

START (STrAtegies for RelaTives) study: a pragmatic randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of a manual-based coping strategy programme in promoting the mental health of carers of people with dementia

Gill Livingston, Julie Barber, Penny Rapaport, Martin Knapp, Mark Griffin, Renee Romeo, Derek King, Debbie Livingston, Elanor Lewis-Holmes, Cath Mummery, Zuzana Walker, Juanita Hoe and Claudia Cooper



***National Institute for
Health Research***

START (STrAtegies for RelaTives) study: a pragmatic randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of a manual-based coping strategy programme in promoting the mental health of carers of people with dementia

Gill Livingston,^{1,2*} Julie Barber,³ Penny Rapaport,^{1,2}
Martin Knapp,^{4,5} Mark Griffin,¹ Renee Romeo,⁵
Derek King,⁴ Debbie Livingston,¹
Elanor Lewis-Holmes,¹ Cath Mummery,⁶
Zuzana Walker,^{1,7} Juanita Hoe¹ and Claudia Cooper^{1,2}

¹Division of Psychiatry, University College London, London, UK

²Services for Ageing and Mental Health, Camden and Islington NHS Foundation Trust, London, UK

³Department of Statistical Science and PRIMENT Clinical Trials Unit, University College London, London, UK

⁴Personal Social Services Research Unit, London School of Economics and Political Science, London, UK

⁵Institute of Psychiatry, King's College London, London, UK

⁶Queen Square, University College London Hospitals NHS Foundation Trust, London, UK

⁷North Essex Partnership University NHS Foundation Trust, Chelmsford, UK

*Corresponding author

Declared competing interests of authors: none

Published October 2014

DOI: 10.3310/hta18610

This report should be referenced as follows:

Livingston G, Barber J, Rapaport P, Knapp M, Griffin M, Romeo R, *et al.* START (STrategies for RelaTives) study: a pragmatic randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of a manual-based coping strategy programme in promoting the mental health of carers of people with dementia. *Health Technol Assess* 2014;**18**(61).

Health Technology Assessment is indexed and abstracted in *Index Medicus/MEDLINE*, *Excerpta Medica/EMBASE*, *Science Citation Index Expanded (SciSearch®)* and *Current Contents®/Clinical Medicine*.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: <http://www.nets.nihr.ac.uk/programmes/hta>

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/14/06. The contractual start date was in September 2009. The draft report began editorial review in December 2013 and was accepted for publication in April 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

© Queen's Printer and Controller of HMSO 2014. This work was produced by Livingston *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Editor-in-Chief of *Health Technology Assessment* and NIHR Journals Library

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Health Sciences Research, Faculty of Education, University of Winchester, UK

Professor Jane Norman Professor of Maternal and Fetal Health, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, University College London, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk

Abstract

START (STrAtegies for RelaTives) study: a pragmatic randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of a manual-based coping strategy programme in promoting the mental health of carers of people with dementia

Gill Livingston,^{1,2*} Julie Barber,³ Penny Rapaport,^{1,2} Martin Knapp,^{4,5} Mark Griffin,¹ Renee Romeo,⁵ Derek King,⁴ Debbie Livingston,¹ Elanor Lewis-Holmes,¹ Cath Mummery,⁶ Zuzana Walker,^{1,7} Juanita Hoe¹ and Claudia Cooper^{1,2}

¹Division of Psychiatry, University College London, London, UK

²Services for Ageing and Mental Health, Camden and Islington NHS Foundation Trust, London, UK

³Department of Statistical Science and PRIMENT Clinical Trials Unit, University College London, London, UK

⁴Personal Social Services Research Unit, London School of Economics and Political Science, London, UK

⁵Institute of Psychiatry, King's College London, London, UK

⁶Queen Square, University College London Hospitals NHS Foundation Trust, London, UK

⁷North Essex Partnership University NHS Foundation Trust, Chelmsford, UK

*Corresponding author g.livingston@ucl.ac.uk

Background: Two-thirds of people with dementia live at home, receiving most care from family carers, about 40% of whom have clinically significant depression or anxiety. This impacts on the person with dementia, families and society, predicting care breakdown. There are currently no clinically effective and cost-effective NHS family carer interventions.

Objectives: To assess the STrAtegies for RelaTives (START) intervention in the short (4 and 8 months) and long term (1 and 2 years) compared with treatment as usual (TAU).

Design: Randomised, parallel-group, superiority trial with blinded assessment recruiting participants 2 : 1 (intervention to TAU) to allow for therapist clustering.

Setting: Three UK mental health services and one neurological service.

Participants: Family carers of people with dementia.

Intervention: Eight-session manual-based coping intervention delivered by supervised psychology graduates to individuals.

Main outcome measures: Affective symptoms [Hospital Anxiety and Depression Scale-total (HADS-T)] and cost-effectiveness. Secondary measures: anxiety and depression symptoms and caseness, quality of life (QoL), abusive behaviour and long-term care home admission.

Results: Two hundred and sixty participants were randomised (173 intervention, 87 TAU). We used intention-to-treat analysis in the short term (152 intervention, 77 TAU) and in the long term (140 intervention, 69 TAU). In the short term, the intervention group had lower HADS-T [mean difference -1.80 , 95% confidence interval (CI) -3.29 to -0.31 ; $p = 0.02$] and higher quality-adjusted life-years (QALYs) (mean difference 0.03 , 95% CI -0.01 to 0.08). Costs were no different between groups [mean $\pounds 252$ (95% CI $-\pounds 28$ to $\pounds 565$) for intervention group]. The cost-effectiveness acceptability curve showed a greater than 99% chance of being cost-effectiveness at a $\pounds 30,000$ /QALY willingness-to-pay threshold and a high probability of cost-effectiveness based on the HADS-T score. Carers in the intervention group had less case-level depression [odds ratio (OR) 0.24 , 95% CI 0.07 to 0.76], a trend towards reduced case-level anxiety (OR 0.30 , 95% CI 0.08 to 1.05), lower Hospital Anxiety and Depression Scale-anxiety (HADS-A) (-0.91 , 95% CI -1.76 to -0.07 ; $p = 0.03$) and Hospital Anxiety and Depression Scale-depression (HADS-D) (-0.91 , 95% CI -1.71 to -0.10 ; $p = 0.03$) and higher Health Status Questionnaire (HSQ) QoL (mean difference 4.09 , 95% CI 0.34 to 7.83). Group differences in abusive behaviour (OR 0.48 , 95% CI 0.18 to 1.27) and the person with dementia's quality of life-Alzheimer's disease (QoL-AD) (mean increase 0.59 , 95% CI -0.72 to 1.89) were not significant. In the long term, the intervention group had lower HADS-T (mean difference -2.58 , 95% CI -4.26 to -0.90 ; $p = 0.03$) and higher QALYs (mean difference 0.03 , 95% CI -0.01 to 0.06). Carers in the intervention group had less case-level depression (OR 0.14 , 95% CI 0.04 to 0.53), a trend towards reduced case-level anxiety (OR 0.57 , 95% CI 0.26 to 1.24), lower HADS-A (-1.16 , 95% CI -2.15 to -0.18) and HADS-D (1.45 , 95% CI -2.32 to -0.57), and higher HSQ (mean difference 7.47 , 95% CI 2.87 to 12.08). Thirty-two (18.7%) people with dementia in the intervention group and 17 (20.2%) in TAU were admitted to a care home (hazard ratio 0.83 , 95% CI 0.44 to 1.56 ; $p = 0.56$). There were no significant differences between groups in abusive behaviour (OR 0.83 , 95% CI 0.36 to 1.94), the person with dementia's QoL-AD (0.17 , 95% CI -1.37 to 1.70) or costs ($\pounds 336$, 95% CI $-\pounds 223$ to $\pounds 895$) for intervention group. The probability that the intervention would be seen as cost-effective at $\pounds 30,000$ /QALY threshold and cost-effectiveness on the HADS-T remained high.

Conclusions: The START intervention was clinically effective and cost-effective in the short and longer term. The results are robust to the sensitivity analyses performed. Future work is needed to consider mechanism of action; the effects on people with dementia in clinical terms (cognition, neuropsychiatric symptoms, longer-term care home admission); and on health and social care costs. In addition, we will explore the effects of carer abusive behaviour on the care recipient's care home admission and if this then reduces abusive behaviour. We would also like to implement START and evaluate this implementation in clinical practice.

Trial registration: Current Controlled Trials ISCTRN70017938.

Funding: The National Institute for Health Research Health Technology Assessment programme.

Contents

| | |
|---|-------------|
| List of tables | xiii |
| List of figures | xv |
| List of abbreviations | xvii |
| Plain English summary | xix |
| Scientific summary | xxi |
| Chapter 1 Introduction | 1 |
| Scientific background | 1 |
| Evidence for a coping-based psychological therapy for carers | 1 |
| The Coping with Caregiving programme | 2 |
| Delivery of therapy | 2 |
| Rationale for new therapy in the NHS | 2 |
| Chapter 2 Objectives | 5 |
| Chapter 3 Methods | 7 |
| Trial registration | 7 |
| Trial design | 7 |
| Patient and public involvement | 7 |
| Participants | 7 |
| <i>Eligibility criteria for participants</i> | 7 |
| Settings and locations where the data were collected | 7 |
| Referrals and recruitment procedure | 8 |
| <i>Randomisation</i> | 8 |
| <i>Blinding</i> | 8 |
| Intervention | 8 |
| <i>Location of interventions</i> | 8 |
| <i>Development of the intervention manual</i> | 9 |
| <i>Training and delivery</i> | 11 |
| Monitoring fidelity to the manualised intervention | 11 |
| Supervision | 11 |
| Case management | 12 |
| Clinical skills development | 12 |
| Ensuring safe practice with clients | 13 |
| Staff support | 13 |
| Treatment as usual | 13 |
| <i>Camden and Islington NHS Foundation Trust</i> | 13 |
| <i>North East London Foundation Trust</i> | 14 |
| <i>North Essex Partnership University NHS Foundation Trust</i> | 14 |
| <i>University College London Hospitals NHS Foundation Trust</i> | 14 |
| <i>Barnet, Enfield and Haringey Mental Health Trust</i> | 14 |

| | |
|--|-----------|
| Chapter 4 Outcomes | 15 |
| Assessments | 15 |
| Changes to trial outcome after trial commenced | 16 |
| Short-term primary outcome (up to 8 months' follow-up) | 17 |
| Long-term main outcomes (12 to 24 months' follow-up) | 17 |
| Seven-year follow-ups | 17 |
| <i>Secondary outcomes</i> | 17 |
| Sample size | 17 |
| Statistical methods | 18 |
| <i>Scoring questionnaires</i> | 18 |
| <i>Clinical outcomes</i> | 18 |
| <i>Cost-effectiveness</i> | 19 |
| | |
| Chapter 5 Results | 23 |
| Participant flow and recruitment | 23 |
| Short-term clinical results (over 8 months) | 23 |
| Participant flow through study | 23 |
| External validity | 23 |
| Baseline data | 25 |
| Intervention | 25 |
| <i>Therapists</i> | 25 |
| <i>Adherence with therapy</i> | 25 |
| <i>Fidelity</i> | 25 |
| <i>Languages, translation and interpreters</i> | 28 |
| <i>Missing outcome data</i> | 28 |
| Clinical outcomes | 29 |
| <i>Primary outcome</i> | 29 |
| <i>Sensitivity analysis</i> | 29 |
| <i>Secondary outcomes</i> | 31 |
| Health economic analysis: short term over 8 months | 32 |
| <i>Service use and costs</i> | 32 |
| <i>Cost-effectiveness</i> | 33 |
| <i>Sensitivity analyses</i> | 36 |
| Long-term outcomes (12 and 24 months) | 37 |
| <i>Missing outcomes</i> | 37 |
| <i>Clinical outcomes</i> | 37 |
| <i>Secondary outcomes</i> | 37 |
| Cost-effectiveness (over 24 months) | 41 |
| <i>Service use and costs</i> | 41 |
| <i>Cost-effectiveness ratio</i> | 43 |
| <i>Sensitivity analysis</i> | 45 |
| | |
| Chapter 6 Discussion | 49 |
| Key findings | 49 |
| <i>Primary and secondary outcome of clinical effectiveness</i> | 49 |
| <i>Primary and secondary outcome of cost-effectiveness</i> | 49 |
| <i>Interpretation</i> | 49 |
| Strengths and limitations | 50 |
| <i>Study design</i> | 50 |
| <i>Sensitivity analyses</i> | 50 |
| <i>Bias</i> | 50 |
| <i>Health economics</i> | 50 |
| <i>Generalisability</i> | 51 |

| | |
|---|-----------|
| Implementation of a complex intervention | 51 |
| Adherence to the intervention | 51 |
| Overall evidence | 52 |
| Comparison of short- and long-term effects | 53 |
| <i>Structured psychological treatment of depression in other groups</i> | 53 |
| <i>Comparison with other health economics studies</i> | 53 |
| Chapter 7 Conclusions | 55 |
| Implications for clinical practice | 55 |
| Unanswered questions and future research | 55 |
| Acknowledgements | 57 |
| References | 59 |
| Appendix 1 Unit cost of services | 65 |
| Appendix 2 Net monetary benefit graphs | 69 |
| Appendix 3 The START manual | 73 |

List of tables

| | |
|--|----|
| TABLE 1 External validity of eligible carers who consented to the trial compared with those who were not randomised | 25 |
| TABLE 2 Baseline carer and patient demographic characteristics by randomisation group | 26 |
| TABLE 3 Baseline carer and patient clinical characteristics by randomisation group | 27 |
| TABLE 4 Number of carers by therapist (intervention group) | 27 |
| TABLE 5 Percentage missing outcome by follow-up and group | 28 |
| TABLE 6 Primary and secondary clinical outcomes for the intervention and TAU groups (at 4 and 8 months): primary and secondary outcomes (at 4 and 8 months) | 29 |
| TABLE 7 Carers' use of health and social care services at baseline, 4 months and 8 months | 32 |
| TABLE 8 Health and social service costs and outcomes at 4 and 8 months for carers in the intervention and TAU groups, and differences between START and TAU groups | 33 |
| TABLE 9 Treatment and cost effects (with 95% bias-corrected CIs) and ICERs over 8 months | 34 |
| TABLE 10 Sensitivity analyses: treatment and cost effects (with 95% CIs) and ICERs over 8 months | 34 |
| TABLE 11 Missing outcomes at 12 and 24 months' follow-up | 36 |
| TABLE 12 Primary and secondary clinical outcomes (at 12 and 24 months): primary and secondary outcomes (at months 12 and 24) for those in the intervention and TAU groups | 39 |
| TABLE 13 Carers' use of health and social care services at 12 and 24 months | 42 |
| TABLE 14 Health and social care service costs and outcomes at 12 and 24 months for carers in the intervention and TAU groups and differences between START and TAU groups | 43 |
| TABLE 15 Treatment and cost effects (with 95% CI) and ICERs over 24 months | 43 |
| TABLE 16 Sensitivity analyses: treatment and cost effects (with 95% CIs) and ICERs over 24 months | 45 |
| TABLE 17 Unit costs of services | 65 |
| TABLE 18 Treatment and cost effects (with 95% CI) and ICERs | 67 |

| | |
|---|-----------|
| TABLE 19 Treatment and cost effects (with 95% CIs) and ICERs following sensitivity analysis adjusting for significant predictors of missing values | 67 |
| TABLE 20 Treatment and cost effects (with 95% CIs) and ICERs, following sensitivity analysis adjusting for baseline imbalances | 68 |

List of figures

| | |
|---|-----------|
| FIGURE 1 The CONSORT flow diagram (short-term analysis) | 24 |
| FIGURE 2 Number of sessions completed by participants | 28 |
| FIGURE 3 Checking model assumptions: residuals and fitted values from the models for HADS-T (based on the model-adjusted only for centre and baseline score) | 30 |
| FIGURE 4 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 8 months | 35 |
| FIGURE 5 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in HADS gain over 8 months | 35 |
| FIGURE 6 Sensitivity analysis of CEAC with QALY as the outcome measure over 8 months | 36 |
| FIGURE 7 The CONSORT flow diagram for long-term outcomes (12 and 24 months) | 38 |
| FIGURE 8 Time until admission to a care home for each randomised group over 24 months' follow-up | 40 |
| FIGURE 9 Modified Conflict Tactic Scale for significant abuse over 24 months in intervention and control groups | 41 |
| FIGURE 10 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months | 44 |
| FIGURE 11 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in HADS gain over 24 months | 44 |
| FIGURE 12 Cost-effectiveness acceptability curve for START with QALY as the outcome measure over 24 months | 46 |
| FIGURE 13 Cost-effectiveness acceptability curve for START with HADS-T as the outcome measure over 24 months | 46 |
| FIGURE 14 Sensitivity analysis of CEAC with QALY as the outcome measure over 24 months | 47 |
| FIGURE 15 Sensitivity analysis of CEAC with HADS-T as the outcome measure over 24 months | 47 |

| | |
|---|----|
| FIGURE 16 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU health and social care perspective, with effectiveness measured in QALY gain over 8 months | 69 |
| FIGURE 17 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured on HADS-T score over 8 months | 69 |
| FIGURE 18 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 8 months following sensitivity analysis adjusting for significant predictors of missing values | 70 |
| FIGURE 19 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 8 months following sensitivity analysis adjusting for baseline imbalances | 70 |
| FIGURE 20 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months | 71 |
| FIGURE 21 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured on HADS-T score over 24 months | 71 |
| FIGURE 22 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months following sensitivity analysis adjusting for significant predictors of missing values | 72 |
| FIGURE 23 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months following sensitivity analysis adjusting for baseline imbalances | 72 |

List of abbreviations

| | | | |
|---------|--|--------|---|
| CBT | cognitive-behavioural therapy | HR | hazard ratio |
| CD | compact disc | HSQ | Health Status Questionnaire |
| CDR | Clinical Dementia Rating | ICC | intracluster correlation coefficient |
| CEAC | cost-effectiveness acceptability curve | ICER | incremental cost-effectiveness ratio |
| CI | confidence interval | ID | identification |
| CIFT | Camden and Islington NHS Foundation Trust | MCTS | Modified Conflict Tactics Scale |
| CONSORT | Consolidated Standards of Reporting Trials | NELFT | North East London Foundation Trust |
| CSRI | Client Service Receipt Inventory | NEPFT | North Essex Partnership Foundation Trust |
| DeNDRoN | Dementias and Neurodegenerative Disease Research Network | NICE | National Institute for Health and Care Excellence |
| DRC | Dementia Research Centre | NMB | net monetary benefit |
| DVLA | Driver and Vehicle Licensing Agency | NPI | Neuropsychiatric Inventory |
| EQ-5D | European Quality of Life-5 Dimensions | OR | odds ratio |
| GP | general practitioner | PSSRU | Personal Social Services Research Unit |
| HADS | Hospital Anxiety and Depression Scale | QALY | quality-adjusted life-year |
| HADS-A | Hospital Anxiety and Depression Scale-anxiety | QoL | quality of life |
| HADS-D | Hospital Anxiety and Depression Scale-depression | QoL-AD | quality of life-Alzheimer's disease |
| HADS-T | Hospital Anxiety and Depression Scale-total | RCT | randomised controlled trial |
| | | SD | standard deviation |
| | | START | STrategies for RelaTives |
| | | TAU | treatment as usual |
| | | UCL | University College London |

Plain English summary

The frequency of dementia is rising as people live longer, meaning that there are more people with dementia, two-thirds of whom are cared for at home by their families. About 40% of those family carers of people with dementia have clinically significant depression or anxiety, often leading to them becoming unable to care so that the person with dementia has to be looked after in a care home. Although there have been some interventions which help reduce family carers' depression and anxiety, they have neither been designed to be used routinely in the NHS nor had their cost-effectiveness tested.

Our START (STrAtegies for RelaTives) study was a randomised controlled trial of an eight-session manual, adapted from an American programme called 'Coping with Caregiving'. It was delivered by psychology graduates to carers individually. We compared it with usual treatment by using a computer program to decide randomly whether or not carers should be in the intervention or the control group. We found that START decreased carers' anxiety and depression and improved their quality of life (QoL) in the short term (8 months after the study started) and that it was as effective on these measures in the longer term (2 years after the study started). The intervention was cost-effective at both times but did not improve the person with dementia's QoL. After 2 years, there was a small, but not significant, decrease in the chance of people with dementia in the intervention group being admitted to a care home.

Scientific summary

Background

The frequency of dementia is rising. Two-thirds of people with dementia live at home, with family providing most of their care. About 40% of family carers of people with dementia have clinical depression or anxiety; others have significant psychological symptoms. This impacts on patients, families and society as carer psychological morbidity predicts care breakdown and, therefore, institutionalisation, as well as elder abuse.

Systematic reviews report successful interventions to reduce carer depression have been individual rather than group; required active participation; and offered multicomponent strategies to be tailored to carers' individual needs. Preliminary evidence suggested that interventions for anxiety might be effective if they include relaxation techniques and strategies to manage caring demands rather than reducing contact. There are no manual-based therapies currently available for dementia carers in the NHS and no evidence regarding whether or not standardised psychological interventions can be realistically, effectively and economically delivered to family carers within NHS services. The National Institute for Health and Care Excellence (NICE) recognises that quality dementia care should include psychological therapy for family carers, but recommends further research regarding cost-effectiveness.

Objectives

To test the STRategies for RelaTives (START) study's clinical effectiveness and cost-effectiveness over the short term (4 and 8 months) and long term (1 and 2 years) post randomisation. The START intervention is a manual-based individual therapy for dementia carers, delivered by psychology graduates.

Methods

This is a parallel-group, superiority, randomised controlled trial recruiting participants 2 : 1 to intervention : treatment as usual (TAU) to allow for therapist clustering.

Participants

We included self-identified family carers giving informed consent and providing support at least weekly to people with dementia, living in their own homes and referred in the previous year.

Settings

We recruited through three mental health trusts and a neurology clinic, encompassing urban, suburban and rural areas, and ethnic and social diversity.

Intervention

The START manual intervention was based on the US 'Coping with Caregiving' intervention.

The eight sessions covered:

1. Learning about dementia, carer stress and understanding behaviours.
- 2–5. Discussion of behaviours or situations the carer finds difficult, incorporating behavioural management, identifying and changing unhelpful thoughts, assertive communication, increasing communication, acceptance, accessing emotional support and positive reframing.

6. Future planning.
7. Pleasant activities.
8. Maintaining skills learnt.

We predefined adherence clinically, as participating in five or more therapy sessions.

Training

We trained and supervised non-clinically trained psychology graduates to deliver the intervention. Therapists recorded one randomly selected therapy session per participant. An independent rater used a checklist to score fidelity from 1, 'not at all', to 5, 'very' focused.

Treatment as usual

We expected TAU from the several teaching trusts to be based on NICE guidelines, i.e. good 'TAU'.

Randomisation

We used an online computer-generated randomisation system, stratified by trust using random permuted blocks.

Blinding

The researchers worked in two teams, each assessing outcomes blinded to randomisation status in some participants and providing therapy to the remaining participants.

Assessments

We interviewed carers at baseline and after 4, 8, 12 and 24 months. At baseline, we collected sociodemographic details. We collected clinical status and resource use at every interview.

Instruments

- The Hospital Anxiety and Depression Scale (HADS) comprises two components, the HADS-depression (HADS-D) and HADS-anxiety (HADS-A), with scores from 0 to 21. The HADS-total score (HADS-T) ranges from 0 to 42 (higher scores indicating more symptoms). We also dichotomised anxiety and depression scores into 'case' and 'non-case,' with a cut-off point of 8 or 9.
- The Zarit Burden Interview is a 22-item questionnaire. Higher scores indicate higher burden (range 0–88).
- The Neuropsychiatric Inventory (NPI) measures psychopathology in dementia patients and higher scores indicate worse symptoms (range 0–144).
- The Modified Conflict Tactics Scale (MCTS) measures potentially abusive behaviour by carers towards care recipients. Ten behaviours, ranging from shouting to slapping, over the previous 3 months are scored as occurring never (0) to all of the time (4). A score ≥ 2 on any item is classified as abusive.
- The Health Status Questionnaire (HSQ) mental health domain measures health-related quality of life (QoL). Higher scores indicate better outcome (range 0–100).
- The Client Service Receipt Inventory (CSRI) covers services used.
- Quality of life-Alzheimer's disease (QoL-AD) is family carer rating of the patient's QoL. Higher scores indicate better outcome (range 13–52).
- European Quality of Life-5 Dimensions (EQ-5D) is a health status measure used to generate quality-adjusted life-years (QALYs).

Primary outcomes (short and long term)

1. HADS-T score.
2. Cost-effectiveness: CSRI and EQ-5D.

Secondary outcomes (short and long term)

1. Depression and anxiety scores and caseness scores on the HADS.
2. Carer mental health (HSQ score) and care recipient QoL (QoL-AD).
3. MCTS.
4. Cost-effectiveness: CSRI and HADS-T.

Long-term secondary outcome

Time to care home admission.

