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.

Health technology
The intervention evaluated was the provision, as an addition to usual care, of problem solving counselling to carers of people with cognitive impairment, by community nurses. The intervention was compared to usual community and respite services for carers of people with cognitive impairment.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was carers of relatives with cognitive impairment who had been referred to a visiting nurse agency for home visits, day programmes or homemaking. Carers were excluded from the study if: they had no contact with their relative (13/140); the cognitively impaired relative had died; or they were unable to read or speak English (2/140).

Setting
The setting for the study was community care. The economic study was carried out in southern Ontario, Canada.

Dates to which data relate
The authors did not report the start and end dates of data collection for effectiveness measures, resource use or prices.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costs were derived from data collected prospectively on the same sample of patients used in the effectiveness evaluation.

Study sample
The authors did not report how or when the sample size was determined but did state that there was 80% power to detect a difference of 10 points on the primary outcome measure (Psychosocial Adjustment to Relatives Illness). The study sample consisted of all carers (83/140) from the study population who were eligible for the study (85%) and who agreed to participate in the study (59%). Of these 83 carers, 77 (55% of referrals) completed baseline assessments (38, intervention group and 39, control group). The sample of carers who completed the study was comparable in age, gender and relationship to the person with cognitive impairment to those who did not participate. However, 18% of
carers refused to participate because they were too overwhelmed to do so. The authors suggested that the study sample of carers and their relatives might have been emotionally and physically healthier than the study population.

**Study design**

The study used a randomised controlled trial design carried out in a single centre. Carers were randomised to the intervention or control group by computerised assignment sealed in opaque envelopes. The carers were followed up for 1 year from baseline. Of the carers who completed the baseline assessments (77), 58 completed the 1-year follow up assessment (29, intervention group, 29, control group). There were statistically significant differences between the completers and dropouts on 2 subscales of the Psychosocial Adjustment to Relatives Illness scale (sexual relationship 4.78 completers, 7.79 drop outs, p=0.02; and psychological distress 8.09 completers, 10.79 drop outs, p=0.03). The authors did not report whether the treatment allocation was concealed from the participants (carers, service providers and investigators). The discussion suggests that treatment allocation was not concealed.

**Analysis of effectiveness**

The analysis of effectiveness was only of those who completed the 1-year follow up for the primary and secondary outcome measures. The primary outcome measure was the Psychosocial Adjustment to Relatives Illness scale. The secondary outcomes were use of health and social services for carers and relatives (The Health and Social Utilisation Questionnaire), Caregiver burden (Caregiver Burden Interview), functional elements of social support (Duke Social Support Questionnaire), coping responses of carers (Indices of Coping). The authors reported the quantity of intervention and carers satisfaction with intervention for all carers who were allocated to the intervention group and who received the intervention. The authors reported the baseline characteristics of the carers for all carers completing baseline assessments, but not separately for the intervention and control groups. The authors stated that the only statistically significant difference between groups at baseline was years of education (1.5 years higher in the intervention group). The authors also noted that all the son or son-in-law carers were randomised to the control group. However, they stated that this was by chance. The primary analysis was conducted with and without these caregivers.

**Effectiveness results**

The effectiveness results were as follows:

There were no statistically significant differences at 1 year follow up on the Psychosocial Adjustment to Relatives Illness scale (change in psychological distress, 0.28 intervention versus 0.83 control, p=0.32, total score at 1 year 42.90 intervention versus 46.14 control, p=0.55).

There were no statistically significant differences in the secondary outcomes of burden and social support at 1 year (data not reported).

There was a statistically significant lower use of logical analysis coping behaviours of carers in the control group than in the intervention group at 1 year (Indices of Coping, logical analysis subscale, 7.32 intervention versus 5.72 control, p=0.02).

Sub group analysis indicated that carers who used few logical analysis coping behaviours at baseline improved their psychological adjustment (p=0.035) and psychological distress (p=0.003) at 1 year in the intervention group compared to those in the control group.

Carers who placed their relative in a nursing home (5 intervention group and 9 control group) improved their poor psychosocial adjustment by 23% whereas those who didn't worsened by 8% (p<0.01).

**Clinical conclusions**

The authors concluded that burden or psychosocial adjustment did not improve for either group and that carers with infrequent logical analysis coping skills at baseline benefited from the intervention.
Measure of benefits used in the economic analysis
No summary measure of health benefit was reported and outcomes were left disaggregated; as such a cost-consequences analysis was conducted. However a primary outcome measure was defined. The authors found no difference in overall effect between the intervention and control groups (with 80% power to detect a statistically significant difference in the primary outcome measure).

Direct costs
The direct costs included health and social services provider costs of family physician, specialist, hospital emergency room, hospital, physiotherapy, occupational therapy, social work, nutrition, community nurse, chiropractor, homemaker, meals on wheels, psychiatrist, day care and ‘other’ for carers and relatives with cognitive impairment, carer expenditure on medications, devices, sitters, travel, and parking. The costs were not discounted, which was appropriate for the timeframe of the analysis. The resource data were calculated from the information collected from the patients and clinic records. The unit costs of resources were estimated from charges. The dates of the resource use and price data were not reported.

Statistical analysis of costs
Mean costs and standard deviations were reported. Mann Whitney and analysis of variance were used to test for differences between the intervention and control groups in the costs from baseline to 1 year follow up.

