
This is the published version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: http://openaccess.city.ac.uk/16412/

Link to published version: http://dx.doi.org/10.1136/bmj.f6276

Copyright and reuse: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.
Clinical effectiveness of a manual based coping strategy programme (START, STReAtegies for RelaTives) in promoting the mental health of carers of family members with dementia: pragmatic randomised controlled trial

Gill Livingston professor of older people’s mental health, Julie Barber lecturer in medical statistics, Penny Rapaport principal clinical psychologist, Martin Knapp professor of social policy, Mark Griffin lecturer in medical statistics, Derek King research fellow, Debbie Livingston trial manager, Cath Mummery consultant neurologist, honorary senior lecturer, Zuzana Walker reader in psychiatry of the elderly, Juanita Hoe senior clinical research associate, Elizabeth L Sampson clinical senior lecturer, Claudia Cooper clinical senior lecturer

1Mental Health Science, University College London, London W1W 7EJ, UK; 2Statistical Science and PRIMENT clinical trials unit, University College London, Gower Street, London, UK; 3Camden and Islington NHS Foundation Trust, London, UK; 4Personal Social Services Research Unit, London School of Economics and Political Science, London, UK; 5Institute of Psychiatry, King’s College London, UK; 6Dementia Research Unit, University College London

Abstract
Objective To assess whether a manual based coping strategy compared with treatment as usual reduces depression and anxiety symptoms in carers of family members with dementia.
Design Randomised, parallel group, superiority trial.

Setting Three mental health community services and one neurological outpatient dementia service in London and Essex, UK.
Participants 260 carers of family members with dementia.
Intervention A manual based coping intervention comprising eight sessions and delivered by supervised psychology graduates to carers.
of family members with dementia. The programme consisted of psychoeducation about dementia, carers’ stress, and where to get emotional support; understanding behaviours of the family member being cared for, and behavioural management techniques; changing unhelpful thoughts; promoting acceptance; assertive communication; relaxation; planning for the future; increasing pleasant activities; and maintaining skills learnt. Carers practised these techniques at home, using the manual and relaxation CDs.

**Main outcome measures** Affective symptoms (hospital anxiety and depression total score) at four and eight months. Secondary outcomes were depression and anxiety caseness on the hospital anxiety and depression scale; quality of life of both the carer (health status questionnaire, mental health) and the recipient of care (quality of life-Alzheimer’s disease); and potentially abusive behaviour by the carer towards the recipient of care (modified conflict tactics scale).

**Results** 260 carers were recruited; 173 were randomised to the intervention and 87 to treatment as usual. Mean total scores on the hospital anxiety and depression scale were lower in the intervention group than in the treatment as usual group over the eight month evaluation period: adjusted difference in means −1.80 points (95% confidence interval −3.29 to −0.31; P=0.02) and absolute difference in means −2.0 points. Carers in the intervention group were less likely to have case level depression (odds ratio 0.24, 95% confidence interval 0.07 to 0.76) and there was a non-significant trend towards reduced case level anxiety (0.30, 0.08 to 1.05). Carers’ quality of life was higher in the intervention group (difference in means 4.09, 95% confidence interval 0.34 to 7.83) but not for the recipient of care (difference in means 0.59, −0.72 to 1.89). Carers in the intervention group reported less abusive behaviour towards the recipient of care compared with those in the treatment as usual group (odds ratio 0.47, 95% confidence interval 0.18 to 1.23), although this was not significant.

**Conclusions** A manual based coping strategy was effective in reducing affective symptoms and case level depression in carers of family members with dementia. The carers’ quality of life also improved.

**Trial registration** Current Controlled Trials ISCTRN70017938.

**Introduction**

The number of people living with dementia is rising rapidly owing to increased longevity. Dementia not only affects the person with the condition but also family members and society, through increasing dependence and challenging behaviour. 1 In the United Kingdom, dementia care is estimated to cost £23bn per year, and this is projected to treble in the next 30 years as the number of older people increases. 2 Families and individuals bear the biggest burden; two thirds of people with dementia live at home and receive most of their care from family members, who therefore save the economy a considerable amount of money. 3 About 40% of carers of family members with dementia have clinically significant depression or anxiety, and others have significant psychological symptoms. 4 These symptoms are more common when the family carer is older, a woman, living with the recipient of care, reports a greater carer burden, and the care recipient has more neuropsychiatric symptoms, although they seem unrelated to the severity of the dementia. 5, 6 The psychological morbidity of carers predicts a breakdown in care and therefore the need for placement in a care home 7 as well as elder abuse. 8 Thus improving the psychological health of the carers may not only improve their quality of life but also that of the recipient of their care. In the long term the need for placement in a care home may be delayed and thus bring economic benefits.

