Martin Knapp, Derek King, Renee Romeo, Barbara Schehl, Julie Barber, Mark Griffin, Penny Rapaport, Debbie Livingston, Cath Mummery, Zuzana Walker, Juanita Hoe, Elizabeth L. Sampson, Claudia Cooper and Gill Livingston

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RESEARCH

Cost effectiveness of a manual based coping strategy programme in promoting the mental health of family carers of people with dementia (the START (STrAtegies for RelaTives) study): a pragmatic randomised controlled trial

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Abstract

Objective To assess whether the START (STrAtegies for RelatTives) intervention added to treatment as usual is cost effective compared with usual treatment alone.

Design Cost effectiveness analysis nested within a pragmatic randomised controlled trial.

Setting Three mental health and one neurological outpatient dementia service in London and Essex, UK.

Participants Family carers of people with dementia.

Intervention Eight session, manual based, coping intervention delivered by supervised psychology graduates to family carers of people with dementia added to usual treatment, compared with usual treatment alone.

Primary outcome measures Costs measured from a health and social care perspective were analysed alongside the Hospital Anxiety and Depression Scale total score (HADS-T) of affective symptoms and quality adjusted life years (QALYs) in cost effectiveness analyses over eight months from baseline.

Results Of the 260 participants recruited to the study, 173 were randomised to the START intervention, and 87 to usual treatment alone. Mean HADS-T scores were lower in the intervention group than the usual treatment group over the 8 month evaluation period (mean difference −1.79 (95% CI −3.32 to −0.33)), indicating better outcomes associated with the START intervention. There was a small improvement in health related quality of life as measured by QALYs (0.03 (−0.01 to 0.08)). Costs were no different between the intervention and usual treatment groups (£252 (−28 to 565) higher for START group). The cost effectiveness calculations suggested that START had a greater than 99% chance of being cost effective compared with usual treatment alone at a willingness to pay threshold of £30 000 per QALY gained, and a high probability of cost effectiveness on the HADS-T measure.

Conclusions The manual based coping intervention START, when added to treatment as usual, was cost effective compared with treatment as usual alone by reference to both outcome measures (affective symptoms for family carers, and carer based QALYs).

Trial Registration ISCTRN 70017938

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Appendix A and B (as supplied by the author) (see http://www.bmj.com/content/347/bmj.f6342?tab=related#webextra)

Introduction

England's *National Dementia Strategy*[1] emphasised that "Family carers are the most important resource available for people with dementia" (p 12), and urged full implementation of the *Carers' Strategy*.[2] There was then, just as there is now, little prospect that state funded services will reduce reliance on unpaid family and other carers over the coming decades. Population ageing will mean substantial growth in the number of people with dementia, with rapidly escalating costs for health and social care systems,[3] while macroeconomic pressures are leading many governments to rein in public spending.

In 2010, an updated *Carers' Strategy* was published[4]; it included recognition that "Caring can be very rewarding and fulfilling but it can also be emotionally and physically draining without recognition and practical and emotional support" (p 26). Among the health consequences for carers, anxiety and depression are highly prevalent.[5] For this reason, the clinical guideline for dementia issued by what was at the time the National Institute for Health and Clinical Excellence (NICE) and the Social Care Institute for Excellence[6] recommended that "Carers of people with dementia who experience psychological distress and negative psychological impact should be offered psychological therapy, including cognitive behavioural therapy, conducted by a specialist practitioner" (p 40). However, NICE noted the paucity of evidence in this area and recommended further research to address the question: "For carers of people with dementia, is a psychological intervention cost effective when compared with usual care?" (p 45).

We conducted a randomised controlled trial to examine the effectiveness and cost effectiveness of a manual based therapy delivered by psychology graduates without clinical qualifications to family carers of people with dementia. The intervention, based on the Coping with Caring programme developed in the United States,[7 8] was added to treatment as usual, and compared with treatment as usual alone. In a companion paper, we report the findings on clinical effectiveness[9]; the aim of this paper is to report the findings on cost effectiveness.

Methods

Setting

Carers in the trial were recruited from memory services in two mental health trusts (Camden and Islington Foundation Trust and North Essex Partnership Foundation Trust), the North East London Foundation Trust Admiral nurse service (specialist nurses for family carers of people with dementia), and a tertiary service whose referrals include a high rate of people with young onset dementia (the Dementia Research Centre, National Hospital for Neurology and Neurosurgery).