Sample size

This was calculated to test our main hypothesis: short-term HADS-T score will be significantly lower in the intervention than in the TAU group.

We originally powered for a primary outcome of HADS-A score to detect (with 90% power, 5% significance) a 2-point difference in mean score and a 0.5 change in standard deviation (SD) (assumed SD 4). To account for therapist clustering, we used a design effect of 1.87 for the intervention group, assuming an average of 30 carers per therapist and an intraclass correlation coefficient (ICC) of 0.03. Inflating for 20% attrition, we planned to recruit 90 for TAU and 168 in the intervention group.

Following recruitment, the research team (with funding body approval) changed the primary outcome to HADS-T score. We calculated that the available sample size (87 TAU, 173 intervention group) would be sufficient to detect a 2.4-point difference in HADS-T score (with 80% power, 5% significance). This calculation assumed a SD for HADS-T score of 7.4 (from pilot data), and allowed for analysis of covariance (assumed correlation 0.5) and repeated follow-up measurements at 4 and 8 months (correlation 0.7). We factored attrition in at 10% (based on that observed), and applied a revised design effect of 1.4 for the intervention arm (ICC of 0.03 and observed average cluster size of 15 carers per therapist).

Statistical methods

Clinical outcomes

We carried out separate analyses to investigate the short- and long-term effects of the intervention. We used multilevel mixed models to estimate group differences in HADS-T score, taking into account the partially clustered design, repeated measurements and adjustment for baseline factors. We adjusted for baseline HADS-T score and centre (each trust was a centre), and for previously reported factors influencing affective symptoms (carer age, sex, burden and care recipient neuropsychiatric symptoms). Analyses were carried out on an intention-to-treat basis, but excluded carers for whom data were missing at both 4 and 8 months (short-term follow-up) or long term (12 and 24 months). We took similar approaches for secondary outcomes. We used parametric shared frailty models for time to 24-month care home admission and random-effects logistic regression for binary outcomes.

Cost-effectiveness

We examined health and social care costs over periods of 8 months and 2 years post randomisation alongside QALYs (calculated from EQ-5D by applying societal weights) and HADS-T scores. We analysed those with complete EQ-5D data at each point, as required to estimate QALYs. We calculated incremental cost-effectiveness ratios (ICERs) as the difference in the cost of START and TAU divided by the outcome difference (QALYs/HADS-T score). We plotted confidence intervals (CIs) for cost-effectiveness acceptability curves (CEACs) and net monetary benefit (NMB) to estimate the impact of uncertainty. We applied a discount rate of 3.5% to costs and outcome.

Sensitivity analyses

We used sensitivity analyses to assess our conclusions' robustness by adjusting for baseline characteristics, imbalances between randomised groups and differential effects of treatment over time (treatment by time interaction). We investigated variation of missing outcome by baseline characteristics using logistic regression, then repeated the main analyses adjusting for factors associated with missingness.

All statistical analyses followed a predefined analysis plan, using Stata version 11 (StataCorp LP, College Station, TX, USA) for clinical outcomes and Stata version 12 for cost-effectiveness.

Results

We randomised 260 (55%) of 472 carers referred. The others declined participation ($n = 181$; 38%), did not meet inclusion criteria ($n = 22$; 5%) or were uncontactable ($n = 9$; 2%). Over the 8-month follow-up period, 12 carers from the control group and 21 from the intervention group withdrew or were lost to follow-up. The known demographics of those who did or did not consent indicate the study sample had good external validity. We randomised 173 (67%) participants to the intervention and 87 to TAU. Randomisation generally achieved good between-group balance of patient and carer demographic and clinical characteristics.

Intervention

One hundred and thirty (75%) carers in the intervention group attended five or more therapy sessions. Eight (5%) withdrew before participating in any sessions. Adherence was better in those of white ethnicity than in other ethnic groups [110 (78%) vs. 19 (61%)], in male carers than in female carers [46 (81%) vs. 84 (72%)] and in those with at least A-level education than in those with a lower level of education [56 (80%) vs. 74 (72%)]. Adherence did not differ by age [aged < 60 years, 75 (77%) vs. 55 (73%)] or work situation [paid work 49 (78%) vs. other 81 (74%)].

We scored fidelity rating for 128 out of 166 (77%) intervention participants. The mean score was 4.70 (SD 0.66). Ten therapists (seven female) delivered the intervention to between 11 and 32 carers each.

Short-term outcomes

Clinical

Analysis of HADS-T scores, adjusting for trust and baseline score, showed a significant difference in the intervention's favour with an average decrease of -1.46 (95% CI -2.89 to -0.03 ; $p = 0.05$). Further adjustment for factors related to outcome (carer age and sex, NPI and Zarit scores) gave similar results (mean difference -1.80 points, 95% CI -3.29 to -0.31 points; $p = 0.02$).

Sensitivity analyses adjusting for missingness predictors gave similar results (mean difference -1.53 , 95% CI -2.96 to -0.10), as did adjusting for baseline imbalances (mean difference -1.78 , 95% CI -3.30 to -0.27).

We found HADS-D cases in the intervention group compared with TAU was significantly reduced [adjusted odds ratio (OR) 0.24, 95% CI 0.07 to 0.76] and some evidence for a reduction in HADS-A caseness (OR 0.30, 95% CI 0.08 to 1.05).

Adjusted models for the HADS-A and HADS-D scales indicated significant beneficial intervention effects, with average decreases in scores of -0.91 (95% CI -1.76 to -0.07 ; $p = 0.03$) and -0.91 (95% CI -1.71 to -0.10 ; $p = 0.03$), respectively. The carer's HSQ mental health was significantly higher (mean difference 4.09, 95% CI 0.34 to 7.83). There was no significant difference between groups in the person with dementia's QoL-AD (mean increase 0.59, 95% CI -0.72 to 1.89) or in abusive behaviour (OR 0.48, 95% CI 0.18 to 1.27).

Cost-effectiveness

Carers who received the intervention had non-significantly higher health and social care costs (£252, 95% CI –£28 to £565 with QALY outcome and £247, 95% CI £0 to £569 with HADS-T outcome), after adjustment for baseline variables. The cost per QALY was £6000. The CEAC showed a > 99% chance of cost-effectiveness at a willingness-to-pay threshold of £30,000 per QALY gained and a high probability of cost-effectiveness on the HADS-T.

Sensitivity analyses adjusting for predictors of missingness gave similar results. The mean ICER values were now £5452 per additional QALY and £107 per 1-point difference in HADS-T score. The intervention had an approximately 95% likelihood of being seen as cost-effective, rising to 98% at the £30,000 threshold. The second sensitivity analysis results, adjusting for baseline characteristics imbalances, were again similar. The mean ICER values were £5756 per additional QALY and £112 per 1-point difference in HADS-T score. At the lower-bound NICE threshold of £20,000, the intervention has a 93% likelihood of being seen as cost-effective, rising to 98% at the £30,000 threshold. The CIs around NMB for these sensitivity analyses, taking into account uncertainty in the estimation, suggest that these findings are robust, although possibly less strong at the £30,000 threshold.

Long-term outcome analysis

Clinical

Long-term mean HADS-T scores were lower in the intervention group than in the TAU group [mean difference adjusted for trust, baseline score, carer age, sex, NPI and Zarit score –2.58 (95% CI –4.26 to –0.90)]. If the model did not include factors relating to outcome then the results were similar [–1.84 (95% CI –3.50 to –0.17; $p = 0.03$)].

Carers in the intervention group were less likely to have case-level depression (adjusted OR 0.14, 95% CI 0.04 to 0.53) and there was a trend towards reduced case-level anxiety (OR 0.57, 95% CI 0.26 to 1.24). The HADS-A and HADS-D indicated significant beneficial intervention effects, with average score decrease of –1.16 (95% CI –2.15 to –0.18) and –1.45 (95% CI –2.32 to –0.57), respectively. Intervention carers had a significantly higher HSQ mental health scale score (mean difference 7.47, 95% CI 2.87 to 12.08). There was no significant difference between groups in the person with dementia's QoL (mean QoL-AD score 0.17, 95% CI –1.37 to 1.70) or in abusive behaviour (OR 0.83, 95% CI 0.36 to 1.94).

There was no interaction of time with outcome.

There was an indication of a decrease risk of admission to 24-hour care in the intervention group. Seventeen participants (20.2%) in the TAU group and 32 (18.7%) in the intervention group were admitted to a care home (hazard ratio 0.83, 95% CI 0.44 to 1.56; $p = 0.56$).

Cost-effectiveness

In the 24-month cost-effectiveness analysis, carers included in this analysis in the intervention group had non-significantly higher costs [£336 (95% CI –£223 to £895) for QALYs; ($n = 144$); £303 (95% CI –£206 to £812) for HADS-T ($n = 156$)], after adjustment for baseline covariates. The cost per QALY was £11,200 and the CEAC showed a 75% chance of cost-effectiveness at a willingness-to-pay threshold of £30,000 per QALY gained. The probability of cost-effectiveness on the HADS-T was 78% at a willingness-to-pay threshold of £50 per 1-point HADS-T improvement.

In the sensitivity analysis adjusting for missingness predictors, the mean ICER values were £9767 per additional QALY and £125 per 1-point difference in HADS-T score. The intervention had an approximately 67% likelihood of being seen as cost-effective, rising to 75% at the £30,000 threshold. In the analysis adjusting for baseline imbalances, the mean ICER values were £8567 per additional QALY, and £209 per 1-point difference in HADS-T score. At the lower NICE threshold of £20,000, the START intervention had a 70% likelihood of being seen as cost-effective, rising to 80% at the £30,000 threshold. The CIs around

NMB for these two sensitivity analyses taking into account uncertainty in the estimation suggest a degree of caution should be exercised when considering the finding.

Discussion

The START intervention was clinically effective and cost-effective over 8 months and 2 years. Although differences were small, they were clinically significant and sustained post intervention, as reflected in QoL improvements and possibly delayed care home admission. This was a pragmatic trial; participants were from NHS services and their diverse backgrounds suggest generalisability.

Conclusion

Future quantitative analysis is needed to consider mechanism of action and the effects on people with dementia in clinical terms (cognition, neuropsychiatric symptoms, longer-term care home admission) and on health and social care costs. In addition, we will explore the effects of carer abusive behaviour on the care recipient's care home admission and if abusive behaviour declines following admission to a care home. We plan qualitative process investigation of whether or not all of the intervention components were valued and how it could be improved.

Trial registration

This trial is registered as ISCTRN70017938.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

Scientific background

The frequency of dementia will rise dramatically over the next 20 years because of increased longevity. In the UK, 700,000 people currently have dementia (> 1% of the entire UK population), and this figure is projected to reach over 1 million by 2020 and double again in the 20 years after that.^{1,2} Dementia affects the person with the illness, his or her family and society through increasing dependence and challenging behaviour. In the UK, dementia care is currently estimated to cost £23B per year and costs are projected to treble in the next 30 years as the number of older people increases;^{2,3} for comparison, the entire NHS budget is currently £96B per year. England's National Dementia Strategy⁴ emphasises that 'Family carers are the most important resource available for people with dementia' (p. 12). Families and individuals bear the biggest financial burden; two-thirds of people with dementia live at home, receiving most of their care from family carers, who save the public purse more than £6B per year.²

About 40% of family carers of people with dementia have clinically significant depression or anxiety, while others have significant psychological symptoms.^{5,6} These symptoms are more common when the family carer is older, a woman, living with the person with dementia and reports greater carer burden and behavioural symptoms of dementia.^{5,6} This impacts on the NHS as well as on patients and families, as carer psychological morbidity, in particular depression, predicts care breakdown and, therefore, institutionalisation,^{7,8} as well as elder abuse.⁹ However, a recent report shows that levels of services and support for people with dementia and families are inadequate.² Specialist, individually tailored, psychological support to people with dementia and their family carers has been shown to reduce the rate of, although not necessarily the time to, care home admission in the USA, although there is no evidence in the UK.^{10,11} Only multicomponent interventions have been shown to be effective in preventing institutionalisation.^{11,12} Nationally, a reduction in care home placements would have huge benefits for society, because most older people want to continue living at home, and those who do live at home report higher quality of life (QoL) than those placed in care homes.¹³ There are also economic benefits, for example, in reduced use of health services by carers suffering from psychological symptoms and, in particular, in reduced use of care homes, which are a very expensive resource.

Evidence for a coping-based psychological therapy for carers

In our team's earlier systematic review of interventions to improve the mental health of carers, we identified, prior to starting this study, 62 references which met our inclusion criteria.¹⁰ We found that behavioural management and coping strategy-based interventions had been efficacious, that interventions targeting individuals tended to work better than group interventions and that the minimum number of sessions of individual behaviour management which had been shown to be efficacious was six. Education about dementia by itself, group behavioural therapy and supportive therapy were not effective carer interventions. An earlier review had suggested that interventions which required active participation of the carers were more effective.¹⁴ In a further systematic review of evidence about treating dementia carer anxiety, we found that cognitive-behavioural therapy (CBT) and other therapies developed primarily to target depression did not effectively treat anxiety.⁵ Preliminary evidence suggested that an intervention might be effective if it included relaxation techniques and other strategies to help carers actively find ways to manage caring demands rather than reducing demands by reducing contact and avoidance. Overall, while evidence is promising, it is scant and of low quality, and further randomised controlled trials (RCTs) of interventions for carer psychological health in dementia are required.¹⁵

The Coping with Caregiving programme

The Coping with Caregiving programme^{16,17} was developed in the USA as a group intervention. It is a manual-based, psychological intervention delivered in weekly group sessions. It was comprehensively evaluated in the Resources for Enhancing Alzheimer's Caregiver Health project, which recruited carers from a range of clinical and community sources in the USA; depression scores were significantly decreased in treatment groups compared with controls in all of the studies¹⁶⁻¹⁹ and self-efficacy scores were increased.¹⁸ Although the impact of this therapy programme on rates of institutionalisation has not been tested, a recent systematic review finds that there is some evidence that carer support can reduce institutionalisation and that therapies such as the Coping with Caregiving programme, which include problem-solving strategies and offer carers a choice of support strategies which can be tailored to their individual needs, are most effective.¹¹

Delivery of therapy

The National Institute for Health and Care Excellence (NICE) recognises that psychological therapy for dementia family carers should be a key component of high-quality dementia care:²⁰ '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, the report noted the paucity of evidence in this area, and recommended that research is needed to address the question: 'For carers of people with dementia, is a psychological intervention cost-effective when compared with usual care?' (p. 45). Our team's systematic review found only one study of the cost-effectiveness of a therapeutic approach [similar to the StrAtegies for RelaTives (START) intervention] for supporting carers.^{20,21} It examined the cost-effectiveness of a modular, multicomponent intervention delivered in carers' homes, in three sessions by telephone, supplemented by five group sessions (five or six carers in each) delivered by telephone. Focusing on hours of caregiving, the authors found a significant difference over the 6-month study period, with carers in the intervention group having more time to dedicate to activities unrelated to caregiving, which has potentially positive impacts on emotional well-being and QoL.^{22,23} Therefore, more evidence is needed of the effectiveness and cost-effectiveness of interventions for supporting caregivers.

Rationale for new therapy in the NHS

Although the efficacy trials discussed above have shown promising reductions in family carer morbidity, there are no manual-based therapies currently available for dementia carers in the NHS, nor is there an evidence base to demonstrate whether or not such standardised psychological interventions can be realistically, effectively and economically delivered to family carers within NHS services. A therapy which is needed by many NHS consumers that can be effectively implemented only by clinical psychologists is unlikely to be economically viable. However, too little professional training is unlikely to be helpful; a recent unstructured, non-manual-based befriending programme delivered by ex-carers was ineffective in reducing anxiety or depression.²⁴

The UK national agenda is to have a stepped care approach to improve access to psychological therapies in which less intensive therapy is delivered by psychology graduates supervised by clinical psychologists.²⁵ In this study, we used similar delivery infrastructure; we anticipated that a psychological therapy specifically tailored to the emotional, practical and information needs of carers could have significant population benefits, including greater carer and care recipient well-being and decreased statutory care costs. Our therapy was delivered by psychology graduates, trained and supervised by the coapplicant experts in psychology, carer involvement, nursing and psychiatry, all of whom work in the NHS. Our intervention was as suggested by the evidence: individual, manualised, with different elements, required active participation, incorporated relaxation and was based on the US Coping with Caregiving programme.

Through our clinical and personal involvement in caring for people with dementia, we are aware that it can be difficult for carers to attend groups held outside their home at one specific time because of their caring commitments. There is evidence from systematic reviews that therapies individualised to the carer receiving them are most effective in delaying institutionalisation,¹¹ and that individual behavioural therapies are more effective than group interventions in reducing carer morbidity.¹⁰ Therefore, with the authors' agreement, we adapted Coping with Caregiving for NHS use as an individual therapy. As a result, sessions were quicker to deliver because, in groups, time is needed for all group members' problems to be discussed; thus, the number of weekly sessions required decreased from 13 to 8 after piloting.

Chapter 2 Objectives

We carried out this RCT to test the clinical effectiveness and cost-effectiveness of the manual-based individual therapy for dementia carers delivered by psychology graduates compared with treatment as usual (TAU) in the short (up to 8 months)^{26,27} and longer term (up to 2 years).

Chapter 3 Methods

Trial registration

This trial is registered as ISCTRN70017938. The full protocol is available online.

Trial design

The study is a randomised, parallel-group superiority trial, with blinded outcome assessment, recruiting participants 2 : 1 to intervention and TAU to allow for therapist clustering.

Patient and public involvement

Shirley Nurock, a former family carer working with the Alzheimer's Society, contributed to the design of the study at the application stage and commented on the study as part of the Trial Management Group throughout, including the information sheet. Lynne Ramsey, a family carer, who was then in a Dementias and Neurodegenerative Disease Research Network (DeNDRoN) group, was a member of the steering group and helped to make decisions about the study. U Hla Htay, a family carer, who we initially met as a University College London MSc student, contributed to the Data Monitoring Committee.

Participants

Eligibility criteria for participants

We included family carers of patients with dementia referred in the previous year who:

- provided emotional or practical support at least weekly
- identified themselves as the primary carer of someone with dementia not living in 24-hour care.

We excluded family carers who:

- were unable to give informed consent to the trial
- were currently taking part in a RCT in their capacity as a family carer (not just as an informant)
- lived more than 1.5 hours' travelling time from the researchers' base.

To help identify these potential participants, we completed the Mini Mental State Examination²⁸ in carers aged ≥ 60 years. Participants who scored < 24 out of 30 were discussed with the investigators GL or CC to determine if the low score was related to cognition, mood or education. If carers were judged to have dementia, they were not included in the study and the referring clinician was informed. This occurred only once in the study.

Settings and locations where the data were collected

Participants were recruited through three mental health trusts: Camden and Islington NHS Foundation Trust (CIFT), North Essex Partnership Foundation Trust (NEPFT) and North East London and Essex Foundation Trust (NELFT) Admiral Nurse Service. We also recruited from a neurology clinic at University College London (UCL) called the Dementia Research Centre (DRC), a tertiary service whose referrals include

a high rate of people with young-onset dementia. Although we had planned to recruit from Barnet, Enfield and Haringey Mental Health Trust, the trust refused to provide extra treatment costs and we did not recruit from there. The sampling frame encompassed urban, suburban and rural areas and ethnic and social class diversity. Recruitment was assisted by North Thames DeNDRoN.

Referrals and recruitment procedure

Prospective participants were initially approached by a clinician they knew and given or sent an information sheet. Those interested in participating were then referred to the research team. The referral gave the name, sex and relationship of the carer to the patient, as well as the patient's sex. The researchers were divided into two teams (A and B). The team that was to carry out blinded assessments for this client (e.g. A) telephoned the client 24 hours or more after they received the information sheet. The team member answered any questions and then arranged to meet those who thought they wished to take part, to obtain their informed consent and complete the baseline assessment before randomisation. Recruitment of carers to the trial commenced on 4 November 2009 and finished on 8 June 2011. The first 4-month follow-up took place on 4 March 2010, with the final 8-month follow-up on 7 February 2012 and the final 24-month follow-up on 7 June 2013.

Randomisation

The assessing team member gave the details of those enrolled to the trial manager, who entered them into the online randomisation system. Randomisation to intervention or TAU was carried out using an online computer-generated randomisation system. Randomisation was stratified by trust using random permuted blocks. An allocation ratio of 2 : 1 (intervention to TAU) was used to allow for potential clustering effects by therapist in the intervention arm.²⁹ It was set up and maintained by an independent Clinical Trials Unit at the Institute of Psychiatry, King's College London, and accessed only by the START trial manager and supervising clinical psychologist.

Blinding

Outcome assessors were blinded to randomisation status, but it was not possible to blind 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. These teams were in different rooms and had supervision separately so as to remain blinded. Assessors asked participants at the beginning of each interview not to disclose their allocation group.

The trial manager told the intervention team (B if the assessment team was A or vice versa) the result, but the assessment team was not informed of the outcome of randomisation. The participant was then telephoned by a member of the intervention team and informed that they had been allocated either to TAU and would be contacted for a 4-month follow-up (by the assessment team A, if the therapy team was A or vice versa) or to the intervention. If allocation was to therapy, an appointment was made for the first session of the therapy to start. Allocation within the individual team was according to workload.

Intervention

See *Appendix 3* for the START manual.

Location of interventions

Participants were usually seen for assessment and for intervention in their own homes, although, if participants so requested, they were seen in other settings. In the intervention group, most participants were seen at home, but a minority were seen at UCL ($n = 7$) or the NHS trust's offices ($n = 13$). One carer was seen both at work and at a local restaurant and another both at home and in the trust.

Development of the intervention manual

Dolores Gallagher-Thompson gave us permission to adapt the 'Coping with Caregiving' manual, a 13-session group therapy. We therefore used it to develop the START manual, an eight-session manual-based individual therapy programme adapted for UK use with individual family carers. The therapy was adapted by the project team, GL, PR, CC and DL, by considering UK usage of language and culture, brevity, and the fact that we were addressing individuals rather than a group.

We began by familiarising ourselves with the structure and content of the manual, which made use of the stress appraisal and coping response model. In this, stress is seen as the mismatch between *primary appraisal* (perceived demand) and *secondary appraisal* (perceived ability to cope and available resources and options, and principles from CBT).

Why change from group to individual intervention?

Carers face difficulties in attending a group intervention, as it can be impossible to make alternative care arrangements for their relative and to be available at a prespecified time. Individual therapy also has the advantage that it can be tailored to the specific problems faced by the carer, and our previous systematic review found that therapies worked better with individuals rather than groups. Individual therapies are quicker to deliver, as, in groups, time is needed for all group members' problems to be discussed and, so, the number of sessions was decreased.

Reducing the number of sessions

We identified the key components of the intervention and began reducing the 13 sessions to eight shorter sessions. This was a collaborative process. At this early stage, care was taken to adapt the language and tone of the American manual to ensure that the language of the revised manual was suitable for its target audience and to ensure that it was written in a clear and accessible style. Although the content of sessions varied, each session followed a broadly similar structure: an introduction, a review of a homework task from the previous session (from session 2 onwards), one or more specific topics including worked examples and space for carers to identify their own examples, a stress reduction technique, a session summary and a homework task (e.g. keeping a diary of challenging behaviours for the following week).

In the original manual, the sessions were (1) stress and well-being, (2) target behaviours, (3) strategies for changing behaviour, (4) refining our behaviour plans, (5) behaviours and thoughts, (6) changing unhelpful thoughts, (7) communication styles, (8) communication and memory problems, (9) planning for the future, (10) more planning for the future, (11) pleasant events, (12) refining your pleasant events and (13) review and conclusion.

Having initially produced the eight-session manual, the team revised each session to ensure that the content was written in appropriate UK English, was without jargon, was comprehensive and included both theoretical components and exercises for the participants to work through their own examples and experiences. Attention was given to ensuring a balance between information provision and interactive exercises inviting the carer to reflect on their own resources and strategies for coping, as well as relaxation exercises. In the original manual, 'planning for the future' emphasised end-of-life care, but, as most of our participants were expected to be seen soon after diagnosis, 'planning for the future' also encompassed getting support from other relatives, increasing community services, considering power of attorney and planning for a care home. The carer could then identify priorities and work through the information which they felt would be most useful. We piloted the manual by the research assistants trying it with PR, GL, CC, DL and each other, and altered it whenever it did not flow, or was unclear or repetitive. The research assistants met in groups, practised delivering the sessions and provided oral and written feedback on how to improve the sessions and increase the accessibility and clarity of the session content.

This process was repeated until the researchers and therapists agreed that the sessions were ready for use. Sessions were practised with each other to ensure that all researchers had the same understanding of how to deliver the therapy. Two separate versions of the manual were written: one for the carer to keep and one for the therapist to use, which included additional prompts and guidance to the therapist. In addition to the text, pictures and images were included to make the manual more user-friendly.

At this point, the sessions were piloted by PR with a carer who would have met the criteria for inclusion in the study. After each session, the clinical psychologist provided feedback to the team on how both the process and content was received by the carer, including the ease of delivery and timing of the sessions and adjustments were made accordingly. Final versions of both the therapist and carer versions of the manual were then produced for use within the study.

