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 enchase 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)

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

- Cumulative incidence (competing risk) of nursing home placement

ALL 17.9% (95% CI: 13.1% to 22.8%)
Results
- Cumulative incidence (competing risk) of nursing home placement, stratified by the treatment groups

sHR (age and sex adjusted)
1.37 (95% CI: 0.75 to 2.52)

Intervention 21.2% (12.5% to 29.9%)
Control 16.1% (10.3% to 21.9%)
Results
- Multivariate* adjusted mean difference in the selected secondary endpoints

    Intervention vs. usual care:

    ΔMMSE = -0.25 (-1.77 to 1.28)
    ΔNPI = 3.35 (-0.97 to 7.67)
    ΔADCS-ADL = -6.90 (-12.45 to -1.52)
    ΔQoL (patient) = -0.05 (-0.14 to 0.026)
    ΔQoL (caregiver) = -0.001 (-0.062 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!