Participants

Family carers were eligible for inclusion in the trial if they provided support at least weekly to patients with dementia referred in the previous year (and who were not living in 24 hour care); if they identified themselves as the primary carer; if they gave informed consent to the trial; if they were not currently participating in another study because of their role as a family carer; if they did not themselves have dementia; and if they lived no more than 1.5 hours travelling time from the researchers' base at University College London.

Design

The study was a pragmatic, multicentre, randomised controlled trial with nested cost effectiveness analysis. As described in the companion paper,[9] eligible family carers were randomised either to the manual based therapy delivered by psychology graduates without clinical qualifications (hereafter referred to as the START intervention) added to treatment as usual, or to treatment as usual alone. Randomisation was conducted using an online computer generated system to conceal allocation, stratified by site using random permuted blocks. An allocation ratio of 1 to 2 (usual treatment to intervention) allowed for potential clustering effects.[10] It was not possible to blind carers to allocation, but outcome assessors were blind to randomisation status. Sample size was calculated on the basis of the power required to demonstrate differences in one of the effectiveness measures and not on the basis of costs or cost effectiveness.

Treatment as usual

Treatment as usual was based around the person with dementia, and could include medical, psychological, and other health services and social care services. In each site, treatment, care, and support aimed to be consistent with NICE guidelines.[6]

Therapy intervention

The individual therapy programme was based on Coping with Caring,[7 8] adapted for use in the UK, and was added to usual treatment. Eligible family carers received the therapy over eight sessions at a location chosen by the carer (usually their own home), without the person with dementia in the room. If the carer did not speak English fluently, the therapy was carried out with an interpreter. The sessions were delivered by psychology graduates with no clinical training but trained to deliver the intervention by adhering to the manual. A clinical psychologist (PR, one of the authors) met with each team of therapists for 1.5 hours of group clinical supervision every two weeks and was also available for individual consultation as needed by the therapists. Each carer had a manual and was given a compact disc to guide relaxation exercises. Further details are given by Livingston et al.[9]

Outcome measures

Assessments of each carer and each person with dementia were carried out at baseline before the intervention, and at four months and eight months after randomisation. Baseline assessments covered sociodemographic characteristics of both the carer and the person with dementia (including age, sex, ethnicity, relationship to person with dementia, level of education, last occupation, and living situation).

The primary clinical outcome for the carer was affective symptoms assessed with the self completed Hospital Anxiety and Depression Scale,[11] for which the total score (HADS-T) ranges from 0 to 42 (higher scores indicating more affective symptoms). The HADS has two subscores, each ranging from 0 to 21: HADS-D (depression) and HADS-A (anxiety).

Carer generic health-related quality of life was rated using the EuroQol (EQ-5D).[12] Other outcome measures used in the economic evaluation (in each case when adjusting analyses for baseline covariates) were:

- Zarit Burden Interview,[13] a 22 item, self reported questionnaire used to assess carer burden, with scores ranging from 0 to 88 (higher scores indicate greater burden)

- Brief COPE,[14] a self completed measure of carer coping strategies, with subscales measuring problem focused, emotion focused, and dysfunctional coping;
- For the person with dementia but completed by carers, the Neuropsychiatric Inventory (NPI),[15] with 12 neuropsychiatric symptom domains scored and summarised as a single continuous score (higher scores indicating worse symptoms).

Service use and costs

Data on services used and support received by the carer and the person with dementia were collected using an adapted version of the Client Service Receipt Inventory[16] at baseline (randomisation), four months, and eight months. On each occasion, the carer was asked to report service use over the previous four months. For the present analyses, our focus is on service use by the carer. This inventory sought to cover all services, including (but not limited to) inpatient stays, outpatient attendances, day hospital treatment, visits to social clubs, meals at lunch clubs, daycare visits, and hours spent in contact with community based professionals (such as community teams for older people, community psychologists, community psychiatrists, general practitioners, nurses (either practice, district or community psychiatric), social workers, occupational therapists, paid home help or care workers, and physiotherapists).

Frequency and intensity of service contacts were multiplied by unit costs to estimate total carer related health and social care costs. Unit costs were obtained from publicly available sources and set at 2009-10 prices: National Health Service Schedule of Reference Costs[17] for inpatient and outpatient attendances; the Personal Social Services Research Unit annual volume[18] for most other services; and voluntary sector bodies for a small number of services used by a few carers (details available from the corresponding author).