The therapy took place in the carers' preferred location, usually their home, without the patient in the room and at a time convenient to them. It was individually tailored to address the particular problems the carer was experiencing with the person for whom they cared. The therapy was carried out with an interpreter if the carer did not speak English fluently. Four participants needed translation, three of whom were randomised to the therapy sessions. The languages were Bengali (two carers), Farsi and Turkish (one each).

The eight sessions covered:

1. Psychoeducation about dementia, carer stress and understanding behaviours of the person cared for. This session discussed what dementia was and identified the difficulties faced by the carer. If the carer did not have any, we had examples of common problems. It introduced the idea of stress and how carers could recognise when they felt stressed.
- 2–5. Discussion of behaviours or situations that the carer finds difficult, incorporating behavioural management techniques including functional analysis; skills to take better care of themselves, including identifying and changing unhelpful thoughts; assertive communication; effective communication with people with dementia and promoting emotion-focused coping strategies and acceptance; and where to get emotional support and positive reframing.
6. Future needs of the patient, with information about care and legal planning specifically adapted to the UK. We discussed what they wanted to plan and who else they wanted to consult. We gave the carers information leaflets about making common decisions as individually appropriate.³⁰
7. Planning pleasant activities. This incorporated aspects of behavioural activation and reflected that many previous pleasant activities were impractical but that there may be many small enjoyable activities which still could be incorporated and the carer could add them to the day for either themselves or the person with dementia.
8. Maintaining the skills learned over time. This encompassed discussing which techniques and ideas the carer had found useful and making a written plan of what they would use in the future.

Each session ended with a different stress reduction technique session. Carers were given homework tasks to complete between sessions, including relaxation, identifying triggers and reactions to challenging behaviours, and identifying and challenging negative thoughts. The therapist and the family carer both had a manual, and carers filled in and kept their own manual. Our group audio-recorded relaxation exercises for use in these sessions and gave them to carers on a compact disc (CD). The relaxation techniques used were signal breath, focused breathing, physical grounding, guided imagery (three different versions), meditation and stretching.

We defined adherence to therapy after consulting with our clinical psychologist supervisor, on clinical grounds, as participating in five or more sessions.

Training and delivery

We employed and trained psychology graduates with no clinical training to deliver the intervention. Researchers in the two groups carried out assessments on carers having received training in taking informed consent, good clinical practice and all the assessment tools being administered. There was a strong practical focus in the training programme on how to deliver the therapy, potential clinical dilemmas, working with interpreters, empathic listening skills, effective use of supervision, safe working practice and when to ask for help. Throughout the training, a strong emphasis was placed upon the researchers guiding carers to where they themselves could get answers to their concerns or questions rather than feeling the need to provide specialised advice themselves within the session. We trained therapists to adhere to the manual and required them to demonstrate, by role-play, competence in delivering each session of the intervention.

Monitoring fidelity to the manualised intervention

Therapists recorded one therapy session per participant. We (PR, CC, DL and GL) devised a fidelity checklist for each session by considering the most important components of the session. The session to be recorded was selected at random by the trial manager using a Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) formula before any interventions were carried out. This session was rated for fidelity to the manual by a therapist in the same team who was not involved in that participant's intervention using the standard checklist. An overall fidelity score for each session was then given by the rater considering whether or not the therapist was 'keeping the carer focused on the manual'. Possible scores ranged from 1, meaning 'not at all', to 5, meaning 'very focused'. We planned to have two researchers rate independently initially while inter-rater reliability was established. Ratings were out of a possible five points. If fidelity scores were not high, the supervising clinical psychologist addressed this in supervision. This was the case for 7 out of the 131 recorded sessions, and often it was because carers had refused to participate in a particular aspect of a session.

Supervision

Following the recruitment and training of the psychology graduates the process of formal clinical supervision began. Our clinical psychologist, PR, met with each of the two teams (of three or four psychology assistants) for 1.5 hours of group supervision a fortnight. In addition to this group supervision, she was available for individual supervision, which either was requested by the psychology graduates on an ad hoc basis or, on occasion, was initiated by the investigators. Additionally, weekly team meetings with DL, GL and PR were held for the entire team, during which both procedural and clinical issues were addressed. The psychology graduates could approach one of the research team at any time if they had concerns or questions relating to their clients, for example if risk issues arose during a session.

A group supervision format was adopted as it was seen as the most effective use of available resources, with psychology graduates benefiting from both the professional expertise of their supervisor and the clinical experiences of their peers. It was hoped that the group format would maximise peer support both within and outside the supervision sessions and facilitate effective teamworking. The supervision format was tailored to reflect the specific needs of the START research project. During the course of the project, supervision performed a number of functions including case management, clinical skills development, monitoring the fidelity to the manualised intervention and ensuring safe practice with clients and staff support. Each of these functions is explored in turn below.

Case management

Once recruitment was under way and psychology graduates were fully trained, they held a caseload of approximately 4–6 clients for intervention. An important function of supervision was to ensure that all of these interventions were being managed effectively and appropriately. Therefore, in every group supervision session, each psychology graduate provided a brief update of his or her caseload, ensuring that clients and any related issues or concerns did not get overlooked, for example if there was a repeated pattern of cancellation or non-attendance that the psychology graduate had not identified. This aspect of supervision was extremely important as the psychology graduates had varied levels of experience and skill in managing their own caseloads and they were juggling delivering the intervention with offering baseline and follow-up assessments. This process also encouraged psychology graduates to be transparent about their work and to recognise when apparently simple or straightforward cases were more complex than initially perceived. As the cases for intervention were allocated and managed within the team, it was useful for psychology graduates to be aware of who their colleagues were seeing and who had space to take on new clients, developing a sense of shared responsibility.

Clinical skills development

Group and individual supervision sessions provided psychology graduates with the opportunity to develop their clinical skills via a range of approaches. In addition to a brief summary of their caseloads, at the start of every supervision session the group would agree an agenda and psychology graduates would identify a clinical challenge or dilemma that they wished to explore in more detail. Generally, each psychology graduate would talk in detail about one client; however, this very much depended on their present caseload. If there was a large agenda, psychology graduates were encouraged to prioritise and negotiate in terms of urgency among themselves. Although the intervention was manualised and psychology graduates were expected to strictly adhere to the manual, there was great variety in the dilemmas that they encountered in delivering the intervention. Often, the challenge for the psychology graduates was how to respond to their clients and overcome difficulties continuing to be empathic while sticking to the prescribed intervention, for example when carers would repeatedly ask them for solutions or direct advice.

For the more in-depth clinical discussions, PR encouraged the psychology graduates to identify a particular focus or question which they wanted to address rather than simply talking about a client in an unfocused way. These clinical discussions encompassed what the psychology graduates thought had worked well and what they had already tried, as well as what they felt that they could have done differently. In addition to offering advice and potential solutions to the psychology graduates, she encouraged them to share ideas and experiences with their peers and to make connections and identify themes across cases so that supervision was a positive learning experience regardless of whether or not their own cases were being discussed. As many of the psychology graduates hoped to develop a career in either clinical or academic psychology, they were keen within supervision sessions to link their practice and experiences to wider psychological theory. Various themes tended to emerge within their discussions of clinical cases, for example around grief and loss, or managing the therapeutic relationship, and the group would choose academic papers and book chapters to read for supervision sessions to extend their learning and understanding and to connect back to their cases.

In addition to using therapy tapes to monitor the fidelity to the intervention manual, listening to tapes of sessions provided the opportunity to reflect upon and develop clinical skills. All of the psychology graduates had the opportunity to play extracts from their taped sessions focusing on both general skills and the specific challenges that they faced in delivering the intervention to carers, for example how to manage sessions where the carer was extremely talkative, or how to respond when carers were unable to identify examples of challenging behaviours or possible coping strategies. Listening to the tapes was often combined with role-playing sections of intervention sessions to experiment with different ways to deliver the manual. Although role-play and listening to tapes can be anxiety provoking, because the psychology

graduates were used to listening to and rating each other's tapes outside supervision, they were more comfortable using these methods within supervision.

Ensuring safe practice with clients

An important aspect of supervision was to identify and respond to any risks identified during the course of assessment or intervention. The psychology graduates were provided with specific training in how to respond to any risks disclosed by carers, in relation to harm to both themselves and the person they were caring for. Psychology graduates would speak to one of the lead investigators if the abuse Modified Conflict Tactic Score (MCTS) was in the possibly abusive range (≥ 2) or if they had any concerns about potential abuse. Similarly, if carers reported high levels of depression or anxiety, this was discussed with the lead investigators. If concerns were raised, a plan was made with one of the lead investigators about how to manage the risk and information was shared with the local clinical teams.

Within supervision, psychology graduates were encouraged to identify any concerns about risk and prioritise these for discussion. As noted above, asking the psychology graduates to talk about their entire caseload at each session was an important way of ensuring that any concerns were identified. By talking about examples of good practice as well as difficulties and ensuring that there was an opportunity for individual supervision on request and a senior member of the team was always available, it was hoped that a culture of transparency developed and that the psychology graduates would always raise concerns about their clients. Time was also taken within supervision to highlight the importance of behaving ethically and safely in all aspects of clinical work, for example reflecting on maintaining clear boundaries clinically and how to practise safely when working alone in people's homes.

Staff support

In offering therapeutic interventions to carers of people with dementia, the psychology graduates, who had limited direct clinical experience, were frequently faced with the often distressing day-to-day lives of the carers and their relatives with dementia. An important dimension of clinical supervision was to provide a supportive context for the psychology graduates to develop self-reflexivity, exploring and making sense of their own responses to the people and situations that they were working with clinically. The combination of group and individual supervision meant that the psychology graduates benefited from the support of their peers and felt that their experiences were validated by their shared experiences.

Treatment as usual

As several teaching trusts were involved, we expected the TAU to be similar to good TAU throughout the UK and based on the NICE guidelines.³¹ Services are based around the person with dementia. Treatment is medical, psychological and social. Thus, it consisted of assessment, diagnosis and information, drug treatment, cognitive stimulation therapy, practical support, treatment of neuropsychiatric and cognitive symptoms and carer support. We have described TAU by trust below.

Camden and Islington NHS Foundation Trust

Patients and carers in this service were referred by a general practitioner (GP) to the Memory Service for assessment and diagnosis, assessed at home with family carer and, after investigations, offered a diagnostic appointment. Medication was prescribed as was appropriate and, if on anti-dementia medication, followed up by memory clinic nurses. Information and education in dementia was offered initially by nurses but then by dementia advisors situated in offices in and managed by the Alzheimer's Society. Patients were offered cognitive stimulation therapy. Risk assessments were carried out and risk plans put in place, for example telecare, driving information to the Driver and Vehicle Registry Agency (DVLA), medical identification (ID)

bracelets, advice regarding power of attorney and capacity assessment, and social services referral for personal care, day centre and financial advice. Neuropsychiatric symptoms in patients were assessed and managed.

North East London Foundation Trust

We recruited from NELFT's Admiral Nurse Service. Admiral Nurses are mental health nurses who specialise in dementia and work with family carers and people with dementia in the community and other settings. Family carers are referred to the Admiral Nursing Service through self-referral, directly from the GP, or from community mental health teams and the Memory Service. They assess the needs of both the carer and the person with dementia, and provide information, education and advice about caring for someone with dementia. Admiral Nurses focus on the needs of the family carer and provide emotional and psychological support to families through the transitional phases of the illness, such as diagnosis, when the condition advances, care home placement and end-of-life care. Referrals may be made to other services and they liaise with other health and social care professionals on behalf of the family.

North Essex Partnership University NHS Foundation Trust

Patients and carers in this service were referred by a GP to the Memory Service for assessment and diagnosis, assessed at home with family carer and, after investigations, offered a diagnostic appointment. The diagnosis was given in the clinic with a doctor or at home with nurses. Other interventions included medication as appropriate and, if on antidementia medication, follow-up by memory clinic nurses; risk assessment with a risk plan put in place, for example telecare and driving information to the DVLA; medical ID bracelet; and social services referral for personal care or day centre. Information and education in dementia was offered initially by nurses but thereafter by dementia advisors. Neuropsychiatric symptoms were assessed and managed. Patients were referred to dementia advisors situated in the Alzheimer's Society and carers were offered support groups.

University College London Hospitals NHS Foundation Trust

Patients were referred by their local GP, memory clinic or specialist to this cognitive disorders clinic. They were assessed in the clinic, with investigations completed during the visit. They were admitted as day case for cerebrospinal fluid examination or for other investigations. A few weeks later they had a diagnostic appointment with a neurologist, when they received the results of any tests, and on the same day saw a nurse consultant for discussion. In this discussion they were given information, education around legal and financial implications and a risk assessment was carried out. All patients were offered the opportunity to take part in clinical trials and other research. Available patient support groups were highlighted to them. This was followed up by telephone consultations. If appropriate, patients returned to the nurse-led therapeutics clinic for medication. Complex cases were followed up in the clinic and all others signposted back to their local services.

Barnet, Enfield and Haringey Mental Health Trust

We did not recruit participants from this trust as they did not agree to extra treatment costs.

Chapter 4 Outcomes

Assessments

Carers were interviewed at baseline and 4, 8, 12 and 24 months after randomisation, usually in their own home, unless they preferred to come to the research team base in UCL. We continued to follow up carers, asking them to remain in the study for 2 years, even if the person they were looking after went into a care home or died. They continued to give us data about themselves and their own use of services and, if the care recipient was in a care home, about the recipient's use of services. Information collected at baseline consisted of sociodemographic details about the carer and the person with dementia, and clinical and resource use items. Collection of clinical and resource use information was repeated at all follow-up data collection time points.

Sociodemographic details obtained at baseline included age, sex, ethnicity, relationship to the patient (e.g. spouse or child), level of education, last occupation and living situation.

Other assessments include:

- The Hospital Anxiety and Depression Scale (HADS)³² is a self-complete scale, and is validated for all age groups and settings, in people who are physically well or ill, and in Asian and African ethnic groups.³³ The scale is summarised as HADS-depression (HADS-D) and HADS-anxiety (HADS-A), with scores ranging from 0 to 21, and as a HADS-total score (HADS-T), with scores ranging from 0 to 42 (higher scores indicating more symptoms). The HADS-T is our chosen primary outcome as it has better sensitivity and positive predictive value than either of the individual scales in identifying depression when compared with *International Classification of Diseases* (ICD) criteria.³⁴ The anxiety and depression scores were also dichotomised as 'case' and 'non-case', with a cut-off point of 8 or 9.³³
- The Zarit Burden Interview is a 22-item self-report questionnaire and is the most consistently used measure of carer burden;³⁵ scores range from 0 to 88, with higher scores indicating more burden. We used it to adjust for the baseline burden on carers as those who have more burden may be expected to be more stressed.
- The MCTS is a self-completed measure of potentially abusive behaviour by the carers towards those for whom they care.³⁶ Ten behaviours are scored on whether or not, during the previous 3 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, through 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, the score was discussed with a supervising clinician and, if it was judged that the person with dementia was at risk, permission was asked to inform the clinical team so that the carer and patient could have appropriate help. This scale has been validated for use in family carers of people with dementia.³⁷
- The Health Status Questionnaire (HSQ)³⁸ mental health domain measures health-related QoL throughout the age range, is sensitive to change and has been validated in older and younger people. It is summarised as a continuous score, ranging from 0 to 100, with higher scores indicating better outcome.
- European Quality of Life-5 Dimensions (EQ-5D)^{39,40} is a standardised measure of health status which provides a simple descriptive profile and a single index value for health status. The EQ-5D descriptive system comprises five dimensions: mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has three levels: no problems, some problems and severe problems. The respondent is asked to indicate his or her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the five dimensions. The digits for the five dimensions can be combined in a five-digit number describing the respondent's health state.

- The Client Service Receipt Inventory (CSRI)⁴¹ comprehensively covers services, including (but not limited to) inpatient stays, outpatient attendances, day hospital treatment, visits to social clubs, meals at lunch clubs, day care visits, and hours spent in contact with community-based professionals such as community teams for older people, community psychologists, community psychiatrists, GPs, nurses (either practice, district or community psychiatric), social workers, occupational therapists, paid home help or care workers, and physiotherapists.

At all time points, carers were also asked for information about the person with dementia using:

- The Neuropsychiatric Inventory (NPI).⁴² The NPI 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). This was included as neuropsychiatric symptoms have been shown to be associated with carer psychological morbidity. Possible scores range from 0 to 144, with higher scores indicating more severe symptoms.
- Quality of Life-Alzheimer's disease (QoL-AD).⁴³ The QoL-AD is an instrument used to rate the QoL of people with dementia and can be observer rated. It was rated by the family carer to assess the patient's overall QoL. The total score ranges from 13 to 52, with higher scores indicating better outcome.
- Clinical Dementia Rating (CDR). The CDR, which we used as an informant instrument, grades the level of impairment of someone with dementia [categories: healthy (0), very mild (0.5), mild (1), moderate (2), severe (3)].⁴⁴

Changes to trial outcome after trial commenced

After the trial commenced, the team began to think further about the clinical relevance of this trial and concluded that the appropriate clinical questions were 'does the intervention work?' and, if it works, 'does it keep working and show more effect over time or does the effect wear off?'. As the intervention targets coping strategies, in theory, over time there may be a larger separation between those who use 'good' strategies and those who do not when dealing with the intractable problem of somebody with dementia. On the other hand, people may revert to their previous tactics and usefulness may be lost over time. In the last case, we might consider whether or not a 'top up' would be appropriate. We therefore proposed to our steering group, data management group and the National Institute of Health Research Health Technology Assessment programme that we split the follow-up period into short- and long-term follow-up.

We agreed with all of them that our primary short-term outcome would be repeated measures of the HADS at 4 and 8 months and our long-term outcome would be repeated measures of the HADS at 1 and 2 years. Our original proposal was inconsistent whether we would use the HADS-A or HADS-D score as a primary outcome. There are three validation studies in community samples (as opposed to solely, for example, people with cancer). The largest of these included 6163 participants, more than five times the sum of the other validation studies and includes random samples of adults throughout the age group and groups of people with psychiatric and physical illnesses.³⁴ Although the HADS is usually used to generate scores and caseness for the two subscales of clinically significant anxiety and depression separately, this study found that HADS-T had better sensitivity and positive predictive value than either of the individual scales in identifying cases when validated against standardised clinical criteria. The authors comment that their results are in line with those of previous smaller studies. We therefore concluded that the HADS-T was the best measure to use.

In addition, we requested and received a 5-year no-cost extension to the trial. We wished to follow up the participants every 6 months to examine carer mental health and care recipient admission to 24-hour care settings (homes and continuing care beds) over the longer term or until death at home. This is because changes in the rate of admissions may become more apparent over a longer time.

We submitted all of these agreed changes as major amendments to National Research Ethics Committee and appropriate research and development departments and they were agreed.

Short-term primary outcome (up to 8 months' follow-up)

1. Carer HADS-T score.^{32,34}
2. Cost-effectiveness: costs were measured using the CSRI.^{40,41} Costs were examined alongside the carer quality-adjusted life-years (QALYs), calculated from the EQ-5D^{40,41} by applying societal weights.^{40,41}

Long-term main outcomes (12 to 24 months' follow-up)

1. Carer HADS-T score.
2. Cost-effectiveness: costs using the CSRI alongside the carer QALYs calculated from the EQ-5D by applying societal weights.

Seven-year follow-ups

Time to entry to 24-hour care (this was added after funding and is not in this report, which covers the 2 years post recruitment).

Secondary outcomes

Short term (up to 8 months' follow-up):

1. depression and anxiety caseness and scores on the HADS³²
2. carer (HSQ mental health⁴⁵) and care recipient (QoL-AD⁴³) QoL
3. MCTS score.^{36,37}

Long term (12–24 months' follow-up):

1. time to entry of the person with dementia to 24-hour care
2. depression and anxiety caseness and scores on the HADS³²
3. carer (HSQ mental health⁴⁵) and care recipient (QoL-AD⁴³) QoL
4. MCTS score.

Sample size

This was calculated to test our main hypotheses that HADS-T score will be significantly lower in the intervention group than in the TAU group.

This study was originally powered for a primary outcome of HADS-A score based on data from a cross-sectional pilot study of family carers. Mean HADS-A scores for this group were 7.2 with a standard deviation (SD) of 4. A decrease of 2 points in mean score and a 0.5 change in SD was considered to be clinically significant (expert consensus). To detect such a difference, with 90% power at 5% significance level, 75 participants per group were required. To account for therapist clustering, a design effect of 1.87 was used for the intervention group, assuming an average of 30 carers per therapist and an intraclass correlation coefficient (ICC) of 0.03.⁴⁶ Based on these calculations and inflating for 20% attrition, we planned to recruit 90 participants in the TAU group (no clustering) and 168 participants in the intervention group (clustering).

For the reasons given above, it was agreed that the primary outcome should be changed to HADS-T score. As recruitment was complete, the sample size available for analysis was fixed with achieved numbers of 87 in the TAU group and 173 in the intervention group. The following power calculation justified that this achieved sample size was adequate to address the new primary objectives based on the HADS-T outcomes at 4 and 8 months.

This power calculation considers the short-term primary analysis of HADS-T score using repeated measurements at 4 and 8 months, with an adjustment (using analysis of covariance) for baseline score. We calculated that the sample size available (87 carers in the control group and 173 in the intervention group) would be sufficient to detect a clinically important difference of at least 2.4 points on the HADS-T.

The calculations assumed a HADS-T SD of 7.4 (as given from our cross-sectional pilot study data), correlation between baseline and follow-up scores of 0.5 and a correlation between repeated follow-up measurements of 0.7 (both chosen as conservative estimates). Based on these values, with the available sample size we have 80% power to detect a difference of 2.4 points on the HADS-T and 90% power to detect a 2.7-point difference, both consistent with differences considered to be clinically important. This calculation has factored in adjustments for 10% dropout and a design effect of 1.4 for clustering in the intervention arm (calculated using the known average cluster size, 15 carers per therapist and an assumed ICC of 0.03).⁴⁶

Statistical methods

Scoring questionnaires

The relevant outcome scores were calculated from the individual items for each instrument according to standard algorithms. Where individual items were missing, standard procedures (where available) for the calculation of these outcome scores were used. Single missing data items on the HADS were imputed using the subscale mean, but cases with more than one missing item in any given subscale were excluded as invalid.⁴⁷ Missing cells on the Brief COPE scale were imputed using the carer's own mean score for that particular subscale if there was one item missing (Charles Carver, University of Miami, 2011, personal communication). For the QoL-AD, if one or two items were missing, the mean of the completed items was used to impute the missing items. For all other outcomes, scores were calculated only where all relevant items had been completed.

Clinical outcomes

Separate regression analyses were used to estimate group differences in HADS-T score over the short term (using 4- and 8-month follow-ups) and the longer term (using 12- and 24-month follow-ups). In both cases, random-effects models accounted for repeated measurements and therapist clustering in the intervention arm. Adjustments were made for baseline HADS-T scores and centre (on which randomisation was stratified), and also on factors believed from the literature to affect affective symptoms (carer age, sex, carer burden and care recipient neuropsychiatric symptoms). All analyses were carried out by intention to treat, but we excluded, in the short term, carers who had data missing at both 4- and 8-month follow-up and, in the longer term, those with data missing at the 12- and 24-month follow-up. If an individual's data were available at 4 months but not at 8 months, or vice versa, their partial data were used in the short-term analysis, and similarly with the 12- and 24-month data for the long-term modelling.

Similar approaches were taken for analyses of the secondary outcomes. Random-effects logistic regression was used for binary outcomes. In the short term, entry of the person with dementia to 24-hour care was compared between groups using a simple comparison of proportions (not allowing for clustering) because of small numbers. For the long-term analyses, the effect of the intervention on the time until institutionalisation was examined using parametric shared frailty models to allow for clustering in the intervention arm and adjustment for baseline factors. (The models fitted had a gamma distribution for the shared frailty and a Weibull survival distribution for time until institutionalisation.)

Model assumptions were examined by checking the normality of the residuals and also plotting the residuals compared with the fitted values both at the individual and therapist cluster level. To quantify therapist clustering, unadjusted ICCs at each follow-up within the intervention group were estimated with 95% confidence intervals (CIs).

Sensitivity analyses were used to reanalyse the outcomes in various ways to assess robustness of our conclusions. These analyses considered adjustment for imbalances in baseline characteristics between the randomised groups and the differential effects of treatment over time (treatment by time interaction). In considering missing data, we examined the extent to which missing outcome varied by baseline characteristics using logistic regression. In these analyses, for each outcome a binary variable was created according to whether or not it was missing (1 = missing score, 0 = valid score). This binary outcome was used in logistic regression to determine associations with baseline factors. In a sensitivity analysis, the main analyses for each outcome were repeated adjusting for those factors found to be associated with missingness, thus making missing at random assumptions more plausible. In the longer-term analyses, we also fitted models incorporating all repeated measurements (at 4, 8, 12 and 24 months) and examined the interaction between treatment group and long-/short-term follow-up.

