Effectiveness of cognitive–behavioural family intervention in reducing the burden of care in carers of patients with Alzheimer's disease

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Background The majority of patients with Alzheimer's disease live outside institutions and there is considerable serious psychological morbidity among their carers.

Aims To evaluate whether family intervention reduces the subjective burden of care in carers of patients with Alzheimer's disease and produces clinical benefits in the patients.

Method A prospective single-blind randomised controlled trial with three-month follow-up in which the experimental group received family intervention and was compared with two control groups.

Results There were significant reductions in distress and depression in the intervention group compared with control groups at post-treatment and follow-up. There were significant reductions in behavioural disturbance at post-treatment and an increase in activities at three months in patients in the intervention group. Based on an improvement on the General Health Questionnaire resulting in a carer converting from a case to a non-case, the number to treat was three immediately post-treatment and two at follow-up.

Conclusions Family intervention can have significant benefits in carers of patients with Alzheimer's disease and has a positive impact on patient behaviour.

Declaration of interest The study was funded through a fellowship from the Alzheimer's Disease Society.

Most patients with Alzheimer's disease live in the community supported by family and friends and there are consistent reports of the high levels of strain, distress and depression among carers (Knight *et al*, 1993; Donaldson *et al*, 1997, 1998; Haley, 1997). The factors that make caring for an individual stressful have been well described and include a variety of behavioural disturbances and psychiatric symptoms (Donaldson *et al*, 1997; Haley *et al*, 1997). Psychological morbidity in carers of patients with Alzheimer's disease is often a major determinant of nursing home placement for patients (Gilleard *et al*, 1984). Thus, alleviating burden and distress in care-givers may have important economic, social and humanitarian implications (Mittelman *et al*, 1996). Studies have demonstrated the benefits of interventions with carers in terms of improved psychological function and delay in nursing home placement for the sufferer (Brodaty & Gresham, 1989; Mittelman *et al*, 1996). The primary hypothesis of the present study was that family intervention would reduce the burden of care in carers, as assessed by measures of psychological distress and depression, compared with management as usual. The secondary hypothesis was that intervention would show a differential effect on cognitive and non-cognitive symptoms in the patient.

METHOD

Design

A prospective randomised controlled trial of family intervention is compared with two control groups with blind and independent assessment, including a three-month follow-up 12 months after trial entry.

Procedure

Patients and their carers were recruited from the Old Age Psychiatric Service of South Manchester University Hospitals NHS Trust and Central Manchester Healthcare NHS Trust. These are representative of old age psychiatry services in the UK. The resources available include access to community psychiatric nurses, social services, old age psychiatry and occupational and physiotherapy. The key elements of the service have been described elsewhere (Lennon & Jolley, 1991). The inclusion criteria were: patients had to satisfy DSM–III–R criteria for primary degenerative dementia of the Alzheimer type (American Psychiatric Association, 1987) and be living in the community with a carer who provided their main support; and the carer had to achieve psychiatric caseness with a score on the General Health Questionnaire (GHQ; Goldberg & Williams, 1988) of 5 or above, indicating significant psychological morbidity.

Subjects were allocated to one of three groups – the family intervention group or one of the two control groups – by means of random number tables independent of the assessor and clinician.

Interventions

Patient and carer dyads were randomly allocated to the family intervention and one of two control groups: one in which the carer was given an in-depth interview, the Camberwell Family Interview (CFI; Leff & Vaughn, 1985); and another group in which no such interview was administered. The two control groups were included to assess any reactance to receiving the CFI. Carers in the intervention group also received the CFI. (Results from the CFI will be reported elsewhere.)

