The Journal of Nutrition, Health & Aging©
Volume 15, Number 10, 2011

HEALTH AND NUTRITION PROMOTION PROGRAM FOR PATIENTS WITH DEMENTIA (NUTRIALZ): CLUSTER RANDOMIZED TRIAL

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Abstract: *Objective:* To assess the effectiveness of health and nutrition program (NutriAlz) versus usual care on functional level in elderly people with dementia living at home, as well as on clinical practice related to nutrition and on the caregiver's burden. *Design:* Cluster randomized multi-centre study with one-year follow-up. *Setting:* 11 Alzheimer outpatients and day care centres (Barcelona, Spain). *Participants:* Nine hundred and forty six home-living Alzheimer patients with identified caregiver were consecutively recruited (intervention group: 6 centres, 448 patients vs control group: 5 centres, 498 patients). *Intervention:* The intervention was a teaching and training intervention on health and nutrition program, NutriAlz, directed both to physician and main caregiver, as well as persons affected by Alzheimer's disease or other dementias, including a standardised protocol for feeding and nutrition. *Main Outcome Measures:* The main outcome measure was the reduction in the loss of autonomy (Activities of daily living (ADL/IADL) scales) assessed at 6 and 12 months. Secondary outcomes measures were Improvement in nutritional status (Mini Nutritional Assessment (MNA), BMI, and weight changes), and caregiver burden (Zarit scale). *Results:* The one-year assessment was completed for 293 patients (65.4%) in the intervention group and 363 patients (72.9%) in the control group (usual care). The annual rate of ADL change was -0.83 vs -0.62 (p=0.984), and the caregiver's subjective burden 0.59 vs 2.36 (p=0.681) in intervention and control group, respectively. MNA, however, showed an improvement (+0.46 vs -0.66, p=0.028), suggesting an effective nutritional behaviour. *Conclusion:* The NutriAlz program had no effect on functional decline in Alzheimer disease patients living at home over one year, but reduced the risk for malnutrition, as recommendations concerning diet and exercise were provided.

Key words: Alzheimer disease, dementia, nutritional program.

Introduction

The prevalence of dementia is between 6-10% of the elderly aged 65 year and over, with 60% having Alzheimer disease (AD) (1-4), resulting in 50% of dependence in the elderly related to AD (5). This increased need of care for elderly with dementia is mainly fulfilled by informal caregivers, primarily family members (6). Information and support intervention for caregivers of people with dementia has shown some positive results in relation to delayed nursing home placement (7, 8), improved quality of care (9). However no uniform effectiveness has been observed (6, 10, 11), probably related to the heterogeneity of evolution of the disease (12).

Further protein-energy malnutrition is frequent in elderly with chronic diseases, associated with dependency on feeding, depression and dementia eating behaviour problems (13). Dependence in daily activities with dementia relates to eating problem and low nutrients intake (14-16). Correlation was found between the risk of malnutrition and cognitive impairment (17), and long-term mortality (18). Correlation was also found between the stage of dementia and weight loss so that the severer the dementia the greater the weight loss; involuntary weight loss has been correlated with a worsening in the state of health (19, 20). Weight loss is also present early in disease or even preceded dementia (19, 21-23), and patients with AD have higher weight loss percentages than healthy people of the same age (24, 25). Weight loss predicts functional decline (26), is associated with malnutrition (27), and elderly with weight loss have a greater risk of being institutionalised (28, 29). Changes in feeding behaviour with poor nutrient intakes relate to the causes of weight loss (16, 30-35).

Strategies to improve dietary intakes and administration of nutritional supplements is effective at improving the anthropometric parameters in elderly with dementia (36, 37).

Physical activity may delay the onset and progression of dementia (38-40) and physical function also relates to malnutrition (32, 41). While there is very little data on positive effect exercise intervention program for care of dementia (42, 43), physical activity counselling may improve management of dementia (40, 44, 45). Thus public healthcare program for weight loss prevention including extensive nutrition education and counselling and a short physical activity program may yield a significant improvement in Alzheimer patient autonomy.