Cost-effectiveness

The primary economic evaluation was a cost-effectiveness analysis comparing differences in treatment costs for carers receiving the START intervention with QALYs computed from the EQ-5D⁴⁰ and societal weights⁴⁸ over 1–8 months' and then 1–24 months' follow-up. In a secondary analysis, differences in treatment costs were compared with changes in in HADS-T score over the same time periods. Both the primary and secondary economic evaluations were undertaken from the perspective of health and social care agencies.

Data on services used and support received by the carer and the person with dementia were collected using an adapted version of the CSRI as above at baseline (randomisation) and at 4, 8, 12 and 24 months. On each occasion, the carer was asked to report service use over the previous 4 months. For the primary economic analyses over 1–8 months and then 1–24 months, our focus was on service use by the carer.

Total carer-related costs were derived by combining health and social care service use data with estimated unit costs. Costs were calculated for the periods 1–8 months and 1–24 months. We did not collect service use data during the period between the 12- and 21-month data collection time points (on average 8 months). Costs during this period were interpolated from the 12- and 24-month data.

Unit costs were obtained from publicly available sources and set at 2009–10 prices: Department of Health National Schedule of Reference Costs 2008–9⁴⁹ for inpatient (accident and emergency) and outpatient attendances; the Personal Social Services Research Unit (PSSRU) unit cost compendium⁵⁰ for some inpatient services such as acute adult inpatient services; most other community-based health and social care professional services; and voluntary organisation services for a small number of services used by a few carers. Unit costs of services are listed in *Appendix 1*.

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 PSSRU compendium,⁵⁰ taking the mid-point 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 CDs based on the market rates for copying and delivering.

We analysed HADS-T and QALY differences between START and TAU interventions using a multilevel, mixed-effects model to account for therapist clustering in the intervention arm and repeated measures at 4, 8, 12 and 24 months. For the HADS-T analysis, we adjusted for baseline HADS-T score, centre and 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.

Differences in total health and social care cost between the START and TAU interventions were regressed 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% CIs for mean costs. Significance ($p < 0.05$) was judged where the bias-corrected 95% CIs of between-group change score excluded zero.

All analyses were conducted on an intention-to-treat basis; carers were excluded if data were missing at *both* 4 and 8 months for the 1–8-month economic analysis, and, for the 1–24-month economic analysis, carers were excluded if data were missing at 4, 8 and 24 months. 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 (ICER) was calculated as the difference in the cost of the START and TAU interventions divided by the difference in outcome (measured by HADS-T score or QALYs). Cost-effectiveness acceptability curves (CEACs) were plotted to locate the findings of the economic evaluation in their wider decision-making context. The CEAC illustrates the probability that the START intervention would be seen as cost-effective compared with TAU across a range of hypothesised values placed on incremental outcome improvements (willingness to pay by health and social care system decision-makers). Each CEAC was derived using a *net benefit approach*. Monetary values of incremental effects and incremental costs for each case were combined and net monetary benefit (NMB) derived as:

$$\text{NMB} = \lambda \times (\text{effect}_b - \text{effect}_a) - (\text{cost}_b - \text{cost}_a), \quad (1)$$

where NMB was net monetary benefit, λ is willingness to pay for a 1-point difference in the outcome measure (HADS-T score or QALYs) and subscripts a and b denote the TAU and START interventions, respectively. We explored a range of λ values for each outcome. We were able to account for sampling uncertainty and make adjustments as necessary in the primary analyses and sensitivity analyses.

For the cost-effectiveness analyses carried out at 24 months' follow-up, costs and outcomes in the second year were discounted at a rate of 3.5%, as recommended by NICE.⁵¹ The discount rate was varied from 0% to 6% to assess the impact changing the NICE-recommended rate had on costs, outcome and the ICER.

Two sensitivity analyses were conducted to assess the robustness of our results. The first sensitivity analysis adjusted for those variables which predicted missing outcomes, HADS-T score and QALYs, and was investigated separately for each outcome using logistic regression. The first step was to model a binary variable (missing vs. 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 which were found to be associated with 'missingness' on each outcome. For the analysis of HADS-T scores, 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 vs. 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 [i.e. adjusting for carers' work situation, relationship to patient, and patients' and carers' education and living situation (coresident or living separately)]. These analyses were chosen so as to be consistent with those used in the effectiveness analysis.⁴¹

We also plotted the CIs around the NMB to estimate the impact of uncertainty.

All economic analyses were carried out using Stata, version 12 (StataCorp LP, Chicago, IL, USA).

Chapter 5 Results

Participant flow and recruitment

Two hundred and sixty (55%) of the 472 carers referred were randomised (CIFT = 182, NELFT = 16, DRC = 35, NEPFT = 27) to the trial. The others declined to participate ($n = 181$; 38%), did not meet inclusion criteria ($n = 22$; 5%) or were uncontactable ($n = 9$; 2%).

Short-term clinical results (over 8 months)

The flow through the study to the short-term (8-month) outcome is shown in the Consolidated Standards of Reporting Trials (CONSORT) diagram (*Figure 1*).

Participant flow through study

Over the 8-month follow-up, 12 carers from the control group and 21 from the intervention group withdrew or were lost to follow-up (see *Figure 1*). 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 the following reasons for withdrawal: wanted treatment but not allocated to it (four in TAU group), did not feel the intervention was for them (three in intervention group), too busy (four in intervention group, one in TAU group), disliked talking about care recipient when they were not there (one in TAU group, one in intervention group), other family member wanted them to withdraw (one in TAU group), unwell (one in intervention group), care recipient died (one in TAU group) and trial too upsetting (one in intervention group). Six gave no reason (five in intervention group, one in TAU group). Three others did not participate and were not contactable at the 4- or 8-month follow-up, but have since come back to the study.

External validity

Table 1 compares the known demographic 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 to the care recipient than those who did not consent.

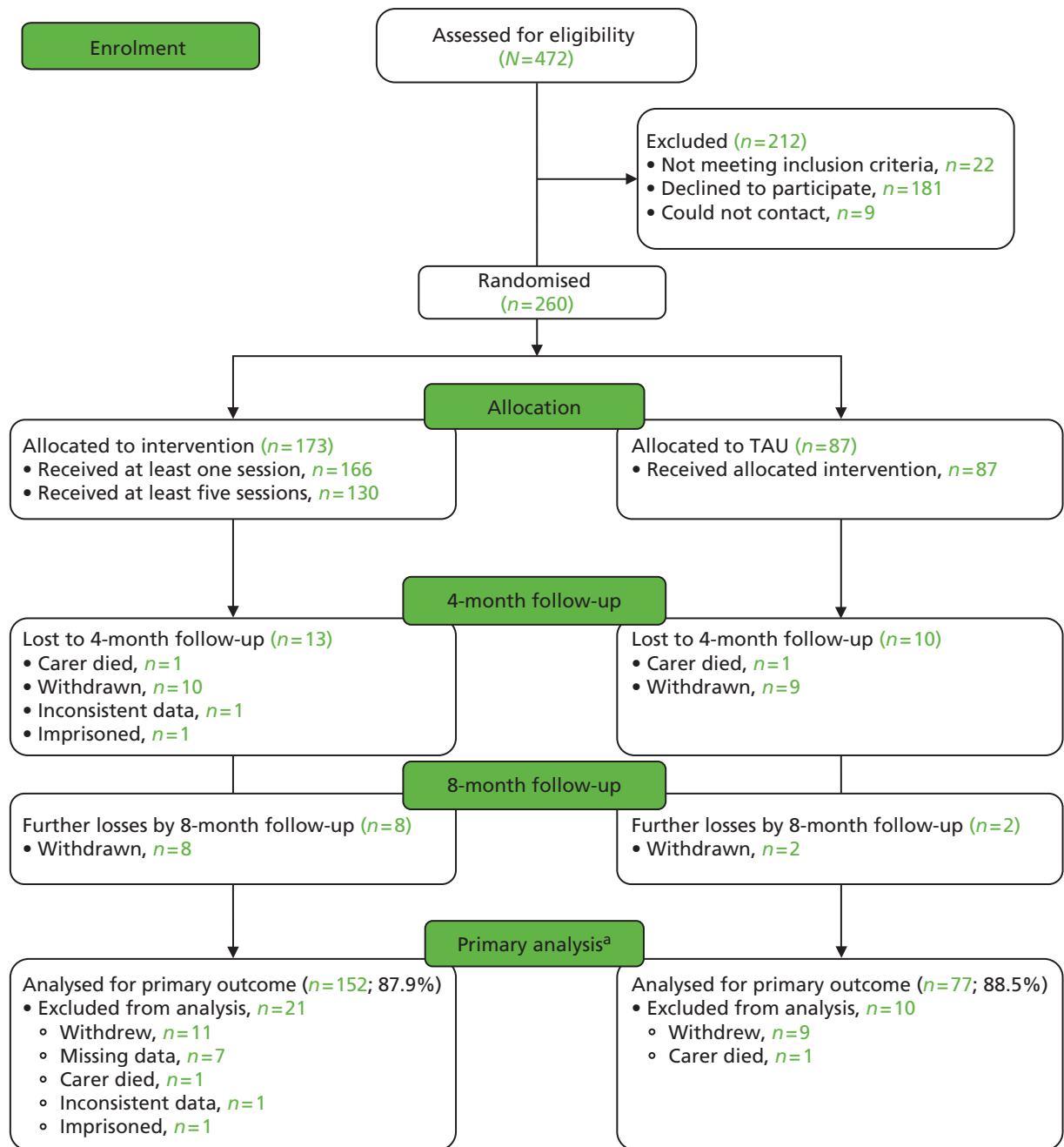


FIGURE 1 The CONSORT flow diagram (short-term analysis). a, To be included in the primary short-term analysis, the individual must have at least one score available for the HADS at 4 or 8 months. Those excluded have no measurements for either.

TABLE 1 External validity of eligible carers who consented to the trial compared with those who were not randomised

| Demographics | Carers eligible but not randomised (n = 190) | Carers randomised (n = 260) |
|-------------------------------|--|-----------------------------|
| Carer sex | | |
| Male | 56 (29%) | 82 (32%) |
| Patient sex | | |
| Male | 75 (39%) | 108 (42%) |
| Patient relationship to carer | | |
| Spouse/partner | 65 (34%) | 109 (42%) |
| Child | 90 (47%) | 113 (43%) |
| Friend | 8 (4%) | 6 (2%) |
| Daughter's/son's partner | 4 (2%) | 12 (5%) |
| Nephew/niece | 8 (4%) | 8 (3%) |
| Grandchild | 4 (2%) | 6 (2%) |
| Sibling | 5 (3%) | 4 (2%) |
| Other | 6 (3%) | 2 (1%) |

Values are numbers (%) of carers.

Baseline data

One hundred and seventy-three (66.5%) participants were randomised to the intervention group and 87 were randomised to TAU. Details are shown in *Table 2*. In general, randomisation achieved good balance for patient and baseline carer demographic and clinical characteristics between the randomised groups (*Tables 2 and 3*).

Intervention

Therapists

We trained 10 psychology graduates with no further clinical training – seven women and three men – who were ethnically white British (eight) and black and minority ethnic (two) in the age range 23–33 years. They worked with between 11 and 32 participants each (mean 17.3 participants) (*Table 4*).

Adherence with therapy

Of the eight therapy sessions offered, five or more were attended by 130 (75.1%) carers in the intervention group (*Figure 2* shows details of number of sessions attended). Seven (4.0%) of those in the intervention group withdrew before taking part in any therapy sessions. Adherence (attending five or more sessions) was better in those of white ethnicity [110 (78.0%) vs. 19 (61.3%)] than in those of other ethnicity and slightly better for male carers [46 (80.7%) vs. 84 (72.4%) of female carers] and those with at least A-level education [56 (80.0%) vs. 74 (71.8%)]. Adherence was similar by age group [aged < 60–75 years (77.3%) vs. 55 years (73.3%)] and work situation [in paid work 49 (77.8%) vs. other 81 (73.6%)].

Fidelity

Double rating was carried out for the first 13 participants; these had a Cohen's kappa value of 0.77, which is substantial agreement.⁵² After this, we judged it was necessary to have only a single rating for the remaining participants. Fidelity rating was carried out for 128 (78%) of the 165 participants who received one or more intervention(s). The remaining 38 either refused to be audiotaped (10) or withdrew before

TABLE 2 Baseline carer and patient demographic characteristics by randomisation group

| Demographics | Carer | | Patient | |
|----------------------------|------------------------------------|-----------------------------|------------------------------------|----------------------------|
| | TAU | Intervention | TAU | Intervention |
| | <i>Mean (SD), minimum, maximum</i> | | <i>Mean (SD), minimum, maximum</i> | |
| Age (years) | 56.1 (12.3), 27, 89 (n=87) | 62.0 (14.6), 18, 88 (n=172) | 78.0 (9.9), 53, 96 (n=87) | 79.9 (8.3), 55, 95 (n=173) |
| | n (%) | | n (%) | |
| Sex | | | | |
| Female | 62 (71.3%) | 116 (67.1%) | 50 (57.5%) | 102 (59.0%) |
| Male | 25 (28.7%) | 57 (32.9%) | 37 (42.5%) | 71 (41.0%) |
| Total | 87 | 173 | 87 | 173 |
| Ethnicity | | | | |
| White UK | 65 (74.7%) | 131 (76.2%) | 61 (70.1%) | 126 (72.8%) |
| White other | 5 (5.7%) | 10 (5.8%) | 6 (6.9%) | 14 (8.1%) |
| Black and minority | 17 (19.5%) | 31 (18.0%) | 20 (23.0%) | 33 (19.1%) |
| Total | 87 | 172 ^a | 87 | 173 |
| Marital status | | | | |
| Not currently married | 25 (28.7%) | 61 (35.3%) | 47 (54.0%) | 92 (53.2%) |
| Married/common law | 62 (71.3%) | 112 (64.7%) | 40 (46.0%) | 81 (46.8%) |
| Total | 87 | 173 | 87 | 173 |
| Education | | | | |
| No qualifications | 18 (20.7%) | 45 (26.0%) | 44 (51.2%) | 73 (44.5%) |
| School-level qualification | 33 (37.9%) | 51 (29.5%) | 16 (18.6%) | 28 (17.1%) |
| Further education | 36 (41.4%) | 77 (44.5%) | 26 (30.2%) | 63 (38.4%) |
| Total | 87 | 173 | 86 | 164 |
| Work situation | | | | |
| Full-time | 28 (32.2%) | 36 (20.8%) | N/A | N/A |
| Part-time | 20 (23.0%) | 27 (15.6%) | N/A | N/A |
| Retired | 23 (26.4%) | 80 (46.2%) | N/A | N/A |
| Not working | 16 (18.4%) | 30 (17.3%) | N/A | N/A |
| Total | 87 | 173 | N/A | N/A |
| Living with carer | | | | |
| Yes | N/A | N/A | 50 (57.5%) | 113 (65.3%) |
| Total | N/A | N/A | 87 | 173 |

N/A, not applicable.

^a Data missing for one carer.

TABLE 3 Baseline carer and patient clinical characteristics by randomisation group

| Scale | Carer | | Patient | |
|---|----------------------|-----------------------|----------------------|-----------------------|
| | TAU | Intervention | TAU | Intervention |
| HADS-T scores ^a | 14.8 (7.4) (n = 87) | 13.5 (7.3) (n = 172) | N/A | N/A |
| HADS-A scores ^a | 9.3 (4.3) (n = 87) | 8.1 (4.4) (n = 172) | N/A | N/A |
| HADS-D scores ^a | 5.5 (3.9) (n = 87) | 5.4 (3.8) (n = 172) | N/A | N/A |
| QoL-AD scores ^a | N/A | N/A | 29.9 (6.9) (n = 87) | 30.2 (6.9) (n = 170) |
| HSQ mental health scores ^a | 58.2 (21.7) (n = 87) | 58.3 (22.4) (n = 171) | N/A | N/A |
| MCTS total scores ^a | 2.7 (3.1) (n = 87) | 2.5 (2.9) (n = 172) | N/A | N/A |
| Zarit total scores ^a | 38.1 (17.0) (n = 84) | 35.3 (18.4) (n = 165) | N/A | N/A |
| NPI total scores ^a | N/A | N/A | 26.6 (20.1) (n = 86) | 24.0 (19.0) (n = 171) |
| CDR overall score ^b | N/A | N/A | (n = 87) | (n = 171) |
| Score 0.5 | N/A | N/A | 12 (13.8%) | 30 (17.5%) |
| Score 1 | N/A | N/A | 43 (49.4%) | 91 (53.2%) |
| Score 2 | N/A | N/A | 30 (34.5%) | 48 (28.1%) |
| Score 3 | N/A | N/A | 2 (2.3%) | 2 (1.2%) |
| HADS-A case (score of ≥ 9) ^b | 48 (55.2%) (n = 87) | 85 (49.4%) (n = 172) | N/A | N/A |
| HADS-D case (score of ≥ 9) ^b | 17 (19.5%) (n = 87) | 36 (20.9%) (n = 172) | N/A | N/A |
| MCTS (at least one item with score of ≥ 2) ^b | 38 (43.7%) (n = 87) | 82 (47.7%) (n = 172) | N/A | N/A |

N/A, not applicable.
a Data are mean (SD).
b Data are number (percentage).

TABLE 4 Number of carers by therapist (intervention group)

| Therapist | Number of carers (%) |
|-----------|----------------------|
| 1 | 11 (6.4) |
| 2 | 21 (12.1) |
| 3 | 12 (6.9) |
| 4 | 19 (11.0) |
| 5 | 12 (6.9) |
| 6 | 11 (6.4) |
| 7 | 32 (18.5) |
| 8 | 21 (12.1) |
| 9 | 17 (9.8) |
| 10 | 17 (9.8) |
| Total | 173 (100.0) |

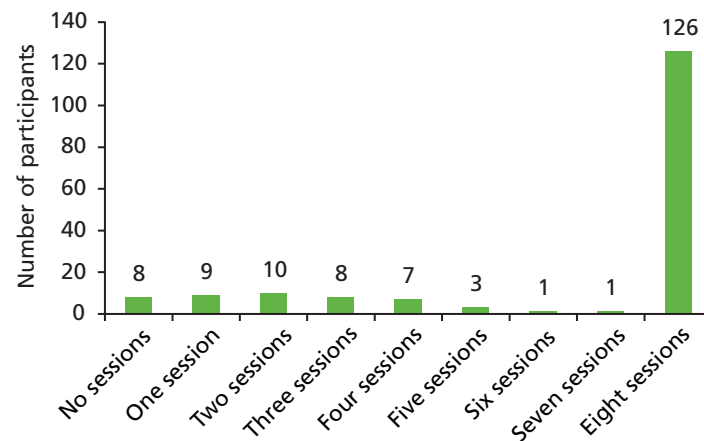


FIGURE 2 Number of sessions completed by participants.

carrying out the session which had been randomly selected for assessment ($n = 28$). For 100 (78%) participants fidelity was rated as 5, for 20 (16%) it was rated as 4, for five it was rated as 3 and for three it was rated as 2. Overall mean fidelity was calculated by adding each average rating (rating 1 plus rating 2, divided by 2) of the first 13 participants to the ratings of the remaining 105 participants, and dividing by the overall number of participants with available fidelity ratings. The mean fidelity score was 4.7 (SD 0.66).

Languages, translation and interpreters

Four eligible participants used translators at the recruitment stage, in Turkish (one), Bengali (two) and Farsi (one), and all four consented and were randomised: three to intervention and one to TAU. One participant allocated to intervention changed his or her mind and withdrew from intervention before session 1 but not follow-ups; one completed five sessions and one completed eight sessions.

Missing outcome data

The proportion of missing data for the main trial outcomes is given in *Table 5* by group and follow-up time. The primary outcome (HADS-T score) was missing for 35 (13.5%) patients at 4 months and for 56 (21.5%) patients at 8 months, with a slightly higher proportion missing in the intervention group: 40 (23.0%) in the intervention group and 16 (18.0%) in the TAU group. Two hundred and twenty-nine (88.1%) had HADS-T data for at least one of the 4- and 8-month points and, so, could be included in the primary analyses. Using logistic regression models, we identified baseline factors that were associated with missing outcome data.

Missingness of HADS-T score at 4 months was associated with the patient living with carer ($p = 0.007$) and for the 8-month outcome with having dependent children at home ($p = 0.003$), patient ethnicity ($p = 0.013$), patient living with carer ($p = 0.002$), patient relationship to carer ($p = 0.011$) and the COPE dysfunction score ($p = 0.004$).

TABLE 5 Percentage missing outcome by follow-up and group

| Scale | Baseline | | 4 months | | 8 months | |
|-------------------|----------------|-------------------------|----------------|-------------------------|----------------|-------------------------|
| | TAU, % missing | Intervention, % missing | TAU, % missing | Intervention, % missing | TAU, % missing | Intervention, % missing |
| HADS-A | 0.0 | 0.6 | 13.8 | 13.3 | 18.4 | 23.1 |
| HADS-D | 0.0 | 0.6 | 13.8 | 13.3 | 18.4 | 23.1 |
| HADS-T | 0.0 | 0.6 | 13.8 | 13.3 | 18.4 | 23.1 |
| Zarit total | 3.4 | 4.6 | 26.4 | 20.2 | 31.0 | 32.4 |
| MCTS total | 0.0 | 0.6 | 20.7 | 20.2 | 26.4 | 30.6 |
| HSQ mental health | 0.0 | 1.2 | 17.2 | 16.8 | 24.1 | 29.5 |
| QoL-AD total | 0.0 | 1.7 | 24.1 | 20.8 | 29.9 | 30.6 |

Clinical outcomes

Primary outcome

Analysis of HADS-T, adjusting for trust and baseline score and for factors related to outcome (carer age and sex, NPI and Zarit scores), showed a mean difference of -1.80 points (95% CI -3.29 to -0.31 points; $p = 0.02$) in favour of the intervention (Table 6). If the model did not include factors relating to outcome, then the results were similar, with an average decrease in score of -1.46 points (95% CI -2.89 to -0.03 points; $p = 0.05$). There was little therapist clustering: ICC at 4 months was 0.02 (95% CI 0.00 to 0.09) and at 8 months was 0.00 (95% CI 0.00 to 0.08).

Model assumptions were examined by checking the normality of the residuals and also plotting the residuals compared with the fitted values. These were done at the individual and therapist cluster level. These plots are shown in Figure 3 and do not indicate concerns about the model fit.

Sensitivity analysis

For the sensitivity analysis we adjusted for baseline factors associated with missingness of the HADS-T outcome. Missingness of the 4-month HADS-T was associated with patient living with carer ($p = 0.007$) and

TABLE 6 Primary and secondary clinical outcomes for the intervention and TAU groups (at 4 and 8 months): primary and secondary outcomes (at 4 and 8 months)

| Measure | TAU | TAU | Intervention | Intervention | Adjusted for baseline score and centre, difference (95% CI) | Adjusted also for carers age, sex, NPI and Zarit, difference (95% CI) |
|--|-------------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|--|---|
| | 4 months, mean (SD) (n = 75) | 8 months, mean (SD) (n = 71) | 4 months, mean (SD) (n = 150) | 8 months, mean (SD) (n = 133) | | |
| HADS-T scores | 14.3 (7.4) (n = 75) | 14.9 (8.0) (n = 71) | 12.4 (7.4) (n = 150) | 12.9 (7.9) (n = 133) | -1.46 (-2.89 to -0.03 ; p -value = 0.05) (n = 229) | -1.80 (-3.29 to -0.31 ; p -value = 0.02) (n = 220) |
| QoL-AD scores | 29.8 (5.8) (n = 66) | 29.7 (6.3) (n = 61) | 30.6 (6.4) (n = 136) | 30.2 (7.2) (n = 119) | 0.80 (-0.45 to 2.05) (n = 205) | 0.59 (-0.72 to 1.89) (n = 197) |
| HSQ mental health scores | 58.4 (18.0) (n = 72) | 58.2 (19.2) (n = 66) | 62.7 (20.8) (n = 144) | 58.6 (22.0) (n = 122) | 4.55 (0.92 to 8.17) (n = 219) | 4.09 (0.34 to 7.83) (n = 211) |
| HADS-A scores | 8.6 (4.2) (n = 75) | 8.8 (4.4) (n = 71) | 7.5 (4.2) (n = 150) | 7.6 (4.4) (n = 133) | -0.62 (-1.43 to 0.19) (n = 229) | -0.91 (-1.76 to -0.07) (n = 220) |
| HADS-D scores | 5.7 (4.0) (n = 75) | 6.1 (4.2) (n = 71) | 4.9 (3.9) (n = 150) | 5.3 (4.0) (n = 133) | -0.88 (-1.68 to -0.09) (n = 229) | -0.91 (-1.71 to -0.10) (n = 220) |
| HADS-A case (score of ≥ 9) | 36 (48.0%) (n = 75) ^a | 33 (46.5%) (n = 71) ^a | 54 (36.0%) (n = 150) ^a | 53 (39.9%) (n = 133) ^a | 0.35 (0.11 to 1.18) (n = 229) ^b | 0.30 (0.08 to 1.05) (n = 220) ^b |
| HADS-D case (score of ≥ 9) | 18 (24.0%) (n = 75) ^a | 23 (32.4%) (n = 71) ^a | 25 (16.7%) (n = 150) ^a | 28 (21.1%) (n = 133) ^a | 0.25 (0.08 to 0.81) (n = 229) ^b | 0.24 (0.07 to 0.76) (n = 220) ^b |
| MCTS (at least one item with score of ≥ 2) | 28 (40.6%) (n = 69) ^a | 23 (35.9%) (n = 64) ^a | 50 (36.0%) (n = 139) ^a | 40 (33.3%) (n = 120) ^a | 0.47 (0.18 to 1.23) (n = 214) ^b | 0.48 (0.18 to 1.27) (n = 206) ^b |

a Data are numbers of people and per cent.

b Data are odds ratios and 95% CIs.