Family intervention

This was derived and modified from the cognitive–behavioural family intervention developed in the treatment of schizophrenia (Tarrier *et al*, 1988; Barrowclough & Tarrier, 1992). It was based on the stress vulnerability family coping skills model and involved detailed assessment of both carer and patient behaviour. The intervention consisted of three components – carer education, stress management and coping skills training – spread over 14 sessions with two-week intervals between each session. The carer education component consisted of three sessions in which the carer's knowledge of dementia was thoroughly assessed by means of the Knowledge about Dementia Interview (KADI), based upon the Knowledge about Schizophrenia

Interview (KASI; Barrowclough *et al*, 1987). This information was used to access the carer's personal model of the illness and causal explanation of the patient's behaviour and provide general information on Alzheimer's disease and practical advice on management. This integrated approach for education was based on the recommendations of Tarrier & Barrowclough (1986). The stress management component consisted of six sessions involving a thorough assessment of the carer's current appraisal and response to stressors, including avoidance, self-sacrificing and isolating behaviour. More adaptive methods of managing personal stress were then taught, including self-monitoring, relaxation training and cognitive and behavioural responses. Lastly, five sessions of training in coping skills were provided. These sessions included advice about and role-play of more effective ways of responding to problematic patient behaviours, and exercises to address carers' feelings of loss concerning changes in the patient or alterations to their own quality of life. Four booklets were given to the carers at the beginning of the intervention, covering information about Alzheimer's disease, the intervention topics and available services. The intervention was described in a treatment protocol and delivered by an experienced consultant clinical psychologist (A.M.), with the patient and carer ratings being made independently.

Control groups

Two control groups were included: neither received any specific intervention and both received the assessment interviews, with one group receiving the CFI and the other not. The CFI is an audiotaped semi-structured interview from which the rating of expressed emotion is derived. It covers several specific areas (household composition and time budgets of family members; psychiatric or illness history; current problems and symptoms, with special emphasis on irritability and areas of conflict between the patient and respondent or other family members; general activities of household members; and the quality of the relationship between patient and respondent) and takes approximately 90 min to complete. The interview was modified for use with the carers of patients with Alzheimer's disease. It was hypothesised that receiving the interview in itself may have a cathartic and non-specific

effect. Anecdotally, by carrying out the CFI with relatives of patients suffering a range of chronic disorders, the relatives have always valued the opportunity that the CFI offers, to talk and be listened to and sometimes to express feelings. Thus two control groups were included, one in which the CFI was included as a brief one-session cathartic interview (the interview control group) and the other group that excluded the CFI (the no-interview control group).

Assessments

The following assessments from patients and their carers were carried out at pre-treatment, post-treatment (nine months after trial entry) and at three-month follow-up (12 months after trial entry). In the intervention group only the GHQ was also administered after the education component of the intervention.

Carer assessments

Carers were assessed on two self-report measures.

General Health Questionnaire. The GHQ–28 (Goldberg & Williams, 1988) is a 28-item questionnaire used to assess the respondent as a 'psychiatric case'. Each item is scored as absent or present and a total score is obtained by summing those obtained for all items. A cut-off of 4/5 was used.

Beck Depression Inventory (BDI). The BDI (Beck, 1988) is a 21-item questionnaire assessing depression. Each item is scored 0–3 and a total score is derived.

Patient assessments

The patients were diagnosed according to DSM–III–R criteria for primary degenerative dementia. Demographic information was collected for each patient and four assessments were carried out.

Mini-Mental State Examination (MMSE; Folstein et al, 1975). The MMSE is a 30-item score of cognitive function, with 30 representing normal cognition.

Cornell Scale for Depression in Dementia (CSDD; Alexopoulos et al, 1988). The CSDD is a 19-item scale assessing depressive symptoms in people suffering from dementia,

each item rated on a three-point scale and the maximum score being 38.

MOUSEPAD (Allen et al, 1996). MOUSEPAD is a 59-item scale assessing a number of psychiatric symptoms and behavioural disturbances in dementia under the categories 'delusions', 'hallucinations', 'misidentifications', 'reduplications', 'walking', 'eating', 'sleeping', 'sexual behaviour' and 'aggression'. Analyses were carried out on the two scales representing psychiatric symptoms and behavioural disturbance.