The cost of the START intervention was calculated using data on time spent by therapists in training and supervision with a clinical psychologist, and contacts that therapists had with carers in delivering the intervention. Cost per hour of contact for therapists and supervising clinical psychologist were based on figures in the Personal Social Services Research Unit volume,[18] taking the midpoint of the relevant scales and including employer costs (national insurance and superannuation contributions) and appropriate overheads (capital, administration, and managerial, including recruitment costs). We added costs for the relaxation compact disks based on the market rates for copying and delivering.

Cost effectiveness

The economic research question was whether the START intervention (manual based coping) was cost effective when added to usual treatment in reducing family carer depression and anxiety symptoms and enhancing carer health-related quality of life over an eight month period.

The cost effectiveness analysis was conducted from a health and social care perspective. Health and social care costs from over the eight month period after randomisation were examined alongside HADS-T (at eight month assessment) and quality adjusted life years (QALYs, over eight months) in turn, the latter calculated from the EQ-5D by applying societal weights.[19]

Statistical analysis

We analysed HADS-T and QALY differences between START and usual treatment using a multilevel mixed effects model to account for therapist clustering in the intervention arm and repeated measures at four and eight months. For the HADS-T analysis, we adjusted for baseline HADS-T, centre, carer age and sex, carer burden (ZARIT), and neuropsychiatric symptoms (NPI) of the person with dementia. For the QALY analyses we adjusted for the same baseline variables, except substituting QALY for HADS-T.

We analysed differences in health and social care cost between START and usual treatment by regressing total cost on treatment allocation, baseline costs, centre, carer age and sex, carer burden (ZARIT), and care recipient neuropsychiatric symptoms (NPI). We used a linear multilevel regression model to account for therapist clustering in the intervention arm and repeated measures for each individual. Non-parametric bootstrapping was used to estimate 95% confidence intervals for mean costs. Significance ($P<0.05$) was judged where the bias-corrected confidence intervals of between-group change score excluded zero.

All analyses were conducted on an intention-to-treat basis, but carers were excluded if data were missing at both four and eight months. If an individual's data were available at four months but not at eight months, or vice versa, their partial data were used in the analysis. Because the estimation of QALYs requires data at each time point, only complete cases were included in the cost effectiveness analysis. No imputation was conducted.

Each incremental cost effectiveness ratio was calculated as the difference in the cost of START and usual treatment divided by the difference in outcome (measured by HADS-T or QALYs). Cost effectiveness acceptability curves were plotted to locate the findings of the economic evaluation in their wider decision making context. The cost effectiveness acceptability curve illustrates the probability that the START intervention would be seen as cost effective compared with usual treatment across a range of hypothesised values placed on incremental outcome improvements (willingness to pay by health and social care system decision makers). Each cost effectiveness acceptability curve was derived using a net benefit approach. Monetary values of incremental effects and incremental costs for each case were combined, and net monetary benefit derived as:

$$\text{Net monetary benefit} = \lambda \times (\text{effect}_b - \text{effect}_a) - (\text{cost}_b - \text{cost}_a)$$

where λ is willingness to pay for a one point difference in the outcome measure (HADS-T or QALYs), and subscripts a and b denote usual treatment and START, respectively. We explored a range of willingness-to-pay values for each outcome. We were able to account for sampling uncertainty and make adjustments as necessary in the primary analyses and sensitivity analyses. We also plotted the confidence intervals around net monetary benefit to estimate the impact of uncertainty.

Sensitivity analysis

Sensitivity analyses were used to assess robustness of our results. In sensitivity analyses we examined the extent to which individuals with missing outcome data varied by baseline characteristics. This was investigated separately for each outcome using logistic regression. The first step was to model a binary variable (missing versus not missing) in bivariate logistic regression with each baseline demographic variable. Those variables identified as significantly associated with missing were then used in multivariate logistic regression to determine which remained significant. The main analyses were then repeated, adjusting for those factors found to be associated

with "missingness" on each outcome. For the analysis of HADS-T, the variables found to be associated with missingness were: patient living with carer, relationship to carer, carer having children at home, patient ethnicity, and COPE dysfunction score. For the QALY outcome, the carer's work situation (employed versus unemployed) and ethnicity were associated with missingness.

A second sensitivity analysis adjusted for imbalances in baseline characteristics between the treatment groups that occurred despite randomisation (that is, adjusting for carers' work situation, relationship to carer, and patients' and carers' education and living situation). These analyses were chosen so as to be consistent with those used in the effectiveness paper.[9]

All statistical analyses followed a predefined analysis plan and were carried out using STATA version 12.[20]

Results

Participants

Of the 260 carers who consented to enter the randomised trial, 173 were randomised to START and 87 to usual treatment. The groups were broadly similar at baseline by reference to demographic and clinical characteristics of both people with dementia and carers, except that carers in the START group were slightly older; more likely to be retired, male, unmarried, without qualifications or tertiary education, and living with the person with dementia; more likely to have case level anxiety; and had slightly lower HADS anxiety scores. Further details of trial participants are given by Livingston et al.[9]

Ten therapists (seven female) delivered the intervention, supporting between 11 and 21 carers each. Therapists were aged in their 20s or 30s, and were psychology graduates.