Although UK policy recognises that psychological therapy for carers of family members with dementia should be a key component of high quality dementia care, in practice resources are not available, and this is partly because so far effective therapies have been delivered only by highly trained clinical psychologists and evidence on cost effectiveness is lacking. 7 The national agenda in the United Kingdom is to have a stepped care approach to improve access to psychological therapies, where less intensive therapy is delivered by graduates supervised by clinical psychologists. A befriending programme delivered by former carers was ineffective in reducing the carers’ anxiety or depression. 9 The Coping with Caregiving programme was developed in the United States. 10, 11 This manual based group intervention comprising 12 sessions delivered by clinical psychologists has been shown to reduce depression. 12, 13 Therapies individualised to carers seem to be most effective in delaying admission of the recipients of care to a care facility and are more effective than group interventions in reducing morbidity in carers. 12, 13 Interventions that require active participation of caregivers have the greatest effect. 14 We carried out a randomised controlled trial in the United Kingdom to test a manual based therapy for carers of family members with dementia and to test the effectiveness of using psychology graduates without clinical qualifications to deliver therapy to this group.

**Methods**

The supplementary file provides the full protocol of this pragmatic multicentre randomised controlled trial. Our intervention, based on the US Coping with Caregiving programme, was individual and manualised and required active participation. Our primary objective was to determine the clinical effectiveness (measured by the hospital anxiety and depression scale) and cost effectiveness (reported in an accompanying paper 9 ) of eight sessions of a manual based coping strategy, delivered over 8-14 weeks by supervised psychology graduates to carers of family members with dementia, compared with usual service provision, over eight months.

The secondary outcomes were depression and anxiety caseness on the hospital anxiety and depression scale; quality of life of both the carer and the recipient of the care; and abusive behaviour by the carer. We plan on analysing time to entry to 24 hour care of the family member with dementia at longer term follow-up (at two and seven years).

**Recruitment and follow-up**

We recruited carers to the trial from 4 November 2009 to 8 June 2011. The first four month follow-up took place on 4 March 2010, with the final eight month follow-up on 7 February 2012.

**Setting**

We recruited through disparate settings: two mental health trusts’ memory services (Camden and Islington Foundation Trust, urban setting; North Essex Partnership Foundation Trust, suburban and rural); the North East London Foundation Trust Admiral nurse, suburban (specialist nurses for carers of family members with dementia); and the Dementia Research Centre-National Hospital for Neurology and Neurosurgery, a tertiary service with a high rate of referrals for young people with early onset dementia.

**Participants**

We included carers of family members referred in the previous year who provided emotional or practical support at least weekly and identified themselves as the primary carer of a family...
member with dementia not living in 24 hour care. We excluded
carers who were unable to give informed consent to the trial,
were currently taking part in a randomised controlled trial in
their capacity as a carer, or who lived more than 1.5 hours
travelling time from the researchers’ base. We administered the
mini-mental state examination to carers aged 60 or over only
at baseline. If they scored less than 24 the research assistant
discussed the participant with GL or CC to see whether this was
related to cognition, mood, or education. If carers were judged
to have a dementia they were not included in the study and we
informed the referring clinician.

Procedure
Prospective participants were initially approached by a clinician and
given or sent an information sheet. Those interested in
participating were referred to the research team. The referral
gave the name, sex, and relationship to the family member of
the prospective participant as well as the patient’s sex. The
researchers telephoned the carer 24 hours or more after they
received the information sheet. The researchers answered any
questions and then arranged to meet those who agreed to take
part to obtain their informed consent and complete baseline
assessment before randomisation.

Allocation to trial groups
To conceal allocation we used an online computer generated
randomisation system to allocate participants to the intervention
or to treatment as usual. This system was set up and maintained
by an independent clinical trials unit and accessed by the START
trial manager. Randomisation was stratified by trust using
random permuted blocks. To allow for potential clustering
effects in the intervention arm we used an allocation ratio of
2:1 (intervention: treatment as usual). A member of the therapy
team then phoned the participants and informed them of their
allocation, either to treatment as usual when they would be
contacted for a four month follow-up or to the intervention when
an appointment was made for the therapy to start. Allocation
within the individual teams was according to workload.

Assessments
Carers were interviewed at baseline and at four and eight months
after randomisation, usually in their own home, unless they
preferred to come to the research team base in University
College London. We have continued to follow up carers, asking
them to remain in the study for two years even if the recipient
of their care had been placed in a care home or died. Results of
this longer term follow-up will be reported separately.
Information collected at baseline consisted of sociodemographic
details about the carer and recipient of the care; and clinical and
resource use items (as detailed in the accompanying paper). At
both the four and eight month follow-up we repeated the
collection of clinical and resource use information.
Sociodemographic details obtained at baseline included age,
sex, ethnicity, relationship to the recipient of care (for example,
spouse, child), level of education, last occupation, and living
situation.
Measures regarding the carer’s health and wellbeing collected
at all three study time points were:

- The hospital anxiety and depression scale, a self
  completed scale, which has been validated for all age
  groups and settings, in people who are physically well or
  unwell, and in Asian and African ethnic groups. The scale
determines caseness of depression and anxiety with scores
ranging from 0 to 21 and as a total score ranging from 0
to 42 (higher scores indicating more symptoms). We chose
the total score as our primary outcome because it has a
better sensitivity and positive predictive value than either of
the individual scales in identifying depression when
compared with the international classification of diseases
criteria. The anxiety and depression score was also
dichotomised as “case” and “non-case,” with a cut-off point
of 8/9.
- The Zarit burden interview, a 22 item self report
  questionnaire, is the most consistently used measure of
  burden in carers; scores range from 0 to 88, with higher
  scores indicating more burden.
- The modified conflict tactics scale is a self completed
  measure of potentially abusive behaviour by carers towards
  the recipient of their care. Ten behaviours are scored as
to whether, during the previous three months, these have
occurred never (0), almost never (1), sometimes (2), most
of the time (3), or all of the time (4), and these items can
be added to make a score. These behaviours range from
shouting to threatening to shaking or slapping. A score of
2 or more on any one of the items is classified as an abusive
behaviour. If participants scored this on any item, we
discussed the score with a supervising clinician and if it
was judged that the recipient of care was at risk, permission
was asked to inform the clinical team so that the carer and
recipient of care could have appropriate help.
- Health status questionnaire, mental health domain,
  measures health related quality of life throughout the age
  ranges and is sensitive to change. It is summarised as a
  continuous score, ranging from 0 to 100, with higher scores
indicating better outcome.
- The brief COPE, a self completed measure of coping
  strategies by the carer, validated in carers of family
members with dementia, with subscales that measure
problem focused, emotion focused, and dysfunctional
  coping.

At all time points, we also asked carers for information about the
recipient of their care:

- The neuropsychiatric inventory is a validated instrument
  with 12 symptom domains that are scored for their severity
  and frequency and summarised as a single continuous score
  (higher scores indicating worse symptoms). We included
  this tool as neuropsychiatric symptoms have been shown
to be associated with psychological morbidity of carers.
- The clinical dementia rating, which we used as an
informant instrument, grades the level of impairment of
someone with dementia (categories: healthy, very mild,
mild, moderate, severe).
- Quality of life-Alzheimer’s disease was rated by the
carers, to assess the family member’s overall quality of
life. The total score ranges from 13 to 52, with higher
scores indicating better outcome.

Blinding
We blinded outcome assessors to randomisation status, but it
was not possible to blind the study participants. The researchers
worked in two teams, each assessing outcomes for
approximately half the participants and providing therapy to
those allocated to treatment in the half of participants they were
not assessing. Assessors asked participants at the beginning of
each interview not to disclose their allocation group.
Therapy intervention

With the first author’s permission, we developed an individual therapy programme (START, StrAtegies for RelaTives) based on the Coping with Caregiving programme from the United States. We adapted it for UK use for individual carers of family members with dementia over eight sessions (box). The therapy took place where the carers preferred, usually in their homes, without the family member with dementia in the room. The therapy was carried out with an interpreter if the carer did not speak English fluently.

Training and delivery

We employed and trained psychology graduates with no clinical training to deliver the intervention. The training programme had a strong practical focus on how to deliver the therapy, potential clinical dilemmas, working with interpreters, empathic listening skills, effective use of supervision, and when to ask for help. We trained the therapists to adhere to the manual and required them to demonstrate, by role play, competence in delivering each session of the intervention. Our clinical psychologist (PR) met with each team of therapists for 1.5 hours of group clinical supervision every fortnight. She also had one hour of dedicated time per week for individual consultation as needed by the therapists. The therapists recorded one therapy session per participant, selected at random, and a researcher not involved in the therapy used a standard checklist to rate the session for fidelity to the manual. Overall fidelity scores ranged from 1 to 5, with 5 being high. If fidelity scores were not high, the supervising clinical psychologist discussed this in supervision.

Treatment as usual

In the treatment as usual group, services were based around the family member with dementia. Standard treatment concerns medical, psychological, and social issues. Thus the treatment consisted of assessment, diagnosis, and information; drug treatment; cognitive stimulation therapy; practical support; treatment of neuropsychiatric and cognitive symptoms; and carer support. In each setting, treatments aimed to be in line with the clinical guidelines for good dementia care of the National Institute for Health and Care Excellence.33

Power calculation

This study was originally powered for a primary outcome of anxiety score on the hospital anxiety and depression scale based on data from a cross sectional pilot study of carers of family members with dementia. Mean anxiety scores for this group were 7.2 (SD 4) points. We considered a decrease of 2 points in mean score and 0.5 change in standard deviation to be clinically significant (expert consensus). To detect such a difference with 90% power at a 5% significance level, we required 75 participants in each group. To account for therapist clustering, we used a design effect of 1.87 for the intervention arm (using an intracluster correlation of 0.0333 and the observed average cluster size of 15 carers for each therapist).