Clinical Dementia Rating (CDR; Hughes et al, 1982; Morris, 1993). The CDR is a widely used global rating of the severity of dementia as mild (I), moderate (II) or severe (III) in six different domains (memory, orientation, judgement and problem-solving, communicative affairs, home and hobbies, personal care). A measure of activities for daily living (ADL) is obtainable from the last three items. The same rater who performed the assessments also carried out the intervention.

Sample size and statistical analysis

The sample size was calculated on the basis of a reduction of four points on the GHQ. In our previous study (Donaldson *et al*, 1998) we found the median score for a sample of 100 carers to be 9, and chose 4 as the score needed to reduce this to the level of caseness/non-caseness. Subjects were stratified in terms of gender and high or low GHQ scores (>9 or <9) and the sample size was calculated to produce 90% power at the 5% level, giving 14 subjects in each of the three groups by assuming a standard deviation of 3. Analyses were performed on SPSS version 8 for Windows. Comparisons were made between groups at post-treatment and at follow-up by means of an analysis of covariance (ANCOVA) using the Greenhouse–Geisser adjustment, with the pre-treatment score as a covariant, and pairwise comparisons between groups by simple contrasts adjusted for multiple comparisons. This analysis is extremely conservative (Gibbons *et al*, 1993). Numbers needed to treat were calculated according to Sackett *et al* (1997).

RESULTS

Seventy-seven carers were interviewed for inclusion in the study. Fourteen refused to participate in the study and twenty-one

scored less than 5 on the GHQ and so were excluded (twelve male and nine female; ten were spouses, seven were daughters and four were sons; average age 65.8 years, range 39–83 years). Forty-two patient–carer dyads were therefore included and allocated to the three groups, with 14 being allocated to each group. One patient and carer dropped out of the intervention and were lost to the study. The characteristics of the sample and the outcome measures are given in Table 1.

Baseline measures

At baseline there were no significant differences between groups on any continuous measure as tested by one-way analysis of variances (ANOVAs), except for the measure of a minor clinically insignificant difference on the CSDD ($F=4.47$, d.f.$=2.39$, $P=0.018$). There were no differences between groups on any categorical variables. Thus it can be assumed that randomisation was successful and there were no pre-treatment differences between the treatment groups.

Effect of intervention: outcome measures

Carer variables

General Health Questionnaire. There was a significant difference at post-treatment between groups ($F=7.35$, d.f.$=2$, $P=0.002$), with a significant difference between the intervention group and no-interview control ($P=0.001$) and between the intervention group and interview control ($P=0.035$). At follow-up there were significant differences between groups ($F=7.9$, d.f.$=2$, $P=0.001$), with significant differences between the intervention group and no-interview control ($P=0.001$) and the intervention group and interview control ($P=0.007$). Paired t-tests indicated that the GHQ before (baseline) and after education in the intervention group did not show a significant difference ($t=0.18$, d.f.$=13$, $P=0.86$).

Caseness. At baseline all carers were psychiatric cases on the GHQ. At post-treatment 11/13 (85%) were cases in the no-interview control group, 13/14 (93%) in the interview control group and 6/13 (46%) in the intervention group. At follow-up the number of cases was: 10/13 (77%) in the no-interview control group; 11/13 (85%) in the interview control group; and

Table I Actual means and standard deviations for the continuous variables and frequencies of the categorical variables in the three treatment groups at pre-treatment, post-treatment and three-month follow-up