Values are means (SD) unless otherwise stated. Treatment effect estimates (differences and odds ratios) are from models which take into account the repeated measurements, therapist clustering in the intervention arm and which are adjusted for baseline characteristics.

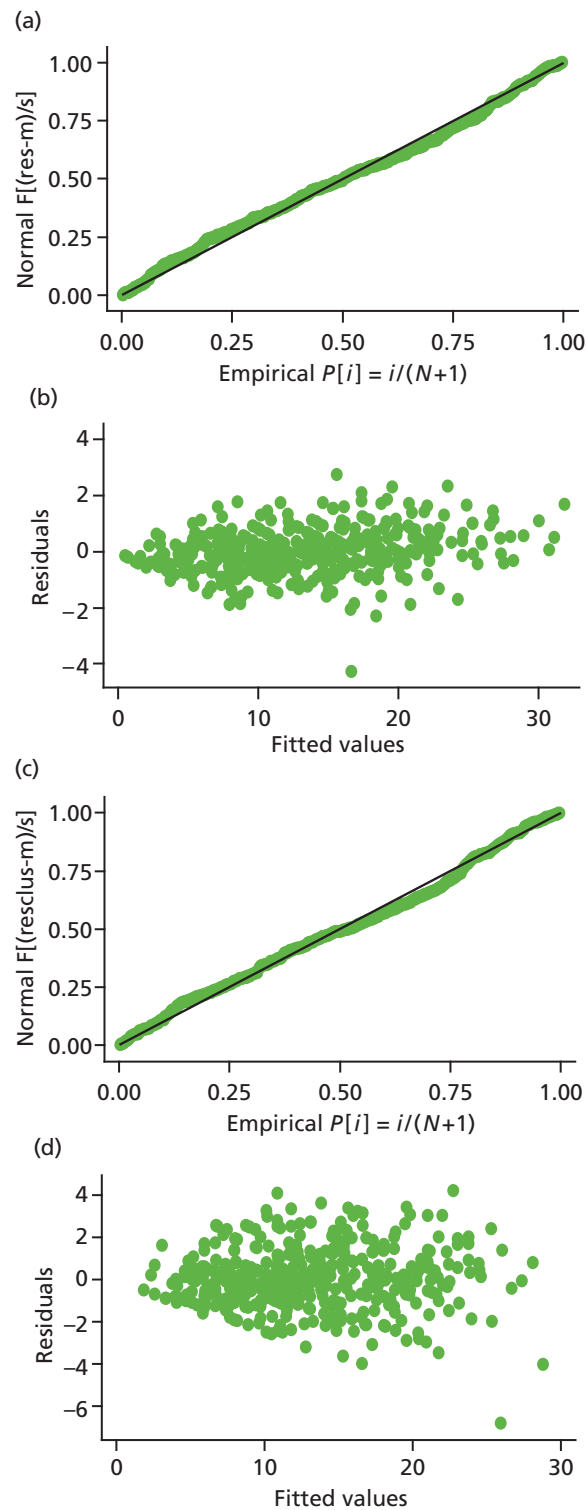


FIGURE 3 Checking model assumptions: residuals and fitted values from the models for HADS-T (based on the model-adjusted only for centre and baseline score). (a) Normality of residuals (individual level); (b) residuals vs. fitted values (individual level); (c) normality of residuals (cluster level); and (d) residuals vs. fitted values (cluster level).

for the 8-month outcome with having dependent children at home ($p = 0.003$), patient ethnicity ($p = 0.01$), patient living with carer ($p = 0.002$), patient relationship to carer ($p = 0.010$) and the COPE dysfunction score ($p = 0.004$). Refitting the main models adjusting for these significant predictors of missing values did not have a significant impact on the results (mean difference -1.53 , 95% CI -2.96 to -0.10). We also carried out a sensitivity analysis to adjust for baseline imbalances, namely carer's work situation, relationship to carer and patient and carer education and living situation, which again gave similar conclusions (mean difference -1.78 , 95% CI -3.30 to -0.27). Models including an interaction with time showed no evidence of a differential effect of the intervention between the 4- and 8-month time points ($p = 0.90$).

Secondary outcomes

Depression and anxiety caseness on the HADS

There was a significant reduction in the odds of HADS-D cases in the intervention group compared with TAU, with an odds four times higher for the TAU group [adjusted odds ratio (OR) 0.24, 95% CI 0.07 to 0.76]. Similarly, there was some evidence for a reduction in odds of HADS-A caseness (OR 0.30, 95% CI 0.08 to 1.05).

Anxiety and depression symptoms

Adjusted models for the individual HADS-A and HADS-D continuous scales indicated significant beneficial effects of the intervention over 8 months, with average decreases in scores of -0.910 (95% CI -1.763 to -0.070) and -0.91 (95% CI -1.71 to -0.10), respectively.

For HADS-A, sensitivity analyses adjusting for significant demographic and clinical predictors of missing values, namely patient living with carer, relationship to carer, carer having dependent children at home, patient ethnicity and COPE dysfunction score, gave a result with no significant difference between groups (mean difference -0.68 , 95% CI -1.49 to 0.11 ; $n = 229$).

The same analysis of HADS-D showed a significant difference between groups (mean difference -0.90 , 95% CI -1.70 to -0.11 ; $n = 229$).

Models including an interaction with time showed no evidence of a differential effect of the intervention between the 4- and 8-month time points for either HADS-A or HADS-D.

Carer (Health Status Questionnaire) and care recipient (Quality of Life-Alzheimer's disease) quality of life

There was no significant difference between groups in the person with dementia's overall QoL (QoL-AD). The HSQ mental health scale for the carer did, however, indicate significantly higher average scores and, hence, improved mental health (mean difference 4.09, 95% CI 0.34 to 7.83).

Models including an interaction with time showed no evidence of a differential effect of the intervention between the 4- and 8-month time points for either the HSQ mental health or the QoL-AD.

Modified Conflict Tactics Scale for significant abuse

There was some evidence of a decrease in abusive behaviour (OR 0.48, 95% CI 0.18 to 1.27). There was no evidence of an interaction between the intervention and the outcome at the 4- and 8-month follow-ups.

Time to care home admission

Fourteen patients were admitted to a care home during the 8-month follow-up period (not included in Table 7): three (3.6%) in the TAU group and 11 (6.4%) in the intervention group. Simple analyses indicate no evidence of a statistically significant difference between the groups (Fisher's exact test, $p = 0.56$).

This outcome will be considered more extensively in analyses of longer-term follow-up.

Health economic analysis: short term over 8 months

Service use and costs

Carers used a wide range of health and social care services over the 8-month period, as can be seen in *Table 7*. We did not impute individual items of service use and means are presented for non-missing cases only. Outpatient hospital and GP services were used by quite high proportions of participants.

The patterns of service use were weighted by their unit costs. Mean costs – grouped into outpatient, community and other services – are given in *Table 8*. The table distinguishes between the START and TAU groups, and reports figures for two time periods: the 4-month period between baseline and the 4-month assessment, and the 4-month period between the 4- and 8-month assessments. Although the number of users of outpatient services was higher in the intervention group (see *Table 8*), their average outpatient service cost was lower as they used outpatient services less frequently than people in the TAU group.

TABLE 7 Carers' use of health and social care services at baseline, 4 months and 8 months

| Service | Baseline, % (n) | | 4 months, % (n) | | 8 months, % (n) | |
|----------------------------------|-----------------|------------------------|-----------------|------------------------|-----------------|------------------------|
| | TAU (N = 87) | Intervention (N = 173) | TAU (N = 75) | Intervention (N = 150) | TAU (N = 71) | Intervention (N = 134) |
| Outpatient services | | | | | | |
| Outpatient hospital services | 33.3 (29) | 37.0 (64) | 32.0 (24) | 38.7 (58) | 28.2 (20) | 37.3 (50) |
| Community-based services | | | | | | |
| Admiral Nurse | 5.7 (5) | 3.5 (6) | 2.6 (2) | 6.0 (9) | 2.8 (2) | 3.7 (5) |
| Chiroprapist | 5.7 (5) | 13.9 (24) | 9.3 (7) | 11.3 (17) | 12.7 (9) | 17.2 (23) |
| Counsellor | 8.0 (7) | 2.3 (4) | 9.3 (7) | 2.7 (4) | 11.3 (8) | 1.5 (2) |
| Dentist | 27.6 (24) | 30.6 (53) | 29.3 (22) | 30.7 (46) | 36.6 (26) | 33.6 (45) |
| GP | 54.0 (47) | 54.3 (94) | 53.3 (40) | 50.0 (75) | 47.9 (34) | 48.5 (65) |
| NHS Direct | 1.1 (1) | 1.2 (2) | 1.3 (1) | 0.0 (0) | 0.0 (0) | 1.5 (2) |
| Optician | 17.2 (15) | 16.8 (29) | 8.0 (6) | 15.3 (23) | 21.1 (15) | 18.7 (25) |
| Outreach worker | 1.1 (1) | 0.6 (1) | 0.0 (0) | 0.7 (1) | 1.4 (1) | 0.0 (0) |
| Home care worker/ care attendant | 2.3 (2) | 1.7 (3) | 4.0 (3) | 1.3 (2) | 1.4 (1) | 1.5 (2) |
| Physiotherapist | 0.0 (0) | 0.6 (1) | 1.3 (1) | 0.0 (0) | 0.0 (0) | 2.2 (3) |
| Hygienist | 0.0 (0) | 0.6 (1) | 0.0 (0) | 0.7 (1) | 1.4 (1) | 0.7 (1) |
| Company medical check-up | 0.0 (0) | 0.6 (1) | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.0 (0) |
| Nurse (advanced) | 1.1 (1) | 0.6 (1) | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.0 (0) |
| Occupational therapist | 0.0 (0) | 0.6 (1) | 0.0 (0) | 0.7 (1) | 0.0 (0) | 0.0 (0) |
| Community psychiatrist | 0.0 (0) | 0.6 (1) | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.0 (0) |
| Practice nurse | 6.9 (6) | 2.3 (4) | 2.6 (2) | 4.7 (7) | 0.0 (0) | 5.2 (7) |
| Ambulance transport | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.7 (1) | 0.0 (0) | 0.0 (0) |
| Dietitian | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.7 (1) | 0.0 (0) | 0.0 (0) |
| Other services | 16.1 (14) | 9.8 (17) | 22.7 (17) | 14.0 (21) | 12.7 (9) | 13.4 (18) |

TABLE 8 Health and social service costs and outcomes at 4 and 8 months for carers in the intervention and TAU groups, and differences between START and TAU groups

| Cost categories and outcomes used in the economic evaluation | TAU, mean (SD) | | Intervention, mean (SD) | | Intervention vs. TAU over 1–8 months, difference (95% CI) adjusted for baseline variables |
|--|-------------------|------------------|-------------------------|------------------|---|
| | 1–4 months | 5–8 months | 1–4 months | 5–8 months | |
| Costs (£, 2009–10) | | | | | |
| 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) |
| Total | 381 (1102) | 244 (450) | 296 (1006) | 262 (598) | –14 (–239 to 211) (n = 193) |
| Outcomes used in the economic evaluation | | | | | |
| HADS-T scores ^a | 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) |

Direct cost of intervention not included.

a HADS-T scores and difference are slightly different from above because different versions of Stata were used for the analyses.

The right-hand column of *Table 8* shows the difference in costs between the START and TAU groups across the whole evaluation period of 8 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 TAU group. After adjustment for baseline characteristics (see above) the standardised difference was £14, with the 95% CI (–£239 to £211) suggesting that there was not a 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 8*.

The calculation of cost of the therapy is 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 6-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 8 weeks). Looking at the average time spent in each session with the carer, excluding those who did not have any sessions and those who used translators ($n = 163$), the median time per session was 1 hour 16 minutes (76 minutes). The mean time per session was 1 hour 17 minutes (77 minutes, SD 20 minutes). For those who used translators, the mean time per session was 3 hours 47 minutes (SD 1 hour 36 minutes), with a range of 2 hours 40 minutes to 4 hours 55 minutes. We calculated that the mean cost per session per carer was £36. Adding in the cost of the relaxation CDs (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 adjusting for baseline variables as we did in the clinical effectiveness calculations, costs for the START group were slightly but not significantly higher than for the TAU group. The mean cost difference was £252 (95% CI –£28 to £565) for sample members on the EQ-5D, and £247 (95% CI £0 to £569) for sample members on the HADS-T measure (*Table 9*).

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 ICERs reported in *Table 10*. 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.

TABLE 9 Treatment and cost effects (with 95% bias-corrected CIs) and ICERs over 8 months

| Outcome | Incremental differences (START minus TAU) and ICERs over 8-month evaluation period |
|--|--|
| With QALY as outcome ($n = 177$) ^a | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £252 (–£28 to £565) |
| Incremental QALY gain, mean (95% CI) | 0.042 (0.015 to 0.071) |
| ICER (£ per QALY) | 6000 |
| With HADS-T as outcome ($n = 191$) ^b | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £247 (£0 to £569) |
| Incremental HADS-T score change, mean (95% CI) | 2.10 (0.51 to 3.75) |
| ICER (£ per unit change on HADS-T) | £118 |

a Sample size based on complete data for QALYs and cost measures.
b Sample size based on complete data for HADS-T and cost measures.

TABLE 10 Sensitivity analyses: treatment and cost effects (with 95% CIs) and ICERs over 8 months

| Outcome | Incremental differences and ICERs over 8-month evaluation period | |
|--|---|-----------------------------------|
| | Adjusting for significant demographic and clinical predictors of missing values | Adjusting for baseline imbalances |
| With QALY as outcome ($n = 177$) ^a | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £229 (–£94 to £552) | £236 (–£101 to £617) |
| Incremental QALY gain, mean (95% CI) | 0.042 (0.014 to 0.070) | 0.041 (0.012 to 0.071) |
| ICER (£ per QALY) | £5452 | £5756 |
| With HADS-T as outcome ($n = 191$) ^b | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £226 (–£74 to £525) | £231 (–£46 to £583) |
| Incremental HADS-T score change, mean (95% CI) | 2.11 (0.41 to 3.81) | 2.07 (0.44 to 3.90) |
| ICER (£ per unit change on HADS-T) | £107 | £112 |

a Sample size based on complete data for QALYs and cost measures.
b Sample size based on complete data for HADS-T and cost measures.

Health and social care system costs were slightly higher for carers who received the START intervention (in addition to TAU) but the difference was not statistically significant, and carers in this group enjoyed significantly better outcomes, whether measured in terms of health-related QoL (QALY) or affective symptoms (HADS-T). Whether or not these results imply that START is cost-effective compared with TAU depends on the decision-maker's willingness to pay for these gains in QoL and affective symptoms. To aid discussion of willingness to pay, we computed the ICERs. We also plotted the associated CEACs and examined the CIs around NMB.

Looking first at QALY as the outcome, the mean cost per QALY gained was £6000. The CEAC is shown in *Figure 4*, 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,

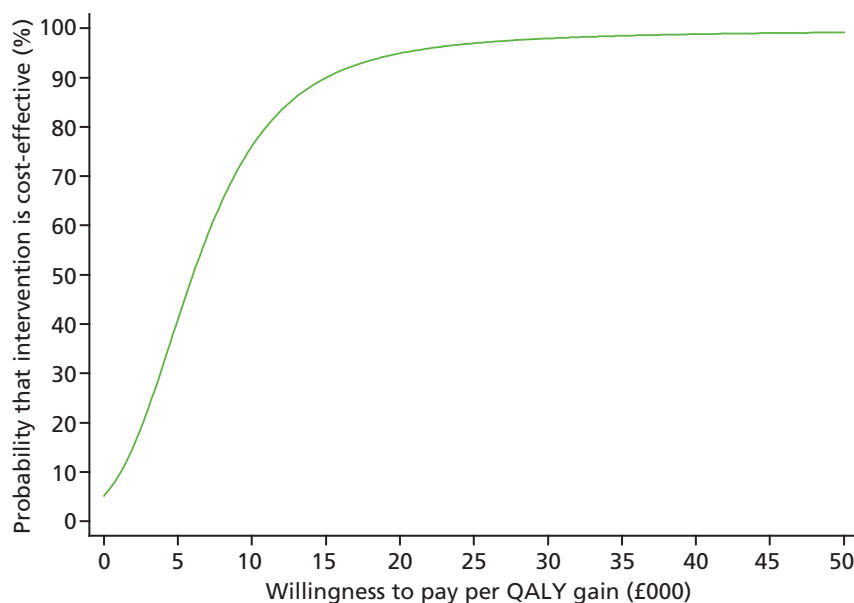


FIGURE 4 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 8 months.

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%.⁵³

The 95% CIs around NMB suggest that there is a strong likelihood that the START intervention is cost-effective at the £30,000 threshold.

For the other outcome measure, the HADS-T measure of affective symptoms, the mean cost per 1-point difference on the HADS-T was £118. The CEAC for this outcome measure is shown in *Figure 5*. We are not aware of any previously suggested monetary thresholds for gauging cost-effectiveness on the HADS. 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 is 1.6. The mean cost of achieving such a change with the START intervention would be £189.

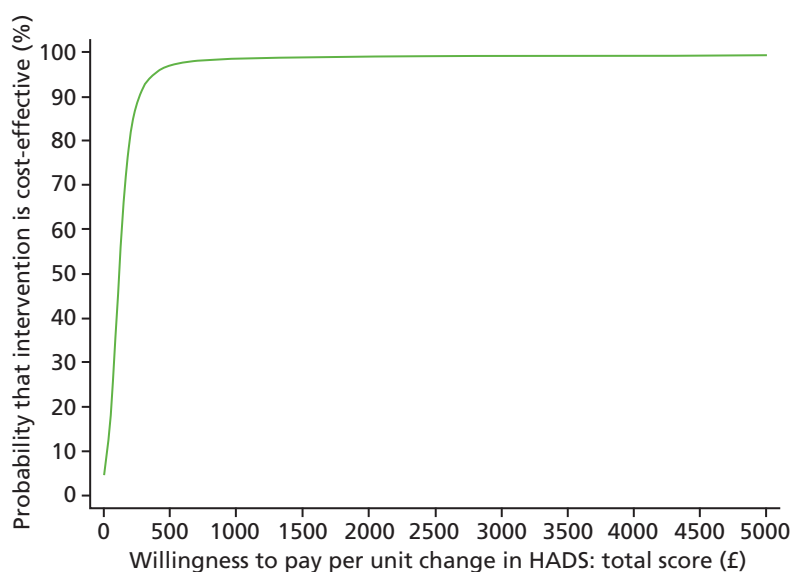


FIGURE 5 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in HADS gain over 8 months.

Sensitivity analyses

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 figures in *Table 10*.

The mean ICER values are now £5452 per additional QALY and £107 per 1-point difference in HADS-T score. *Figure 6* shows the CEAC with QALY as the outcome measure; at the lower-bound NICE threshold of £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 figures in *Table 11*. The mean ICER values from this further analysis are £5756 per additional QALY, and £112 per 1-point difference in HADS-T score.

The CEAC with QALY as the outcome measure is shown in *Figure 6*. At the lower-bound NICE threshold of £20,000, the START intervention has a 93% likelihood of being seen as cost-effective, rising to 98% at the £30,000 threshold.

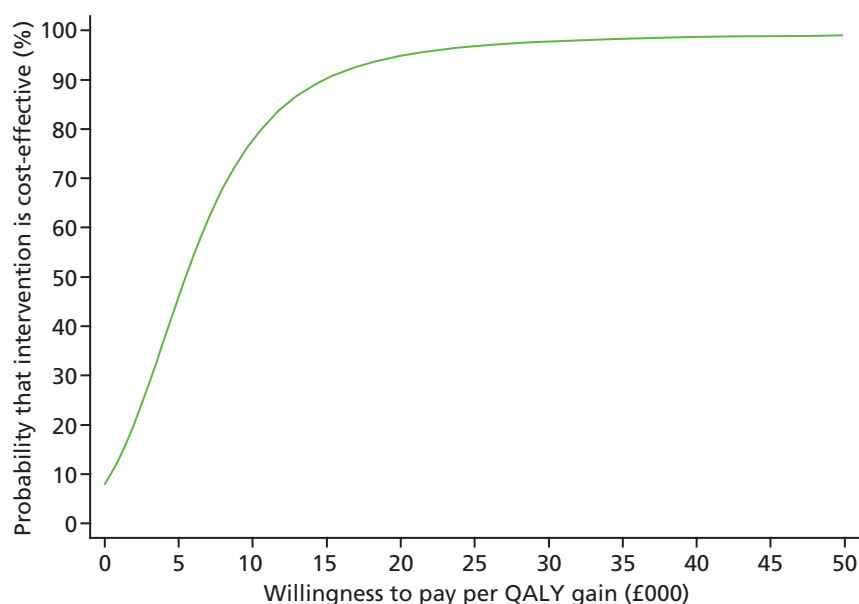


FIGURE 6 Sensitivity analysis of CEAC with QALY as the outcome measure over 8 months.

TABLE 11 Missing outcomes at 12 and 24 months' follow-up

| Measure | Missing at 12 months, <i>n</i> (%) | | Missing at 24 months, <i>n</i> (%) | |
|-------------------|------------------------------------|--------------|------------------------------------|--------------|
| | Randomised group | | Randomised group | |
| | TAU | Intervention | TAU | Intervention |
| HADS-A | 20 (23) | 35 (20) | 23 (26) | 41 (24) |
| HADS-D | 20 (23) | 35 (20) | 23 (26) | 41 (24) |
| HADS-T | 20 (23) | 35 (20) | 23 (26) | 41 (24) |
| MCTS total | 32 (37) | 59 (34) | 40 (46) | 78 (45) |
| HSQ mental health | 26 (30) | 52 (30) | 32 (37) | 60 (35) |
| QoL-AD total | 34 (39) | 58 (34) | 38 (44) | 77 (45) |

The CIs around NMB for these two sensitivity analyses are shown in *Appendix 2*. Taking into account uncertainty in the estimation suggests that a degree of caution should be exercised in concluding that START is necessarily cost-effective.

Long-term outcomes (12 and 24 months)

The CONSORT diagram (*Figure 7*) shows the flow of participants through the study up to the 2-year follow-up. The primary outcome (HADS-T score) was missing for 55 (21.2%) patients at 12 months and for 64 (24.6%) patients at 24 months. Two hundred and nine (80.4%) patients had HADS-T data for at least one of the long-term follow-up points, and so could be included in the primary analyses.

Missing outcomes

The proportion of missing data for the main trial outcomes is given in *Table 11* by group and follow-up time.

Clinical outcomes

Primary and secondary clinical outcomes are shown in *Table 12*. This summarises average scores at months 12 and 24 and gives the estimated effect of therapy compared with TAU for primary and secondary outcomes.

Analysis of HADS-T scores, adjusting for trust and baseline score and for factors related to outcome (carer age and sex, NPI and Zarit scores), showed a mean difference of -2.58 points (95% CI -4.26 to -0.90 points; $p = 0.003$) 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 -1.84 (95% CI -3.50 to -0.17 ; $p = 0.03$). The therapist ICC at 12 months was 0.00 (95% CI 0.00 to 0.07) and at 24 months was 0.00 (95% CI 0.00 to 0.07).

Sensitivity analyses adjusting for significant demographic and clinical predictors of missing values, namely patient living with carer and COPE dysfunction score, still gave a result with significant difference between groups (difference in means -2.69 , 95% CI -4.39 to -0.98 ; $p = 0.002$; $n = 200$), as did sensitivity analyses adjusting for factors imbalanced at baseline (carer work, carer education, patient education, relationship with carer, lives with carer; difference in means -2.37 , 95% CI -4.11 to -0.63 , $p = 0.008$).

Models including an interaction with time showed no evidence of a differential effect of the intervention between the 4- and 8-month time points or between the 12- and 24-month time points for HADS-T score ($p = 0.92$) and indicated a similar long-term treatment effect.

Model assumptions were examined by checking plots assessing the normality of the residuals and also plotting residuals versus fitted values. These were done for residuals at both the individual and the therapist cluster level. These plots did not indicate concerns about the model fit.