Service use and costs

Carers used a wide range of health and social care services over the eight month period, as can be seen from the summary statistics in table 1⇓. We did not impute individual items of service use, and means are presented for non-missing cases only. Outpatient hospital and general practice services were used by high proportions of participants.

These patterns of service use were weighted by their unit costs, which are detailed in the final two columns of table 1⇓. Mean costs—grouped into outpatient, community, and other services—are given in table 2⇓. The table distinguishes the START and usual treatment groups and reports figures for two time periods, the four month period between baseline and the four month assessment, and the four month period between the four month and eight month assessments. Although the number of users of outpatient services was higher in the intervention group (table 1⇓), their average outpatient service cost was lower as they used outpatient services less frequently than people in the usual treatment group.

The right hand column of table 2⇓ shows the difference in costs between the START and usual treatment groups across the whole evaluation period of eight months. Excluding the direct cost of the intervention itself, mean costs over the study period (1-8 months) were £558 in the START group and £625 in the usual treatment group. After adjustment for baseline characteristics (see above), the standardised difference was £14, with the 95% confidence interval (−239 to 211) suggesting that there was no significant difference in costs between the two groups. For purposes of comparison, scores on the two outcome measures used in the economic evaluation are included towards the bottom of table 2⇓.

Based on the time spent by the 10 therapists in delivering one-to-one therapy to carers, their own training sessions (40 sessions of 2.5 hours over a six week period), time spent making telephone calls to participants, time spent writing up notes, and supervision of the therapists by the clinical psychologist (1.5 hours each per week for eight weeks), we calculated that the mean cost per session per carer was £36. Adding in the cost of the relaxation compact disks (which totalled £284), the overall mean direct intervention cost averaged £232.15 per carer.

Including the cost of intervention itself in the comparison between the groups, and now adjusting for baseline variables, costs for the START group were slightly but not significantly higher than for the usual treatment group. The mean cost difference was £252 (95% confidence interval −28 to 565) for sample members on the EQ-5D, and £247 (0 to 569) for sample members on the HADS-T measure (table 3⇓).

Cost effectiveness

Results from the net benefit regression using the two outcomes examined in the economic evaluation (QALYs and HADS-T score) are summarised, and the incremental cost effectiveness ratios (ICERs) reported, in table 3⇓. The cost and outcome differences are obtained after adjustment for baseline characteristics and are influenced slightly by size of sample with complete data for each outcome.

Carers who received the START intervention (manual based coping strategy in addition to treatment as usual) generated slightly, though not statistically significantly, higher health and social care system costs but enjoyed significantly better outcomes, whether measured in terms of health-related quality of life (QALY) or affective symptoms (HADS-T). Whether these results imply that START is cost effective compared with usual treatment depends on the decision maker's willingness to pay for these gains in quality of life and affective symptoms. To aid discussion of willingness to pay, we computed the ICERs. We also plotted the associated cost effectiveness acceptability curves and examined the confidence intervals around net monetary benefit.

Looking first at QALY as the outcome, the mean cost per QALY gained was £6000. The acceptability curve is shown in figure 1⇓, illustrating the probability of cost effectiveness for each of a number of different hypothesised values of willingness to pay. At the £20 000 per QALY threshold associated with NICE recommendations,[21] the probability that the START intervention would be seen as cost effective was 93%, and at the higher NICE threshold of £30 000 it was 99%. The 95% confidence intervals around net monetary benefit suggest that there is a strong likelihood that START is cost effective at the £30 000 threshold (see appendix B on bmj.com).

For the other outcome measure, the HADS-T measure of affective symptoms, mean cost per one point difference on the HADS-T scale was £118. The cost effectiveness acceptability curve for this outcome measure is shown in figure 2⇓. We are not aware of any previously suggested monetary thresholds for gauging cost effectiveness on the HADS scale. However, if we assumed a willingness to pay of £500, the probability that the START intervention would be seen as cost effective would be 95%. We can also refer to a previous suggestion that a minimally important clinical difference on the HADS-T scale is 1.6. The mean cost of achieving such a change with START would be £189.

