Effects of the Finnish Alzheimer Disease Exercise Trial (FINALEX): a randomized controlled trial

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
The objective was to assess the impact of exercise on health and social service costs and physical functioning, for patients with Alzheimer's disease. The authors concluded that exercise administered in the patient's home could slow the decline in physical functioning, without increasing costs. The study was well conducted, with some limitations in the cost reporting that introduced uncertainty in the cost outcomes. It was not clear that the authors' findings could be generalised to other settings and populations.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to assess the impact of exercise, on health and social service costs and physical functioning, for patients aged 65 years or older, with Alzheimer's disease, who were living at home.

Interventions
Two exercise interventions were assessed – group exercise, and home exercise. Group exercise consisted of twice-weekly four-hour active sessions, lasting about an hour, delivered by two physiotherapists, at adult rehabilitation daycare centres, to groups of 10 patients. Home exercise consisted of twice-weekly one-hour training sessions, delivered by physiotherapists who specialised in dementia. Each intervention lasted for one year, and they were compared with the usual community care, plus oral and written advice on nutrition and exercise, given by the study nurses.

Location/setting
Finland/secondary care.

Methods
Analytical approach:
The economic evaluation was based on a published multicentre randomised controlled trial (see Other Publications of Related Interest). The trial recruited 210 pairs of patients and their caring spouses. Health outcomes were assessed at 12 months; costs were assessed over two years. The perspective was not explicitly stated.

Effectiveness data:
The primary outcome of the trial was the patients' physical functioning. This was evaluated using the Functional Independence Measure (FIM) which collected the caregivers' assessment of the patients' performance at home. Mobility was assessed using the Short Physical Performance Battery. The outcomes were collected by the nurse or physiotherapist at the start, and at three, six, and 12 months. Complications (including falls, fractures and hospitalisations, per patient) were recorded by spouses on calendars returned to the study nurses at each visit.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The health benefit was measured using the clinical outcomes of the trial: physical functioning and mobility.
Cost data:
The analysis included the total health care costs for patients and caregivers, and the cost of the intervention. Resource use for health and social services was collected from central registers and medical records, for the two years after randomisation, or until the patient's death. The use of community services was collected from central registers and medical records. The service costs from the 2006 registers were inflated to 2012 values. The costs were converted from 2012 Euros to US $ at a rate of one Euro equalled $1.3319. The costs were adjusted for age, gender and Clinical Dementia Rating.

Analysis of uncertainty:
Standard deviations or 95% confidence intervals were reported alongside the outcomes. Bootstrapping was used to derive the 95% confidence intervals for the cost outcomes.

Results
Physical functioning deteriorated in each group over time. The deterioration in FIM score was significantly slower in the two intervention groups than with usual care. At one year, the mean difference in FIM score was -7.1 (95% CI -3.7 to -10.5) with home exercise, -10.3 (95% CI -6.7 to -13.9) with group exercise, and -14.4 (95% CI -10.9 to -18.0) with usual care (p=0.015). With usual care, patients suffered significantly more falls per person per year, than with the interventions (p<0.001). There were no statistically significant differences in mobility between the groups.

The total adjusted mean cost per patient-caregiver pair per year was $34,121 (95% CI 24,559 to 43,681) with usual care, $25,112 (95% CI 17,642 to 32,581) with home exercise, and $22,066 (95% CI 15,931 to 28,199) with group exercise. Including only the patient costs, the costs per person per year were $29,745 (95% CI 20,985 to 39,986) with usual care, $22,646 (95% CI 16,115 to 30,792) with home exercise, and $19,274 (95% CI 13,440 to 25,941) with group exercise. The mean intervention costs were $7,838 for home exercise, and $9,407 for group exercise.

Authors' conclusions
The authors concluded that exercise administered in the patient's home could slow their decline in physical functioning, without increasing total health and social service costs, and without significant adverse effects.

CRD commentary
Interventions:
The interventions were clearly stated and described with sufficient detail. An appropriate comparator, standard care, was analysed.

Effectiveness/benefits:
The clinical outcomes of the trial were clearly reported. The initial characteristics of the patients were clearly reported, but it was unclear if an assessment of any differences between groups was conducted. Most characteristics seem to have been similar, except the proportion of patients using a mobility device. Analysis of covariance was conducted to test for differences in the outcomes, but it was unclear if initial values were controlled for; if not, the results may be subject to bias. The authors pointed out that physiotherapy and daycare use, with usual care, were high; differences between groups could have been affected by the better quality of community care received by these patients. This is only an issue if the level of care received by these patients was higher than expected with usual care.

Costs:
Individual unit costs and resource use were clearly reported. Appropriate sources appear to have been used for health care costs. It was unclear how the additional costs for travel to group sessions, and for physiotherapist visits, were calculated, so it was unclear if these costs were appropriately derived. The study perspective was not stated, but the included costs were relevant to a health service perspective.

Analysis and results:
The results of the analysis were clearly reported. The outcomes were from a randomised controlled trial, which is the gold standard design. Due to practicality, the study workers and assessors were not blinded to treatment allocation, which introduced a risk of bias in the results. The authors pointed out that the small sample, with a 23% drop-out rate at one year, might have lacked the power to detect differences between group exercise and usual care. They appropriately compared their findings with those of other studies, and provided explanations for any differences. They indicated that
their participants adhered to therapy better than those in other studies. They were motivated volunteers, all of whom were White, and the interventions were delivered by dementia specialists. Caution should be used when generalising the findings to other populations.

Concluding remarks:
The study was well conducted, with some limitations in the cost reporting, which introduced uncertainty in the cost outcomes. It was not clear that the authors' findings could be generalised to other settings and populations.

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Other publications of related interest

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