Secondary outcomes

Results of models considering the long-term effect of intervention on secondary outcomes are also given in *Table 12*.

Depression and anxiety caseness on the HADS

From the adjusted models there was a significant reduction in the odds of HADS-D cases in the intervention group compared with TAU, with an odds seven times higher for the TAU group (OR 0.14, 95% CI 0.04 to 0.53). Similarly, there was some evidence for a reduction in odds of HADS-A caseness (OR 0.57, 95% CI 0.26 to 1.24).

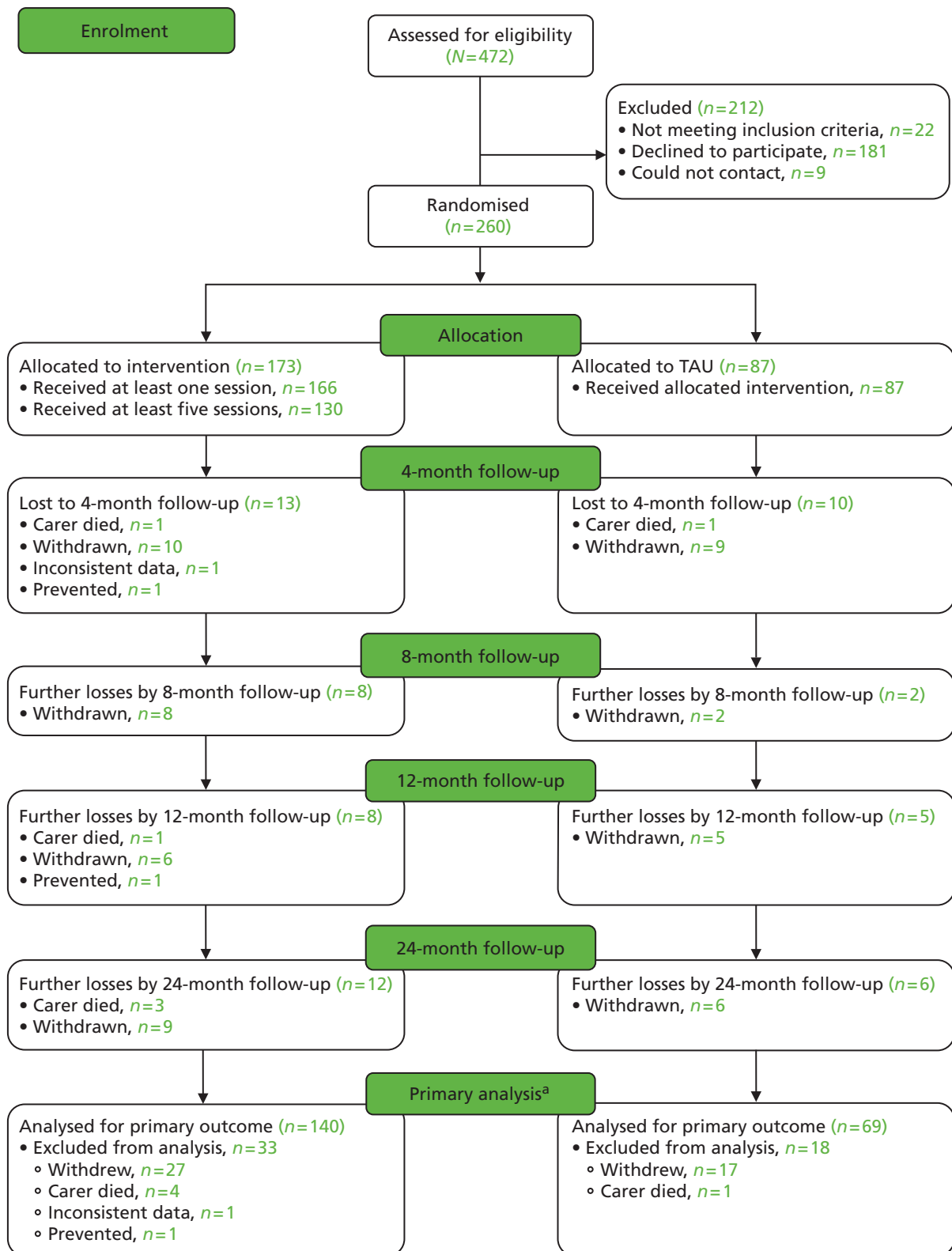


FIGURE 7 The CONSORT flow diagram for long-term outcomes (12 and 24 months). a. To be included in the primary long-term analysis, the individual must have at least one score available for the HADS at 12 or 24 months. Those excluded have no measurements at 12 or 24 months.

TABLE 12 Primary and secondary clinical outcomes (at 12 and 24 months): primary and secondary outcomes (at months 12 and 24) for those in the intervention and TAU groups

| Measure | TAU | | Intervention | | Adjusted for baseline score and centre, difference (95% CI) | Adjusted also for carer's age, sex, NPI and Zarit, difference (95% CI) |
|--|------------------------------------|------------------------------------|-------------------------------------|-------------------------------------|---|--|
| | 12 months, mean (SD) (n) | 24 months, mean (SD) (n) | 12 months, mean (SD) (n) | 24 months, mean (SD) (n) | | |
| HADS-T scores | 14.6 (8.9) (n = 64) | 15.5 (9.5) (n = 64) | 12.5 (7.9) (n = 138) | 13.6 (8.3) (n = 132) | -1.84 (-3.50 to -0.17) ^b (n = 209) | -2.58 (-4.26 to -0.90) ^b (n = 200) |
| QoL-AD scores | 30.0 (6.4) (n = 53) | 29.4 (7.0) (n = 49) | 30.5 (6.7) (n = 114) | 29.9 (6.7) (n = 95) | 0.16 (-1.30 to 1.63) ^b (n = 174) | 0.17 (-1.37 to 1.70) ^b (n = 168) |
| HSQ mental health scores | 56.2 (22.5) (n = 61) | 55.0 (21.2) (n = 55) | 61.9 (20.6) (n = 121) | 60.2 (19.8) (n = 113) | 7.16 (2.72 to 11.60) (n = 189) | 7.47 (2.87 to 12.08) ^b (n = 183) |
| HADS-A scores | 8.8 (5.1) (n = 67) | 9.2 (5.3) (n = 64) | 7.5 (4.4) (n = 138) | 8.1 (4.9) (n = 132) | -0.75 (-1.75 to 0.25) ^b (n = 209) | -1.16 (-2.15 to -0.18) ^b (n = 200) |
| HADS-D scores | 5.9 (4.3) (n = 67) | 6.3 (4.9) (n = 64) | 5.0 (4.2) (n = 138) | 5.5 (4.2) (n = 132) | -1.14 (-2.00 to -0.28) ^b (n = 209) | -1.45 (-2.32 to -0.57) ^b (n = 200) |
| HADS-A case (score of ≥ 9) | 33 (49.3) ^a (n = 67) | 32 (50.0) ^a (n = 64) | 54 (39.1) ^a (n = 138) | 57 (43.2) ^a (n = 132) | 0.53 (0.24 to 1.16) ^c (n = 209) | 0.57 (0.26 to 1.24) ^c (n = 200) |
| HADS-D case (score of ≥ 9) | 18 (26.9) ^a (n = 67) | 19 (29.7) ^a (n = 64) | 24 (17.4) ^a (n = 138) | 30 (22.7) ^a (n = 132) | 0.22 (0.05 to 0.96) ^c (n = 209) | 0.14 (0.04 to 0.53) ^c (n = 192) |
| MCTS (at least one item with score of ≥ 2) | 21 (38.2) ^a (n = 55) | 11 (23.4) ^a (n = 47) | 41 (36.0) ^a (n = 114) | 28 (29.5) ^a (n = 95) | 0.96 (0.42 to 2.19) ^c (n = 176) | 0.83 (0.36 to 1.93) ^c (n = 171) |

a Data are numbers and percentages.

b Data are treatment effect (intervention – TAU) with 95% CIs.

c Data are ORs and 95% CI.

Values are means (SD) unless otherwise stated. Treatment effect estimates (differences and ORs) are from models which take into account the repeated measurements, therapist clustering in the intervention arm and which are adjusted for baseline characteristics.

Anxiety and depression symptoms

Adjusted models for the individual HADS-A and HADS-D continuous scales indicated significant beneficial effects of the intervention at 24 months, with average decreases in scores of -1.16 (-2.15 to -0.18; $n = 200$) and -1.45 (95% CI -2.32 to -0.57), respectively.

Models including an interaction with time showed no evidence of a differential effect of the intervention between the 4- and 8-month time points or between the 12- and 24-month time points for HADS-A or HADS-D ($p = 0.99$ and $p = 0.86$, respectively).

Carer (Health Status Questionnaire) and care recipient (Quality of Life-Alzheimer's disease) quality of life

There was no significant difference between groups for the person with dementia's overall QoL (QoL-AD). The HSQ mental health scale for the carer did, however, indicate significantly higher average scores and hence improved mental health (mean difference 7.47, 95% CI 2.87 to 12.08; $n = 183$).

Models including an interaction with time showed no evidence of a differential effect of the intervention between the 4- and 8-month time points or between the 12- and 24-month time points for either QoL-AD or HSQ mental health ($p = 0.24$ and $p = 0.14$, respectively).

Time to care home admission

Two hundred and fifty-nine (87 in TAU and 172 in the intervention group) individuals were included in the analysis. We found that one person with dementia was included twice as two different carers (spouse and daughter) had been included and gave different dates of birth of the patient. The individual was included only once and from the first recruitment date (spouse carer's recruitment). Both carers had been in the intervention group.

For four people (three in TAU and one in the intervention group), the baseline date and the last known at home date were the same; thus, they were censored at time = 0 days.

Of the remaining 84 in the TAU group, 17 (20.2%) were admitted to a care home, and in the intervention group, 32 (18.7%) of the remaining 171 were admitted, within the 24-month follow-up period.

Figure 8 shows a Kaplan–Meier plot for time until admission to a care home for each randomised group.

A parametric shared frailty model assuming a gamma distribution for the shared frailty with a Weibull survival distribution was fitted for the time to institutionalisation. The model included trust and randomisation group and additionally adjusted for carer age, carer sex, baseline NPI total and baseline Zarit total. This model included 242 people with dementia. The estimated hazard ratio (HR) was 0.83 with 95% CI 0.44 to 1.56 ($p = 0.56$), showing no significant evidence of an effect of the intervention compared with TAU. Sensitivity analyses fitted the same model with additional adjustment for baseline imbalances (carer work, carer education, patient education, relationship with carer, lives with carer). This gave HR 0.62 (95% CI 0.31 to 1.23; $p = 0.17$; $n = 232$).

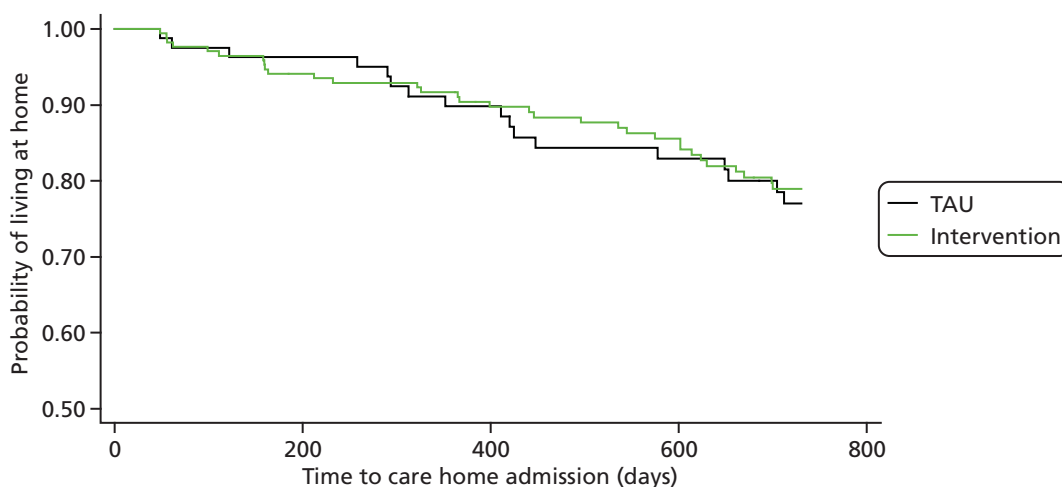


FIGURE 8 Time until admission to a care home for each randomised group over 24 months' follow-up.

Modified Conflict Tactics Scale for significant abuse

There was no evidence for a decrease in abusive behaviour (adjusted OR 0.83, 95% CI 0.36 to 1.93) (Figure 9).

Cost-effectiveness (over 24 months)

Service use and costs

Economic data for the 24-month follow-up period were available for 196 carers (75%): 64 in the TAU group and 132 in the intervention group. The number of carers using services in the 24-month follow-up period is detailed in Table 13. As can be seen in Table 13, carers used a wide range of health and social care services. GP services were used by a high proportion of participants.

Mean health and social care costs are reported in Table 14. The table distinguishes the START and TAU groups and reports figures for the 4-month period from 9 to 12 months and the 4-month period from 21 to 24 months. In contrast to the outpatient service costs over the 4-month period between baseline and the 4-month assessment and the 4-month period between the 4- and 8-month assessments, outpatient service costs over 9–12 months and 21–24 months were higher in the intervention group as participants in this group used outpatient services more frequently than those in the TAU group.

Table 14 shows the difference in costs between the START and TAU groups across the whole evaluation period of 24 months. To calculate costs over 24 months, we summed costs over the study periods 1–8 months, 9–12 months, 13–20 months and 21–24 months. Costs during the period between the 12- and 21-month data collection time points (on average 8 months) were interpolated from 12- and 24-month data. Mean costs over the study period (1–24 months) were £1492 in the START group and £1578 in the TAU group. After adjustment of baseline characteristics, the standardised difference was £173, with the 95% CI (–£115 to £460) suggesting that there was no significant difference in costs between the two groups. The scores on the two outcome measures used in the economic evaluation are included at the bottom of Table 14.

Mean costs (including the direct costs of intervention and health and social care system costs) for the 24-month period for carers in the START group were higher, although not significantly so, than for carers in the TAU group. The mean cost difference was £336 (95% CI –£223 to £895) for sample members on the EQ-5D and £303 (95% CI –£206 to £812) for sample members on the HADS-T measure (Table 15).

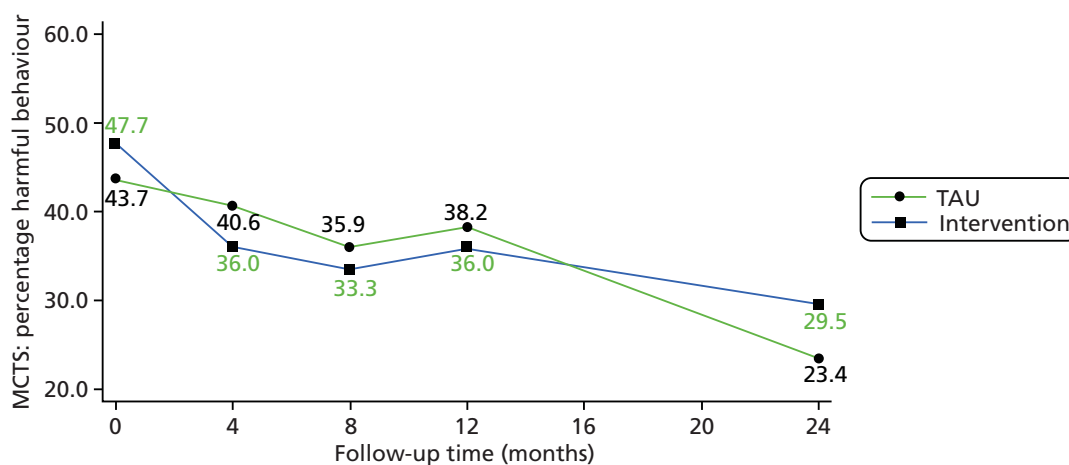


FIGURE 9 Modified Conflict Tactic Scale for significant abuse over 24 months in intervention and control groups.

TABLE 13 Carers' use of health and social care services at 12 and 24 months

| Services | 12 months | | 24 months | |
|---------------------------------|---|--|---|--|
| | TAU (<i>N</i> = 67), % (<i>n</i>) using service | Intervention (<i>N</i> = 138), % (<i>n</i>) using service | TAU (<i>N</i> = 64), % (<i>n</i>) using service | Intervention (<i>N</i> = 132), % (<i>n</i>) using service |
| Outpatient services | | | | |
| Outpatient hospital services | 24.7 (19) | 32.7 (50) | 27.6 (24) | 32.9 (53) |
| Community-based services | | | | |
| Admiral Nurse | 3.9 (3) | 3.3 (5) | 1.3 (1) | 1.9 (3) |
| Chiropodist | 6.5 (5) | 11.1 (17) | 6.5 (5) | 8.5 (13) |
| Counsellor | 3.9 (3) | 3.3 (5) | 2.6 (2) | 1.9 (3) |
| Dentist | 28.6 (22) | 27.0 (40) | 23.4 (18) | 31.3 (48) |
| GP | 42.9 (33) | 35.2 (53) | 48.1 (37) | 44.4 (68) |
| Optician | 10.4 (8) | 8.5 (13) | 16.4 (25) | 16.4 (25) |
| Outreach worker | 1.3 (1) | 0.0 (0) | 0.0 (0) | 0.0 (0) |
| Home care worker/care attendant | 0.0 (0) | 0.7 (1) | 3.9 (6) | 0.0 (0) |
| Physiotherapist | 1.3 (1) | 2.1 (3) | 1.4 (2) | 1.4 (2) |
| District nurse | 2.6 (2) | 0.7 (1) | 0.7 (1) | 0.7 (1) |
| Support worker | 0.0 (0) | 0.7 (1) | 0.7 (1) | 0.7 (1) |
| Psychotherapist | 0.0 (0) | 0.7 (1) | 0.0 (0) | 0.7 (1) |
| Occupational therapist | 0.0 (0) | 0.7 (1) | 0.7 (1) | 0.7 (1) |
| Speech and language therapist | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.7 (1) |
| Practice nurse | 1.3 (1) | 0.7 (1) | 0.0 (0) | 3.9 (6) |
| Cardiac nurse | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.7 (1) |
| Ambulance transport | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.7 (1) |
| Social worker | 0.0 (0) | 0.0 (0) | 0.0 (0) | 0.7 (1) |
| Other services | 2.6 (2) | 0.7 (1) | 0.0 (0) | 2.7 (3) |

TABLE 14 Health and social care service costs and outcomes at 12 and 24 months for carers in the intervention and TAU groups and differences between START and TAU groups

| Cost categories and outcomes used in the economic evaluation ^a | TAU, mean (SD) | | Intervention, mean (SD) | | Intervention vs. TAU over 1–24 months, difference (95% CI) adjusted for baseline variables |
|---|------------------|------------------|-------------------------|------------------|--|
| | 9–12 months | 21–24 months | 9–12 months | 21–24 months | |
| Costs (£, 2009–10) ^a | | | | | |
| Outpatient | 88 (190) | 102 (289) | 90 (154) | 111 (213) | 26 (–117 to 170; <i>n</i> = 176) |
| Community | 143 (336) | 94 (170) | 132 (329) | 108 (144) | –44 (–172 to 84; <i>n</i> = 176) |
| Other | 5 (31) | 0 (0) | 2 (19) | 67 (699) | 67 (–162 to 296; <i>n</i> = 176) |
| Total | 236 (390) | 196 (332) | 224 (373) | 286 (765) | 173 (–115 to 460; <i>n</i> = 175) |
| Outcomes used in the economic evaluation ^b | | | | | |
| EQ-5D | 0.81 (0.19) | 0.75 (0.18) | 0.79 (0.23) | 0.72 (0.24) | 0.05 (–0.03 to 0.13; <i>n</i> = 184) |
| HADS-T scores ^a | 14.6 (8.9) | 14.4 (8.9) | 12.5 (7.9) | 12.7 (7.7) | –2.45 (–4.01 to –0.90; <i>n</i> = 200) |

a Direct cost of intervention not included.

b Discounted rate = 3.5%; formula $1/(1+r)^n$; *r* = discount rate, *n* = years into the future.

TABLE 15 Treatment and cost effects (with 95% CI) and ICERs over 24 months

| Measure | Incremental differences (START minus TAU) and ICERs 24-month evaluation time point |
|---|--|
| With QALY as outcome (<i>n</i> = 144) ^a | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £336 (–£223 to £895) |
| Incremental QALY gain, mean (95% CI) | 0.03 (–0.01 to 0.06) |
| ICER (£ per QALY) | £11,200 |
| With HADS-T as outcome (<i>n</i> = 156) ^b | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £303 (–£206 to £812) |
| Incremental HADS-T score change (reversed so higher scores show better outcomes), mean (95% CI) | 1.52 (–0.57 to 3.62) |
| ICER (£ per unit change on HADS-T) | £199 |

a Sample size based on complete data for QALYs and cost measures.

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

Cost-effectiveness ratio

Results from the net benefit regression using the two outcomes examined in the economic evaluation (QALYs and HADS-T score) over 1–24 months are summarised and the ICERs reported in *Table 15*. Similar to the analyses conducted over the 8-month time period, the costs and outcome differences are obtained after adjustment for baseline characteristics and are influenced by the sample with complete data for each outcome.

Over the 24 months, carers who received the START intervention had slightly, but not statistically significantly, higher total costs and better, although not statistically significant, differences in outcomes whether measured in terms of health-related QoL (QALY) or affective symptoms (HADS-T). We explored the decision-maker's willingness to pay for gains in QoL and affective symptoms to assess whether or not

these results imply that the START intervention is cost-effective. We computed the ICERs and plotted the associated CEACs, and examined the CIs around NMB.

Looking at QALY as the outcome, the mean cost per QALY gain was £11,200. The CEAC is shown in *Figure 10*. At the £20,000 per QALY threshold associated with NICE recommendations, the probability that the START intervention would be seen as cost-effective was 65%, and at the higher NICE threshold of £30,000 it was 75%.

For the other outcome measure, the HADS-T measure of affective symptoms, mean cost per 1-point difference on the HADS-T was £199. The CEAC threshold for this outcome measure is shown in *Figure 11*. Assuming a willingness to pay of £500, the probability that the START intervention would be seen as cost-effective would be 78%.

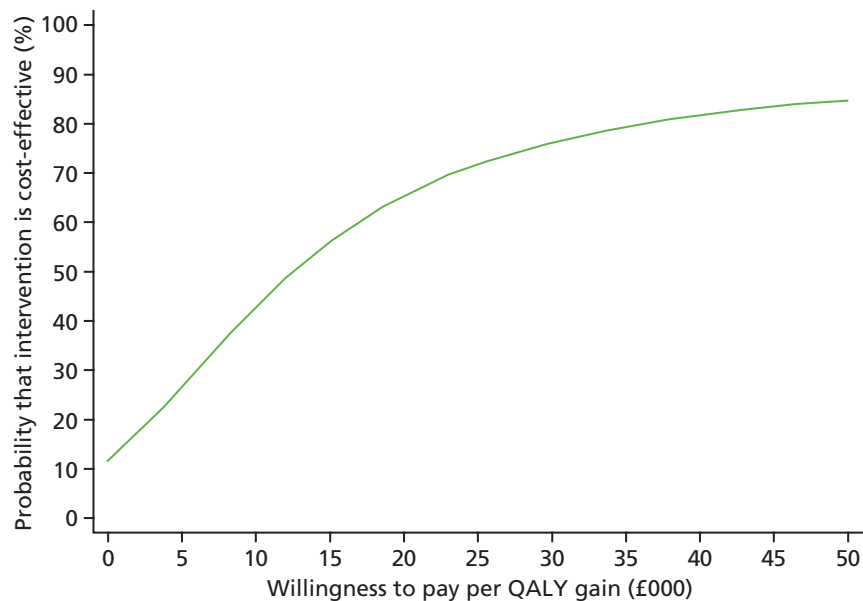


FIGURE 10 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months.

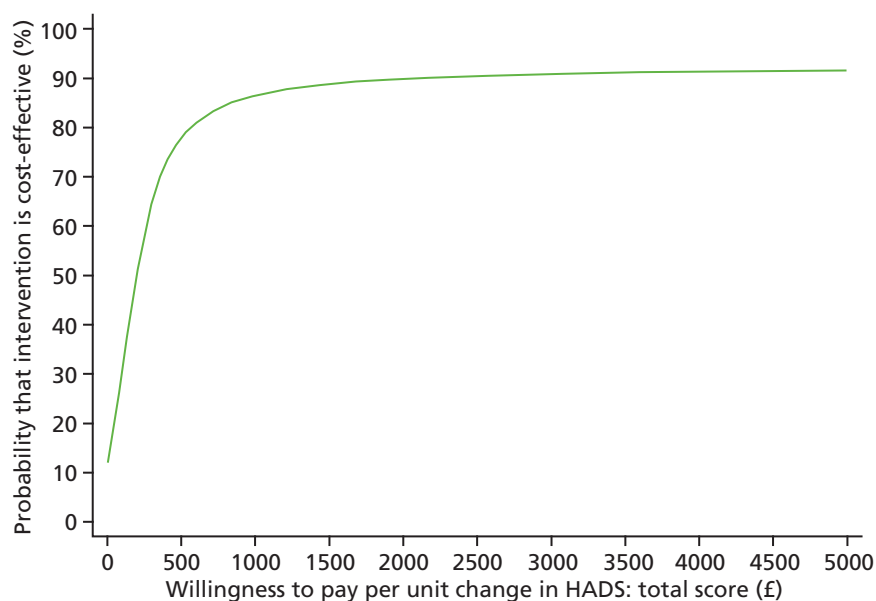


FIGURE 11 Cost-effectiveness acceptability curve: START intervention (manual-based coping strategy therapy) vs. TAU; health and social care perspective, with effectiveness measured in HADS gain over 24 months.

