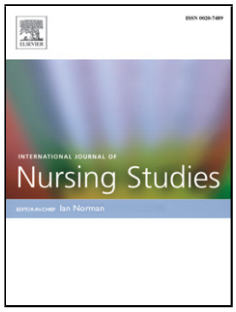


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# The efficacy of a nutrition education intervention to prevent risk of malnutrition for dependent elderly patients receiving Home Care: a randomized controlled trial

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## ABSTRACT

**Objective:** To assess the effect of a nutrition education intervention included in the Home Care Program for caregivers to prevent the increasing risk of malnutrition of dependent patients at risk of malnutrition.

**Design:** Randomized controlled multicenter trial of 6 months of duration and 12 months follow-up.

**Settings:** 10 Primary Care Centers, Spain

**Participants:** Patients enrolled in the Home Care Program between January 2010 and March 2012, who were dependent and at risk of malnutrition, older than 65, and had caregivers (n = 190).

**Intervention:** The nurses conducted initial educational intervention sessions for caregivers and then monitored at home every month for 6 months.

**Measurements:** The nutritional status was assessed using the Mini Nutritional Assessment test (primary outcome), diet, anthropometry, and biochemical parameters (albumin, prealbumin, hemoglobin and cholesterol). Other descriptive and outcome measures were recorded: current medical history, Activities of daily living (Barthel test), cognitive state (Pfeiffer test), and mood status (Yesavage test). All the measures were recorded in a schedule of 0–6–12 months.

**Results**: 173 individuals participated after exclusions (intervention n=101; control n=72). Mean age was 87.8±8.9 years, 68.2% were women. Difference were found between the groups for Mini Nutritional Assessment test score change (repeated measures ANOVA, F=10.1; *P*<.001), the intervention improved the Mini Nutritional Assessment test score of the

participants in the intervention group. The egg consumption (F=4.1; *P*=.018), protein intake (F=3.0; *P*=.050), polyunsaturated fatty acid intake (F=5.3; *P*=.006), folate (F=3.3; *P*=.041) and vitamin E (F=6.4; *P*=.002) showed significant group X time interactions.

**Conclusion**: A nutrition education intervention for caregivers halted the tendency of nutritional decline, and reduced the risk of malnutrition of older dependent patients.

**Trial Registration**: Clinical Trial Registration-URL: www.clinicaltrials.gov. Identifier: NCT01360775

**Keywords**: Aged; Activities of Daily Living; Home Care; Caregivers; Malnutrition; Nutrition education; Primary Health Care

## INTRODUCTION

Malnutrition can be defined as "a state resulting from lack of uptake or intake of nutrition leading to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease" (Cederholm et al., 2015; Sobotka et al., 2011). The consequences of malnutrition are multiple, including increased risk of falls, loss of independence, reduced quality of life, hospitalizations, institutionalization, comorbidity and mortality (Agarwal et al., 2013; Lim et al., 2012; Marshall et al., 2014; Muscaritoli et al., 2016).

The risk of malnutrition is common among community-dwelling older people, according to a meta-analysis the prevalence of malnutrition is 5.8% and the risk of malnutrition 31.9% (Kaiser et al., 2010). This risk increases when the patients have difficulties performing basic Activities of Daily Living (Tamura et al., 2013) and need the support of a caregiver.

Most intervention studies aim to improve nutritional status or delay nutritional deterioration among the elderly by using oral nutritional supplements (Milne et al., 2009; Mucci and Jackson, 2008; Pivi et al., 2011). A recent Cochrane review has shown that using oral

nutritional supplements increases weight in older people (Milne et al., 2009), and other studies have also shown a positive effect on the nutritional status and biochemical parameters (Mucci and Jackson, 2008; Pivi et al., 2011). Other studies have used different strategies, such as educational interventions. These have been effective in improving the nutritional status of community-dwelling "healthy" elderly people (Bandayrel and Wong, 2011; Lyons, 2014; Sahyoun et al., 2004), but few studies are aimed at caregivers of the dependent elderly (Lauque et al., 2004; Pivi et al., 2011; Salvà et al., 2011). In all these previous studies, the patients had cognitive impairments or Alzheimer's Disease, and the studies have been shown to be effective in preventing a deterioration in nutritional status. In our region in Spain (Catalonia), the public Primary Health Care services have developed a free of charge Home Care Program which covers homebound patients (of any age), most of whom are dependent, to ensure continuity of care, access to nursing and medical services, and equality in care of patients who for various reasons are unable to visit a Primary Health Care Center.

The objective of this study is to assess the effect of a nutrition education intervention within the Home Care Program, aimed at caregivers, on preventing the increasing risk of malnutrition of dependent patients at risk of malnutrition.

## MATERIALS AND METHODS

### *Design*

The study was designed as a multicentric randomized controlled trial; the intervention consisted of nutrition education for caregivers of 190 dependent patients at risk of malnutrition, conducted in the Home Care program in various Primary Health Care Centers in the Tarragona-Reus area between January 2010 and March 2012. Data assessments were conducted at three different time points (baseline, after 6 and 12 months).

The study complied with the Declaration of Helsinki and was approved by the Jordi Gol Ethics Committee of the Institute of Primary Care Research (IDIAP) on April 27, 2009. Written informed consent was obtained from all participants.

The study design is described in detail elsewhere (Arija et al., 2012).The study was registered at the Clinical Trial Registry (www.clinicaltrials.gov) with number NCT01360775.The CONSORT statement was used as a guide for the report of this study (Altman et al., 2001).

*Participants*

Subjects met the following inclusion criteria: 1) participation in the Home Care Program-*Atenció Domiciliària* (ATDOM), 2) aged 65 years or older, 3) Mini Nutritional Assessment score between 17 to 23.5 points (range for "at risk of malnutrition")(Guigoz et al., 1996), and 4) have difficulties to perform Activities of Daily Living, be caregiver-dependent and must have a caregiver. Exclusion criteria were: 1) Mini Nutritional Assessment score outside the range of 17 to23.5 points, 2) enteral feeding required, 3) severe dysphagia,4) any serious illness that progresses to malnutrition (such as "cancer" or "severe Chronic obstructive pulmonary disease"), and 5) consumption of vitamin and/or dietary supplements.

Each of the subjects had a caregiver, and the caregivers were the contents of the nutrition education sessions.