This study was undertaken to study the effectiveness of a teaching and training intervention of health and nutrition program directed to physician and main caregiver, as well as the person affected by Alzheimer's disease or other dementias. The main objective of this healthcare study is to assess the effectiveness of the Nutrition Program, NutriAlz, on functional level in elderly people with dementia living at home; secondary

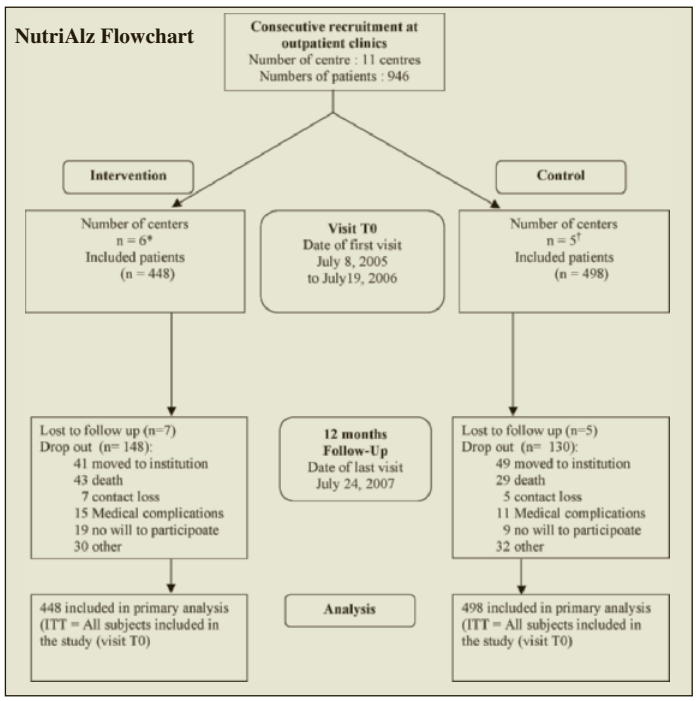
Received June 1st, 2011
Accepted for publication June 22, 2011

aims are to evaluate the effect on nutritional status and weight change, as well as on clinical practice related to nutrition and possibly on the caregiver's burden.

Subjects and methods

The study was approved by the institutional ethic commission of the Autonomous University of Barcelona (Universitat Autònoma de Barcelona), Spain. Written informed consent to take part to the study was given by the participants or the responsible relative or legal guardian. The Figure 1 describes the flow of patients through the study. Study design and baseline data have been previously published in detail (46).

Figure 1
Flow of Participants through the NutriAlz Study



*Speciality of the 6 Intervention centres: 3 centres: Neurology; 2 centres: Geriatry; and 1 centre: Psychiatry; † Speciality of the 5 control centres: 2 centres: Neurology; 2 centres: Geriatry; and 1 centre: Psychiatry

Study Design

In this trial, we used a cluster randomized design comparing 2 groups: intervention group (Nutrition program) versus control group (usual care). The unit of randomization was the medical centres (geriatrics, neurology and psychiatry); the unit of analysis was the patient. This design allowed minimizing the risk of cross-influencing the patients because our intervention concerned physician practice.

The trial is reported according to the CONSORT statement and its extensions to cluster randomized trials (47, 48) and to non-pharmacological treatment interventions (49).

Recruitment

The patients were consecutively recruited to the study from 11 outpatients' clinics (ambulatory diagnostic unit) and day hospital care from July 2005 through July 2006.The participating hospitals included different specialities chosen according to the recruitment capacity.

Patients included were diagnosed with dementia according to DSM IV criteria (50) and were considered to have mild to moderate dementia with MMSE less than or equal to 26. Only ambulatory subjects living at home and who had an identified caregiver were included. Exclusion criteria included MMSE over 26, residence in an institution, as well as patient having nasal-gastric tube feeding or in a terminal situation, and patient participating in another nutritional intervention study.

Sample Size

Our primary hypothesis was that patients in the intervention group would achieve a lower level of dependency compared with patients in the usual care-control group at 12 months. We considered a significant benefit in the intervention group to be a reduction of 30% in the proportion of subject who lose more than 0.5 points according to the ADL score over one year (5). In our original power calculations, we determined that a sample size of 300 participants in each group would result in 90% power to detect such a difference using a 2-tailed test with an alpha level of 0.05. Moreover, taking into account the estimated rate of attrition in demented patients, we planned to recruit at least 438 patients within each group. The objective was then set to 100 patients per centre to reach about 1000 patients (500 per group). We have to acknowledge that we did not take into account the clustering effect induced by the design (i.e. randomization of clusters). Indeed, this study had been planned prior to the publication of the extension of the CONSORT Statement. Nevertheless, the statistical analysis has been performed as recommended by these international guidelines.

To prevent the potential of cross-influence due to the intervention training of the different healthcare professionals, randomization was done by centre taking into account the centre speciality (neurology, geriatrics and psychiatry). Prospective cluster randomised multi-centre study, allowing comparison of a group benefiting from the intervention with a control group after a year of monitoring.