Sensitivity analysis

The first sensitivity analysis adjusted for significant baseline differences on demographic and clinical predictors of missing values. The results were similar to those from the primary analyses and are summarised in the first column of data in table 4⇓. The mean ICER values are now £5452 per additional QALY, and £107 per one point difference in HADS-T score. Figure 3⇓ shows the cost effectiveness acceptability curve with QALY as the outcome measure: at the lower bound NICE threshold (£20 000), the START intervention has an approximately 95% likelihood of being seen as cost effective, rising to 98% at the £30 000 threshold.

The second sensitivity analysis adjusted for imbalances in baseline characteristics. The results were again quite similar to those from the primary analyses and are summarised in the second column of data in table 4⇓. The mean ICER values from this further analysis are £5756 per additional QALY, and £112 per one point difference in HADS-T score. The cost effectiveness acceptability curve with QALY as the outcome measure is shown in figure 4⇓: at the lower bound NICE threshold (£20 000), the START intervention has a 93% likelihood of being seen as cost effective, rising to 98% at the £30 000 threshold.

The confidence intervals around net monetary benefit for these two sensitivity analyses, taking into account uncertainty in the estimation, suggest a degree of caution in concluding that START is necessarily cost effective.

Discussion

Principal findings

We examined whether eight sessions of manual based coping strategy therapy, delivered over 8-14 weeks by supervised psychology graduates to family carers of people with dementia, added to treatment as usual, was cost effective compared with treatment as usual alone. Over the eight month evaluation period, the START intervention was found to have a high probability of being seen as cost effective by reference to both primary outcome measures examined: improvements in carers' affective symptoms and gains in carers' quality adjusted life years. The sensitivity analyses, considering alternative approaches to the analysis, suggest a more cautious conclusion as to the cost effectiveness of START.

Strengths and limitations of the study

Each carer recruited to the study was scheduled to have eight sessions with the therapist, but some carers had fewer sessions.[9] Although this was taken into account in calculating the costs of the intervention, the impact that different numbers of sessions might have had on carers' outcomes was not the focus of this study.

The evaluation was conducted from a health and social care perspective, and concentrated on outcomes experienced by carers. We did not, therefore, measure the costs of treatment and care services used by the individuals with dementia who were being supported by these carers, nor did we attach monetary values to the time spent by carers in providing support to their relatives. We will examine those wider cost measures, and the outcomes experienced by the patients with dementia, in later work. We will also examine longer term cost effectiveness in later work, as participants in this study are being followed for longer than the eight months considered in this paper.

Sample size for the study design was calculated on the basis of the power required to demonstrate differences in one of the effectiveness measures and not on the basis of costs or cost effectiveness. Although it would have been preferable for the study also to have been powered on an economic variable, this would have required a considerable increase in sample size given that economic measures tend to be highly skewed.[22] In turn, this would have had implications for both the research budget and ethics, since it would have been necessary to recruit participants beyond the point where clinical dominance has been determined. We used cost effectiveness acceptability curves to represent the uncertainty in the estimation of the incremental cost effectiveness ratio.[23]

Comparison with other studies

There is little previous evidence on the cost effectiveness of psychosocial interventions for carers of people with dementia: a recent review found some evidence that such interventions could lead to greater improvements in outcome and also generate cost savings.[24] However, only one of the studies covered by that review employed a similar therapeutic approach to the START intervention: Nichols et al[25] examined the cost effectiveness of a modular multicomponent intervention delivered in carers' homes, with three sessions by telephone, supplemented by five group sessions (five or six carers in each) delivered by telephone. Focusing on hours of care giving, the authors found a significant difference over the six month study period, with carers in the intervention group having more time to dedicate to activities unrelated to care giving, which has potentially positive impacts on emotional wellbeing and quality of life.[26 27]

Implications for policy and practice

The encouraging outcomes from the START trial suggest that a manual based therapy for family carers of people with dementia, delivered by psychology graduates without clinical qualifications, was effective as measured on several dimensions.[9] From the present paper, the intervention is also likely to be perceived as cost effective by reference to NICE thresholds: there is therefore both a clinical and an economic case for supporting carers of people with dementia using such an approach. This cost effectiveness advantage arises because the intervention improved carer outcomes while not significantly increasing overall costs, with the additional cost of the intervention being partly counterbalanced by a reduction in service related costs.