*Recruitment*

A random selection at 10 Catalan Health Institute Primary Health Care Centers in Reus and Tarragona counties (Spain), stratified to represent different geographical areas: a) 5 Centers in 2 cities over 100,000 population, b) 2 Centers in the suburbs of these cities, c) 1 Center in a medium-sized urban area (about 30,000 inhabitants), and d) 2 Centers in rural areas.

All patients of the Home Care Program registered with the Primary Health Care Center who met the inclusion criteria were recruited to this present study. The subjects were selected by

initial identification in the electronic medical record (e-cap) according to Mini Nutritional Assessment score and age. A second assessment at e-cap was performed to explore if they meet the criteria to participate and were verified by performing a baseline Mini Nutritional Assessment. The patients, who accepted to participate, signed their informed consent.

*Sample size*

In order to obtain a good precision, the sample size was calculated including all the elderly patients of these Primary Health Care Centers. The main variable was the Mini Nutritional Assessment score, which had an approximate average of 25.4±3.7 points in the Spanish population (Harris et al., 2008). A variation of 2 points was considered a clinically relevant value. Considering a one-sided hypothesis, and admitting an alpha error of 0.05 and a power of 95%, a sample of 72 subjects in each group was needed to observe a difference of 2 points in the Mini Nutritional Assessment test after educational intervention with a precision of 80%.

*Randomization*

The subjects were classified randomly, individually and stratified by Primary Health Care Center. From a common database, the subjects were computer-assigned to the intervention group and non-intervention group in each Primary Health Care Center. The allocation ratio was 3:2 in each stratum favoring the intervention group because we expected more loss to follow-up in the intervention group due to its higher engagement requirement. Participants, nurses and researchers were not blinded because of practical impossibilities. The laboratory technicians analyzing biochemistry parameters were blinded to the group assignment.

*Intervention*

The nurses of the Home Care Program-ATDOM conducted an individual session to explain the project and causes and consequences of malnutrition to the caregiver and the patient. The caregivers were informal or formal (relatives of the patients or contracted by them), and they were their regular caregivers, each of the caregiver took care of one patient. Then, the nurses conducted a group session among several caregivers of their Primary Health Care Center, and further individual dietary monitoring of the patient in the presence of his caregiver.

The group educational session aimed at caregivers was a one-hour, standardized educational session, conducted by a nurse in small groups of 15 caregivers, based on the Spanish recommendations for the elderly (SENC, 2004), with the following content:

- The nurses gave general information about foods, macronutrients and some micronutrients. They showed foods rich in nutritional content.
- They nurses explained how to design a healthy diet, focusing in macronutrient distribution and food choices.
- They gave advice on dietary adaptation to address the most common nutritional problems in this group, such as energy, protein, vitamin, mineral and water deficiency, and adaptation of textures.
- They gave recommendations on basic cooking techniques.

Monitoring of educational intervention: Primary Health Care Center nurses monitored patients at home every month up to 6 months, and then at 12 months, in the presence of the caregiver. Nurses strengthened concepts learned during the session (e.g. healthy diet design and cooking techniques), and established objectives with the caregiver to accomplish from one visit to the other, based on the topics of the group session.

To provide individualized dietary advice as necessary, standardized ad hoc cards were developed, that contained appropriate dietary advice according to the patient’s needs and the established objectives between caregiver and nurse.

Controls: the control subjects did not receive nutrition intervention; they were visited once to complete an initial assessment and received regular Home Care visits, and also the study-specific 6 months and 12 months visits. The regular Home Care consisted on home care visits, where the nurses and doctors provided care to the patients.

Different nurses conducted the groups to avoid influence between them, but in the smaller centers the same nurse conducted both groups.

*Training*

The nurses had previous advanced training in nutrition (Bachelor or Continuing training). Four 2-hour sessions (8 hours in total) for the nurses were held to standardize the procedure and train the nurses of from the various participating Primary Health Care Centers.

The contents of these sessions included:

- Presentation of the study.
- Reminder of the general concepts of nutrition and food in nutritional risk situations.
- Standardization of education for caregivers.
- Creation of educational material.
- Procedures and data collection.
- Training for dietary assessment and detection of specific nutritional needs and difficulties to meet the recommendations (SENC, 2004). The objectives to be achieved during the month were established based on these difficulties.

These sessions were conducted by expert nutrition researchers with experience in educating health professionals.

*Baseline and Outcome variables*

Patient variables in the intervention and nonintervention groups: these variables were collected at baseline and except for sociodemographic variables and current medical history, again at 6 months (end of the intervention), and 12 months.

*Baseline variables*

*Sociodemographic variables*: Age and sex were recorded, and social risk was evaluated by assessment of the Family socio-scale designed and validated by Primary Health Care of Gijón. This social risk scale contained five areas: financial status; family status; housing; social relations; and support of social networks. Scores were categorized as: low social risk (≤ 7), moderate social risk (8-9), severe social risk (≥10) (Garcia Gonzalez et al., 1999).

*Current medical history*: Chronic diseases registered (e-cap), type of teeth (natural or dentures, and if prosthesis, good or bad fit).

*Primary outcome measures*

*Nutritional status variables*: the key variable Mini Nutritional Assessment is a validated test with sensitivity and specificity for the diagnosis of malnutrition (Guigoz et al., 1996). This test is specific for elderly population, and it is the nutritional screening tool most used in Primary Health Care. The categories of the Mini Nutritional Assessment test are:

24 – 30 points: Normal nutritional status

17 – 23.5 points: At risk of malnutrition

<17 points: Malnourished

We sum the items in 3 dimensions: health status related items (including item of loss of appetite, weight lost, mobility, acute disease, neuropsychological problems, independently living, medication, skin ulcers, mode of feeding, self view of nutritional status and health status), anthropometric items (BMI, Mid-arm circumference and calf circumference) and dietary intake related items (daily full meals, protein intake, fruit and vegetable intake and beverage intake).

*Secondary outcomes measures*

*Anthropometric measurements*: Determination of standing height: height was measured with stadiometer with 1 cm precision. In case of bedridden person, the formula of Chumlea was used to estimate height (Chumlea et al., 1985).