Intervention: the NutriAlz program

In the centres of the "intervention" group, a standardised protocol for feeding and nutrition was proposed, which included:

1. A personalized presentation and hand over of a briefcase containing: information about Alzheimer's disease (booklet 1), about nutrition in particular (booklet 2), physical exercise (booklet 3), available aid and services, specifically about the program (booklet 4), schedule for collecting data such as weight and height, coupons for monitoring in a database, etc. This information (briefcase) was given to patients and their relatives with oral information on hotline access, Nutrition

Program newsletter.

2. Training for families, caregivers were requested to attend 4 sessions of educational intervention done by a dietician which were divided into the following sessions and topics:

- Session 1: Presentation of the participants, presentation of the nutritional support program, presentation of the available resources (hotline, etc.), information on weight loss with Alzheimer's disease, how to carry out nutritional monitoring, how to weigh, how to fill in the nutritional schedule, on lifestyle habits, on a balanced diet and the food pyramid
- Session 2: Continuous information on lifestyle habits, on a balanced diet and the food pyramid, and program on creation of menus, conservation of food, cooking methods, how to increase calorific and protein intake, how to substitute foods that are rejected, nutritional support preparations, and nutritional supplements (what they are for, who prescribes them, how and when to take them, where they can be obtained) further motivation for interest in physical exercise
- Session 3: Information on Eating behaviour problems (EBP), practical recommendations on how to cope with EBPs, nutrition and medication, nutrition and illnesses or chronic problems, as well as diabetes, constipation, hypertension, and dyslipidemia.
- Session 4: General review, practical examples, problem-solving in the creation of menus.

3. Support in weight monitoring. A voluntary individual weight monitoring system was established through the postal dispatch to the Aging Institute (Autonomous University of Barcelona) of coupons with information about the weight of the person affected but without revealing data, which may identify them. According to the evolution of the weight curve written recommendation were sent by mail and if weight loss was identified as susceptible to making the illness worse, they were recommended to visit a doctor.

4. Periodic information for the families. A voluntary system was established (which was accessed through signing a coupon) through which the carers who so desired could receive general information about nutrition, nutritional needs of those with Alzheimer's or other problems related with nutrition. The resulting register was of the caregivers (not the patients) and complied with all legal requirements. The management of this section was by the Aging Institute (Autonomous University of Barcelona).

5. Action protocols and standardised help decision trees, related to malnutrition risks, for professionals were designed with the participation of at least one person of each intervention centre. Each centre was asked to designate a senior member of the medical and/or nursing staff. The healthcare professionals in the intervention group received training and followed the program recommendations through these forms and action standards.

Outcome Measures

Each centre appointed a nurse and/or doctor to carry out the evaluations, and data collection was controlled and monitored by the study supervisor. At entrance into the study (day 0) socio-demographic and personal characteristics (age, sex, living accommodations, education, income, medication, hospitalisation) were registered; at day 0 (entrance into study), at 6 months and 12 months of study the following data were collected: Medical history, including comorbidities and treatment received: Charlson Index (51, 52); anthropometry (weight, height, mid-arm and calf-circumference); cognitive state assessed by the Mini Mental State Examination (MMSE, score min-max: 0-30 points) (53) and Clinical Dementia Rating scale (CDR, global score: 0-3) (54, 55); a nutritional evaluation using the Mini Nutritional Assessment (MNA, score: 0-30) (56, 57) and the Eating Behaviour Scale (EBS, score: 0-18) (58, 59); behavioural problems were assessed by the Neuropsychiatric Inventory questionnaire (NPI-Q, score: 0-12; severity score: 0-46) (60-62); depression by the Cornell scale (score: 0-38) (63, 64); autonomy in daily activities by the Activities of Daily Living scale (ADL, score 0-6; coded for each activity: independent = 1; need help = 0.5, dependent = 0) (65) and Instrumental Activities of Daily Living scale (IADL, score 0-6) (66); Health care cost were evaluated by the Resource Utilisation in Dementia (RUD) (67); and caregiver burden by the Zarit scale (score: 0-88) (68) and information on main caregiver (age, activity).

Statistical Analysis

Primary analysis was done on Intention-to-treat population (ITT) (i.e. including all randomized participants) and protocol population (PP) (i.e. all subjects included in the study without major protocol deviation). For clarity of presentation only ITT population results are presented; no difference in outcomes results was observed between ITT and PP populations.