Statistical analysis

In the primary analysis we used regression methods to estimate group differences in total score on the hospital anxiety and depression scale over the eight month follow-up. We used random effects models to account for the therapist clustering in the intervention arm and repeated measurements at four and eight months. We adjusted for baseline total score and centre (on which randomisation was stratified) and also on factors believed to affect affective symptoms (carer’s age, sex, carer burden, and neuropsychiatric symptoms of the recipient of the care). We carried out all analyses by intention to treat but excluded carers with data missing at both the four and the eight month follow-up.

We used sensitivity analyses to reanalyse the primary outcome and to assess robustness of our conclusions. Analyses considered adjustment for imbalances in baseline characteristics between the randomised groups and the differential effects of treatment over time (treatment by time interaction). Using logistic regression we also investigated the extent to which missing outcomes varied by baseline characteristics; we then repeated the main analyses adjusting for those factors associated with missingness.

We applied similar approaches for analysis of the secondary outcomes. For binary outcomes we used random effects logistic regression. We compared entry of the family member with dementia to 24 hour care between groups using a simple comparison of proportions (not allowing for clustering) because of small numbers.

All statistical analyses followed a predefined analysis plan and were carried out using STATA version 11.

Results

The figure shows the recruitment and flow of participants in the trial. Of the 450 carers eligible for the study, 260 (58%) consented to take part in the trial; the remained refused to participate or were not contactable. The numbers recruited from individual trusts were: Camden and Islington Foundation Trust n=183, North East London Foundation Trust n=16, Dementia Research Centre n=35, and North Essex Partnership Foundation Trust n=26. Table 1 compares the known personal details of those who consented and those who did not and shows that the study sample had good external validity. Those who consented were, however, slightly more likely to be married or partnered with the recipient of care than those who did not consent. Overall, 173 (67%) participants were randomised to the intervention group and 87 to treatment as usual. In general, the randomised groups were well balanced for patient and baseline carer personal and clinical characteristics (tables 2 and 3).
Employment status, however, appeared imbalanced, with a higher proportion of retired carers in the intervention group. Carers in the intervention group were also slightly older and included a higher proportion of those currently unmarried. Higher proportions of carers in the intervention group were living with the recipient of care, were spouses or partners, and with either no school level qualifications or tertiary education. In terms of clinical characteristics those in the intervention group less frequently had case level anxiety and had slightly lower anxiety scores and total scores on the hospital anxiety and depression scale.

The 10 therapists (seven women) in the intervention arm each saw between 11 and 32 participants. All the therapists were psychology graduates with no further clinical training and aged 20-35 years.

**Treatment fidelity and participant follow-up**
Over the eight months after baseline, 10 carers from the control group and 21 from the intervention group were withdrawn or lost to follow-up (figure). These included two who died (one from each group). In the intervention group one carer gave inconsistent data and was withdrawn by the team, and one was in prison. The participants gave several reasons for withdrawal: wanted treatment but not allocated to it (four, treatment as usual), could not feel the intervention was for them (three, intervention), too busy (four, intervention; one, treatment as usual), disliked talking about the recipient of care without him or her present (one, treatment as usual; one, intervention), other family member wanted them to withdraw (one, treatment as usual), unwell (one, intervention), recipient of care died (one, treatment as usual), and trial to upset (intervention). Six gave no reason (five, intervention; one, treatment as usual). Three others did not participate and were not contactable at the four or eight month follow-up, but have since come back to the study.

Overall, 128 participants in the intervention group agreed to a therapy session being audio-recorded to assess fidelity to the manual (from 1 for poor to 5 for excellent); 100 (78%) rated fidelity as 5, 20 (16%) as 4, five as 3, and three as 2.

Of the eight therapy sessions offered, five or more were attended by 130 (75%) carers in the intervention group (table 4). Eight (5%) of those in the intervention group withdrew before taking part in any therapy sessions. Adherence (attending ≥5 sessions) was better in those of white ethnicity compared with other ethnicity (n=110 (78%) v n=19 (61%)) and slightly better for male compared with female carers (46 (81%) v 84 (72%)) and those with at least A level education (56 (80%) v 74 (72%)).

**Primary and secondary clinical outcome results**
Table 5 summarises average scores at months 4 and 8, and gives the estimated effect of therapy versus treatment as usual for primary and secondary outcomes.