Determination of body weight: nursed measured body weight with a portable scale with 100g precision. To determine body weight when it could not be measured, the following formula was applied:

- Men : (Middle-Upper Arm circumference * 2.31) + (Calf circumference * 1.5) – 50.1
- Women : (Middle-Upper Arm circumference * 2.31) + (Calf circumference * 1.43) - 37.46

Body Mass Index (BMI) ($kg/m^2$) was classified in 3 categories: underweight 18.5-22 $kg/m^2$, normal weight: 22-26.9 $kg/m^2$; and overweight-obese: >27 $kg/m^2$ (Wanden-Bergue, 2007). Middle-Upper Arm circumference and Calf circumference were measured using a non-extensible tape with 1 mm of precision (Cuervo et al., 2009). Calf circumference < 31 cm was considered as underweight (Guigoz et al., 1996).

*Consumption of food:* We used a food frequency questionnaire with 45 items, validated in the same population (age range 10 – 69 years) of the same area (with coefficient scores for reproducibility of 0.60 and validity of 0.43) (Trinidad Rodríguez et al., 2008). The questions referred to usual consumption in the last 3 months. The consumption of each item was calculated based on the weekly and monthly food frequency of each item, further calculated per day and multiplied by portion size (one option). The portion size obtained from data from a previous study (Arija et al., 1996), in which data of habitual portion size of the general population in this geographical area was recorded by 24h recalls during 3 different periods. Energy and nutritional intake were calculated using an adapted computerized food composition table specifically for this questionnaire. This adapted computerized food

composition table was created with data from the mentioned previous study, with the following procedures: Each item of the food frequency questionnaire represents a food group, so for each item it was added the consumption of all the foods included in this group. The proportion of each food per items was calculated, and the resulting percentage was used as weighting factors. These weighting factors were applied to the Regal Food Composition table (Favier SC, Ireland-Repart J, 1995) to calculate a new adapted computerized food composition table.

Daily intake of foods and beverage was grouped into 12 food and beverage groups: dairy, meat, fish, eggs, vegetables, fruit, starch, legumes, nuts, sweets, soft drinks and alcoholic drinks.

*Biochemical markers:* The biochemical parameters analyzed were:

- Serum albumin and prealbumin (colorimetry).
- Hemoglobin and hematocrit (fluorescence and optics).
- Cholesterol (enzymatic technique)

The extraction was performed in patients' homes by Primary Health Care nurses.

*Degree of dependency*: The Barthel Test was used to perform a physical functional assessment (basic activities of daily living) of patients. The collection was carried out by direct observation or by asking the patient if possible. The range is from 0 to 100. A higher score indicated greater independence:

Severe dependence (<30), moderate dependence (30–60) and mild dependence (60–90) (Mahoney and Barthel, 1965).

*Cognitive function*: Cognitive impairment was assessed by Pfeiffer's test, a validated screening questionnaire of cognitive impairment. Score were classified as no cognition

decline (0-2 mistakes), mild (3-4 mistakes), moderate (5-7 mistakes), severe cognitive decline (8-10 mistakes) (Martinez de la Iglesia et al., 2001).

*Mood:* The mood rating of the population 65 years old and over on the Yesavage Depression Scale identifies the presence of depression. Scores were classified as: no depression (0-1), at risk of depression (≥ 2) (De Dios Del Valle R, Hernández Sánchez AM, Rexach Cano LI and AJ, 2001).

*Caregiver variables in the intervention and control groups*

*Sociodemographic data*: Age, sex, socioeconomic status, education, and the patient's connections (family, volunteers, employee). These variables were collected at baseline for both groups.

*Knowledge acquisition*: an 11-item questionnaire on basic concepts explained in the nutrition education intervention, designed by researchers. This questionnaire was collected only in the intervention group before the education session, immediately afterwards, and at 1–6–12 months thereafter.

*Procedure*

Nurses collected all this information by interviewing the patients (the caregiver was interviewed, when the patient was unable to answer due to cognitive decline), and also by direct observation, and they took anthropometric and biochemical measures.

*Statistical analysis*

Standard tests (Kolmogorov-Smirnov and Shapiro-Wilks) were used to verify the hypothesis of a normal distribution of quantitative variables. Non-parametric tests were used if the preconditions for the application of statistical tests were fulfilled.

The variables were described as the mean and standard deviation, and the percentages for quantitative and qualitative variables respectively. The quantitative variables were compared using the Student-Fisher T test and analysis of variance for the categorical variables, and the chi-square statistical test.

Repeated measures ANOVA tested group X time interactions to assess if there were differences between intervention and control groups over the three phases: baseline, 6 months, 12 months post assessments with a Bonferroni post-hoc comparison. Models were controlled for sex and age.

The bilateral null hypothesis of normality, no difference and no significance of regression coefficients, was discarded when their probability was less than 5%. As sensitive analyses, we performed multiple imputation for the missing values and we repeated the analyses with imputed data. SPSS/PC version 20.0 was used for data analysis.

**RESULTS**

*Study participants*

A total of 241 men and women were found to be eligible (Figure 1), after being assessed for eligibility according to Mini Nutritional Assessment score and age. 190 were included in the study, and after exclusions 173 were randomized to the control group (n=72) and the intervention group (n=101).A total of 139 participants completed the 6-month examination and 111 the 12-month follow-up: 66.7 %in the control group and 62.4 % in the intervention group. The reasons for dropout are described in Figure 1. Patients who were lost to follow up had similar baseline Mini Nutritional Assessment and other characteristics, but they were older ($P$=0.007), had a lower BMI ($P$=0.034) and lower albumin levels ($P$=0.033).

The baseline social demographic and clinical characteristics were similar in both groups (Table 1).The mean age was 87.8±8.9 years, 68.2% were women, 56.0 % had a moderate social risk and the average body mass index was 26.9±5.6 kg/m$^2$, with 19.1% underweight and 43.4% overweight. The most prevalent chronic disease in this population was hypertension (64.0%), 52.6% had cognitive impairment and 59.8% were at risk of depression.

*Dietary outcomes*

The dietary data at baseline and after 6 months and 12 months of follow-up is shown in Table 2 and Table 3. Participants in the intervention group increased their consumption of eggs in comparison with the control group (F=4.1; *P*=0.018). They also increased their intake of fruits (234.1±121.3 vs 263.6±138.3 g/d) and nuts (0.7±1.8 vs 1.6±3.8 g/d) but there was not a significant group X time interaction.