The primary outcome hypothesis was that the NutriAlz program would reduce the loss of autonomy measured by the ADL and IADL scales. Secondary outcomes were an improvement in nutritional state of the patient evaluated by their change in weight, BMI and MNA, as well as a reduction in burden on caregiver (Zarit scale) and a reduction in the use of healthcare and social resources (RUD scale).

Analysis of bivariance and mixed models were done, adjusted for confounding factors and took into account randomisation by centre in the comparison of the intervention group and the control group (47, 69, 70). For quantitative outcome variables: mixed covariance analysis (parametric) or, if the assumptions (normality and homogeneity of the variances) were not met, mixed covariance analysis performed on rank data (non-parametric), were used with centre as random factor. Other covariates (fixed factors) were defined in the appropriate section. For binary outcome variables: Mixed logistic model with centre as random factor were used, with other covariates (fixed factors) defined in the appropriate

section. Statistical analyses are performed with SAS® V8 (SAS Institute Inc, Cary, NC) and AdClin® 3.2. Primary outcome and all other tests were considered significant at 5% of significance ($p \leq 0.05$).

Following analysis with adjustment for confounding factors were made for each specific change reported at 12 months follow-up in the results:

ADL: mixed covariance analysis adjusted for confounding variables: ADL at time0, for MMSE score at T0, for Zarit at T0, and MNA atT0;

IADL: mixed covariance analysis adjusted for confounding variables: ADL at time0, for MMSE score at T0, for Zarit at T0, MNA atT0, and gender;

Weight: mixed logistic model adjusted for confounding variables: weight at T0, MMSE score at T0, Zarit score at T0, and ADL score at T0;

BMI: mixed covariance analysis adjusted for confounding variables: BMI at T0, and MMSE score at T0;

MNA: mixed covariance analysis adjusted for confounding variables: MNA score at T0, MMSE score at T0, Zarit score at T0, and ADL score at T0;

MMSE: mixed covariance analysis adjusted for confounding variables: MMSE score at T0, and MNA score at T0;

CDR: mixed covariance analysis adjusted for confounding variables: CDR global score at T0, and MMSE score at T0;

NPI-Q severity score: mixed covariance analysis adjusted for confounding variables: NPI-Q severity score at T0, and MMSE score at T0;

Zarit score: mixed covariance analysis adjusted for confounding variables: Zarit score at T0 and MMSE score at T0;

Eating Behaviour Scale (EBS) :mixed covariance analysis adjusted for confounding variables: EBS score at T0, and MMSE score at T0.

Results

Demographics and Baseline characteristics

A total of 946 patients were included, mean age 79.0 ± 7.3 years; formal education 4.8 ± 4.3 years and 3.2% living alone. There was no significant difference for the socio-demographic variables (age, education, and living arrangement) between intervention and control group. In the intervention group, a lower proportion of subjects had mild dementia (MMSE score between 20-26 and CDR score of 0.5), more had behavioural problems (NPI-Q score) and was less autonomous (ADL score), and showed a higher caregiver burden (Zarit scale). While the subjects had similar weight and BMI in both groups, the intervention group had more subjects malnourished and at risk of malnutrition at study entrance according to the MNA (malnourished 7.8% versus 2.8% and at risk of malnutrition 51.5% versus 34.5% in the intervention and control group respectively) (46). These baseline clinical characteristics suggested that the intervention group was more frail compared to the control group at start of study with cluster randomization used to prevent treatment contamination (Table 1) (46).

Table 1

Baseline Characteristics of Patients and their Caregivers. Values are means ± standard deviation unless otherwise stated