Variable	No-interview control group	Interview control group	Family intervention group
Carer gender	11 female	9 female	9 female
Patient gender	10 female	10 female	10 female
Carer age (years)	58.1 (16.7)	63.0 (14.0)	69.6 (15.2)
Patient age (years)	77.7 (6.8)	76.3 (10.6)	76.6 (9.3)
Relationship of carer to patient	Spouse 5/14	Spouse 8/14	Spouse 9/14
	Offspring 8/14	Offspring 6/14	Offspring 3/14
	Sibling 1/14		Sibling 2/14
Duration of dementia (months)	37.9 (17.5)	53.6 (30.6)	57.9 (31.6)
Duration of caring (months)	31.6 (17.1)	37.8 (24.6)	44.1 (28.7)
Carer measures			
GHQ pre-treatment	9.6 (3.8)	10.8 (5.9)	9.5 (4.8)
GHQ post-treatment	12.4 (6.4)[a]	11.0 (6.2)[a]	5.1 (5.5)[b]
	12.7 (s.e. 1.2)	9.9 (s.e. 1.2)	6.0 (s.e. 1.2)
GHQ follow-up	10.7 (5.5)[a]	9.9 (7.8)[a]	3.2 (4.2)[b]
	10.8 (s.e. 1.3)	9.1 (s.e. 1.3)	3.9 (s.e. 1.3)
BDI pre-treatment	9.9 (5.5)	12.0 (7.4)	11.5 (9.5)
BDI post-treatment	10.9 (5.6)[a]	11.5 (6.8)[a]	7.2 (7.5)[b]
	11.8 (s.e. 0.8)	10.8 (s.e. 0.8)	6.9 (s.e. 0.8)
BDI follow-up	11.1 (6.4)[a]	11.4 (7.1)[a]	6.3 (5.7)[b]
	11.8 (s.e. 1.1)	10.9 (s.e. 1.1)	6.1 (s.e. 1.1)
Patient measures			
MMSE pre-treatment	14.6 (7.7)	9.1 (8.1)	13.7 (6.3)
MMSE post-treatment	13.9 (7.2)	6.5 (7.2)	9.9 (6.2)
MMSE follow-up	13.0 (7.1)	5.8 (6.8)	9.2 (7.2)
CSDD pre-treatment	6.4 (2.7)	10.1 (2.9)	7.3 (4.6)
CSDD post-treatment	6.1 (2.8)	10.8 (3.0)	7.2 (4.4)
CSDD follow-up	6.1 (3.2)	10.6 (3.1)	7.3 (4.7)
MOUSEPAD psychiatric symptoms pre-treatment	1.2 (1.1)	2.9 (3.1)	1.6 (2.0)
MOUSEPAD psychiatric symptoms post-treatment	1.2 (1.1)	2.8 (3.1)	1.6 (2.0)
MOUSEPAD psychiatric symptoms follow-up	1.4 (1.1)	2.8 (3.1)	1.7 (1.9)
MOUSEPAD behavioural disturbance pre-treatment	4.6 (2.1)	5.7 (2.8)	5.4 (2.6)
MOUSEPAD behavioural symptoms post-treatment	5.1 (2.2)[a]	5.4 (2.5)[a,b]	5.1 (2.1)
	5.6 (s.e. 0.2)	5.0 (s.e. 0.2)	4.9 (s.e. 0.2)
MOUSEPAD behavioural symptoms follow-up	5.2 (2.0)	5.5 (2.4)	5.3 (2.0)
CDR pre-treatment	9.2 (3.3)	11.3 (4.3)	9.2 (3.4)
CDR post-treatment	10.7 (2.8)	13.0 (4.2)	11.9 (3.8)
CDR follow-up	11.6 (3.3)	13.9 (4.3)	12.0 (3.7)
ADL pre-treatment	4.3 (1.8)	5.4 (2.1)	4.6 (1.7)
ADL post-treatment	5.1 (1.8)	6.6 (2.0)	5.4 (1.9)
ADL follow-up	5.9 (1.7)[a]	7.0 (2.0)[a]	5.5 (2.0)[b]
	6.4 (s.e. 0.3)	6.5 (s.e. 0.3)	5.5 (s.e. 0.3)

Different letter superscripts indicate where there were significant differences between groups using ANCOVA, in which case estimated marginal means (adjusted for covariants) and standard errors are given.