There was an increase in protein intake in the intervention group over the 12 months of the intervention (60.2±14.4 vs 64.3±17.8) with a significant group X time interaction (F=3.0; *P*=0.050). There were also significant group-by-time interactions on micronutrients, such as polyunsaturated fatty acids (F=5.3; *P* = 0.006), folate (F=3.3; *P* = 0.041) and vitamin E (F=6.4; *P*=0.002).

*Scores, anthropometric and biochemistry outcomes*

The intervention improved the Mini Nutritional Assessment score of the participants in the intervention group (Table 4) over the 12 months intervention (F=10.1; *P*<0.001), while the Mini Nutritional Assessment score of the control group fell significantly after this period, from 19.8±2.9 to 18.3±3.8
(Fig. 2). The items of the MNA that had a significant group X time interaction were the health status related items (F=4.1; P=0.018) and the dietary intake related items (F=21.1; P<0.001) (Table 4). At 6 months follow-up, 9% of the participants of the intervention group were malnourished (Mini Nutritional Assessment <17 points), whereas in the control group

22.6% of the participants were malnourished. At 12 months follow-up, 4.8% were malnourished in the intervention group and 35.4% in the control group (data not shown). There were also statistically significant differences between the participants who reached the normal nutritional status range (24 – 30 points), at 6 months follow up 26.9% in the intervention group and 11.3% in the control group and the 12 month follow up 19% vs 4.8% (data not shown).

The intervention maintained Barthel score, weight and body mass index in the intervention group, whereas they decreased in the control group. However, there was not a group X time significant interaction for these measures, and also for any other outcomes.

After the education intervention, the intervention group improved their nutritional knowledge by 1.5 points (8.2±1.4 vs. 9.7±1.2; $P<0.001$) according to the 11-item questionnaire. This improvement persisted throughout the 12-month follow-up. The effect of the intervention was B=3.22 ($P<0.001$) in the adjusted multiple linear regression model (Table 5). The baseline BMI (B=0.17; 95%CI=0.05, 0.28; $P=0.005$) and baseline Barthel score (B=0.03; 95%CI=0.01, 0.06; $P=0.013$) were the factors positively associated with the Mini Nutritional Assessment score after 12 months of follow-up.

Sensitive analyses were performed with imputed data, and the estimates were similar, except for protein, PUFA and vitamin E intakes that were attenuated.

## DISCUSSION

The results of this study indicated that over a 12-month follow-up, a 6-month nutrition education intervention for caregivers significantly improved the Mini Nutritional Assessment score and dietary intake of older, community-dwelling dependent patients at risk of malnutrition. Meanwhile, the Mini Nutritional Assessment score in the control group fell. The intervention did not have effect on anthropometrics and biochemistry parameters. The decline suffered by the participants of the control group is the expected in participants with these characteristics and it is consistent with the decline recently reported by Meyer S et al

after 1 year follow up (Meyer et al., 2015). These results suggested that nutrition education for caregivers may be an effective intervention to reduce the risk of malnutrition and the decline of nutritional status, and to improve the dietary habits of older dependent patients. To our knowledge, this is the first randomized nutrition education intervention aimed at caregivers of older dependent patients living at home conducted in Spain, including patients with and without cognitive problems. Previous studies have mostly focused on oral nutritional supplements, home-delivered meals and dietetic counseling, with different results. Whilst oral nutritional supplements and home-delivered meals seemed to be effective in increasing body weight (Gollub and Weddle, 2004; Milne et al., 2009; Sahyoun and Vaudin, 2014; Zhu and An, 2014), dietetic counseling showed inconclusive results (Beck et al., 2013; Schilp et al., 2013)

Some studies have focused on educational interventions for elders (Lyons, 2014; Sahyoun et al., 2004) (Locher et al., 2008) but many of these studies do not include caregivers. The participation of caregivers is essential in avoiding decline of the health status of a dependent patient, because this population has difficulties performing Activities of Daily Living, and they need support for many activities related to food intake, such as buying, cooking, and feeding, in severe cases. Some of the difficulties that caregivers found are food preference modification, reduced appetite and loss of autonomy (Silva et al., 2013). In fact, a recent review (Marshall et al., 2013) reported that in order to prevent malnutrition and its consequences, informal caregivers must be involved in the identification, prevention and treatment of malnutrition. Furthermore, educational interventions aimed at caregivers were effective in preventing and treating malnutrition in community-dwelling older adults (Lauque et al., 2004; Pivi et al., 2011; Riviere et al., 2001; Salvà et al., 2011). Most of these interventions were aimed at caregivers of patients with cognitive impairment, and although just 30% of our subjects had cognitive impairment, our intervention had also a positive effect on the nutritional status (Lauque et al., 2004; Pivi et al., 2011; Riviere et al., 2001; Salvà et

al., 2011). Similar to our study, in one study conducted with Alzheimer's Disease patients, although the weight change was not significant, the Mini Nutritional Assessment score remained unchanged in the intervention group and fell in the control group (Riviere et al., 2001). However, another randomized trial improved the BMI of 25 Alzheimer's Disease patients after 10 group sessions for caregivers (Pivi et al., 2011). Lauque et al. also reported an increase in weight and fat free mass, as well as energy and protein intake, but this intervention combined oral nutritional supplements and an educational intervention (Lauque et al., 2004). It is difficult to determine the extent to which the positive effect was due to oral nutritional supplements or the educational intervention, or a combination of both. The NutriAlz program had a similar limitation, because the recipients of the intervention were the informal caregivers and also physicians of the Home Care Program, unlike our study, in which only the caregivers received the intervention. This program reported a positive effect on Mini Nutritional Assessment after a one-year follow-up (Salvà et al., 2011).

Unlike the studies mentioned above, this is the first one to include dietary data. However, the changes in dietary patterns and food choices post-intervention were modest. However, our study improved protein intake and nutritional intake without using oral nutritional supplements. Some authors maintained that oral nutritional supplements are even more effective at reducing the risk of malnutrition than education programs (Pivi et al., 2011). Furthermore, several studies have found that the use of ONS in malnourished patients lead to important medical cost savings (Freijer et al., 2012; Snider et al., 2015), but we hypothesize that an educational intervention for caregivers as part of a Home Care Program may be an adequate strategy to prevent and reduce the risk of malnutrition in early stages and also to reduce the cost of treatments. However, further studies are needed to evaluate the cost efficacy of educational interventions in comparison with ONS use.

