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NUTRITIONAL INTERVENTION OF PATIENTS WITH ALZHEIMER'S DISEASE LIVING AT HOME WITH THEIR SPOUSE: A RANDOMIZED CONTROLLED TRIAL. BASELINE FINDINGS AND FEASIBILITY

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Abstract: *Background:* Alzheimer patients (AD) and their caregivers are a good target group for nutritional care. AD patients are known to be at risk of malnutrition, and their older caregivers often have multiple diseases and may also have nutritional problems. *Purpose:* To present the baseline findings of a randomized controlled trial exploring the effectiveness of tailored nutritional treatment among home-dwelling AD patients and their caregivers and the feedback given by spouses regarding the trial. *Subjects and methods:* Central AD registers in Finland were used to recruit AD patients (n= 99) living at home with their spouses for a randomized controlled trial lasting one year. The intervention group received tailored nutritional advice and care in their homes 4-8 times during the intervention, and the control group received a written guide on nutrition for older people. The participants were asked to give anonymous feedback about the study at the end of the study. Nutrition was assessed with the Mini-Nutritional Assessment (MNA) and three-day food diaries. *Results:* The mean age of AD patients was 77.4 years (SD 5.6) and the mean age of their spousal caregivers was 75.2 (SD 7.0). The patients' mean MMSE score was 19.3 (SD 5.6). 44 % of patients and 16 % of caregivers were at risk of malnutrition according to the MNA. At the baseline the mean energy intake was 1714 (SD 477) kcal, protein 73 g (SD 24) and calcium 964 mg (Md 913) per day in AD patients and 1557 kcal (SD 417), 68 g (SD 19) and 886 mg (Md 839) for caregivers. However, the intake levels of nutrients varied widely. Of spousal caregivers, 88 % were satisfied with how the study home visits were organized. *Conclusions:* We randomized 99 patients with Alzheimer's disease and 99 aged spouses in a tailored nutrition trial. There was a great heterogeneity in the intake of protein and other nutrients among participants. The feedback from spousal caregivers was positive.

Key words: Nutritional intervention, Alzheimer, home dwelling, nutrient intake.

Introduction

Malnutrition and weight loss are a common problem among older individuals with Alzheimer disease (AD) (1, 2). AD patients often suffer from frailty, sarcopenia, functional impairments, and comorbidities (2). Weight loss of older patients is a predictive factor of mortality (3, 4). The AD patients living at home are an important target group for nutritional care (5). Their old spousal caregivers also have comorbidities and functional disabilities, and multicomponent support has been shown to be effective (6-8). The possibilities of nutritional care in this group of older people have remained largely unexplored (1).

Nutritional interventions have had beneficial effects on the nutritional status and nutrient intake of AD patients in different settings (5, 9-12). Some studies have suggested that nutritional supplements improve cognitive functioning, increase body weight and decrease morbidity among AD patients (13, 14). It has also been shown that programmes to educate caregivers about nutrition have had a positive effect on AD patients' weight and cognitive function and caregiver burden (9). Studies on the benefits of nutritional care and the ways of implementing it are needed (5). Although nutritional care has been examined and proven effective in some studies (5, 9, 10-12, 14), the effects of nutritional care on health, quality of life (QoL), functional ability among AD patients and their elderly spouses have not been investigated in randomized controlled studies.

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Our controlled randomized trial aimed at investigating the effectiveness of tailored nutritional care among AD patients and their older spouses during a year intervention targeting participants´ weight, nutrition, functioning and quality of life. In this article we present the baseline characteristics and nutrient intake of people with AD and their spouses and the feedback given by spouses regarding the trial.

Methods

The study was approved by the Ethics Committee of Helsinki University Central Hospital. Informed consent was obtained from each patient and/or their spousal caregiver before any study procedures. The study procedure has been described in detail elsewhere (15). The trial was registered as doi: 10.1186/1745-6215-13-66.