Analysis of the total score on the hospital anxiety and depression scale, adjusting for centre and baseline score and for factors related to outcome (carers’ age and sex, neuropsychiatric inventory score, and Zarit burden interview score) showed a mean difference of −1.80 points (95% confidence interval −3.29 to −0.31 points; P=0.02) in favour of the intervention. If the model did not include factors relating to outcome then the results were similar, with an average decrease in score of −1.46 (−2.89 to −0.03); P=0.05). The therapist intracluster correlation at four months was 0.02 (95% confidence interval 0.00 to 0.09) and at eight months was 0.00 (0.00 to 0.08). Sensitivity analyses adjusting for significant personal and clinical predictors of missing values—namely, recipient of care living with carer, relationship to carer, carer having dependent children at home, ethnicity of recipient of care, and COPE dysfunction score—gave similar results (mean difference −1.53, 95% confidence interval −2.96 to −0.10) as did analyses adjusting for baseline imbalances—namely, carer’s work situation, relationship to carer and recipient of care, and carer’s education and living situation (mean difference −1.78, −3.30 to −0.27). Models including an interaction with time showed no evidence of a differential effect of the intervention between the four and eight month time points (P=0.90). Models for the individual anxiety and depression continuous scales also showed evidence of beneficial effects of the intervention (table 5).

**Secondary outcomes**
Depression and anxiety caseness—a reduction in the odds of cases of depression on the hospital anxiety and depression scale in the intervention group compared with treatment as usual was significant, with an odds four times higher for the treatment as
usual group (odds ratio 0.24, 95% confidence interval 0.07 to 0.76). Similarly there was some evidence for a reduction in odds of caseness on the hospital anxiety and depression scale (0.30, 0.08 to 1.05).

**Significant abuse**—there was some evidence of a decrease in abusive behaviour on the modified conflict tactics scale (odds ratio 0.48, 0.18 to 1.27).

**Quality of life of carer and recipient of care**—There was no significant difference between the groups for overall quality of life for the family members with dementia. The health status questionnaire, mental health scale for the carer did, however, indicate significantly higher average scores and hence improved mental health (mean difference 4.09, 95% confidence interval 0.34 to 7.83).

**Entry of family members with dementia to 24 hour care**

Fourteen family members with dementia were admitted to a care home during the eight month follow-up period; three (4%) in the treatment as usual group and 11 (6%) in the intervention group. Simple analyses indicate no evidence of a statistically significant difference between the groups (Fishers exact test P=0.56). This outcome will be considered more extensively in analyses of longer term follow-up. Cost effective results are reported in the accompanying paper.

**Discussion**

Carers of family members with dementia referred to secondary or tertiary care benefit from a structured psychological intervention delivered by psychology graduates, supervised by clinical psychologists. The effect size in terms of the total mean affective symptoms was small, but previous evidence where researchers set out to calculate what a clinically important difference would be on the hospital anxiety and depression scale, suggests that treatment effects are in the range that is important to patients. Incidence of clinical depression increased in the treatment as usual group but not in the intervention group and the odds ratios indicate that at follow-up, those in the treatment as usual group were four times more likely to have clinically significant depression, suggesting the intervention is clinically important. In keeping with this, the quality of life improved for carers. We thought that in the long term this intervention may also delay admission to care homes for people with dementia and therefore increase their quality of life. This short term follow-up over eight months did not show that but we plan to continue collecting data at two years and for care home admission over the following five years, and we will reconsider this effect.

**Strengths and limitations of this study**

This was a pragmatic study with broad inclusion criteria, including participants from a range of settings and backgrounds, with varied personal characteristics, suggesting the results are generalisable and directly relevant to the National Health Service. Further evidence of external validity is the similarity in characteristics between those who did and did not consent. The intervention is standardised, and the high fidelity ratings and the low intracluster correlations within therapists suggested that the intervention can be delivered consistently. The follow-up rate of 88.1% overall was satisfactory, with similar rates in both arms. The instruments were validated and standardised.

The levels of anxiety and depressive symptoms, case level anxiety and depression, neuropsychiatric symptoms, and carer abusive behaviour were slightly higher than in a recent cohort study of newly referred people with dementia, so those with more problems may have been more likely to consent to the study. We informed the clinical teams about abusive behaviour of the carers in the treatment as usual group when there was not an intervention in place and thus may have improved the outcome for that group. Although randomisation was independent and follow-up raters were blinded to allocation, the carers inevitably knew to which group they had been randomised. We found it difficult to deliver the therapy to people who did not speak English, although only four such carers were in the study, three of whom were in the intervention group. In retrospect, we did not allow enough time and budget to translate the whole manual and deliver the therapy with translators. As translating the manual is a one-off process, this will be less of a problem as we come to implement our findings in the NHS.

**Comparisons with other studies and meaning and implications of this study**

Other recent psychosocial interventions have been, in contrast, ineffective for both carer psychological symptoms and quality of life; thus showing our findings were not explained by the offer of a therapist to spend time and attention. Our study is consistent with the US study from which we derived the intervention, in that a similar intervention helped depressive symptoms in carers, but it was more practical for many carers as we did not require them all to come to a group session at the same time. It was deliverable by psychology graduates without previous clinical training—a group who are relatively inexpensive and available. Within the United States, a similar therapy to ours delivered at an individual level was found to be significantly cost effective in completers compared with controls for freeing up time spent on care. We are not aware of any other interventions in this group for which health economic evaluations have been undertaken and this is in our accompanying paper. In our earlier studies we found that family carers tended to become more anxious and depressed over time without intervention, and that this was associated with an increase in abusive behaviour, and thus we included carers who were not depressed at presentation to services. The preventive effect that was found highlights that these carers can benefit from early intervention.