The discounted incremental costs and outcomes at 24 months, at rates of 0% and 6%, are shown in *Appendix 1*. Discounting the incremental cost and outcomes by 0% and 6% did not greatly alter the findings.

Sensitivity analysis

We followed the same approach as in the 8-month analysis to assess the robustness of the findings of the cost-effectiveness analysis at 24 months. In the first sensitivity analysis, we adjusted for significant differences on demographic and clinical predictors of missing values. This analysis did not alter the results and is summarised in *Table 16*. The mean ICER values from this analysis are £9767 per additional QALY and £125 per 1-point difference in HADS-T score.

Figure 12 shows the CEAC with QALY as the measure of outcome. The START intervention has an approximately 67% likelihood of being seen as cost-effective at the lower bound of NICE threshold of £20,000, rising to 75% at the £30,000 threshold.

Figure 13 shows the CEAC with HADS-T score as the measure of outcome. The START intervention has an approximately 89% likelihood of being seen as cost-effective at £500. The likelihood of cost-effectiveness is above 95% if the willingness to pay for a 1-point improvement in outcome is > £1000.

In the second sensitivity analysis adjusted for imbalances in baseline characteristics, the findings were similar to those from the primary analyses. The results are shown alongside those of the first sensitivity analysis in *Table 16*. The mean ICER values from this second sensitivity analysis are £8567 per additional QALY and £209 per 1-point difference in HADS-T score.

TABLE 16 Sensitivity analyses: treatment and cost effects (with 95% CIs) and ICERs over 24 months

| Measure | Incremental differences (START minus TAU) and ICERs over 24-month evaluation time period | |
|--|--|-----------------------------------|
| | Adjusting for significant demographic and clinical predictors of missing values | Adjusting for baseline imbalances |
| With QALY as outcome ($n = 144$) ^a | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £293 (–£277 to £862) | £257 (–£333 to £847) |
| Incremental QALY gain, mean (95% CI) | 0.03 (–0.01 to 0.06) | 0.03 (–0.01 to 0.06) |
| ICER (£ per QALY) | £9767 | £8567 |
| With HADS-T as outcome ($n = 156$) ^b | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £252 (–£294 to 799) | £282 (–£265 to £828) |
| Incremental HADS-T score change, mean (95% CI) | 2.02 (–0.06 to 4.08) | 1.35 (–0.95 to 3.64) |
| ICER (£ per unit change on HADS-T) | £125 | £209 |

a Sample size based on complete data for QALYs and cost measures.

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

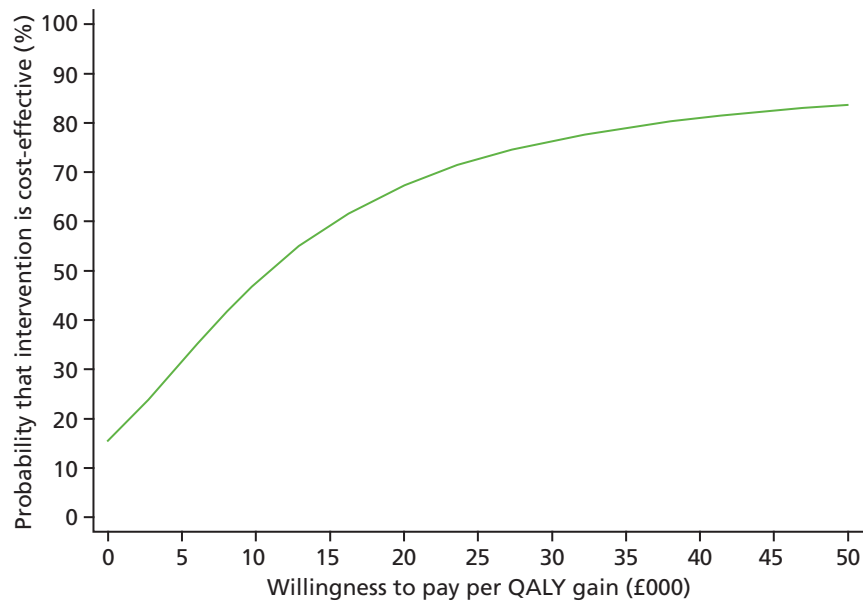


FIGURE 12 Cost-effectiveness acceptability curve for START with QALY as the outcome measure over 24 months.

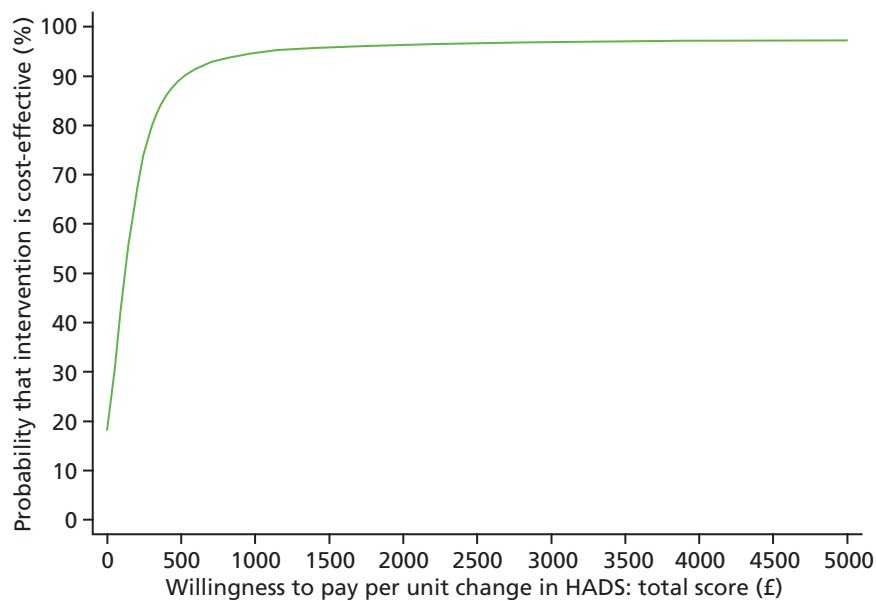


FIGURE 13 Cost-effectiveness acceptability curve for START with HADS-T as the outcome measure over 24 months.

The CEAC with QALY as the outcome measure is shown in *Figure 14*. At a threshold of £20,000, the START intervention has a likelihood of being seen as cost-effective of 70%, rising to 80% at the £30,000 threshold.

Figure 15 shows the CEAC with HADS-T score as the measure of outcome. This second sensitivity analysis adjusting for factors associated with imbalances in baseline characteristics slightly increased the likelihood that the START intervention would be seen as cost-effective. In this sensitivity analysis, the START intervention has an approximately 72% likelihood of being seen as cost-effective at £500 and remained above 82% if the willingness to pay for a 1-point improvement in outcome is over £1000.

The CIs around NMB for these two sensitivity analyses are shown in *Appendix 2*.

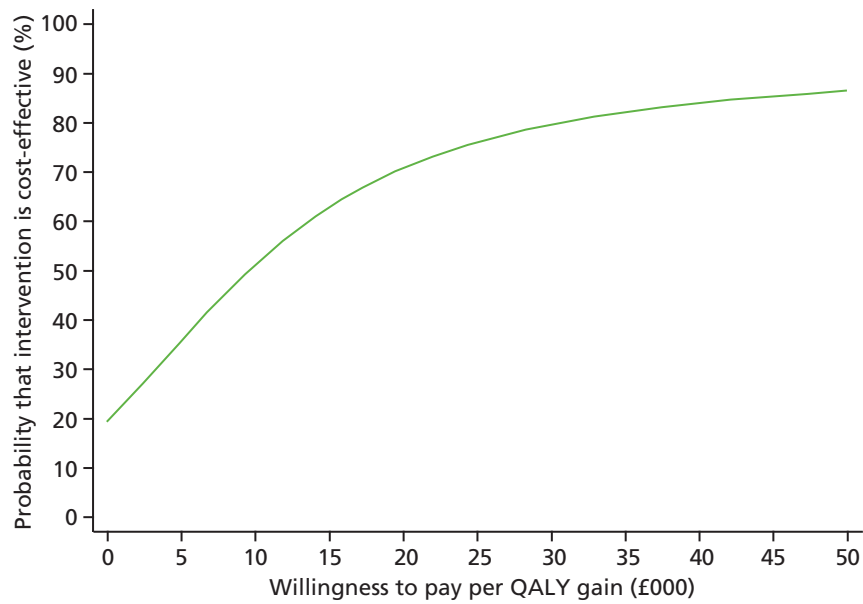


FIGURE 14 Sensitivity analysis of CEAC with QALY as the outcome measure over 24 months.

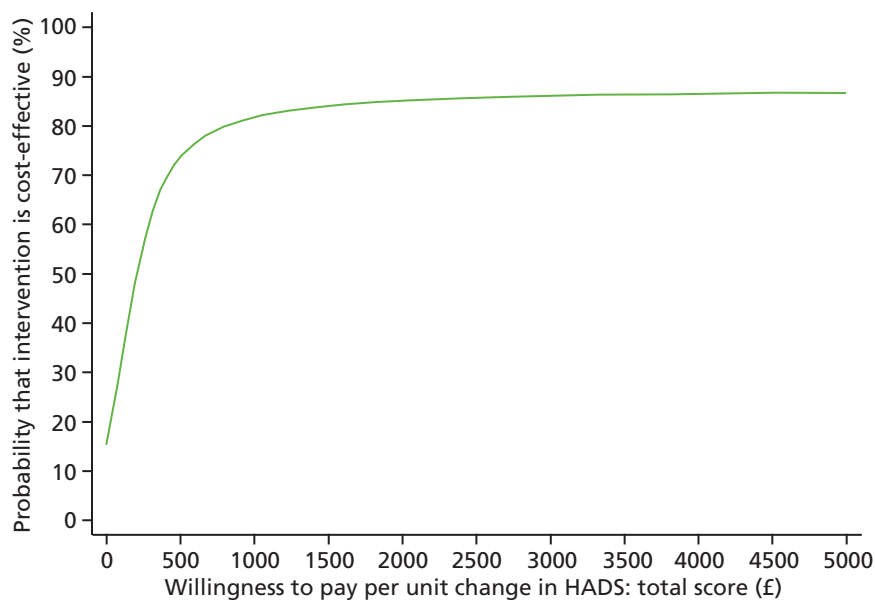


FIGURE 15 Sensitivity analysis of CEAC with HADS-T as the outcome measure over 24 months.

Chapter 6 Discussion

Key findings

Primary and secondary outcome of clinical effectiveness

This study was a pragmatic RCT of a multicomponent intervention. It is the first study to show that family carers of people with dementia referred to secondary or tertiary care benefit from a structured psychological intervention delivered by psychology graduates and supervised by a clinical psychologist. This change was significant in terms of both depression and anxiety symptoms and also in QoL and depression caseness. The intervention was effective 8 months after randomisation and continued to work 2 years later. Abusive behaviour reduced in both groups and there was no significant difference between them. There was an indication of possible reduction in the chances of being admitted to a care home but this was not significant.

Primary and secondary outcome of cost-effectiveness

We examined whether or not 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 TAU was cost-effective compared with TAU alone. Over the 8-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, i.e. improvements in carers' affective symptoms and gains in carers' health-related QoL. The sensitivity analyses considering alternative approaches to the analysis suggest a more cautious conclusion as to the cost-effectiveness of the START intervention.

Interpretation

The effect size in terms of the total mean affective symptoms was small, but previous evidence from studies in which researchers set out to calculate what a clinically important difference in the HADS would be suggests that treatment effects are in the range that is important to patients.⁵⁴ This study, based on consideration of an emotional function and mastery domain from a scale administered at the same times as the HADS, found the minimally important difference in the HADS-T score to be 1.61 and 1.68 for the former and latter domain, respectively.

Incidence of clinical depression increased in the control group but not in the intervention group, and the ORs indicate that, at follow-up at 8 months, those in the TAU group were four times more likely, and at 24 months were five times more likely, to have clinically significant depression, suggesting that the intervention is clinically important. In keeping with this, carer QoL improved.

We thought that in the long term this intervention may also delay care home admission of the person with dementia and, therefore, increase his or her QoL. The short-term follow-up over 8 months did not show this but at 2 years there was an indication that it may tend to delay care home admission and we will reconsider this effect over the following 5 years. Previous studies of information and advice to people with dementia and their families have suggested this can improve the patient's QoL but not the carer's psychological symptoms and an intervention which is targeted at the carer may not help the person with dementia to the same extent.⁵⁵

This may be the explanation for the lack of effect on care recipients' QoL. However, QoL is a complex phenomenon and the measure we used is a global one, thus considering finance, housing and physical health in addition to well-being, and this may have made it less likely to change.

The cost-effectiveness finding is driven more by the outcome differences between the groups than by the cost difference; for example, at the 8-month time point, carers in the control group were four times more likely to have clinically significant depression than carers receiving the START intervention.

Our study was effective over time and acceptable to most participants, who made time and space for it despite the commitments of being a carer and, frequently, also being employed or being unwell themselves. There is little evidence of harm with withdrawal from the treatment being at a similar rate to withdrawal from TAU arm, although one carer said that he found the therapy too upsetting and three felt that it was not for them.

There are currently no interventions which have been shown to reduce elder abuse.^{56,57} Our study was not powered to find a significant change in abuse and for ethical reasons we made clinicians aware of clinically significant abusive behaviour in the control group; thus, abused carers in this group were often offered clinical and social support as well as monitoring of the behaviour and, if felt appropriate, adult protection measures were taken. Thus, we think it is unlikely that there would be a significant difference between groups. We were pleased that abusive behaviour went down over time in both groups and previous research has not suggested that this is what would happen without intervention.⁵⁸ We do not know whether those people who acted in an abusive way were more likely to refuse to participate in the study (although the high rates of abusive behaviour even in relation to prevalence studies make this less likely)⁵⁹ or to leave the study or if the care recipient was more likely to be admitted to a care home.

Strengths and limitations

Study design

This was designed as a pragmatic study with broad inclusion criteria and followed closely the Medical Research Council guidance on the evaluation of a complex intervention. The clustering of therapists was accounted for by the analysis, and outcome measures were carefully considered for validity and to ensure the participants were not overburdened and an economic evaluation was conducted. The follow-up rates were satisfactory at > 80% and sensitivity analyses adjusting for missing outcome data showed similar results.

Sensitivity analyses

One of the strengths of the study is the sensitivity analyses, which showed the same results as for the primary analysis.

Bias

We took care to minimise bias in several ways. We used standardised measures validated for the population. Although randomisation was independent and follow-up raters were blinded to allocation to avoid bias in allocation or in rater assessment, the family carers inevitably knew which group they were in. Similarly, although the data were entered and cleaned while blind to intervention status, the statistical team were aware that the intervention group was the larger group.

Health economics

Each carer recruited to the study was scheduled to have eight sessions with the therapist but some carers had fewer sessions. 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.

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. In turn this would have had implications for both the research budget and ethics, as it would have been necessary to recruit participants beyond the point at which clinical dominance has been determined. We used CEACs to represent the uncertainty in the estimation of the ICER.

Generalisability

We recruited a sample of carers with varying demographic and clinical characteristics from a range of services. People were only excluded if they had dementia or lived too far away for the therapy to be delivered. Further evidence of external validity is the demographic similarity between those who consented and those who did not. Participants were recruited from three mental health trusts and from a neurology centre for rare dementias and were from urban, suburban and rural areas. The trust differed in geographical location (Essex and London) and in referrers (psychiatrists, neurologists, Admiral Nurses and other mental health professionals).

Participants were in the main children (44%) or partners (42%) of the person with dementia but were also in-laws, nieces and nephews, grandchildren, siblings and friends. The participants were of either sex (31% male), throughout the adult age range (18–89 years) and from a range of ethnic (around three-quarters white UK) and socioeconomic backgrounds. We had thought that those carers in paid work might be unable to access the intervention, but this did not appear to be the case, and carers were working full-time or part-time, or were retired or not currently working.

The carers' scores on the outcome measures and burden at baseline ranged widely. Most of the people with dementia had relatively mild dementia at baseline, with the mean clinical dementia scale rating being 1.5–1.6, with 1 meaning mild and 2 meaning moderate dementia. Thus, we think that the intervention is generally acceptable to and the results are generally applicable to the family carers around the time people present to secondary care with dementia in the UK. The levels of anxiety and depressive symptoms, case-level anxiety and depression, neuropsychiatric symptoms and carer abusive behaviour, however, were slightly higher than in a recent cohort study of newly referred people with dementia and so those with more problems may have been more likely to consent to the study.^{9,60}

We did, however, inform the clinical teams about abusive behaviour of the carers in the TAU group when there was no intervention in place and, thus, may have improved the outcome for the TAU.

Implementation of a complex intervention

The intervention was manual based, standardised and supervised, and the high-fidelity ratings and lack of clustering by therapist suggests that the intervention can be delivered consistently. However, our researchers saw most people at their homes and were more flexible in timing than most non-emergency services within the NHS, sometimes seeing people in the evening. The researchers saw 19 out of 173 participants in the evenings or out of hours for their intervention sessions. There was a very satisfactory follow-up rate of 88.1% overall at 8 months with similar rates in both arms. At 2 years, the follow-up rate was still over 80%. The instruments were validated and standardised. These results suggest that our findings are valid.

Adherence to the intervention

Over three-quarters of the participants fulfilled our definition of compliance to the intervention. We found it difficult to deliver the therapy to people who did not speak English, although there were only four of those carers 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. It is, thus, difficult to determine the effect of using the manual through a translator. As translating the manual is a one-off process, the cost should be less of an issue if our findings are implemented in the NHS.

We have not been able to consider how many sessions were necessary to effect change as those people who did not finish the sessions were different from those who did, often stopping through their own illness or that of a family member. In addition, most people did all the sessions, and so the numbers are small.

Overall evidence

Earlier studies of similar interventions in the USA have shown results consistent with ours. The study from which we derived START uses a similar intervention and it also alleviated depressive symptoms in carers, but we judge that our intervention is more practical for many carers as we did not require them all to come to a group at the same time.¹⁷ There is no other rigorous study of an intervention delivered by psychology graduates without previous clinical training, a group who are relatively available and inexpensive but with a background in understanding the concepts. Within the USA, a similar therapy to ours delivered to individuals was found to be significantly cost-effective in completers compared with controls in terms of freeing up caring time.²¹ We are not aware of any other interventions in this group for which health economic evaluations have been undertaken and we discuss this below.

Not all psychosocial interventions in family carers of people with dementia are effective.¹⁵ Recent RCTs of psychosocial interventions in Europe (UK, Denmark and Norway) using different models have been ineffective in terms of carer psychological symptoms and QoL, thus showing that our findings were not explained solely by the offer of a therapist to spend time and attention.^{24,61,62}

The earliest study of the three used trained ex-carers in a voluntary sector befriending intervention and was not taken up by many carers.²⁴ This suggests that acceptability, as well as the theoretical background, needs to be a major focus of any intervention. Danish Alzheimer's Intervention Study (DAISY) was a multifaceted intervention involving both the person with mild Alzheimer's disease and the carer.⁶¹ The intervention was individualised to the dyad, who were seen both individually and together by a nurse for counselling, based on validating the participants and focusing on retained and positive attributes and skills. It allowed patient and carer to tell their own life story and explain what mattered to them. Carers and those cared for also attended separate courses over a period of 1 year to educate them about dementia. Like our study, it did not improve the patient's QoL. Unlike ours, it did not help the carer's QoL. In contrast to the former study, 72% of participants completed the intervention according to the study's definition (attending three or more of individual and educational sessions). This suggests that the content of the intervention, as well as its acceptability in terms of take-up, is also important. The intervention contrasts with our study in validating the carer's and care recipient's position. Ours was more focused on accepting difficulties, changing the carer's thoughts and behaviour, and the carer finding ways to look after themselves, communicate their needs, increase pleasant events and find help. The most recent study was also aimed at the carer and the person with dementia.⁶² It was delivered by trained and supervised nurses and occupational therapists and families and comprised education about dementia in two half-day sessions, five individual counselling sessions when the therapist worked with them using a problem-solving model, and six group meetings of 2 hours each, concentrating on problem-solving and increasing pleasant events. Again, while the pleasant events were similar to our model, the focus on problem-solving rather than acceptance differed.

Our earlier studies have found that family carers tend to become more anxious and depressed over time without intervention, and that this is associated with an increase in abusive behaviour, and thus we included carers who were not depressed at presentation to services.^{63,64} The preventative effect that was found highlights that these carers can benefit from early intervention. This contrasts with a

study of cognitive-behavioural interventions in patients with hip fracture which was unsuccessful in preventing depression.⁶⁵

Comparison of short- and long-term effects

The START intervention was effective in the short and long term (2 years); there was no difference between the clinical effects at either time period. There is a paucity of literature which considers how long it takes for a psychological intervention to work and the period for which it continues to work. Previous research in carers had shown that interventions continue to work for an average of 7–11 months.⁶⁶ One previous intervention with spouse carers of people with dementia with flexible content which included behavioural management of difficult behaviour, promoting communication among family members and staff availability to help with emergent behaviours and problems, found there was no significant effect at 4 months, but there was an effect at 1 year which was sustained for 3 years after the intervention.⁶⁷

We thought that it was possible either that the effect of the intervention might wear off over time as carers resorted to earlier coping strategies or that carers might continue to change their coping strategies and the difference between groups would increase over time. Neither of these seemed to be the case (at least alone) and there is no evidence of a 'top-up' being necessary to maintain the effect.

Structured psychological treatment of depression in other groups

A recent structured intervention in family carers of people with stroke with care competencies taught and assessed by nurses did not improve their mood, QoL or burden, or improve patient outcome.¹⁵ This is further evidence that knowledge by itself is not efficacious.

Previous work has found that a RCT of telephone-administered psychotherapy for depressive symptoms worked over the 16 weeks it was administered, but was no longer significantly efficacious at 1 year.⁶⁸ Similarly, a RCT of a 'coping with depression' psychoeducational group programme, with booster session up to 4 months after the intervention had finished, was effective in reducing depression at 6 months but not at 12 months.⁶⁹

In contrast, a RCT of CBT as an adjuvant therapy for treatment-resistant depression found that it was effective at the 6- and 12-month follow-up.⁷⁰ Ten therapist-delivered sessions of CBT over the internet were effective in reducing depression at 4 and 8 months (equivalent to our short-term measures).⁷¹ CBT treatment for health anxiety was effective at 6 months, 1 and 2 years with no significant increase in costs for anxiety and depression, but was ineffective in increasing health-related QoL.⁷²

We are unsure what the difference is between the therapies that continue to be efficacious for affective symptoms and those that do not, but our intervention adds to the evidence that therapies can continue to be effective over years.

Comparison with other health economics 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.²⁰ However, only one of the studies covered by that review employed a similar therapeutic approach to the START intervention.²¹ It 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 6-month study period, with carers in the intervention group having more time to dedicate to activities unrelated to caregiving, which has potentially positive impacts on emotional well-being and QoL.

Chapter 7 Conclusions

Implications for clinical practice

The START intervention is clinically effective in terms of carer impacts in the short term (8 months) and long term (2 years) both for mood and for QoL.

Many countries, including the UK, face rapidly growing numbers of single people over the coming decades, 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 QoL, should be made more widely available.

From these results, it would appear that 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.

Our group has developed training and the manual is available online with the *British Medical Journal* papers from this study and so it would be possible to disseminate this further to other memory services to offer START as part of the routine management of dementia. In Camden and Islington, Memory Services and Improving Access to Psychological Therapies services are piloting it.⁷³ Further follow-up will consider longer-term effects on carer mood, QoL, abusive behaviour and cost-effectiveness, and whether or not, as in other longer-term studies, patient's time to care home admission has been lengthened.⁷⁴

Unanswered questions and future research

This study reports carer outcomes and that there was no evidence of a change in the magnitude of effectiveness between 4 and 8 months, or at 12 months and 2 years, thus suggesting some lasting effect. We have no data after 2 years. However, what we have is more than in many antidepressant trials, and further analysis of the effectiveness of the intervention compared with antidepressants and the calculation, if possible, of standardised effect size would help to put it in context.