3/13 (23%) in the intervention group. This reduction in the number of cases on the GHQ was significant across the three groups immediately after the intervention ($\chi^2=8.57$, d.f.$=2$, $P=0.014$) and at follow-up ($\chi^2=15.08$, d.f.$=2$, $P=0.001$). The number needed to treat, based on this reduction, was two at post-treatment (100/54–11) and two at follow-up (100/85–19). Changes from pre- to post-treatment (McNemar's test, $P=0.016$) and from pre-treatment to follow-up (McNemar's test, $P=0.001$) were significant for the intervention group but not for the two control groups. (There were missing data for one carer at post-treatment and follow-up in the no-interview control groups and for one carer at follow-up in the interview control group.)

Beck Depression Inventory. There was a significant difference between groups ($F=10.34$, d.f.$=2$, $P<0.001$), with a significant difference between the intervention group and no-interview control ($P<0.01$) and between the intervention group and interview control ($P=0.002$). At follow-up there was a significant difference between groups ($F=7.75$, d.f.$=2$, $P=0.002$), with a significant difference between the intervention group and no-interview control ($P=0.001$) and between the intervention group and interview control ($P=0.004$). There were no significant differences between the two control groups.

Patient variables

Behavioural disturbance (from the MOUSE-PAD). There was a significant difference between groups at post-treatment ($F=4.14$, d.f.$=2$, $P=0.024$), with a significant difference between the intervention group and no-interview control ($P=0.01$) but not between the two control groups. There were no significant differences at follow-up.

Activities of daily living (from the CDR). There were no significant differences at post-treatment but at follow-up there was a significant group difference ($F=3.47$, d.f.$=2$, $P=0.042$), with a significant difference between the intervention group and no-interview control group ($P=0.043$) and between the intervention group and interview control ($P=0.021$). There were no significant group differences on the CSDD depression scale, psychotic symptoms, cognitive ability or overall severity of dementia. No other comparisons were significant.

Outcome predictors

Stepwise multiple regression analyses were carried out with GHQ at post-treatment and follow-up as dependent variables, respectively. Only the baseline GHQ entered the model, with carer and patient gender and age, the carer's relationship to the patient, co-habitation or not, duration of dementia and duration of caring being excluded from the model, thus indicating that background factors were not significantly associated with outcome.

DISCUSSION

Outcome

The main findings of the study were that: family intervention was acceptable to patients and their carers; the intervention significantly reduced burden in carers and behavioural disturbance in patients; the opportunity, through the CFI interview, for relatives to discuss aspects of the patient's behaviour had little effect; and providing information alone to the carer had no effect on burden.

The serious mental and physical effects on the carer of looking after someone suffering from Alzheimer's disease have been well documented (Haley, 1997). Depression occurs in up to 50% of carers (Teri, 1994) and the physical effects include impaired immune function, raised plasma lipids and blood pressure, poor self-care and higher use of medication (Schulz et al, 1995; Haley, 1997). Predictors of burden have been demonstrated (Donaldson et al, 1997), and factors particularly associated with stress include a variety of psychiatric symptoms and behavioural disturbances, such as depression, delusions, hallucinations, aggression and wandering (Donaldson et al, 1998).

Effect of the intervention

There have only been a small number of interventions that have tried specifically to reduce carer burden in patients with Alzheimer's disease (Hinchcliffe et al, 1992). Early studies emphasised the need for education and information, which is greatly valued by carers (Haley et al, 1992). We found little evidence that information alone significantly reduced burden or had an impact on the patient, a result similar to that found in schizophrenia research (Tarrier et al, 1988). Respite care similarly is perceived well, but there is little evidence to suggest long-term benefit to the

patient or their carer or improved outcomes (Montgomery & Borgatta, 1989). Support groups are also well received but they are generally less effective than individualised highly structured interventions (Gallagher-Thompson & DeVries, 1994). Psychotherapy may be of some benefit in patients with dementia but, because of cognitive loss, some adaptation of the technique is required and the involvement of carers is often necessary (Cheston, 1998).