Characteristics	Intervention NutriAlz Program n = 448	Control Usual Care n = 498
Mean age (years)	79.4 ± 7.0	78.6 ± 7.5
Men/Women	148/300	154/344
Education (years in formal education)	4.95 ± 3.9	4.6 ± 4.55
Lives alone (n (%))	20 (4.5%)	10 (2%)
Time since symptoms of dementia (years)	5.1 ± 3.0	5.35 ± 3.0
Time since diagnosis (years)	2.7 ± 2.1	2.9 ± 2.1
MMSE score*	14.7 ± 6.0	16.0 ± 6.25
CDR global score‡	1.8 ± 0.8	1.7 ± 0.8
Charlson Comorbidity Index‡	2.2 ± 1.5	2.0 ± 1.3
Number of comorbid problems	4.6 ± 2.2	4.2 ± 2.6
Fallen over the last year (n (%))	186 (41.5%)	162 (31.5%)
ADL score*	3.75 ± 1.8	4.2 ± 1.7
Number of activities without difficulties	2.9 ± 2.1	3.6 ± 2.0
Lawton IADL score*	2.2 ± 2.1	2.5 ± 2.3
Number of activities without difficulties	0.55 ± 1.3	0.85 ± 1.8
NPI-Q score‡	4.7 ± 2.6	4.2 ± 2.6
MNA score†	22.3 ± 3.8	24.0 ± 3.0
Weight (kg)	63.5 ± 12.5	65.1 ± 12.5
BMI ((Kg/m2)	26.6 ± 4.4	27.3 ± 4.6
Eating behaviour scale Score‡	15.45 ± 3.8	16.4 ± 3.5
Zarit score‡	30.6 ± 15.4	24.5 ± 15.0
Time since the caregiver took care of the patient (years)	4.1 ± 3.3	4.1 ± 3.3
Age of caregiver (years)	58 ± 13	62 ± 14
Caregiver relationship with patients		
Spouse, son or daughter (n (%))	391 (87%)	438 (88%)
Paid caregiver (n (%))	9 (2.0%)	6 (1.2%)
Cornell scale score‡	9.9 ± 6.6	7.1 ± 5.4

MMSE=Mini-mental state examination; CDR=Clinical dementia rating scale; ADL=Activities of daily living; IADL=Instrumental activities of daily living; NPI-Q=Neuropsychiatric inventory questionnaire; MNA=Mini-nutritional assessment; BMI=Body mas index; * Higher scores represent better function; † Higher scores represent better nutritional status; ‡ Higher scores represent worse symptoms

ITT Outcomes Analyses

At 12-month follow-up, no significant differences in primary outcome, nor reduction in loss of autonomy assessed by the change ADL total score and IADL Lawton score were observed (Table 2). The mean difference (95% confidence interval (95% CI)) in ADL was -0.83 (-0.97 to -0.69) for the intervention group and -0.74 (-0.86 to -0.62) for the control group, with a p=0.984 for group effect. For IADL Lawton scores the mean change (95% CI) was -0.75 (-0.91 to -0.59) for the intervention group and -0.63 (-0.79 to -0.47) for the control group, with a p=0.229 for group effect. The small change in ADL and IADL Lawton scores over a year suggests, however, maintenance of autonomy with both levels of care, NutriAlz program or usual care.

The secondary outcomes reflect direct effects of the NutriAlz program: weight changes, BMI and evaluation of the risk of malnutrition (Table 2). Also for the secondary outcome, related to weight changes, no difference was observed between

Table 2
Outcome criteria at each visit (entrance into study, 6 and 24 months) and changes at 24 months - ITT population. Values are means (95% confidence interval)

Variables	Entrance (T0)	6 Mo follow-up (T6M)	12 Mo follow-up (T12M)	P values
ADL score				
Intervention	3.75 (3.57 to 3.93)	3.54 (3.34 to 3.73)	3.24 (3.02 to 3.46)	
Control	4.23 (4.07 to 4.39)	4.14 (3.96 to 4.32)	3.89 (3.71 to 4.07)	
ADL score change at 12 months				
Intervention		-0.83 (-0.69 to -0.97)		0.948*
Control		-074 (-0.62 to -0.86)		
IADL Lawton score				
Intervention	2.22 (2.00 to 2.44)	1.91 (1.67 to 2.15)	1.67 (1.43 to 1.91)	
Control	2.50 (2.26 to 2.74)	2.23 (1.99 to 2.47)	2.12 (1.86 to 2.38)	
IADL Lawton score change at 12 months				
Intervention		-0.75 (-0.91 to -0.59)		0.229†
Control		-0.63 (-0.79 to -0.47)		
Weight , kg				
Intervention	63.5 (62.4 to 64.7)	64.2 (62.9 to 65.5)	63.9 (62.6 to 65.3)	
Control	65.1 (64.0 to 66.2)	66.2 (64.9 to 67.4	65.5 (64.2 to 66.8)	
Weight change at 12 months				
Intervention		0.26 (-057 to 1.09)		0.598‡
Control		0.09 (-0.70 to 0.52)		
BMI, kg/m2				
Intervention	26.6 (26.2 to 27.1)	26.9 (26.5 to 27.4)	26.8 (26.3 to 27.3)	
Control	27.3 (26.9 to 27.7)	27.6 (27.2 to 28.1)	27.3 (26.8 to 27.8)	
BMI change at 12 months				
Intervention		-0.01 (-0.21 to 0.19)		0.843§
Control		-0.06 (-0.22 to 0.22)		
MNA				
Intervention	22.3 (22.0 to 22.7)	23.3 (22.9 to 23.7)	23.4 (23.0 to 23.9)	
Control	24.0 (23.7 to 24.2)	24.0 (23.7 to 24.3)	23.5 (23.1 to 23.8)	
MNA change at 12 months				
Intervention		0.46 (0.09 to 0.83)		0.028¶
Control		-0.66 (-0.80 to -0.21)		