This study was effective in improving the patient's Mini Nutritional Assessment, nutritional intake and nutritional knowledge of the caregivers, but the intervention did not improve

biochemistry values. This may be explained because this population has no baseline alterations in the biochemistry values. In fact, we chose this population at risk of malnutrition because we believed this was a key period in avoiding malnutrition, and we hypothesized that this kind of intervention may have no effect in already malnourished subjects. Another explanation of this lack of an effect could be that these biochemical parameters could be better assessed with a larger sample or a longer follow-up. An example is a study based on dietary counseling of elderly people at risk of malnutrition without oral nutritional supplements, which had a positive effect in serum albumin with a follow-up of 2 years (Nykänen et al., 2014). However, the use of these biomarkers have some limitations, since they can be altered in the presence of disease and according to a recent consensus, they should not be used for diagnosis and screening of malnutrition (Cederholm et al., 2015).

We also observed no clear effect on functional performance, because the members of the intervention group maintained their baseline Activities of Daily Living, and it moderately declined in the control group, although it was not statistically significant. This lack of effect was consistent with non-educational nutrition interventions for disabled elderly people, which could improve their weight status but not their disability level (Daniels et al., 2008; Payette et al., 2002). There was also no effect on slowing the cognitive decline, but we did not observe any decline in controls either. The length of the trial may need to be longer to detect an effect on the decline (Ferry et al., 2013).

A major strength of this study was that it combined two different methodologies, as a group nutrition education session aimed at caregivers with individual monitoring. The effect of the intervention was assessed with the Mini Nutritional Assessment, a validated screening tool, as well as the change in dietary habits, anthropometric measurements and biochemistry parameters related to nutritional status (Artaza-Artabe et al., 2016; Bonnefoy et al., 2015; Vellas et al., 2000). We also used validated tools to assessed factors that have been associated with malnutrition, such as: degree of dependency, mood, and cognition decline (Favaro-

Moreira et al., 2016; Naidoo et al., 2015; Serrano-Urrea and García-Meseguer, 2014). A further strength was the generalizability of the study, since the selection of the Primary Health Care Centers was randomized and all the patients of the Home Care Program of the selected Primary Health Care Centers were included in the study in order to avoid selection bias.

The inclusion of the educational intervention in an existing Home Care Program facilitated the implementation of the study and guarantees continuity as a part of the Program, and the study was conducted using trained nurses in the regular Home Care Program.

The study had some limitations. Different nurses generally conducted the groups to avoid influence between them, but in the smaller centers the same nurse conducted both groups and this may have contaminated the participants of the control group. Another limitation was the use of a food frequency questionnaire in the elderly for memory recall reasons; the collaboration of the caregiver in the food frequency questionnaire was therefore necessary. The food frequency questionnaire has some limitations such as measurement error and the quantification of food portions, since food portions are based on habitual portion size of the general population, and there is an overestimation of actual dietary consumption, as reported in a previous study with the same population that found that 31.6% of participants overestimated the intake (Fernández-Barrés et al., 2016). However, the food frequency questionnaire is useful to assess the change of dietary consumption between before and after the intervention (Thomson et al., 2003).

Another limitation was that our population was old and frail with many comorbidities, and this study had a high dropout level (35.8%), similar to other studies conducted in elderly population (Badia et al., 2015; Feldblum et al., 2011). Although, the data from the 6 month follow-up was valuable, we should interpreted the findings carefully. Because the participants who were lost to follow-up were older and the drop out for death and institutionalization was higher in the intervention group compared to the control group, meaning that the sicker participants of the intervention group were excluded from the analyses and they could have attenuated the effect of the intervention.

*Conclusion*

From this study, we can conclude that an educational intervention for caregivers may reduce the risk of malnutrition among older dependent patients and improve their dietary habits and nutritional intake. However, further research is needed to include a nutrition education intervention as a standard part of care in a home-care program for community-dwelling dependent older patients, to prevent malnutrition.

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Contributions of the paper

What is already known about the topic?

- Older patients living in the community have a high prevalence of malnutrition.
- Aged patients with difficulties to perform the Activities of Daily Living are more likely to have a caregiver and be included in a Home Care Program.
- Difficulties to perform the Activities of Daily Living are associated with an increase risk of malnutrition.
- Nutrition education interventions are effective in improving the nutritional status of elderly people without difficulties to perform the Activities of Daily Living.

What this paper adds

- The results provided evidence that a nutrition education intervention included in a home care program halted the tendency of nutritional decline of older patients with difficulties to perform the Activities of Daily Living compared to regular home care.
- A nutrition education intervention for informal caregivers included in a home care program improved nutrient intake of patients with difficulties to perform the Activities of Daily Living compared to regular home care.

***Conflict of interest***

Conflicts of interest: none.