The intervention was effective in the short term and acceptable to most participants, who made time for it despite their care commitments, and often also being employed or unwell themselves. We found little evidence of harm with withdrawal from the treatment, being at a similar rate to withdrawal from the treatment as usual arm, although one carer said they found the therapy too upsetting and three thought it was not for them. We think memory services should consider offering the intervention as part of the routine management of dementia, and it is being piloted by our local services. Our group has developed the training and the manual is available (see supplementary file). Currently, no interventions have been shown to reduce the abuse of elders. Our study was not powered to find a significant change in abuse, and for ethical reasons we made clinicians aware of abuse in the control group; thus carers were often offered clinical and social support.

**Unanswered questions and future research**

This study reports short term outcomes for carers and that there was no evidence of a difference between groups at four and eight months, thus possibly suggesting some lasting effect. In one study, continued therapy led to improvement in carers’
mental health over years and a reduction in nursing home admissions for patients, but we do not yet know whether our short therapeutic intervention to change strategies will also be effective in the longer term.42

We are following this cohort to answer these questions. In addition, the effect on abuse is promising but more work is required for confirmation of this effect. The longer term outcome may help to clarify this situation.

Conclusions

The intervention was clinically effective for the impact on carers in the short term. Further follow-up will consider longer term effects on carers’ mood, quality of life, and abusive behaviour, and on cost effectiveness, and whether, as in other longer term studies, patients’ time to care home admission has been lengthened.43

We thank Dolores Gallagher Thompson for her original manual and allowing us to change it; the participating carers; the Camden and Islington NHS Foundation Trust, University College London Hospital, the North East London Foundation Trust, and the North Essex Partnership Professoriate; Vincent Kirchner and Lisa Gee for referring many patients; members of the steering committee: Joanna Murray (chair), Thana Balamurali, Kate Maxmin, Lynne Ramsay, Mabel Saill, and Lynis Lewis; and the data monitoring committee: Damien Catena (chair) and U Hia Htay. The Start research team acknowledges the support of the National Institute for Health Research, through the Dementia and Neurodegenerative Research Network (DeNDRoN).

Contributors: GL, CC, JH, ZW, DL, SN, CM, MK, ELS, and PR contributed to the conception and design of the study. GL, CC, JH, ZW, JB, and MG contributed to the analytic plan. JB and MG analysed the clinical data. GL, CC, JH, ZW, and CM led recruitment from their trusts. GL drafted the article and JB, PR, MK, MG, DK, DL, CM, ZW, JH, ELS, and CC revised it 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 Keochane, 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. GL will act as guarantor.

Funding: This project was funded by the National Institute for Health Research Health Technology Assessment (HTA) programme (project No 08/14/06) and will be published in full in Health Technology Assessment. Further information on the project is available at www.ncbi.nlm.nih.gov/projects/hta/081406. The authors analysed results and prepared this manuscript independently of the funding body. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, National Institute for Health Research, National Health Service, or the Department of Health. The study was sponsored by University College London. Neither funders nor sponsors had a role in the study design and the collection, analysis, and interpretation of data and the writing of the article and the decision to submit it for publication. The researchers were independent from funders and sponsors. All researchers could access all the data.

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

Ethical approval: The trial was conducted in accordance with Good Clinical Practice guidelines, the Declaration of Helsinki, the Clinical Trials Regulations and local laws and regulations. We obtained ethics approval for the study from East London and the City Research Ethics Committee 1 for the trial (ID: 09/H0703/84) and Research and Development permission from the local trusts. All participants gave written informed consent.

Data sharing: No additional data available.

Transparency: The lead author 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. The lead author in this statement is the study guarantor.

15. Pinquart M, Sörensen S. Helping caregivers of persons with dementia: which interventions work and how large are their effects? Int Psychogeriatr 2006;18:577-95.
26. Carver CS. You want to measure coping but your protocol’s too long: consider the brief COPE. J Behav Med 1997;20:3-40.
What is already known on this topic

About 40% of carers of family members with dementia have clinically significant depression or anxiety, and others have significant psychological symptoms.

A manual based group intervention delivered by clinical psychologists in the United States has been shown to reduce depression.

Effective therapies have so far only been delivered by highly trained clinical psychologists.

What this study adds

A manual based coping strategy programme can be delivered by graduate psychologists without clinical training.

The intervention was effective in reducing affective symptoms and case level depression of carers of family members with dementia.