The cost effectiveness finding is driven more by the outcome differences between the groups than the cost difference; for example, at the eight month point, carers in the control group were four times more likely to have clinically significant depression than carers who had received the START intervention.[9] Carers in the intervention group were given information on where to get emotional support and were given techniques to help them to better understand behaviours of the person they cared for, manage behaviour, change unhelpful thoughts, promote acceptance, relax, and engage in meaningful activities. Previous studies have shown that counselling can reduce depression among carers of people with Alzheimer's disease,[28] and long term intensive social work support has the potential to reduce carer burden.[29]

Many countries, including the UK, face rapidly growing numbers of elderly people, while policy frameworks continue to assume that families will remain the frontline providers of (unpaid) care and support. Most people with dementia also prefer to receive support from family members. In these

circumstances, an intervention that is cost neutral, even over a relatively short period, and which significantly improves carer mental health and quality of life should be made more widely available.

Conclusion

The START intervention is cost effective when added to usual care, when costs are measured from the perspective of the health and social care system, and when outcomes are measured in terms of carers' affective symptoms and health related quality of life over an eight month period.

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Contributors: GL, CC, JH, ZW, DL, **SN [QtoA: Is this Shirley Nurock?]**, CM, MK, ELS, and PR contributed to the conception and design of the overall START study, which was led by GL. MK, RR, and DK developed the analytic plan for the economic evaluation. JB and MG analysed the clinical data. BS and MK calculated the costs of services. MK, RR, DK, and BS analysed the economic data. MK, RR, and DK led on preparation of the manuscript. GL, CC, ZW, JH, and CM led recruitment from their trusts. DL was the trial manager. All authors revised the article critically for important intellectual content and gave final approval of the version to be published. The researchers/therapists Monica Manela, Ryan Li, Elanor Lewis-Holmes, Ruth Shanley, Amy Waugh, Lynsey Kelly, Allana Austin, Peter Keohane, Shilpa Bavishi, Amanda Shulman, and Jonathan Bradley collected and entered the data and implemented the manual. Shirley Nurock gave advice throughout as an expert family carer. MK acts as guarantor.

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Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: support from the Health Technology Assessment (HTA) for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Obtained from East London and the City Research Ethics Committee 1 for the trial and Research and Development permission from the local trusts. All participants gave written informed consent.

Declaration of transparency: The lead author (MK) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing: No additional data available

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What is already known on this subject

Family carers are the mainstay of dementia care in the UK

There is little evidence on interventions to support carers that have been shown to be cost effective

What this study adds

Looking at health and social care services used by carers, the START intervention is not more expensive than usual care

The START intervention is cost effective when added to usual care by reference to reductions in carer affective symptoms and improvements in carer health related quality of life.

Tables

Table 1| Carers' use of health and social care services at baseline and at four months and eight months of evaluation period. Values are percentages (numbers) of participants unless stated otherwise

	Baseline		4 Months		8 Months			
Service	Usual treatment (n=87)	Intervention (n=173)	Usual treatment (n=75)	Intervention (n=150)	Usual treatment (n=71)	Intervention (n=134)	Unit cost (£*)	Unit
Outpatient hospital services	33.3 (29)	37.0 (64)	32.0 (24)	38.7 (58)	28.2 (20)	37.3 (50)	18-296	Per attendance†
Community based services:								
Admiral nurse	5.7 (5)	3.5 (6)	2.6 (2)	6.0 (9)	2.8 (2)	3.7 (5)	31	Per hour
Chiropodist	5.7 (5)	13.9 (24)	9.3 (7)	11.3 (17)	12.7 (9)	17.2 (23)	22	Per hour
Counsellor	8.0 (7)	2.3 (4)	9.3 (7)	2.7 (4)	11.3 (8)	1.5 (2)	34	Per hour
Dentist	27.6 (24)	30.6 (53)	29.3 (22)	30.7 (46)	36.6 (26)	33.6 (45)	87	Per attendance‡
General practitioner	54.0 (47)	54.3 (94)	53.3 (40)	50.0 (75)	47.9 (34)	48.5 (65)	28	Per consultation
NHS Direct	1.1 (1)	1.2 (2)	1.3 (1)	0 (0)	0 (0)	1.5 (2)	3	Per hour
Optician	17.2 (15)	16.8 (29)	8.0 (6)	15.3 (23)	21.1 (15)	18.7 (25)	29	Per hour
Outreach worker	1.1 (1)	0.6 (1)	0 (0)	0.7 (1)	1.4 (1)	0 (0)	15	Per hour
Home care worker or care attendant	2.3 (2)	1.7 (3)	4.0 (3)	1.3 (2)	1.4 (1)	1.5 (2)	21	Per weekday hour
Physiotherapist	0 (0)	0.6 (1)	1.3 (1)	0 (0)	0 (0)	2.2 (3)	22	Per hour
Hygienist	0 (0)	0.6 (1)	0 (0)	0.7 (1)	1.4 (1)	0.7 (1)	174	Per hour
Company medical check-up	0 (0)	0.6 (1)	0 (0)	0 (0)	0 (0)	0 (0)	175	Per session§
Nurse (advanced)	1.1 (1)	0.6 (1)	0 (0)	0 (0)	0 (0)	0 (0)	37	Per hour
Occupational therapist	0 (0)	0.6 (1)	0 (0)	0.7 (1)	0 (0)	0 (0)	39	Per hour
Community psychiatrist	0 (0)	0.6 (1)	0 (0)	0 (0)	0 (0)	0 (0)	22	Per hour
Practice nurse	6.9 (6)	2.3 (4)	2.6 (2)	4.7 (7)	0 (0)	5.2 (7)	26	Per hour
Ambulance transport	0 (0)	0 (0)	0 (0)	0.7 (1)	0 (0)	0 (0)	40-246	Per journey¶
Dietician	0 (0)	0 (0)	0 (0)	0.7 (1)	0 (0)	0 (0)	22	Per hour
Other services	16.1 (14)	9.8 (17)	22.7 (17)	14.0 (21)	12.7 (9)	13.4 (18)	3.5-174	Per hour