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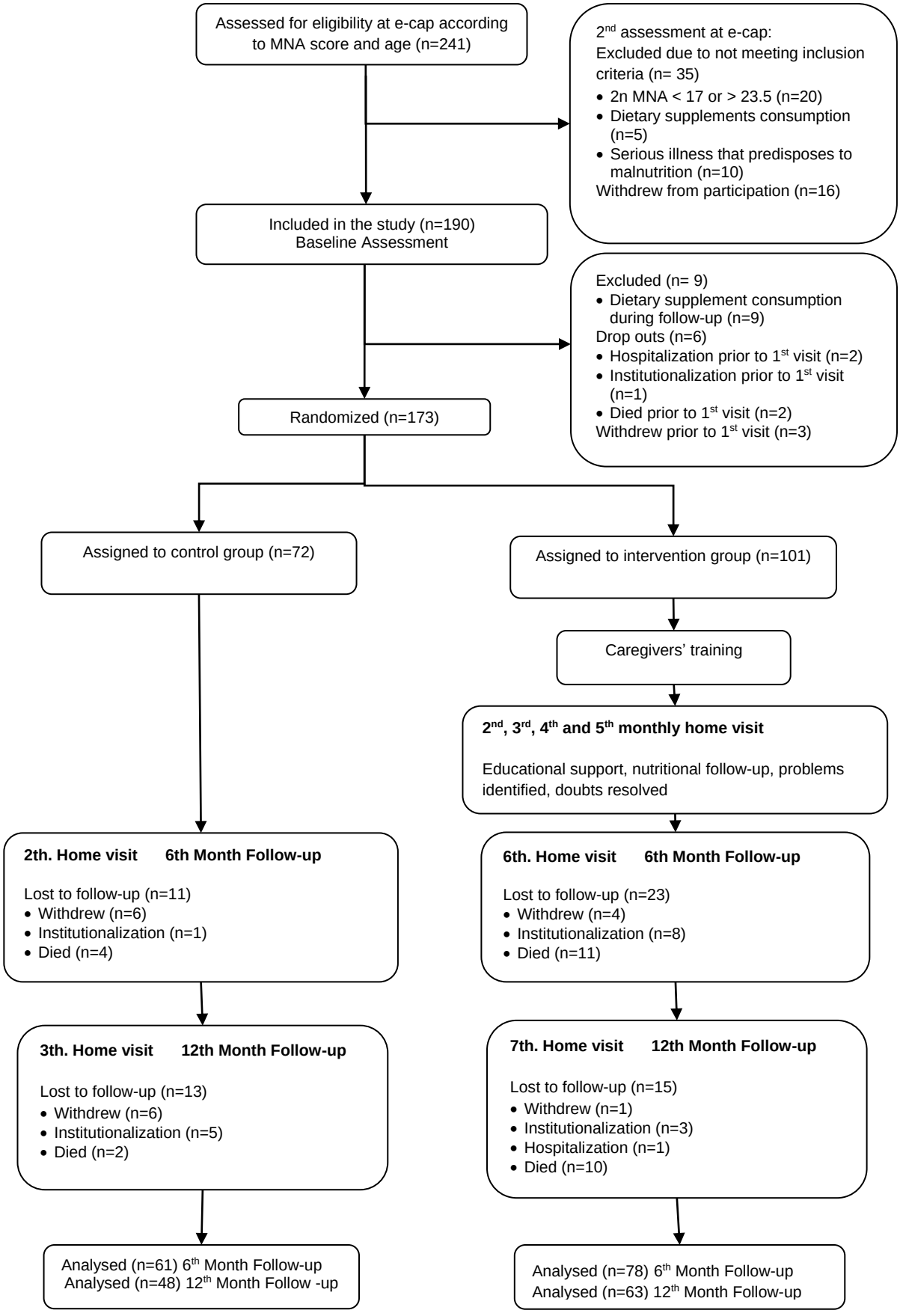


Fig. 1 Consort Flow Diagram

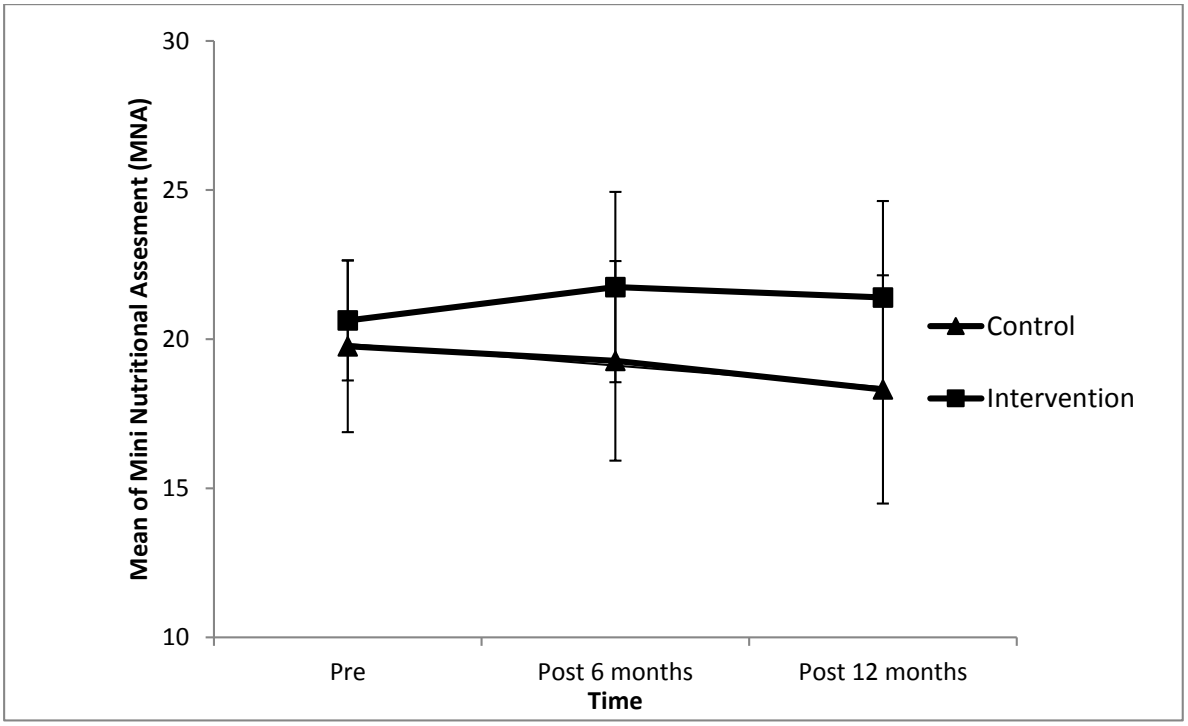


Fig. 2. Comparison of the changes of mean Mini Nutritional Assessment (MNA) according to the intervention groups.

There was a significant group X time interaction (repeated measures ANOVA; $P < 0.001$) adjusted for participant age and gender.

**Table 1 Baseline Characteristics**

| | **Intervention** | **Control** | **p** |
|---|---|---|---|
| | **n:101** | **n: 72** | |
| **Patient's characteristics:** | | | |
| Age, years[a] | 84.3±6.7 | 85.4±7.6 | 0.308 |
| Sex, % (females) | 71.3 | 63.9 | 0.303 |
| MNA TOTAL, Score[a] | 20.6±2.0 | 19.9±2.7 | 0.060 |
| Moderate social risk, % | 50.5 | 65.5 | 0.179 |
| Weight, kg[a] | 63.6±13.3 | 63.3±17.6 | 0.919 |
| BMI, kg/m$^2$[a] | 27.0±5.0 | 26.9±6.3 | 0.935 |
| BMI, % underweight - % overweight | 19.8-45.5 | 18.1-40.3 | 0.926-0.593 |
| Chronic diseases, % | | | |
| 1. COPD | 12.9 | 14.1 | 0.824 |
| 2. HTA | 65.3 | 62 | 0.747 |
| 3. Dyslipemia | 19.7 | 31.7 | 0.115 |
| 4. Diabetes Mellitus | 23.8 | 32.4 | 0.228 |
| Dental problem, % | 53.5 | 60.6 | 0.442 |
| Limited mobility, % | 24.8 | 23.6 | 0.982 |
| Feeding with difficulties, % | 39.5 | 40.0 | 0.974 |
| Dependence, % mild - % severe | 64.4 - 17.8 | 63.4 – 19.7 | 0.948 |
| Cognitive impairment, % mild - % severe | 36.4-14.1 | 37.5-18.1 | 0.725 |
| Risk of depression, % | 59.4 | 60.3 | 0.906 |
| **Caregiver's characteristics:** | | | |
| Age, years[a] | 58.7±14.1 | 60.7±17.1 | 0.405 |
| Sex, % (females) | 86.1 | 85.5 | 0.908 |
| Type (informal), % | 83.2 | 84.5 | 0.815 |
| Education, %: | | | |
| 1.None or unfinished | 27.7 | 29.6 | 0.925 |
| 2.Primary or secondary | 67.6 | 67.3 | 0.899 |
| 3.University | 5.0 | 2.8 | 0.760 |

