of the enrichment group resulted in 200.22 Kcal/day [132.97, 267.48] p<0.00001. Nevertheless, the heterogeneity was high (I^2= 85%) (Figure 3).

The sensitivity analysis showed a discrete improvement of the heterogeneity (I^2 =74%) when eliminating Smoliner et al. (9) study with a difference in the intake in favor of the enrichment group 228,33 (95%CI: 182.54 to 274.12). This study was carried out in nursing homes, and a Mini Nutritional Assessment (MNA)≤ 23.5 was used as inclusion criteria, while Barton (7) and Gall (15), developed in the hospital environment, and Weekes (13) in chronic obstructive pulmonary disease (COPD) outpatient patients, did not use as a inclusion criteria the prior nutritional status (Figure 4).

Protein intake showed differences in the meta-analysis of 7.01 g/day (1.42, 12.60), p<0.00001, although as previously, the heterogeneity was high (I^2=98%) (Figure 5).

After sensitivity analysis were carried out, protein intake was 4.35 mg/day (95%CI: 0.82 to 7.88) in favor of the experimental group (Figure 6). The eliminated study had not the protein increase as an objective, but the energy supplementation.

Other outcomes, included only in some studies, could not be meta-analyzed. Among them, we can distinguish three types: nutritional status (impedance and dynamometry, weight), functional status (respiratory function, dyspnea, number of infections, activities of daily living) and quality of life.

Discussion

The aim of this review was to determine the effectiveness of food-based fortification to prevent risk of malnutrition in elderly patients, either in the community, hospitalized or institutionalized, compared to alternatives for nutritional support.

Our results show that food enrichment by fortification or densification increases energy and protein intake. Nevertheless, due to heterogeneity of studies, these results should be taken with caution. Heterogeneity in most cases could be attributed to different profiles of patients included in the studies, as well as diversity of modalities of enrichment used. Some studies combined both fortification and densification, whereas other studies only one of them. Further studies that compare which modality is more effective should be necessary to explore this uncertainty.

The benefits of supplements consumed by mouth or nasogastric tube (17) have been shown in the hospitalized, malnourished elderly, in malnourished patients who will have surgery (18), and in the prevention of pressure ulcers (19). However, there is a lack of consensus on whether these supplements are effective at maintaining or improving long-term nutritional status (20). The follow-up periods of the studies included in our review prevent to evaluate this point, because the follow-up period did not exceed the 6 months.

Some research has found that, when a frail, elderly person is already malnourished, nutritional intervention often comes too late, and preventive strategies are needed to improve nutritional status and minimize functional impairment (21). Some promising biomarkers as citrulline has shown its potential benefits in measuring the grastrointestinal tract state in older people and its relation to malnutrition due to malabsorption (22). However, how these patients could benefit from less costly actions, such as nutritional enrichment or densification, currently remains poorly investigated. Moreover, early interventions could lead to higher benefits, included potential effects on areas such as cognitive function (23).

One of the first signs of malnutrition risk is a decrease in intake, so it seems appropriate to develop strategies to increase caloric and protein intake, with equal or lower volume. Normally, when a person is suspected to be malnourished, a high-calorie diet is recommended as the first-line option. Therefore, foods that can be consumed in small quantities but are rich in nutrients (densification), are the basis to stimulate appetite in patients who need to consume a sufficient volume to achieve adequate nutrition (22, 24).

It seems clear in light of this review that patients who are highly malnourished or have lower energy intake patterns obtain the higher benefit from food fortification, although it is possible that these results are due to a threshold effect. Castellanos's study took an interest approach (14) which showed differences caused by the patients' appetite at the moment that fortified foods were eaten; those who ingested greater amounts of food consumed more calories when eating enriched breakfast foods, but not lunch ones. In contrast, small consumers increased energy intake with the enrichment of any meal. Therefore, for small consumers who have a higher risk of malnutrition and weight loss, food fortification should be included in more than one meal.

In Odlund's study (1996), the experimental group did not gain weight despite the prolonged intervention and favorable results from a preliminary study with a shorter intervention period.

It is generally assumed that enrichment interventions could be much cheaper than industrial preparations, although the complexity of some designs may incur an extra cost when

staff time is considered. On the other hand, industrial and enrichment supplements and densification may present differences in acceptability and compliance that have to be considered (23, 25).

This review has several limitations. First, the poor methodological quality of included studies invites caution about the conclusions. As mentioned before, heterogeneity of studies invite to be cautious about the impact of diet enrichment, and long-term effects of the intervention remains unsolved.

Conclusions

Despite the poor methodological quality of most studies analyzed due to their simplicity, low cost, and absence of contraindications, simple dietary interventions based on the food-based fortification or densification with protein or energy of the standard diet could be considered in patients at risk of malnutrition, because its effect on total amount of Kcal ingested and protein intake. Nevertheless, further studies to determine which modality of enrichment is more effective, and long-term follow-up are needed. Moreover, studies that include functional and quality of life outcomes, as well as cost-effectiveness analyses are recommended.

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Conflict of interest: All the authors (JC Morilla-Herrera, FJ Martin-Santos, J Caro-Bautista, S Garcia-Mayor, MC Saucedo-Figueredo and JM Morales-Asencio) declare that they have no conflict of interest. The authors conducted this study independently with the support of only the Department of Nursing of the University of Málaga (Spain).

Ethical standards: This study complies with the current laws that regulate research in Spain.

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