Beneficial effects of specific interventions include diminished carer stress, as measured by the GHQ (Brodaty & Gresham, 1989), significantly reduced nursing home placements at follow-up (Mittelman et al, 1993), improved survival (Brodaty et al, 1993), and reduction of depression in carers (Mittelman et al, 1995). Teri & Uomoto (1991) used a strategy to increase the experience of pleasant events in patients with dementia, which resulted in improvements in depression and activity. They extended this work (Teri et al, 1997) in an intervention trial looking specifically at the effects of depression in patients and their carers. Patients were randomised to one of four treatment conditions: behaviour therapy concentrating on pleasant events; behaviour therapy concentrating on problem solving; usual care; and a waiting list group (who received nothing). Both behavioural interventions significantly reduced depression, not only in patients but also in their carers.

Carers who received family intervention show significant improvements on measures of distress and depression at post-treatment and three-month follow-up compared with the two control groups. There are no significant differences between the two control groups, indicating that there was no reactance effect of the CFI. If the CFI is seen as equivalent to one session of discussion and expression of feelings, then such a brief intervention is ineffective compared with the full family intervention. There were significantly lower numbers of carers in the intervention group who remained psychiatric cases, indicating a return to within a normal range for a good percentage of those who received the family intervention compared with the control groups. This is especially noticeable at follow-up, when only 23% of the intervention group remain cases compared with 77% and 85% in the two control groups.

The intervention evaluated in this study aims to reduce carer stress and distress as its primary purpose. Thus, the primary hypothesis of the study was confirmed.

Impact on patients

The secondary aim of the intervention was to improve management skills in carers, which in part was related to reducing the subjective stress of caring by imparting skills and making the carer feel more in control and less helpless, but in part also so that patient outcomes may also improve. Thus, the secondary hypothesis that family intervention would have an impact on cognitive and non-cognitive symptoms of Alzheimer's disease receives some modest support in the effect on the latter. There was a significant effect of family intervention at post-treatment on behavioural disturbance; however, this was not sustained at follow-up. There was a significant improvement in ADL at follow-up but not at post-treatment.

Clinical implications

Unlike family interventions used with patients with schizophrenia and their carers, family intervention with Alzheimer's disease does not have as its principal aim the reduction of relapse or amelioration of the disorder. In Alzheimer's disease the focus of family intervention is reduction of carer stress *per se* rather than any modification of the disease. However, the principles of family intervention are basically the same. The carers and family members control, at least in part, the contingencies that operate on the patient and may be influential in determining their behaviour. If the carer is stressed and they feel poorly in control, then there is an increased probability that they will behave in a less consistent and more erratic manner, reacting to their own emotional states rather than to the demands of the situation. The aims of intervention are to help carers cope better with their own emotional states and to have a clear perspective on how best to deal with difficult and challenging circumstances so that their own behaviour becomes more consistent and the contingencies and environment become more predictable. The reduction of carer burden and the improved feeling of being able to cope and having some control over the situation that this may bring about may have positive consequences in retaining the patient in the community and reductions in the use of support services.

This study – the first randomised controlled trial of focused cognitive–behavioural intervention in Alzheimer's disease in the UK – replicated other studies (Brodaty & Gresham, 1989; Mittelman *et al*, 1993; Teri *et al*, 1997) in showing that specific interventions have positive benefits. Using the CFI as a means of stimulating a cathartic approach was novel but we had no difficulty in adapting the interview to this different client group. Replication studies are needed, as is a cost–benefit analysis. Studies combining pharmacological and non-pharmacological approaches seem another appropriate next step.

CLINICAL IMPLICATIONS

■ A focused intervention, based on a cognitive–behavioural family intervention model, significantly reduces stress in carers.

■ Modification of behavioural disturbances in patients occurs as a result of the intervention.

■ Little benefit is obtained from a cathartic interview with the carer.

LIMITATIONS

■ The sample size is relatively small and the study requires replication.

■ The intervention used was lengthy, which has resource implications for its implementation in clinical practice.

■ The cognitive–behavioural family intervention model requires specialist training.

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(First received 27 July 1999, final revision 16 December 1999, accepted 16 December 1999)

ACKNOWLEDGEMENTS

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