*Costs at 2009-10 prices.

†Unit cost varies with clinical specialty; for details see appendix A on bmj.com.

‡Attendance assumed to last 30 minutes.

§Session lasts 30 minutes.

¶£40 for transport to hospital; £246 for emergency transport.

Table 2| Health and social service costs and outcomes used in the economic evaluation at 4 and 8 months for carers in the START intervention and usual treatment groups, and differences between the groups. Values are means (standard deviations) unless stated otherwise

Costs and outcomes	Usual treatment		Intervention		Difference (95% CI) for intervention *v* usual treatment over 1–8 months*
	1–4 months	5–8 months	1–4 months	5–8 months	
Costs (£†):	381 (1102)	244 (450)	296 (1006)	262 (598)	−14 (−239 to 211) (n=193)
Outpatient	140 (428)	125 (385)	99 (183)	99 (237)	−42 (−118 to 34)
Community	107 (148)	110 (153)	101 (180)	96 (153)	−7 (−34 to 19)
Other	134 (1028)	9 (36)	96 (845)	68 (461)	27 (−151 to 205)
Outcomes:					
HADS-T‡	14.3 (7.4)	14.9 (8.0)	12.4 (7.4)	12.9 (7.9)	−1.79 (−3.22 to −0.37) (n=220)
EQ-5D	0.77 (0.23)	0.79 (0.14)	0.77 (0.22)	0.76 (0.24)	0.03 (−0.01 to 0.08) (n=212)

HADS-T= Hospital Anxiety and Depression Scale total score. EQ-5D=EuroQol health-related quality of life scale.

*Adjusted for baseline variables

†Costs at 2009-10 prices.

‡HADS-T scores and difference are slightly different from those in related clinical effectiveness paper[9] because different versions of STATA statistical software were used for the analyses.

Table 3| Differences in treatment and cost effects (with 95% confidence intervals corrected for bias) and incremental cost effectiveness ratios between the START intervention and usual treatment groups over 8 month evaluation period

Effect	Mean differences (95% CI) and ICERs
With QALY as outcome (n=177*)	
Incremental health and social care costs (£†)	252 (−28 to 565)
Incremental QALY gain	0.042 (0.015 to 0.071)
ICER (£ per QALY)	6000
With HADS-T as outcome (n=191‡)	
Incremental health and social care costs (£†)	247 (0 to 569)
Incremental HADS-T change	2.10 (0.51 to 3.75)
ICER (£ per unit change on HADS-T)	118

ICER=Incremental cost effectiveness ratio. QALY=quality adjusted life year. HADS-T=Hospital Anxiety and Depression Scale total score.

*Sample size based on complete data for QALY and cost measures.

†Costs at 2009-10 prices.

‡Sample size based on complete data for HADS-T and cost measures.