Participants

In 2010, a sample of AD patients (≥65 years) and their spouses cohabiting in the Helsinki Metropolitan Area of Finland was retrieved from the centralized Drug Imbursement Register of the Social Insurance Institution of Finland. In order to receive reimbursement for AD medication, AD patients have to undergo a detailed diagnostic assessment, including cognitive and neuropsychological testing, neuroimaging and laboratory tests, to fulfill the requirements of a probable AD diagnosis according to the NINCDS-ADRDA Alzheimer's criteria (16). Those who were interested in taking part in the study were requested to send a return letter to research team. All AD patients and their spouses who showed interest in participation were first contacted and interviewed by telephone to confirm their fulfillment of the inclusion criteria (living in the greater Helsinki area, Finnish speaking, AD diagnosis, age ≥65y, able to stand on the scale, no acute, severe disease). Those couples fulfilling the criteria were invited to a first meeting with a nutritionist, where they were given oral and written information about the study and asked to sign an informed consent. In the case of an AD patient's inability to give informed consent, the spousal caregiver gave proxy consent for both spouses.

Measurements

At the baseline both AD patients and their spouses were assessed and interviewed during a two hour visit. The diagnoses and medications were confirmed from medical records provided by the couples. The participants with AD were assessed with the Mini Mental State Examination (MMSE, scale 0-30) (17), Clinical Dementia Rating Scale (CDR, scale 0.5-3) (18), Health-related Quality- of-life,15D© (19) and Mini Nutritional Assessment (MNA, scale 0-30) (20). The spouses were assessed with the MMSE, MNA, 15D©, Zarit Burden Scale (21). The weight and height of all participants were measured, and activities of daily living tested with the Instrumental Activity of Daily Living (IADL) (22).

Food and nutrient intake were assessed with three-day food diaries. At the first visit the nutritionist gave written and spoken instructions how to keep the food diaries. She also gave the participants 100 mL, 15 mL and 5 mL measuring cups for measuring food items such as drinks consumed and spreads used on the bread. They were asked to fill in food diaries for three days while keeping their usual diet. After they had completed the food diaries, the participants sent the diaries by mail to the nutritionist, and she phoned all the spouses and checked the diaries. Commonly, the things that were checked included the type of milk and fat, and the trademarks of food items or the amounts of food eaten. Energy, protein and nutrient intake were calculated using the Nutrica program (23). After calculating the nutrient intake from the food diaries, the couples were randomized to the intervention and control group in clusters of six as described in our previous article (15).

There are several recommendations regarding the nutrient intake of the elderly (1). The Dietary Reference Intake (DRI) provides reference values for people over 70 years of age (24). For this study, we compared the daily energy and nutrient intakes of participants with the recommendations of the Finnish National Nutrition Council (25), which are based on the Nordic Nutrition Recommendations (NNR 26). For protein intake we used the limit of 1g of protein/ kg/day, which is considered to be the minimum for older people (27).

The intervention

The intervention included tailored nutritional advice on the basis of the food diaries, the results of the assessments, home visits, discussions with participants and weight control every third month.

The participants in the control group received a written guide on nutrition for older adults by mail. Their weight was assessed once during the intervention at the point of six months. The primary outcome measure was the change in weight of AD patients. The secondary outcome measures were nutrient intake, MNA, MMSE, quality of life, NPI, Cornell and Zarit burden scale for spouses. The effect of intervention is reported in a separate article.

Feedback analyses

At the end of the study, the caregivers were asked to give feedback on the study. The questionnaire was returned anonymously to ensure sincerity. The questions are shown in table 3.

Statistical analyses

The data were analyzed with a SPSS/PASW 18.0 statistical program. Standard descriptive statistics were used for baseline characterization of the intervention and the control group. Categorical variables were tested using the Chi-squared test (X2) or the Fisher's exact test and continuous variables with the two sided t-test or the Mann Whitney U –test.

Results

In 2010-2011 a total of 99 couples were recruited for the trial and randomized to intervention and control groups. The mean age of patients with AD was 77.4 years (SD 5.6), 69% were male. The complete baseline characteristics are shown in Table 1. Of the patients, 56% were at a mild stage of dementia (CDR 0.5-1), 36 % at moderate (CDR 2) and 7% at a severe (CDR 3) stage. The mean MMSE score of the AD patients was 19.3 (<SD 5.6). The mean number of medications was 5.6 (SD 2.6) and the mean IADL score 3.6 (SD 2.2).

The mean BMI of the AD patients was 26.3 (SD 3.8). Over half of the patients (55%) had a good nutritional status (MNA points >23.5) and 42 % were at risk of malnutrition (MNA 17-23). The AD patients' mean energy intake was 1714 kcal (SD 477), protein intake 73.3 g/day (SD 24) and dietary fibre 22 g/day (Md 21). The mean intake of vitamin C was 81mg (Md 77), vitamin E 9.5 mg (Md 8.7), vitamin D 10.4 μg (Md 8.6) and folic acid 233 μg (SD 74) (Table 1.)

