

EARLY PSYCHOSOCIAL INTERVENTION TO DELAY INSTITUTIONALIZATION OF PATIENTS WITH ALZHEIMER'S DISEASE - A Randomised Controlled Trial (ALSOVA)

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Background

Alzheimer's disease, Intervention Effect, Progression, Care, Quality of Life, Health Economics

- The cost of dementia
 - The current global cost estimate for dementia is around US\$604 billion (World Alzheimer Report 2010)
 - In Europe, annual mean costs per patient with dementia range from US\$16,500 to US\$49,000
 - In Finland, the average annual (direct) cost per patient is for:
 - Full institutional care: 46,000€ (~ US\$ 61,000)
 - Home care: 19,000€ (~US\$ 25,000)
 - Home care (including also a carer's direct health and social care costs): 23,000€ (~US\$30,000)
- Potential cost savings could be obtained by delaying the nursing home placement
- Previous studies have shown that counseling and psychosocial interventions may delay the nursing home placement in patients with moderate/severe AD caregivers (e.g., Mittelman et al. 1996 JAMA)
- However, so far evidence of positive effects in patients with mild AD has been lacking

Objectives

- To assess the efficacy of an early psychosocial counseling intervention for outpatients with mild AD and their caregivers to delay nursing home placement
- To assess whether the intervention has positive effects on cognition, (caregiver-reported) neuropsychiatric symptoms, and activities of daily living

Methods

- Study design

- Five-years, prospective, randomized, and controlled rehabilitation study
- Study participants were recruited from April 2002 to September 2006
- Inclusion criteria for the patients:
 - ≥ 65 years of age
 - very mild (CDR 0.5) or mild (CDR 1) AD
 - given informed consent
 - a family caregiver
- AD-specific medication was prescribed for patients in both groups at the baseline
- Follow-up visits were conducted once a year
- The study was approved by a local ethics committee
- Final sample size was 240 patient-caregiver dyads

Description of ALSOVA-intervention

- Eligible patient-caregiver pairs were randomized (1:2) to one of two groups
 - The intervention group
 - Usual care + intensive psychosocial courses during the first 2 years after diagnosis
 - The control group
 - Only the usual care
- The intensive psychosocial courses included
 - Evaluation of current family situation
 - Information lectures about AD, available social services, and methods to cope with stress
 - Tailored exercises aiming to increase physical activity
 - Social activities to enhance caregivers' and persons with AD involvement in social activities (e.g., theater or concert)
- The ultimate target was to support caregivers' skills and fortitude to use internal and external recourses available

Methods

- Primary and secondary endpoints

- A primary outcome was the effect of the intervention on cumulative risk of nursing home placement during the three years of follow up.
- Secondary outcome measures were
 - Change in cognitive function (MMSE)
 - Change in behavioral symptoms (NPI)
 - Change in activities of daily living (ADCS-ADL)
 - Change in patient's quality of life (QoL-VAS)
 - Change in caregiver's quality of life (QoL-VAS)

Methods

- Statistical Analyses

- In the analysis of nursing home placement, Fine and Gray's (1999) proportional subhazards model was applied to adjust the impact of competing risk (i.e., death)
 - Competing risks are events that prevent an event of interest from occurring, rather than just prevent you from seeing it happen (i.e., censoring)
- Secondary endpoints were analyzed as adjusted mean differences (95%CI) between the groups
 - Multivariate regression models were used for adjustment
 - For the comparison of baseline values, dyads with missing values were omitted.
- All analyses were conducted by STATA 12.0 and SPSS 19.0