**Accepted:** 30 September 2013

Cite this as: *BMJ* 2013;347:f6276

This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 3.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/3.0/.
### Table 1: External validity of eligible carers who consented to the trial compared with those who were not randomised

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Not randomised (n=190)</th>
<th>Randomised (n=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male carers</td>
<td>56 (29)</td>
<td>82 (32)</td>
</tr>
<tr>
<td>Male recipients of care</td>
<td>75 (39)</td>
<td>108 (42)</td>
</tr>
<tr>
<td>Carers relationship to recipient of care:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse or partner</td>
<td>65 (34)</td>
<td>109 (42)</td>
</tr>
<tr>
<td>Child</td>
<td>90 (47)</td>
<td>113 (44)</td>
</tr>
<tr>
<td>Friend</td>
<td>8 (4)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Daughter’s or son’s partner</td>
<td>4 (2)</td>
<td>12 (5)</td>
</tr>
<tr>
<td>Nephew or niece</td>
<td>8 (4)</td>
<td>8 (3)</td>
</tr>
<tr>
<td>Grandchild</td>
<td>4 (2)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Sibling</td>
<td>5 (3)</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>6 (3)</td>
<td>2 (1)</td>
</tr>
</tbody>
</table>
### Table 2: Baseline personal characteristics of carers and family members with dementia by randomisation group. Values are numbers (percentages) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Carers Treatment as usual group (n=87)</th>
<th>Carers Intervention group (n=173)</th>
<th>Recipients of care Treatment as usual group (n=87)</th>
<th>Recipients of care Intervention group (n=173)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age (years) (range)</td>
<td>56.1 (12.3) (27-89)</td>
<td>62.0 (14.6) (18-88)</td>
<td>78.0 (9.9) (53-96)</td>
<td>79.9 (8.3) (55-95)</td>
</tr>
<tr>
<td>Women</td>
<td>62 (71)</td>
<td>116 (67)</td>
<td>50 (57)</td>
<td>102 (59)</td>
</tr>
<tr>
<td>Men</td>
<td>25 (29)</td>
<td>57 (33)</td>
<td>37 (43)</td>
<td>71 (41)</td>
</tr>
<tr>
<td>Ethnicity:</td>
<td></td>
<td>n=172</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White UK</td>
<td>65 (75)</td>
<td>131 (76)</td>
<td>61 (70)</td>
<td>126 (73)</td>
</tr>
<tr>
<td>White other</td>
<td>5 (6)</td>
<td>10 (6)</td>
<td>6 (7)</td>
<td>14 (8)</td>
</tr>
<tr>
<td>Black and in minority ethnic group</td>
<td>17 (20)</td>
<td>31 (18)</td>
<td>20 (23)</td>
<td>33 (19)</td>
</tr>
<tr>
<td>Marital status:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not currently married</td>
<td>25 (29)</td>
<td>61 (35)</td>
<td>47 (54)</td>
<td>92 (53)</td>
</tr>
<tr>
<td>Married or cohabiting</td>
<td>62 (71)</td>
<td>112 (65)</td>
<td>40 (46)</td>
<td>81 (47)</td>
</tr>
<tr>
<td>Education:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No qualifications</td>
<td>18 (21)</td>
<td>45 (26)</td>
<td>44 (51)</td>
<td>73 (45)</td>
</tr>
<tr>
<td>School level qualifications</td>
<td>33 (38)</td>
<td>51 (29)</td>
<td>16 (19)</td>
<td>28 (17)</td>
</tr>
<tr>
<td>Further education</td>
<td>36 (41)</td>
<td>77 (45)</td>
<td>26 (30)</td>
<td>63 (38)</td>
</tr>
<tr>
<td>Employment status:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>28 (32)</td>
<td>36 (21)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Part time</td>
<td>20 (23)</td>
<td>27 (16)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Retired</td>
<td>23 (26)</td>
<td>80 (46)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Not working</td>
<td>16 (18)</td>
<td>30 (17)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Living with carer</td>
<td>NA</td>
<td>NA</td>
<td>50 (57)</td>
<td>113 (65)</td>
</tr>
<tr>
<td>Relationship to recipient of care:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse or partner</td>
<td>31 (36)</td>
<td>78 (45)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Child</td>
<td>42 (48)</td>
<td>71 (41)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>14 (16)</td>
<td>24 (14)</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA = not applicable.
Table 3 Baseline clinical characteristics of carers and family members with dementia by randomisation group. Values are means (standard deviations) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Carers</th>
<th>Recipients of care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment as usual group (n=87)</td>
<td>Treatment as usual group</td>
</tr>
<tr>
<td></td>
<td>Intervention group (n=172)</td>
<td>Intervention group</td>
</tr>
<tr>
<td>HADS scale:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>14.8 (7.4)</td>
<td>NA</td>
</tr>
<tr>
<td>Anxiety</td>
<td>9.3 (4.3)</td>
<td>NA</td>
</tr>
<tr>
<td>Depression</td>
<td>5.5 (3.9)</td>
<td>NA</td>
</tr>
<tr>
<td>Quality of life-Alzheimer’s disease</td>
<td>NA</td>
<td>29.9 (6.9) (n=87)</td>
</tr>
<tr>
<td>Health status questionnaire (mental health)</td>
<td>58.2 (21.7)</td>
<td>30.2 (6.9) (n=170)</td>
</tr>
<tr>
<td>Total scores:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCTS scale</td>
<td>2.7 (3.1)</td>
<td>NA</td>
</tr>
<tr>
<td>Zarit burden interview</td>
<td>38.1 (17.0) (n=84)</td>
<td>NA</td>
</tr>
<tr>
<td>Neuropsychiatric inventory</td>
<td>NA</td>
<td>26.6 (20.1) (n=86)</td>
</tr>
<tr>
<td>Clinical dementia scale</td>
<td>NA</td>
<td>24.0 (19.0) (n=171)</td>
</tr>
<tr>
<td>HADS anxiety case (No (%) scoring ≥9)</td>
<td>48 (55)</td>
<td>NA</td>
</tr>
<tr>
<td>HADS depression case (No (%) scoring ≥9)</td>
<td>17 (20)</td>
<td>NA</td>
</tr>
<tr>
<td>MCTS (No (%) with at least 1 item scoring ≥2)</td>
<td>38 (44)</td>
<td>NA</td>
</tr>
</tbody>
</table>