Table 4| Sensitivity analyses of differences in treatment and cost effects (with 95% confidence intervals) and incremental cost effectiveness ratios between the START intervention and usual treatment groups over 8 month evaluation period

	Mean differences (95% CI) and ICERs	
Effect	**Adjusting for significant demographic and clinical predictors of missing values**	**Adjusting for baseline imbalances**
With QALY as outcome (n=177*)		
Incremental health and social care costs (£†)	229 (−94 to 552)	236 (−101 to 617)
Incremental QALY gain	0.042 (0.014 to 0.070)	0.041 (0.012 to 0.071)
ICER (£ per QALY)	5452	5756
With HADS-T as outcome (n=191‡)		
Incremental health and social care costs (£†)	226 (−74 to 525)	231 (−46 to 583)
Incremental HADS-T change	2.11 (0.41 to 3.81)	2.07 (0.44 to 3.90)
ICER (£ per unit change on HADS-T)	107	112

ICER=Incremental cost effectiveness ratio. QALY=quality adjusted life year. HADS-T=Hospital Anxiety and Depression Scale total score.

*Sample size based on complete data for QALY and cost measures.

†Costs at 2009-10 prices.

‡Sample size based on complete data for HADS-T and cost measures.

Figures

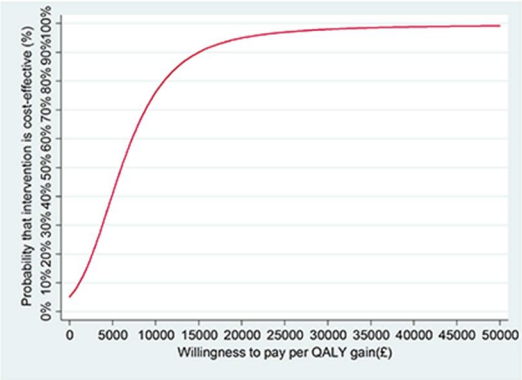

Fig 1 Cost effectiveness acceptability curve: START intervention (manual based coping strategy therapy) versus treatment as usual; health and social care perspective, with effectiveness measured in quality adjusted life year (QALY) gain, over eight months

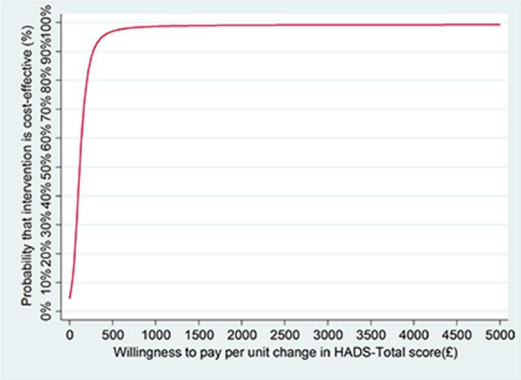

Fig 2 Cost effectiveness acceptability curve: START intervention (manual based coping strategy therapy) versus treatment as usual; health and social care perspective, with effectiveness measured on the Hospital Anxiety and Depression Scale total score (HADS-T), over eight months

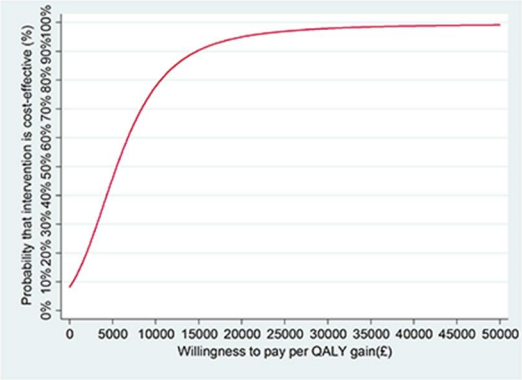

Fig 3 Cost effectiveness acceptability curve: START intervention versus treatment as usual; health and social care perspective, with effectiveness measured in quality adjusted life year (QALY) gain, over eight months, following sensitivity analysis adjusting for significant predictors of missing values

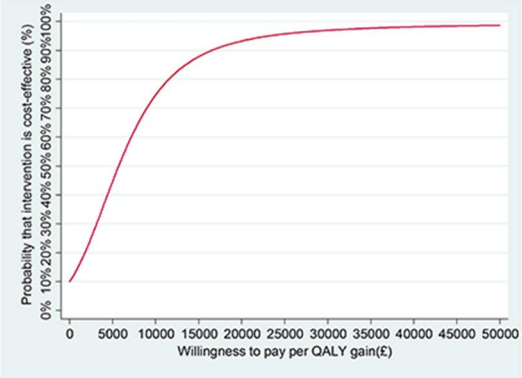

Fig 4 Cost effectiveness acceptability curve: START intervention versus treatment as usual; health and social care perspective, with effectiveness measured in quality adjusted life year (QALY) gain, over eight months, following sensitivity analysis adjusting for baseline imbalances