Following analysis with adjustment for confounding factors were made for each specific change reported at 12 months follow-up: *ADL: mixed covariance analysis adjusted for confounding variables: ADL at time0, for MMSE score at T0, for Zarit at T0, and MNA atT0; †IADL: mixed covariance analysis adjusted for confounding variables: ADL at time0, for MMSE score at T0, for Zarit at T0, MNA atT0, and gender; ‡Weight: mixed logistic model adjusted for confounding variables: weight at T0, MMSE score at T0, Zarit score at T0, and ADL score at T0; §BMI: mixed covariance analysis adjusted for confounding variables: BMI at T0, and MMSE score at T0; ¶MNA: mixed covariance analysis adjusted for confounding variables: MNA score at T0, MMSE score at T0, Zarit score at T0, and ADL score at T0.

the to treatment groups, mainly due to stable weight throughout the study. Weight change (mean (95% CI)) was of 0.26 (-0.57 to 1.09) kg for the intervention group and of -0.09 (-0.70 to 0.52) kg, with a non-significant difference in weight decrease over 4%, 22% of patients (n = 100) in the intervention group and 19% (n = 95) in the control group (p = 0.598). BMI, reflecting that the body composition was also stable during the study and changes were not significant between treatments. The observed BMI change (mean (95% CI)) for the treatment was -0.01 (-0.21 to 0.19) and of -0.06 (-0.22 to 0.10) for usual care, with a p = 0.843. The nutritional status, assessed using the MNA (mean (95% CI)), showed a significant improvement of 0.46 (0.09 to 0.83) points, while the control group showed a worsening of the risk for malnutrition -0.66 (-0.80 to -0.21) points, with p = 0.028 for group effect. This is further marked by the percentage of patients at risk of malnutrition decreasing from 51% at T0 to 36% at one year in the intervention group, NutriAlz program, while in the control group this percentage increased from 34% to 41% of the patients.

The NutriAlz program diminished the risk of malnutrition during this study, while weight and BMI were stable. In addition the success of the program is also illustrated by the recommendation concerning nutrition from the healthcare team (74% in the intervention group versus 9% in the control group), and regarding physical exercise (67%, Intervention, 9% control). Dietary intervention and modification seem, however, somewhat more difficult to implement: recommendations regarding dietary supplement or complementary products were 49% in the intervention group (and 5% in the control group). Dietary modifications implemented were 12% at 12 months (control 4%).

Additional Analysis

Evolution of the severity of dementia and behaviour problems, assessed by MMSE, CDR and the NPI-Q scores, showed no differences between study groups (Table 3). Change

Table 3
Additional Analysis at each visit (entrance into study, 6 and 24 months) and changes at 24 months - ITT population. Values are means (95% confidence interval)

Variables	Entrance (T0)	6 Mo follow-up (T6M)	12 Mo follow-up (T12M)	P values
MMSE				
Intervention	14.7 (14.2 to 15.3)	13.6 (12.9 to 14.3)	12.8 (12.1 to 13.6)	
Control	16.0 (15.5 to 16.6)	15.4 (14.7 to 16.0)	14.3 (13.6 to 15.0)	
MMSE change at 12 months				
Intervention		-2.21 (-2.68 to -1.74)		p=0.954*
Control		-2.21 (-2.60 to -1.82)		
CDR global score				
Intervention	1.81 (1.73 to 1.89)	1.96 (1.88 to 2.04)	2.11 (2.03 to 2.19)	
Control	1.73 (1.65 to 1.81)	1.87 (1.79 to 1.95)	1.98 (1.90 to 2.06)	
CDR change at 12 months				
Intervention		0.35 (0.29 to 0.41)		p=0.690†
Control		0.35 (0.29 to 0.41)		
NPI-Q severity score				
Intervention	8.1 (7.6 to 8.7)	7.0 (6.5 to 7.6)	6.9 (6.3 to 7.6)	
Control	7.6 (7.1 to 8.2)	6.7 (6.1 to 7.2)	6.2 (5.7 to 6.7)	
NPI-Q severity change at 12 months				
Intervention		-0.64 (-1.19 to 0.09)		p=0.781‡
Control		-0.93 (-1.48 to -0.38)		
Zarit score				
Intervention	30 (29 to 32)	29 (27 to 31)	29 (27 to 31)	
Control	25 (23 to 26)	24 (22 to 25)	25 (24 to 27)	
Zarit change at 12 months				
Intervention		0.59 (-0.99 to 2.17)		p=0.681§
Control		2.36 (1.26 to 3.46)		
EBS score				
Intervention	15.5 (15.1 to 15.8)	15.2 (14.8 to 15.6)	14.5 (14.0 to 15.0)	
Control	16.4 (16.1 to 16.7)	16.4 (16.0 to 16.7)	16.0 (15.7 to 16.4)	
EBS change at 12 months				
Intervention		-1.65 (-2.04 to -1.28)		p=0.697¶
Control		-1.24 (-1.61 to -0.87)		