The mean age of caregivers was 75.2 (SD 7.0), 31% were male. The mean MMSE score of the caregivers was 27.5 (SD 2.2). The mean BMI was 26.6 (SD 4.1). Most of the caregivers (83%) had a good nutritional status (MNA points >23.5) and 17 % were at risk of malnutrition (MNA 17-23). The mean Zarit score measuring the burden of caregivers was 29.3 (SD 3.9). The mean number of medications was 3.9 (SD 2.4). There were no differences between the intervention and control group except for the Zarit score, which was higher in the control group. The spouses' mean energy intake was 1557 kcal (SD 419), protein intake 68 g/day (SD 19) and dietary fibre 20 g/day (SD 8). The mean intake of vitamin C was 77mg (Md 69), vitamin E 9.2 mg (Md 8.1), vitamin D 9.3 μg (Md 8.1) and folic acid 224 μg (SD 69) (Table 2.)

Table 1

Baseline characteristics of the home-dwelling patients with Alzheimer disease

Characteristic	All (n=99)	Intervention (n=50)	Control (n=49)	P-value[1]
Mean age (SD)	77.4 (5.6)	78.0 (5.5)	76.7 (5.6)	0.261
Males (%)	69	72	65	0.521
Education < 8 years (%)	29	28	31	0.716
Income (%)				
Good	55	48	48	
Moderate	37	42	42	
Poor	8	10	10	0.400
CDR (%)				
0.5	20	14	27	
1	36	40	33	
2	36	38	35	
3	7	8	6	0.477
Mean MMSE (SD)	19.3 (5.6)	19.3 (6.3)	19.5 (4.8)	0.864
MNA (%)				
< 17 points	0	0	0	
17-23.5 points	44	46	41	
> 23.5 points	57	54	59	0.686
Mean BMI (SD)	26.3 (3.8)	26.4 (3.6)	26.3 (4.1)	0.629
Mean IADL (SD)	3.6 (2.2)	3.5 (2.2)	3.8 (2.1)	0.472
Mean QoL, (SD)	27.3(7.9)	27.6 (6.3)	27.1 (8.0)	0.711
Mean number of medication (SD)	5.6 (2.6)	5.9 (2.8)	5.3 (2.3)	0.214
Nutrient intake				
Mean energy, kcal (SD)	1714 (477)	1717 (465)	1710 (494)	0.905
Mean protein, g (SD)	73.3 (24)	73.8 (24)	72.7 (24)	0.806
Mean fiber, g (SD/Md)	22 (21*,20-23)	21 (21*,18-23)	23 (9)	0.188
Mean calcium, mg (SD/ Md)	964 (914*,887-1042)	983 (396)	945 (824*, 834-1056)	0.450
Mean vitamin C, mg (SD/Md)	81(77*,72-90)	85 (74*, 69-100*)	77 (34)	0.972
Mean vitamin E, mg (Md)	9.5 (8.7*, 8.6-10)	9.1 (7.8*, 7.8-10.3*)	9.9 (9.7*, 8,7-11.2)	0.184
Mean vitamin D, μg (Md)	10.4 (8.6*, 8.9-12)	9.8 (8.9*, 8.2-11.4)	11.1 (8.6*, 8.4-13.8)	0.785
Folic acid, μg (SD)	233 (74)	233 (77)	233 (72)	0.928

1. Differences between characteristics in intervention and control groups were tested with X2 –test for categorical variables and with Mann Whitney U-test for non-normally distributed continuous variables and with student T-test for normally distributed continuous variables; SD standard deviation; Md Mediaani* for not normally distributed variables, confidence interval for mean 95%, Lower-Upper; CDR= Clinical dementia Rating Scale (0.5 suggests possible dementia, 1 mild, 2 moderate and 3 severe dementia), MMSE=Minimental State Examination (Folstein et al 1975); BMI= Body mass index (kg/m2); MNA= Mininutritional Assessment [Guigoz et al 2006](< 24 suggests risk for malnutrition or malnourishment); IADL=Instrumental activities of daily living [Lawton, Brody1969)]; 15D=Health related quality of life [Sintonen 2001].