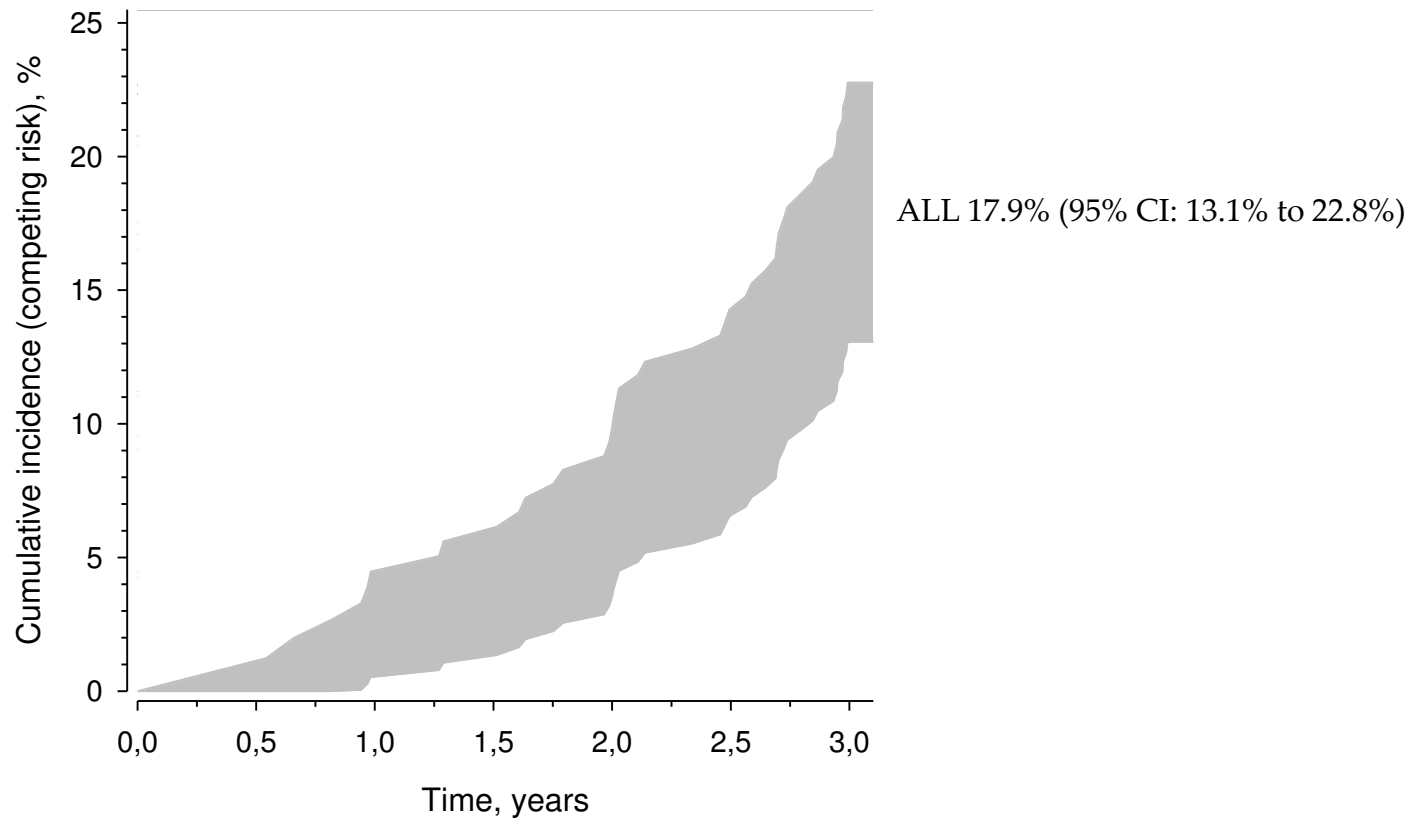
Results

- Baseline characteristics (n=240)

	Control Group (n=155)	Intervention Group (n=85)
Patient characteristics		
Sex (female %)	52.3%	49.4%
Age (years)	75.2 (74.2 to 76.2)	75.1 (73.5 to 76.7)
Education (years)	7.4 (6.8 to 7.9)	7.8 (7.1 to 8.7)
Clinical variables		
AD-specific medication	96.1%	97.6%
MMSE	21.28 (20.7 to 21.8)	21.82 (21.1 to 22.6)
NPI	9.1 (7.5 to 10.7)	8.48 (6.4 to 10.6)
ADCS-ADL	63.8 (62.4 to 65.3)	65.8 (64.0 to 67.6)
QoL-VAS (0-1)	0.77 (0.75 to 0.80)	0.82 (0.79 to 0.85)
Caregiver characteristics		
Sex (female %)	68.4%	64.7%
Age (years)	65.7 (63.8 to 67.4)	65.3 (62.5 to 68.0)
Education (years)	9.4 (8.8 to 10.0)	10.1 (9.3 to 11.0)
QoL-VAS (0-1)	0.75 (0.72 to 0.77)	0.73 (0.69 to 0.77)