Following analysis with adjustment for confounding factors were made for each specific change reported at 12 months follow-up: *MMSE: mixed covariance analysis adjusted for confounding variables: MMSE score at T0, and MNA score at T0; †CDR: mixed covariance analysis adjusted for confounding variables: CDR global score at T0, and MMSE score at T0; ‡NPI-Q severity score: mixed covariance analysis adjusted for confounding variables: NPI-Q severity score at T0, and MMSE score at T0; §Zarit score: mixed covariance analysis adjusted for confounding variables: Zarit score at T0 and MMSE score at T0; ¶Eating Behaviour Scale (EBS) :mixed covariance analysis adjusted for confounding variables: EBS score at T0, and MMSE score at T0.

in MMSE score (mean (95% CI)) was -2.21 (-2.68 to -1.74) points in the intervention group and -2.21 (-2.60 to -1.82), with a p = 0.954. Change in CDR global scores (mean (95% CI)) was 0.35 (0.29 to 0.41) for the intervention group and 0.35 (0.29 to 0.41) for the control group, p = 0.690. Severity of dementia determined by CDR classes (CDR score of 0.5 representing questionable dementia, T0 n= 81 (9%), T6 n=41 (5.5%) T12 n=26 (4%); CDR score of 1 mild dementia, T0 n= 293 (31%), T6 n=197 (27%) T12 n=138 (21%); CDR score of 2 moderate dementia, T0 n=374 (40%), T6 n=307 (41.5%) T12 n=290 (44%); and CDR score of 3 severe dementia, T0 n= 197 (20%), T6 n=194 (26%) T12 n=201 (31%)) correlated strongly with the risk of malnutrition, MNA scores, p≤0.0001 (mixed covariance analysis performed on ranked data), independently of treatment group.

Change in NPI-Q severity score (mean (95% CI)) was -0.64 (-1.19 to 0.09) for the intervention group and -0.93 (-1.48 to -0.38) for the control, with p = 0.781.

As evaluated by the Zarit scale Table 3), no difference in caregiver burden between level of care was observed: mean change (95% CI) in Zarit score was 0.59(-0.99 to 2.17) for the intervention group and of 2.36 (1.26 to 3.46) for the control, with p = 0.681.

No changes in functional ability during eating, measured by the Eating Behaviour Scale (EBS) was observed (Table 3). Change in EBS (mean (95% CI)) was -1.65 (-2.04 to -1.28) for the intervention and -1.24 (-1.61 to -0.87), with p = 0.697 for group effect.

Resource utilization data are not presented, since In general the health care use of services listed in the resource utilization in dementia (RUD)-instrument was very low, mainly "delivered-meals service" and "transport". This might represent a cultural aspect of northern Spain, where the family is taking care of the elders.

Evaluation of the satisfaction of patients and their families in relation to the NutriAlz program was assessed by a short questionnaire on use and relevance of information briefcase and sessions given, weight follow-up, nutrition counselling and

diary, and hot line for nutritional supplement request. Information cards were used by 94.5% of families with 26% of users finding them very useful, 67% useful and 8% only not very useful. Nutrition course was used by 66% of the families with 24% finding it very useful, 65% useful, 9% not very useful, and weight curve sent were used by 88% (13% very useful, 78% useful, and 7% not very useful). While Information sessions were used by 75% of the families (32% very useful, 61.5% useful and 6% not very useful) and hotline was used by only 33% of the families with 17% finding it very useful, 51% useful, 20% not very useful and 115 not useful. These results suggest that the NutriAlz program was well accepted and useful for the families

Dropouts, Rates and Reasons

Of the 946 persons who participated in the study, 656 (69%) completed the one-year follow up (65% in the intervention group and 73% in the control group). Of the 290 (31%) who dropped out, 90 (9.5%) moved to an institution, 72 (8%) died, 3% had medical complications, for 12 (1%) the contact was lost, 62 (7%) were lost for other reasons, and only 28 (3%) refused to continue. No differences were observed between the intervention and control group.