Table 2
Baseline characteristics of the spousal caregivers

Characteristic	All (n=99)	Intervention (n=50)	Control (n=49)	P-value[1]
Mean age (SD)	75.2 (7.0)	76.3 (6.2)	74.0 (7.6)	0.111
Males (%)	31	28	35	0.473
Education < 8 years (%)	20	19	21	0.837
Income (%)				
Good	42	50	35	
Moderate	57	50	63	
Poor	1	0	2	0.156
Mean MMSE (SD)	27.5 (2.2)	27.6 (2.1)	27.4 (2.3)	0.598
MNA (%)				
< 17 points	0	0	0	
17-23.5 points	16	16	16	
> 23.5 points	84	84	84	0.100
Mean BMI (SD)	26.6 (4.1)	26.9 (4.5)	26.3 (3.5)	0.482
Mean IADL (SD)		7.9 (0.2)	7.9 (0.7)	0.694
Mean QoL,15D©, (SD)	27.5 (2.2)	27.6 (2.1)	27.4 (2.3)	0.598
Mean Zarit (SD)	29.3 (15.8)	25.9 (14.3)	32.0 (16.1)	0.049
Mean number of medications (SD)	3.9 (2.4)	4.1 (2.3)	3.9 (2.3)	0.660
Nutrient intake				
Mean energy, kcal (SD)	1557 (419)	1645 (407)	1468 (416)	0.020
Mean protein, g (SD)	68 (19)	73 (20)	63 (18)	0.005
Mean fiber, g (SD)	20 (8)	21 (8)	20 (8)	0.314
Mean calcium, mg (Md)	886 (839*, 811-961)	970 (898*, 852-1088)	801(795*, 711-890)	0.028
Mean vitamin C, mg (SD/Md)	77 (69*, 69-86)	82 (67*, 69-96)	72 (36)	0.659
Mean vitamin E, mg (Md)	9.2 (8.1, 8.3-10)	9.7 (8.2*, 8.6-11)	8.6 (8.0*, 7.5-9.7)	0.272
Mean vitamin D, μg (Md)	9.2 (8.1*,8.3-10)	9.7 (9.1*8.2-11.1)	8.9 (6.6*,7.1-10.8)	0.188
Mean folic acid, μg (SD)	224 (69)	238 (70)	210 (66)	0.032

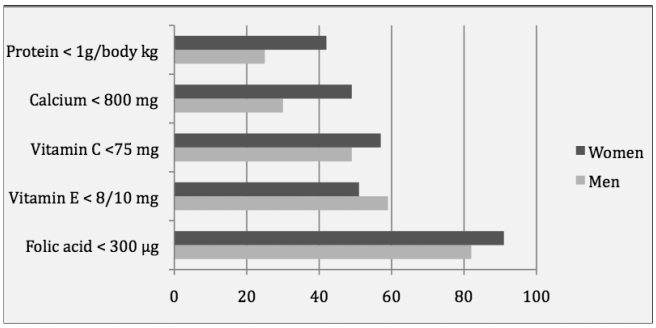
1. Differences between characteristics in intervention and control groups were tested with X2 –test for categorical variables and with Mann Whitney U-test for non-normally distributed continuous variables and with student T-test for normally distributed continuous variables; SD standard deviation; Md Mediaani* for not normally distributed variables, confidence interval for mean 95% Lower-Upper; MMSE=Minimental State Examination (Folstein et al 1975); BMI= Body mass index (kg/m2); MNA= Mininutritional Assessment [Guigoz et al 2006](< 24 suggests risk for malnutrition or malnourishment); IADL=Instrumental activities of daily living [Lawton, Brody1969)]; 15D=Health related quality of life [Sintonen 2001].

Table 3
Feedback questionnaire for spousal caregiver of Alzheimer disease patients (response rate 73 %). Questionnaire was presented anonymously after the last visit

Question	Yes (%)
What made you make the decision to participate the study?	
1. Interest towards nutrition	50
2. Interest towards my own health	34
3. Somebody recommended	3
4. Other	12
Were you satisfied how the study was organized?	
1. Yes, we were satisfied	88
2. We were quite satisfied	10
3. No, we were not satisfied	0
Were you in an intervention or in a control group?	
1. Intervention group	48
2. Control group	41
How would you estimate the written material of nutrition you received?	
1. Material was useful	74
2. Material was not useful	9
3. We did not read the material we received	5
4. Other comments	7
Did you feel participating the study was useful for you (only intervention group)?	
1. No	3
2. I don´t know	38
3. Yes	36

The intake levels of energy, protein and other nutrient intakes varied widely among both AD patients and spouses. Low energy and protein intakes were more common in women than in men. Nearly all of the participants received less folic acid than recommended. Vitamin C and E were also below recommended levels in nearly half the participants (Figure 1).