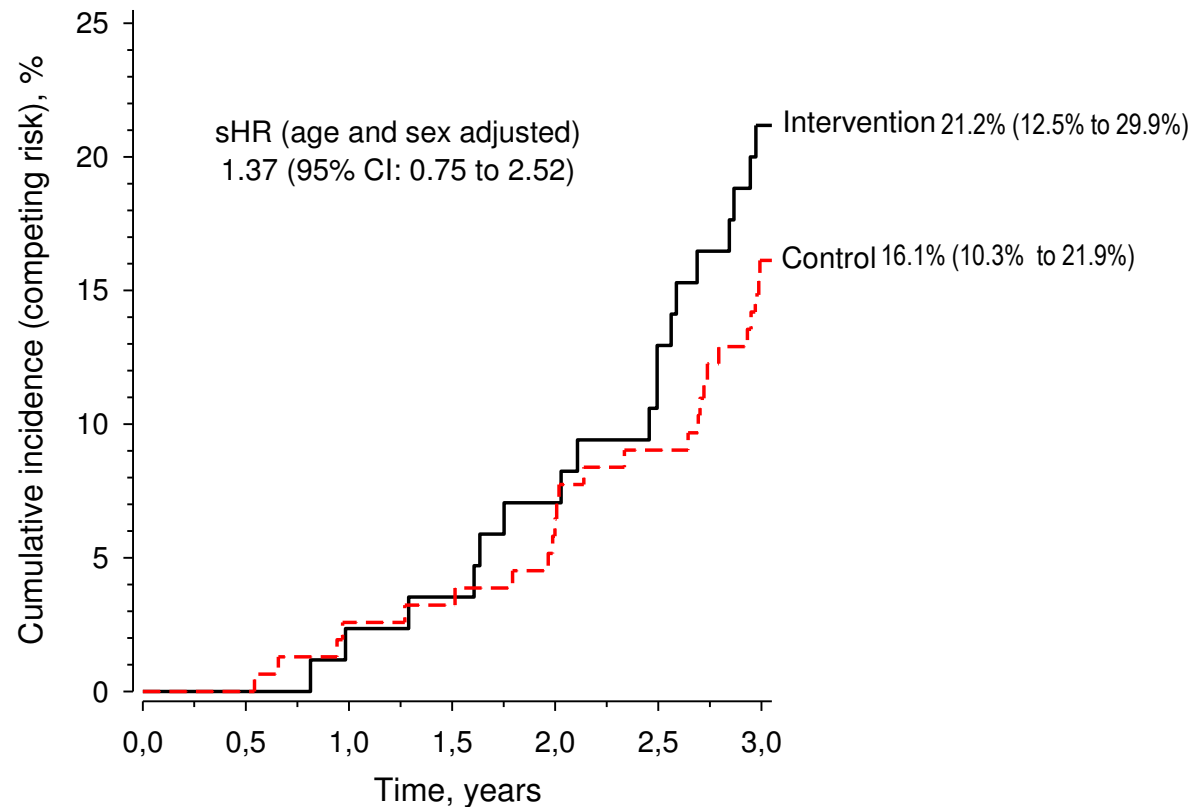
Results

- Cumulative incidence (competing risk) of nursing home placement



Results

- Cumulative incidence (competing risk) of nursing home placement, stratified by the treatment groups



Results

- Multivariate* adjusted mean difference in the selected secondary endpoints

Intervention vs. usual care:

$$\Delta\text{MMSE} = -0.25 (-1.77 \text{ to } 1.28)$$

$$\Delta\text{NPI} = 3.35 (-0.97 \text{ to } 7.67)$$

$$\Delta\text{ADCS-ADL} = -6.90 (-12.45 \text{ to } -1.52)$$

$$\Delta\text{QoL (patient)} = -0.05 (-0.14 \text{ to } 0.026)$$

$$\Delta\text{QoL (caregiver)} = -0.001 (-0.062 \text{ to } 0.06)$$

* Adjusted for the baseline value of secondary endpoint, patient's/caregiver's sex, age, and years of education

Conclusion

- Intensive psychosocial intervention for patients with mild AD and their caregivers did not manage to delay time to the nursing home placement
- The results of the present study are in line with a recently published study (Waldorff et al. 2012 BMJ) reporting no effect of semi-tailored intervention with counseling, education, and support for patients with mild AD and their caregivers
- Even if, the ALSOVA study did not manage to show statistically significant difference between the study groups, it provides the valuable dataset for studying of long-term disease progression and its consequences for patients with AD and their caregivers

The ALSOVA Study Group

Alzheimer's disease, Intervention Effect, Progression, Care, Quality of Life, Health Economics

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Thank you!



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