Discussion

In comparison to other community studies, the REAL.FR (5, 32), the PLASA (71) and the ICTUS (72) studies, our cohort of elderly living at home had more severe dementia, reported by MMSE and/or CDR, with much less individuals living alone (46), suggesting more impaired elderly, and possible cultural difference.

Concerning the evolution at one year, the more malnourished in the REAL.FR and the ELSA cohorts worsened in cognitive and functional capacities (28, 32, 73), while no differences were observed between the intervention and control group in the present study; even with a higher risk of malnutrition in the intervention group at study entrance. A baseline lower nutritional status, assessed by MNA, and a lower cognitive performance on the Alzheimer Disease Assessment Scale are predictors of dementia progression (17, 55). The risk of malnutrition significantly decreased in the intervention group supporting the importance of this global nutritional intervention program for demented patients living at home.

The maintenance in autonomy, assessed by ADL, in cognitive function (MMSE and CDR), the small but not significant worsening in behavioural disturbances (NPI), as well as the maintenance of weight, in both groups, support the quality of the usual care. This suggests that family care longer and well, allowing patient with moderate to severe dementia to live at home with the right management.

Loss of autonomy and loss of weight have been reported to be linked to the nutritional status at baseline (12, 32, 74), as well as physical performance (41). This loss of autonomy can be modulated by physical exercise but is difficult to modify on the long term (40, 75) and nutritional education program or nutritional intervention had positive effects on weight but not on autonomy (76, 77). The change in nutritional and physical activity reported following the recommendations show a significant modification of the care. More intense and patient specifically oriented nutritional intervention and activity program, however, should be applied. These could include specific exercise program (40, 78) and nutritional intervention including tailored diet strategies and nutritional supplement (15, 36, 79, 80), specific nutrients with a potential impact on the neurodegenerative disease (81-84), as well as behavioural disturbances intervention (43, 85).

While the Nutritional Program for Dementia Elderly Patient, NutriAlz, had no effect on activities of daily living (ADL), it decreased significantly the risk of malnutrition, and modified the health care practice related to nutrition and physical activity. More intense and specifically patient oriented physical activity and nutritional intervention should be applied to maintain autonomy.

Acknowledgement: We thank the members of our dedicated NutriAlz group for their hard work and contributions: Carmen Espinosa (Hospital Sent Jaume. Mataró), Isabel Fort (Centre Socisanitari El Carme. Badalona), Salvador Altimir (Hospital Germans Tries i Pujol. Badalona), Mercel Rossich (Institut Pere Mata. Reus), Jesús Ruiz (Policlínica de la Mercè. Barcelona), Consol Almenar (Benito Menni CASM. Sant Boi) Pau Sanchez (Consorci Sanitari Integral. Hospitales), Lluis Tàrrega (Fundació ACE. Barcelona), Miquel Aguilar (Hospital Mútua de Terrassa), Secundí López Pousa (Institut D'assistència Sanitària. Girona), Sergio Ariño (Hospital de Granollers).

Contributions: AS, SA and BV conceived and designed the study. EF, BD, and the NutriAlz group acquired the data. SA, JM and XR were responsible for the statistical analysis. AS, SA, EJS, BD, YG and BV analysed and interpreted the data. YG, SA, AS and BV prepared the manuscript. All authors reviewed the manuscript and approved the final version, had full accessed to all data in the study, and take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding: This study was supported by Nestec Ltd, Vevey Switzerland.

Competing interests: All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that EJS, JM and BD are are employed by Nestec Ltd, Vevey Switzerland ,YG is retired employee and external consutant to Nestec Ltd, Vevey Switzerland. AS, EF and XR have received funding from Nestec Ltd, Vevey Switzerland; SA and BV have received research grants from Nestlé.

Sponsor's role: Nestec Ltd, Vevey Switzerland, financed the study.

Ethical approval: The study was approved by the institutional ethic commission of the Autonomous University of Barcelona (Universitat Autònoma de Barcelona), Spain.

Data Sharing: No additional data available

Trial Registration: ClinicalTrials.gov Identifier: NCT00479843

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