[a]Mean±Standard deviation; BMI: Body Mass Index; MUAC: Middle Upper Arm circumference; CC: Calf circumference; COPD: Chronic obstructive pulmonary disease. MNA: Mini Nutritional Assessment; Dependence by Barthel Index; Cognitive impairment by Pfeiffer Test; Risk of depression by Yesavage Scale.

**Table 2 Changes in Diet after the Intervention**

| | **Intervention** | | | **Control** | | | **Group X Time** | |
|---|---|---|---|---|---|---|---|---|
| | **Pre** | **Post 6** | **Post 12** | **Pre** | **Post 6** | **Post 12** | **F** | **p-** |
| | **n = 63** | **n = 63** | **n = 63** | **n = 48** | **n = 48** | **n = 48** | | |
| | mean±sd | mean±sd | mean±sd | mean±sd | mean±sd | mean±sd | | |
| **Dairy, g/d** | 413.5±18 | 427.6±21 | 445.5±223 | 317.6±15 | 318.3±193. | 345.4±1 | 0.1 | 0.896 |
| **Meat, g/d** | 77.0±36.4 | 81.7±34.0 | 76.8±32.8 | 87.7±29.0 | 80.5±31.1 | 85.5±33. | 2.0 | 0.144 |
| **Fish, g/d** | 49.3±33.3 | 47.8±31.0 | 53.7±33.0 | 49.6±27.3 | 43.6±25.0 | 50.2±33. | 0.5 | 0.590 |
| **Eggs, g/d** | 17.3±8.8 | 20.1±9.6 | 20.7±10.8 | 18.3±9.9 | 16.0±9.9 | 16.3±10. | 4.1 | 0.018 |
| **Vegetables,** | 92.3±43.5 | 98.4±44.4 | 97.9±45.2 | 95.8±42.0 | 90.7±41.4 | 92.6±44. | 1.5 | 0.223 |
| **Fruits, g/d** | 234.1±12 | 251.4±14 | 263.6±138 | 183.5±95. | 195.1±116. | 188.2±1 | 0.4 | 0.682 |
| **Starchy, g/d** | 161.6±62. | 148.6±59. | 158.5±63. | 165.5±68. | 140.4±61.6 | 144.4±5 | 1.5 | 0.216 |
| **Legumes,** | 14.2±10.7 | 14.5±10.7 | 30.7±32.9 | 13.8±8.5 | 13.3±8.1 | 26.5±14. | 0.3 | 0.745 |
| **Nuts, g/d** | 0.7±1.8 | 1.1±2.6 | 1.6±3.8 | 1.2±3.2 | 1.1±3.3 | 0.4±1.1 | 3.6 | 0.056 |
| **Sweets, g/d** | 30.1±20.1 | 28.8±21.9 | 27.4±22.0 | 35.2±37.2 | 35.1±31.8 | 31.2±30. | 0.2 | 0.804 |
| **Soft drinks,** | 6.9±28.0 | 11.7±35.6 | 8.5±26.1 | 7.1±30.5 | 1.5±6.1 | 5.4±29.3 | 1.4 | 0.244 |
| **Alcoholic** | 11.6±29.6 | 11.7±34.4 | 5.7±14.5 | 15.3±42.7 | 13.4±37.5 | 12.7±36. | 0.7 | 0.502 |

Repeated-measures analysis of variance adjusted for participant age and gender.

**Table 3 Changes in Macronutrient and Micronutrient Intakes after the Intervention.**

| | **Intervention** | | | **Control** | | | **Group X Time** | |
|---|---|---|---|---|---|---|---|---|
| | **Pre** | **Post 6** | **Post 12** | **Pre** | **Post 6** | **Post 12** | **F** | ***P*-** |
| | **n = 63** | **n = 63** | **n = 63** | **n = 48** | **n = 48** | **n = 48** | | |
| | mean±sd | mean±sd | mean±sd | mean±sd | mean±sd | mean±sd | | |
| **Energy** | 1825.1±3 | 1780.7±32 | 1850.0±38 | 1751.4±297. | 1648.3±319 | 1719.5±3 | 0.6 | 0.568 |
| **Proteins.** | 60.2±14. | 60.1±13.9 | 64.3±17.8 | 58.9±9.5 | 53.3±12.0 | 58.7±10. | 3.0 | 0.050 |
| **Carbohydra** | 190.8±61 | 140.4±82. | 189.2±60. | 174.4±55.4 | 161.5±60.2 | 171.5±69 | 0.0 | 0.994 |
| **Fat, g/d** | 89.2±10. | 89.7±10.0 | 91.4±13.3 | 89.0±8.8 | 86.3±10.0 | 87.3±9.3 | 2.5 | 0.088 |
| **PUFA, g/d** | 9.5±1.2 | 9.5±1.0 | 9.8±1.4 | 9.6±0.9 | 9.2±1.1 | 9.3±0.9 | 5.3 | 0.006 |
| **MUFA, g/d** | 49.3±3.4 | 49.6±3.4 | 50.0±4.6 | 49.5±3.3 | 48.5±3.6 | 48.8±3.3 | 2.9 | 0.059 |
| **SFA, g/d** | 24.1±5.1 | 24.2±5.2 | 25.0±6.8 | 23.6±4.3 | 22.6±4.9 | 23.1±4.8 | 1.1 | 0.330 |
| **Fibre, g/d** | 13.7±3.9 | 13.6±3.8 | 15.6±4.8 | 12.8±3.3 | 12.1±3.8 | 13.5±4.3 | 1.1 | 0.371 |
| **Iron, mg/d** | 7.2±2.0 | 7.4±1.7 | 8.1±2.3 | 7.0±1.5 | 6.7±1.8 | 7.5±2.0 | 1.9 | 0.152 |
| **Calcium,** | 793.5±26 | 810.8±295 | 867.1±357 | 665.8±198.0 | 640.3±256. | 700.1±21 | 0.6 | 0.554 |
| **Folate, µg/d** | 207.4±54 | 215.6±56. | 240.3±70. | 192.9±41.5 | 179.8±48.6 | 200.4±51 | 3.3 | 0.041 |
| **Vitamin D,** | 1.9±1.2 | 1.9±1.1 | 2.1±1.1 | 1.9±0.9 | 1.7±0.9 | 1.9±1.2 | 0.6 | 0.570 |
| **Vitamin E.** | 9.5±0.8 | 9.7±0.8 | 9.9±1.0 | 9.4±0.7 | 9.2±0.8 | 9.2±0.7 | 6.4 | 0.002 |