HADS= hospital anxiety and depression scale; MCTS= modified conflict tactics scale; NPI= neuropsychiatric inventory.
<table>
<thead>
<tr>
<th>No of sessions attended</th>
<th>No (%) of carers</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>8 (5)</td>
</tr>
<tr>
<td>1</td>
<td>9 (5)</td>
</tr>
<tr>
<td>2</td>
<td>11 (6)</td>
</tr>
<tr>
<td>3</td>
<td>8 (5)</td>
</tr>
<tr>
<td>4</td>
<td>7 (4)</td>
</tr>
<tr>
<td>5</td>
<td>3 (2)</td>
</tr>
<tr>
<td>6</td>
<td>1 (1)</td>
</tr>
<tr>
<td>7</td>
<td>1 (1)</td>
</tr>
<tr>
<td>8</td>
<td>125 (72)</td>
</tr>
<tr>
<td>Total</td>
<td>173 (100)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Treatment as usual group</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td></td>
<td>4 months</td>
</tr>
<tr>
<td>HADS total score</td>
<td>14.3 (7.4) (n=75)</td>
</tr>
<tr>
<td>Quality of life-Alzheimer’s disease</td>
<td>29.8 (5.8) (n=66)</td>
</tr>
<tr>
<td>Health status questionnaire (mental health)</td>
<td>58.4 (18.0) (n=72)</td>
</tr>
<tr>
<td>HADS:</td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>8.6 (4.2) (n=75)</td>
</tr>
<tr>
<td>Depression</td>
<td>5.7 (4.0) (n=75)</td>
</tr>
<tr>
<td>Anxiety case (No (%) scoring ≥9)</td>
<td>36 (48) (n=75)</td>
</tr>
<tr>
<td>Depression case (No (%) scoring ≥9)</td>
<td>18 (24) (n=75)</td>
</tr>
<tr>
<td>MCTS (No (%) with at least 1 item scoring ≥2)</td>
<td>28 (41) (n=69)</td>
</tr>
</tbody>
</table>

Treatment effect estimates (differences and odds ratios) are from models taking into account repeated measurements and therapist clustering in intervention arm and that are adjusted for baseline characteristics.

HADS=hospital anxiety and depression scale, MCTS=modified conflict tactics scale.

*Adjusted for baseline score and centre.
†Adjusted also for carers’ age, sex, neuropsychiatric inventory score, and Zarit burden interview.
‡Odds ratio.
Figure

Flow of participants through study

Enrollment

Assessed for eligibility (n=472)

Excluded (n=212) Did not meet inclusion criteria (n=22), Declined to participate (n=181), Could not be contacted (n=9)

Randomised (n=260)

Allocated to intervention (n=173) Received at least 1 session (n=166), received at least 5 sessions (n=130)
Allocated to treatment as usual (n=87) Received allocated intervention (n=87)

4 month follow-up

Lost to 4 month follow-up (n=13) Carer died (n=1), withdrawn (n=10) inconsistent data (n=1), in prison (n=1)

Lost to 4 month follow-up (n=19) Carer died (n=1), withdrawn (n=8)

8 month follow-up

Further losses by 8 month follow-up (n=8) Withdrawn (n=8)

Further losses by 8 month follow-up (n=2) Withdrawn (n=2)

Primary analysis

Analysed for primary outcome (n=152; 87.9%) Excluded from analysis (n=21) Withdrawn (n=11), missing data (n=7), carer died (n=1), inconsistent data (n=1), in prison (n=1)

Analysed for primary outcome (n=77; 87.5%) Excluded from analysis (n=10) Withdrawn (n=9), carer died (n=1)