Indirect Costs
Indirect costs of carers’ lost wages and lost family wages were estimated from the carer questionnaire responses. The costs were not discounted, which was appropriate for the timeframe of the analysis. The dates for the data were not reported.

Currency
Canadian dollars (Can$). No currency conversions were reported.

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
The cost results were as follows:

The total annualised costs per person in the intervention group were Can$3,078 (SD Can$4,480) for carer health and social care, Can$1,355 (SD Can$3,856) for carer expenditure, Can$23,437 (SD Can$38,013) for relatives health and social care and Can$112 (SD Can$604) for indirect costs.

The total annualised costs per person in the control group were Can$1,669 (SD Can$2,775) for carer health and social care, Can$336 (SD Can$614) for carer expenditure, Can$15,151 (SD Can$17,765) for relatives health and social care and Can$0 (SD Can$0) for indirect costs.

There were no statistically significant differences in costs of health and social care for carers. However the difference in the combined carer expenditure and indirect costs was statistically significant (p=0.025).

The carers with few logical analysis coping behaviours had higher annual costs (p=0.01).
The difference in the costs of relatives' health and social care was not statistically significant.

**Synthesis of costs and benefits**
The authors did not report a synthesis of costs and benefits.

**Authors' conclusions**
The authors concluded that the costs of health and social care for carers and relatives are high and that there were no overall differences in outcome between the intervention and control groups.

**CRD COMMENTARY - Selection of comparators**
The study evaluated usual care plus problem-solving counselling delivered by nurses compared with usual care alone in southern Ontario, Canada. Usual care was defined as ongoing available community and respite services provided by other nurses and voluntary agencies. The authors did not report the level of service provided by usual care in detail, which makes it difficult to assess whether this is widely available in other settings. The authors briefly described alternative individualised interventions to support carers, and concluded that more research is needed. You as a user of this database should decide if the comparator of usual care is likely to represent current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a randomised controlled trial design to measure carer outcomes and use of health and social care. The authors noted in the introduction, that research on caregiver support should: identify interaction effects on subgroups; determine confounding variables; select highly stressed individuals; use random assignment; measure services used; use emotional outcome measures; and report positive and negative effects in detail. Participants in the trial did not appear to have been masked to allocation, which may have influenced the patients and assessors subjective reports. This may also have influenced the provision and use of services in the usual care arm, which in turn may have affected the outcomes for carers in this group. The authors note in the discussion that both groups had access to a range of services and that the providers of these were not aware of the carers' treatment allocation. However, the primary service providers may have referred carers differentially according to treatment allocation, or the carers may have informed providers of what they were currently receiving, thus influencing access to and use of support services and outcomes. These factors may have confounded the results of the trial. The authors noted that the study sample might have been physically and emotionally healthier than the study population, which could have reduced the need for and therefore effectiveness of the intervention. It may also mean that the authors did not select highly stressed individuals (see above). The groups were statistically similar. However, the control group contained all the son/son-in-law carers recruited to the trial. The analysis was repeated excluding these carers' data. The analysis only included data from those carers who completed the one-year follow up, which may have biased the results. Appropriate statistical techniques were used to explore interaction effects and identify sub groups likely to benefit. The evaluation used validated instruments to measure a range of subjective outcomes and health and social care use. The authors noted that internal consistency and observed agreement were high for these measures. However, the reliability of the logical analysis coping subscale of the Indices of Coping was associated with lower reliability (alpha=0.6). This was the measure that indicated an effect of the intervention.

**Validity of estimate of measure of benefit**
The authors specified a primary outcome for the effectiveness analysis. However, they did not state that this was an economic evaluation and did not specify an outcome to represent the measure of benefit. No clear differences in effectiveness were found. However, the trial was not designed to test equivalence. It is not clear whether there was sufficient power to indicate equal effectiveness. These factors indicate that the economic component of the evaluation was a cost-consequences study.

**Validity of estimate of costs**
The resource use data were obtained from patient questionnaires and records. These were costed using local charge
data. However, resource use and costs were not reported separately. The authors did not state the perspective of the analysis. However, direct health and social care costs of services used by the carers and relatives were included, plus carers’ personal expenditures and indirect costs represented by the lost wages of the carers and family. This would suggest that a broad perspective was used. However, the authors did not report the time spent by the carer in caring for the relative. It is not clear that the lost wages reported included values for time spent by carers who were not in paid employment. This omission may have resulted in an underestimation of the costs of both the intervention and control groups. If the additional services used by the intervention group were a replacement for time spent by carers not in paid employment, then the cost analysis may have been biased against the intervention group.

Other issues
The authors presented a review of the literature in the introduction of the paper. However, they did not directly compare the results of the trial with previous studies. The literature reviewed indicated that carer support interventions might improve carer outcomes, reduce the use of institutional care for the relative and reduce costs. The results of this study are not consistent with these findings. However, the authors also noted that the evidence about carer support was uncertain. The authors discussed the results and possible interpretation of the data in detail. However, they did not present a clear discussion of the generalisability of the results to other settings or populations, or the limitations of the study. The lack of detail presented about the comparator, resource use and charge data make it difficult to assess the relevance of the evaluation to other settings.

Implications of the study
The authors concluded that carers will need a range of services including nurse counselling and that further research is required to determine the long term effects of counselling, who would benefit most and the complete costs of care.

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