



# 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 < 0.001), the intervention improved the Mini Nutritional Assessment test score of the participants in the intervention group. The egg consumption (F = 4.1; P = 0.018), protein intake (F = 3.0; P = 0.050), polyunsaturated fatty acid intake (F = 5.3; P = 0.006), folate (F = 3.3; P = 0.041) and vitamin E (F = 6.4; P = 0.002) showed significant group × 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](http://www.clinicaltrials.gov). Identifier: NCT01360775

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## 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.

## 1. 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 and Allison, 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.

## 2. Materials and methods

### 2.1. 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](http://www.clinicaltrials.gov)) with number NCT01360775. The CONSORT statement was used as a guide for the report of this study (Altman et al., 2001).

### 2.2. 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 17–23.5 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 17–23.5 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.

### 2.3. 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.

### 2.4. 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  $25.4 \pm 3.7$  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

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