Figure 1
The proportion (%) of participants whose intake of some nutrients was below the recommendations



The caregivers were invited to give feedback on the study, and the response rate was 73 % (table 3). The main reason for participating in this study was the subjects' interest in nutrition (50 %) and their own health (34 %). When asked about how the study was organized, 88 % of participants answered they were satisfied with it. The majority of participants (76 %) thought that the material on nutrition they had received was useful. In contrast, only 7 % either considered the material unuseful or had not read it at all (Table 3).

Discussion

We recruited 99 home-dwelling AD patients, aged 65 years and older, and their caregivers for a randomized controlled trial exploring the effectiveness of tailored nutritional advice compared to a control group which received a written booklet on nutrition for the elderly. The randomization groups were similar, except for a Zarit burden scale for spouses. Nutrient intake of participants varied greatly in both patients and spouses.

The AD participants were a good representative sample of home dwelling AD patients. The mean age was 77 years and the mean MMSE score 19. The participants had a high number of medications. The CDR findings show that most of the AD patients were at a mild or moderate stage of dementia. Half the AD patients were at risk of malnutrition, which is in line with previous studies (2, 5, 9, 10). According to the previous study, AD patients were heterogeneous in cognition and only very few had a poor nutritional status according to the MNA (28). In addition to AD diagnosis, we used tests for evaluating patients' state of cognition. All this background information was useful when tailoring the nutrition advice and care.

There are also some differences as compared to home-dwelling AD patients in general. In our study there were more men with AD than women, because our inclusion criteria required that there had to be a spouse living with the AD patient. Our patients were better educated than older people in general in Finland, which is in the line with previous findings that lower socioeconomic groups are underrepresented in intervention studies (29). Our study participants were interested in nutrition and their own health, since those were the main reasons for participating in this study. This means that the nutrient intakes of this study population may be better than that of average home-dwelling AD patients and their spouses.

The study population was very heterogeneous, and the intake levels of protein and other nutrients varied widely among both AD patients and spouses. In large epidemiological studies among older people, the nutrient intake levels seem to be quite good (30). However, it seems that the heterogeneity in the nutrient intake of older people has been missed. Even when the average intakes of many nutrients were adequate compared to recommendations in our study, there were many participants whose nutrient intakes didn't reach the recommended levels. More than 80% of the participants didn't receive enough folic acid in their diets. Furthermore, the intake of vitamin C and E was inadequate among half of participants. The female participants were particularly prone to an inadequate intake of protein. This is worrisome because adequate protein intake is known to be important for the immune system, muscle function and strength as well as for preventing and managing sarcopenia (27, 31, 32). It is also worth noticing that we used the value of 1g/body kg as the reference value (27), even though the protein intake of frail individuals should, in some cases be as much as 1,2 - 1,5g/ body kg (27, 32).

The strength of this study is that all AD participants are well diagnosed, as they were recruited from the AD drug reimbursement register. We were also able to receive detailed three-day food diaries from the AD patients and their spouses, formerly a challenging group for nutritional interventions. The limitation is that food consumption was only assessed for three days, which may not give an accurate picture of subjects' average food intake over a longer period of time. On the other hand, food habits were discussed during the home visits, and it seems that many older people have rather similar daily eating habits. There may also be over or underestimation in the nutrient intakes because the elderly participants completed their food diaries by themselves. However, food diaries are assumed to be good method for gathering food records in older people. Furthermore, the low intakes of nutrients in older adults in this study are probably real intakes. Therefore it should not be

reasonable to use any cut points to remove low nutrient levels (33).

In this study the baseline data show that there is great heterogeneity among home dwelling older AD patients and their spousal caregivers. Therefore, the nutrient intake of older and frail individuals should be assessed more often in order to identify those who need nutritional advice and care. The positive feedback from the participants also shows that older adults are interested in their health and nutrition and are therefore a good target group for nutritional advice and care.

Conclusions

This is the first trial to investigate the effect of tailored nutritional care among home-dwelling AD patients in Finland. Baseline assessments and randomization have been successful, and the feedback about the study was positive. There was great heterogeneity in the intake of protein and other nutrients among the participants.

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