Repeated-measures analysis of variance adjusted for participant age and gender.

PUFA: polyunsaturated fatty acid; MUFA: monounsaturated fatty acid; SFA: saturated fatty acid.

**Table 4 Changes in Scores, Anthropometrics and Biochemistry after the Intervention**

| | **Intervention** | | | **Control** | | | **Group X Time** | |
|---|---|---|---|---|---|---|---|---|
| | **Pre** | **Post 6 months** | **Post 12 months** | **Pre** | **Post 6 months** | **Post 12 months** | **F** | ***P-*** |
| | **n = 63** | **n = 63** | **n = 63** | **n = 48** | **n = 48** | **n = 48** | | |
| | mean±sd | mean±sd | mean±sd | mean±sd | mean±sd | mean±sd | | |
| **MNA, Score** | 20.6±2.0 | 21.7±3.2 | 21.4±3.2 | 19.8±2.9 | 19.3±3.3 | 18.3±3.8 | 10.1 | < |
| **MNA Health** | 13.2±1.8 | 13.6±2.5 | 13.4±2.5 | 12.0±2.3 | 11.8±2.6 | 10.9±3.2 | 4.1 | 0.0 |
| **MNA** | 4.3±1.1 | 4.2±1.2 | 4.1±1.3 | 4.1±1.2 | 4.0±1.2 | 3.9±1.5 | 0.0 | 0.9 |
| **MNA Dietary** | 3.2±1.1 | 3.9±0.8 | 3.9±1.0 | 3.6±1.0 | 3.4±1.1 | 3.4±1.1 | 21.1 | < |
| **Barthel, Score** | 61.7±23. | 61.9±25.6 | 60.2±26.1 | 60.8±25. | 58.4±27.0 | 53.8±30. | 1.1 | 0.3 |
| **Pfeiffer, Score** | 3.2±3.3 | 3.5±3.1 | 3.4±3.1 | 3.9±3.1 | 4.1±3.2 | 4.1±3.2 | 0.1 | 0.9 |
| **Yesavage, Score** | 1.9±1.1 | 1.8±1.0 | 1.9±1.1 | 2.0±1.3 | 2.1±1.4 | 2.2±1.4 | 0.4 | 0.6 |
| **Weight, kg** | 64.5±13. | 64.3±13.7 | 64.2±14.4 | 65.6±18. | 65.5±19.8 | 62.7±17. | 2.5 | 0.0 |
| **BMI, kg/m²** | 27.4±5.0 | 27.3±5.3 | 27.3±5.5 | 27.9±6.8 | 27.5±7.0 | 26.8±6.5 | 1.4 | 0.2 |
| **Albumin, g/dl** | 3.9±0.3 | 4.0±0.4 | 3.9±0.3 | 4.0±0.3 | 4.1±0.3 | 4.0±0.4 | 0.2 | 0.8 |
| **Prealbumin, mg/dl** | 24.0±6.8 | 23.5±5.7 | 23.3±6.2 | 22.1±5.6 | 23.5±5.0 | 21.6±6.2 | 1.9 | 0.1 |
| **Haemoglobin, g/dl** | 13.1±1.4 | 12.9±1.4 | 12.7±1.3 | 12.5±1.3 | 12.3±1.2 | 12.1±1.4 | 0.1 | 0.9 |
| **Cholesterol, mg/dl** | 186.5±40 | 179.3±38.6 | 174.8±41. | 186.5±4 | 179.3±38.6 | 174.8±41 | 0.2 | 0.7 |

Repeated-measures analysis of variance adjusted for participant age and gender.

MNA: Mini Nutritional Assessment; Barthel: Barthel Test ofBasic activities of daily living; Pfeiffer: Pfeiffer's test of cognitive impairment; Yesavage: Yesavage Depression Scale;BMI: Body Mass Index;

**Table 5 Effect of the Educative Nutritional Intervention on the MNA Score at 12 Months.**

| | | **B** | **95%CI** | ***P*-value** |
|---|---|---|---|---|
| **Model 1: crude** | Intervention group (no,yes) | 3.08 | (1.75-4.41) | *P < 0.*001 |
| **Model 2 : adjusted** | | | | |
| | Intervention group (no, yes) | 3.22 | (1.97, 4.47) | *P < 0.*001 |
| | Age (years) | 0.09 | (-0.01, 0.19) | 0.073 |
| | Sex (Male, Female) | -1.88 | (-3.42, -0.34) | 0.017 |
| | Baseline BMI(kg/m$^2$) | 0.17 | (0.05, 0.28) | 0.005 |
| | Baseline Barthel Score | 0.03 | (0.01, 0.06) | 0.013 |
| | Baseline energy intake (kcal) | 0.00 | (0.00, 0.00) | 0.849 |

Model 1: $R^2_{c.100}$=15.5 $F^1_{109}$=21.13. *P <0.*001. Simple linear regression.

Model 2: $R^2_{c.100}$=28.9 $F^6_{104}$=8.4.*P <0.*001.Multiple linear regression adjusted for: sex, age and baseline variables: Body Mass Index (BMI), Barthel (Test of Basic activities of daily living)and energy intake.