One previous study found therapy led to improvement in spouse carer mental health over many years and a reduction in nursing home admissions for patients.⁷⁴ Patients whose spouses received the intervention experienced a 28.3% reduction in the rate of nursing home placement compared with usual care controls, with a difference in model-predicted median time to placement of 557 days. Improvements in carers' satisfaction with social support, response to patient behaviour problems and symptoms of depression collectively accounted for 61.2% of the intervention's beneficial impact on placement. We do not yet know whether or not our short therapeutic intervention will lead to a long-term reduction in carer nursing home placement but are extending this study to find out. It may be that the inclusion of non-carers (and, therefore, more often non-resident carers) means these outcomes differ.

Further qualitative research is needed to consider whether or not all of the intervention components were valued by family carers, whether or not it was delivered at the appropriate time and how it could be improved; we have now done this and our findings suggest that different carers use different components and that a multimodel intervention is therefore appropriate.⁷⁵ Future analysis should consider mechanism of action, in terms of both coping strategies and freeing up carer time.

In addition, it is important to consider the effects on people with dementia in terms of clinical outcome (cognition, neuropsychiatric symptoms) and on health and social care costs. A cost-effectiveness analysis considering the costs for both carers and care recipients, and the clinical and QoL effectiveness for them both would be very informative and may add to the policy implications. In addition, we wish to analyse the effect on abuse further and in particular the interaction between abuse and care home admission as abuse may lead to admission and this may prevent further abuse.

Finally, the purpose of research is implementation of clinically effective and cost-effective interventions in clinical practice and we have successfully applied for an implementation grant from the Alzheimer's Society, which includes assessing the implementation.

Acknowledgements

We would like to thank the participating carers, the CIFT, UCL Hospital, the NELFT, the NEPFT and, in particular, Vincent Kirchner and Lisa Gee for referring many patients. We would like to thank the members of the Steering Committee – Joanna Murray (chairperson), Thana Balamurali, Kate Maxmin, Lynne Ramsay, Mabel Saili, Lynis Lewis – and of the Data Monitoring Committee – Cornelius Katona (chairperson) and U Hla Htay. Shirley Nurock gave advice throughout as an expert family carer. The START research team acknowledges the support of the National Institute for Health Research through the DeNDRoN.

We would like to thank the researchers/therapists Monica Manela, Ryan Li, 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. Barbara Schehl calculated the costs of services.

Contributions of authors

Gill Livingston is a professor of older people's mental health; **Julie Barber** is a lecturer in medical statistics; **Penny Rapaport** is a principal clinical psychologist; **Martin Knapp** is a professor of social policy; **Mark Griffin** is a lecturer in medical statistics; **Renee Romeo** is a lecturer in health economics; **Derek King** is a research fellow; **Debbie Livingston** is a trial manager; **Elanor Lewis-Holmes** is a research assistant; **Cath Mummery** is a consultant neurologist and honorary senior lecturer; **Zuzana Walker**, is a reader in psychiatry of the elderly; **Juanita Hoe** is a senior clinical research associate; and **Claudia Cooper** is a clinical senior lecturer.

Gill Livingston, Claudia Cooper, Juanita Hoe, Zuzana Walker, Debbie Livingston, Cath Mummery, Martin Knapp, Elanor Lewis-Holmes and **Penny Rapaport** contributed to the conception and design of the study.

Gill Livingston, Claudia Cooper, Juanita Hoe, Zuzana Walker, Julie Barber and **Mark Griffin** contributed to the analytic plan.

Julie Barber and **Mark Griffin** analysed the clinical data.

Renee Romeo, Martin Knapp and **Derek King** analysed the health economic data.

Gill Livingston, Claudia Cooper, Zuzana Walker, Juanita Hoe and **Cath Mummery** led recruitment from their trusts.

Gill Livingston drafted most of the report.

Renee Romeo drafted the health economic section.

Elanor Lewis-Holmes drafted some of the method.

Julie Barber, Penny Rapaport, Martin Knapp, Mark Griffin, DK, Debbie Livingston, Cath Mummery, Zuzana Walker, Juanita Hoe, Elanor Lewis-Holmes and **Claudia Cooper** revised it critically for important intellectual content and gave final approval of the version to be published.

Gill Livingston will act as guarantor.

References

1. Ferri CP, Prince M, Brayne C, Brodaty H, Fratiglioni L, Ganguli M, *et al.* Global prevalence of dementia: a Delphi consensus study. *Lancet* 2005;**366**:2112–17. [http://dx.doi.org/10.1016/S0140-6736\(05\)67889-0](http://dx.doi.org/10.1016/S0140-6736(05)67889-0)
2. Knapp M, Prince M, Albanese E, Banerjee S, Dhanasiri S, Fernández JL, *et al.* *Dementia UK*. London: Alzheimer's Society; 2007.
3. Department of Health. *Living Well with Dementia: A National Dementia Strategy*. London: Department of Health; 2009.
4. Burns A, Robert P. The National Dementia strategy in England. *BMJ* 2009;**338**:b931. <http://dx.doi.org/10.1136/bmj.b931>
5. Cooper C, Balamurali TBS, Selwood A, Livingston G. A systematic review of intervention studies about anxiety in caregivers of people with dementia. *Int J Geriatr Psychiatry* 2007;**22**:181–8. <http://dx.doi.org/10.1002/gps.1656>
6. Mahoney R, Regan C, Katona C, Livingston G. Anxiety and depression in family caregivers of people with Alzheimer disease: the LASER-AD study. *Am J Geriatr Psychiatry* 2005;**13**:795–801. <http://dx.doi.org/10.1097/00019442-200509000-00008>
7. Morris LW, Morris RG, Britton PG. The relationship between marital intimacy, perceived strain and depression in spouse caregivers of dementia sufferers. *Br J Med Psychol* 1988;**61**:231–6. <http://dx.doi.org/10.1111/j.2044-8341.1988.tb02784.x>
8. Gallagher D, Ni Mhaolain A, Crosby L, Ryan D, Lacey L, Coen RF, *et al.* Determinants of the desire to institutionalize in Alzheimer's caregivers. *Am J Alzheimers Dis Other Demen* 2011;**26**:205–11. <http://dx.doi.org/10.1177/1533317511400307>
9. Cooper C, Selwood A, Blanchard M, Walker Z, Blizard R, Livingston G. The determinants of family carers' abusive behaviour to people with dementia: results of the CARD study. *J Affect Disord* 2009;**121**:136–42. <http://dx.doi.org/10.1016/j.jad.2009.05.001>
10. Selwood A, Johnston K, Katona C, Lyketsos C, Livingston G. Systematic review of the effect of psychological interventions on family caregivers of people with dementia. *J Affective Disord* 2007;**101**:75–89. <http://dx.doi.org/10.1016/j.jad.2006.10.025>
11. Spijker A, Vernooij-Dassen M, Vasse E, Adang E, Wollersheim, Grol R, *et al.* Effectiveness of nonpharmacological interventions in delaying the institutionalization of patients with dementia: a meta-analysis. *J Am Geriatr Soc* 2008;**56**:1116–28. <http://dx.doi.org/10.1111/j.1532-5415.2008.01705.x>
12. Olazarán J, Reisberg B, Clare L, Cruz I, Peña-Casanova J, Del Ser T, *et al.* Nonpharmacological therapies in Alzheimer's disease: a systematic review of efficacy. *Dement Geriatr Cogn Disord* 2010;**30**:161–78. <http://dx.doi.org/10.1159/000316119>
13. Hoe J, Katona C, Orrell M, Livingston G. Quality of life in dementia: care recipient and caregiver perceptions of quality of life in dementia: the LASER-AD study. *Int J Geriatr Psychiatry* 2007;**22**:1031–6. <http://dx.doi.org/10.1002/gps.1786>
14. 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. <http://dx.doi.org/10.1017/S1041610206003462>

15. Thompson CA, Spilsbury K, Hall J, Birks Y, Barnes C, Adamson J. Systematic review of information and support interventions for caregivers of people with dementia. *BMC Geriatr* 2007;**7**:18. <http://dx.doi.org/10.1186/1471-2318-7-18>
16. Coon DW, Thompson L, Steffen A, Sorocco K, Gallagher-Thompson D. Anger and depression management: psychoeducational skill training interventions for women caregivers of a relative with dementia. *Gerontologist* 2003;**43**:678–89. <http://dx.doi.org/10.1093/geront/43.5.678>
17. Gallagher-Thompson D, Areal P, Rivera P, Thompson LW. A psychoeducational intervention to reduce distress in Hispanic family caregivers. *Clin Gerontol* 2001;**23**:17–32. http://dx.doi.org/10.1300/J018v23n01_03
18. Steffen AM. Anger management for dementia caregivers: a preliminary study using video and telephone interventions. *Behav Ther* 2000;**31**:281–99. [http://dx.doi.org/10.1016/S0005-7894\(00\)80016-7](http://dx.doi.org/10.1016/S0005-7894(00)80016-7)
19. Gallagher-Thompson D, Coon DW, Solano N, Ambler C, Rabinowitz Y, Thompson LW. Change in indices of distress among Latino and Anglo female caregivers of elderly relatives with dementia: site-specific results from the REACH national collaborative study. *Gerontologist* 2003;**43**:580–91. <http://dx.doi.org/10.1093/geront/43.4.580>
20. Knapp M, Lemmi V, Romeo R. Dementia care costs and outcomes: a systematic review. *Int J Geriatr Psychiatry* 2013;**28**:551–61. <http://dx.doi.org/10.1002/gps.3864>
21. Nichols LO, Chang C, Lummus A, Burns R, Matindale-Adams J, Graney MJ, et al. The cost-effectiveness of a behavior intervention with caregivers of patients with Alzheimer's disease. *J Am Geriatr Soc* 2008;**56**:413–20. <http://dx.doi.org/10.1111/j.1532-5415.2007.01569.x>
22. Gonyea JG, O'Connor M, Carruth A, Boyle PA. Subjective appraisal of Alzheimer's disease caregiving: the role of self-efficacy and depressive symptoms in the experience of burden. *Am J Alzheimers Dis Other Demen* 2005;**20**:273–80. <http://dx.doi.org/10.1177/153331750502000505>
23. Coen RF, O'Boyle CA, Coakley D, Lawlor BA. Individual quality of life factors distinguishing low-burden and high-burden caregivers of dementia patients. *Dement Geriatr Cogn Disord* 2002;**13**:164–70. <http://dx.doi.org/10.1159/000048648>
24. Charlesworth G, Shepstone L, Wilson E, Reynolds S, Mugford M, Price D, et al. Befriending carers of people with dementia: randomised controlled trial. *BMJ* 2008;**336**:1295–7. <http://dx.doi.org/10.1136/bmj.39549.548831.AE>
25. The Centre for Economic Performance's Mental Health Policy Group. *The Depression Report. A New Deal for Depression and Anxiety Disorders*. London: London School of Economics; 2006.
26. Livingston G, Barber J, Rapaport P, Griffin M, King D, Livingston D, et al. Clinical effectiveness of a manual based coping strategy programme (START, STRategies for Relatives) in promoting the mental health of carers of family members with dementia: pragmatic randomised controlled trial. *BMJ* 2013;**347**:f6276. <http://dx.doi.org/10.1136/bmj.f6276>
27. Knapp M, King D, Romeo R, Schehl B, Barber J, Griffin M, et al. 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. *BMJ* 2013;**347**:f6342. <http://dx.doi.org/10.1136/bmj.f6342>
28. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;**12**:189–98. [http://dx.doi.org/10.1016/0022-3956\(75\)90026-6](http://dx.doi.org/10.1016/0022-3956(75)90026-6)
29. Roberts C, Roberts SA. Design and analysis of clinical trials with clustering effects due to treatment. *Clin Trials* 2005;**2**:152–62. <http://dx.doi.org/10.1191/1740774505cn076oa>

30. Livingston G, Leavey G, Manela M, Livingston D, Bavishi S, Shahriyarmolki K, *et al.* Making decisions for people with dementia who lack capacity: qualitative study of family carers in UK. *BMJ* 2010;**341**:d4184. <http://dx.doi.org/10.1136/bmj.c4184>
31. National Institute for Health and Care Excellence and Social Care Institute for Excellence (NICE/SCIE). *Dementia: Supporting People with Dementia and their Carers in Health and Social Care*. London: NICE/SCIE; 2006.
32. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;**67**:361–70. <http://dx.doi.org/10.1111/j.1600-0447.1983.tb09716.x>
33. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res* 2002;**52**:69–77. [http://dx.doi.org/10.1016/S0022-3999\(01\)00296-3](http://dx.doi.org/10.1016/S0022-3999(01)00296-3)
34. Spinhoven P, Ormel J, Sloekers PPA, Kempen GIJM, Speckens AEM, VanHemert AM. A validation study of the Hospital Anxiety and Depression Scale (HADS) in different groups of Dutch subjects. *Psychol Med* 1997;**27**:363–70. <http://dx.doi.org/10.1017/S0033291796004382>
35. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *Gerontologist* 1980;**20**:649–55. <http://dx.doi.org/10.1093/geront/20.6.649>
36. Beach SR, Schulz R, Williamson GM, Miller LS, Weiner MF, Lance CE. Risk factors for potentially harmful informal caregiver behavior. *J Am Geriatr Soc* 2005;**53**:255–61. <http://dx.doi.org/10.1111/j.1532-5415.2005.53111.x>
37. Cooper C, Maxmin K, Selwood A, Blanchard M, Livingston G. The sensitivity and specificity of the Modified Conflict Tactics Scale for detecting clinically significant elder abuse. *Int Psychogeriatr* 2009;**21**:774–8. <http://dx.doi.org/10.1017/S1041610209009387>
38. Pettit T, Livingston G, Manela M, Kitchen G, Katona C, Bowling A. Validation and normative data of health status measures in older people: the Islington study. *Int J Geriatr Psychiatry* 2001;**16**:1061–70. <http://dx.doi.org/10.1002/gps.479>
39. Radosevich D, Pruitt M. *Twelve-Item Health Status Questionnaire: HSQ-12 Version 2.0*. Bloomington, IN: Health Outcomes Institute; 1995.
40. EuroQoL Group. EuroQoL – a new facility for the measurement of health-related quality of life. *Health Policy* 1990;**16**:199–208. [http://dx.doi.org/10.1016/0168-8510\(90\)90421-9](http://dx.doi.org/10.1016/0168-8510(90)90421-9)
41. Beecham J, Knapp M. Costing psychiatric intervention. In Thornicroft G, editor. *Measuring Mental Health Needs*. London: Gaskell; 1992. pp. 200–224.
42. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. *Neurology* 1994;**44**:2308–14. <http://dx.doi.org/10.1212/WNL.44.12.2308>
43. Logsdon RG, Gibbons LE, McCurry SM, Teri L. Assessing quality of life in older adults with cognitive impairment. *Psychosom Med* 2002;**64**:510–519. <http://dx.doi.org/10.1097/00006842-200205000-00016>
44. Morris JC. Clinical dementia rating: a reliable and valid diagnostic and staging measure for dementia of the Alzheimer type. *Int Psychogeriatr* 1997;**9**(Suppl. 1):173–6. <http://dx.doi.org/10.1017/S1041610297004870>
45. Barry TL, Kaiser KL, Atwood JR. Reliability, validity, and scoring of the Health Status Questionnaire-12 version 2.0. *J Nurs Meas* 2007;**15**:24–35. <http://dx.doi.org/10.1891/106137407780851778>
46. Walwyn R, Roberts C. Therapist variation within randomised trials of psychotherapy: implications for precision, internal and external validity. *Stat Methods Med Res* 2010;**19**:291–315. <http://dx.doi.org/10.1177/0962280209105017>

47. Snaith RP. The Hospital Anxiety And Depression Scale. *Health Qual Life Outcomes* 2003;**1**:29. <http://dx.doi.org/10.1186/1477-7525-1-29>
48. Dolan P, Gudex C, Kind P, Williams A. *A Social Tariff for EuroQol: Results from a UK Population Survey*. Discussion paper 38. Centre for Health Economics, University of York; 1995.
49. Department of Health. *National Schedule of Reference Costs 2008–09 for NHS Trusts and PCTs Combined*. London: Department of Health; 2010.
50. Curtis L. *Unit Costs of Health and Social Care 2010*. Canterbury: PSSRU, University of Kent; 2010.
51. National Institute for Health and Care Excellence. *Guide to the Methods of Technology Appraisal*. London: NICE; 2004.
52. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;**33**:159–74. <http://dx.doi.org/10.2307/2529310>
53. National Institute for Health and Care Excellence. *Guide to the Methods of Technology Appraisal*. London: NICE; 2008.
54. Puhan MA, Frey M, Buchi S, Schunemann HJ. The minimal important difference of the hospital anxiety and depression scale in patients with chronic obstructive pulmonary disease. *Health Qual Life Outcomes* 2008;**6**:46. <http://dx.doi.org/10.1186/1477-7525-6-46>
55. Corbett A, Stevens J, Aarsland D, Day S, Moniz-Cook E, Woods R, *et al*. Systematic review of services providing information and/or advice to people with dementia and/or their caregivers. *Int J Geriatr Psychiatry* 2012;**27**:628–36. <http://dx.doi.org/10.1002/gps.2762>
56. Ploeg J, Hutchinson B, MacMillan H, Bolan G. A systematic review of interventions for elder abuse. *J Elder Abuse Negl* 2009;**21**:187–210. <http://dx.doi.org/10.1080/08946560902997181>
57. Cooper C, Selwood A, Livingston G. Knowledge, detection and reporting of abuse by health and social care professionals: a systematic review. *Am J Geriatr Psychiatry* 2009;**17**:826–38. <http://dx.doi.org/10.1097/JGP.0b013e3181b0fa2e>
58. Cooper C, Blanchard M, Selwood A, Walker Z, Livingston G. Family carers' distress and abusive behaviour: longitudinal study. *Br J Psychiatry* 2010;**196**:480–5. <http://dx.doi.org/10.1192/bjp.bp.109.071811>
59. Cooper C, Selwood A, Blanchard M, Walker Z, Livingston G. The CARD study abuse of people with dementia by family carers. *BMJ (Clinical Research Ed)* 2009;**22**:583–6.
60. Cooper C, Selwood A, Livingston G. The prevalence of elder abuse and neglect: a systematic review. *Age Ageing* 2008;**37**:151–60. <http://dx.doi.org/10.1093/ageing/afm194>
61. Waldorff FB, Buss DV, Eckermann A, Rasmussen MLH, Keiding N, Rishøj S, *et al*. Efficacy of psychosocial intervention in patients with mild Alzheimer's disease: the multicentre, rater blinded, randomised Danish Alzheimer Intervention Study (DAISY). *BMJ* 2012;**345**:e4693. <http://dx.doi.org/10.1136/bmj.e4693>
62. Bruvik FK, Allore HG, Ranhoff AH, Engedal K. The effect of psychosocial support intervention on depression in patients with dementia and their family caregivers: an assessor-blinded randomized controlled trial. *Dement Geriatr Cogn Dis Extra* 2013;**3**:386–97. <http://dx.doi.org/10.1159/000355912>
63. Cooper C, Katona C, Orrell M, Livingston G. Coping strategies, anxiety and depression in caregivers of people with Alzheimer's disease. *Int J Geriatr Psychiatry* 2008;**23**:929–36. <http://dx.doi.org/10.1002/gps.2007>

64. Cooper C, Selwood A, Blanchard M, Walker Z, Blizard R, Livingston G. Abuse of people with dementia by family carers: representative cross sectional survey. *BMJ* 2009;**338**:b155. <http://dx.doi.org/10.1136/bmj.b155>
65. Burns A, Banerjee S, Morris J, Woodward Y, Baldwin R, Proctor R, *et al.* Treatment and prevention of depression after surgery for hip fracture in older people: randomized, controlled trials. *J Am Geriatr Soc* 2007;**55**:75–80. <http://dx.doi.org/10.1111/j.1532-5415.2007.01016.x>
66. Sørensen S, Duberstein P, Gill D, Pinquart M. Dementia care: mental health effects, intervention strategies, and clinical implications. *Lancet Neurol* 2006;**5**:961–73. [http://dx.doi.org/10.1016/S1474-4422\(06\)70599-3](http://dx.doi.org/10.1016/S1474-4422(06)70599-3)
67. Mittelman MS, Roth DL, Coon DW, Haley WE. Sustained benefit of supportive intervention for depressive symptoms in caregivers of patients with Alzheimer's disease. *Am J Psychiatry* 2004;**161**:850–6. <http://dx.doi.org/10.1176/appi.ajp.161.5.850>
68. Mohr DC, Hart SL, Julian L, Catledge C, Honos-Webb L, Vella L, *et al.* Telephone-administered psychotherapy for depression. *Arch Gen Psychiatry* 2005;**62**:1007–14. <http://dx.doi.org/10.1001/archpsyc.62.9.1007>
69. Ellison JA, Greenberg LS, Goldman RN, Angus L. Maintenance of gains following experiential therapies for depression. *J Consult Clin Psychol* 2009;**77**:103–112. <http://dx.doi.org/10.1037/a0014653>
70. Wiles N, Thomas L, Abel A, Ridgway N, Turner N, Campbell J, *et al.* Cognitive-behavioural therapy as an adjunct to pharmacotherapy for primary care based patients with treatment resistant depression: results of the CoBaIT randomised controlled trial. *Lancet* 2013;**381**:375–84. [http://dx.doi.org/10.1016/S0140-6736\(12\)61552-9](http://dx.doi.org/10.1016/S0140-6736(12)61552-9)
71. Kessler D, Lewis G, Kaur S, Wiles N, King M, Weich S, *et al.* Therapist-delivered Internet psychotherapy for depression in primary care: a randomised controlled trial. *Lancet* 2009;**374**:628–34. [http://dx.doi.org/10.1016/S0140-6736\(09\)61257-5](http://dx.doi.org/10.1016/S0140-6736(09)61257-5)
72. Tyrer P, Cooper S, Salkovskis P, Tyrer H, Crawford M, Byford S, *et al.* Clinical and cost-effectiveness of cognitive-behaviour therapy for health anxiety in medical patients: a multicentre randomised controlled trial. *Lancet* 2013;**383**:219–25. [http://dx.doi.org/10.1016/S0140-6736\(13\)61905-4](http://dx.doi.org/10.1016/S0140-6736(13)61905-4)
73. Department of Health. *Improving Access to Psychological Therapies Implementation Plan: National Guidelines for Regional Delivery*. London: Department of Health; 2008.
74. Mittelman MS, Haley WE, Clay OJ, Roth DL. Improving caregiver well-being delays nursing home placement of patients with Alzheimer disease. *Neurology* 2006;**67**:1592–9. <http://dx.doi.org/10.1212/01.wnl.0000242727.81172.91>
75. Sommerlad A, Manela M, Cooper C, Rapaport P, Livingston G. START (STrategies for RelaTives) coping strategy for family carers of adults with dementia: participants' views about the intervention. *BMJ Open* 2014; in press. <http://dx.doi.org/10.1136/bmjopen-2014-005273>

Appendix 1 Unit cost of services

TABLE 17 Unit costs of services

| Service | Unit cost (£) 2009–10 ^a | Source |
|--|---------------------------------------|---|
| Anticoagulant service (per attendance) | 18 | Department of Health (2010) ⁴⁹ |
| Physiotherapy (per attendance) | 38 | Department of Health (2010) ⁴⁹ |
| Podiatry (per attendance) | 43 | Department of Health (2010) ⁴⁹ |
| Electrocardiography (per attendance) | 45 | Department of Health (2010) ⁴⁹ |
| Ophthalmology (per attendance) | 73 | Department of Health (2010) ⁴⁹ |
| Ear nose and throat (per attendance) | 85 | Department of Health (2010) ⁴⁹ |
| Other adult outpatient services (per attendance) | 90 | Department of Health (2010) ⁴⁹ |
| Dermatology (per attendance) | 93 | Department of Health (2010) ⁴⁹ |
| Diagnostic imaging – CT scan (brain) (per attendance) | 95 | Department of Health (2010) ⁴⁹ |
| Orthopaedics (per attendance) | 99 | Department of Health (2010) ⁴⁹ |
| Urology (per attendance) | 102 | Department of Health (2010) ⁴⁹ |
| Accident and emergency not-leading-to-admitted (per attendance) | 106 | Department of Health (2010) ⁴⁹ |
| Endocrinology (per attendance) | 110 | Department of Health (2010) ⁴⁹ |
| General surgery (per attendance) | 112 | Department of Health (2010) ⁴⁹ |
| Gynaecology (per attendance) | 118 | Department of Health (2010) ⁴⁹ |
| Clinical oncology (per attendance) | 126 | Department of Health (2010) ⁴⁹ |
| Medical gastroenterology (per attendance) | 128 | Department of Health (2010) ⁴⁹ |
| Diabetic medicine (per attendance) | 130 | Department of Health (2010) ⁴⁹ |
| Cardiology (per attendance) | 134 | Department of Health (2010) ⁴⁹ |
| Rheumatology (per attendance) | 138 | Department of Health (2010) ⁴⁹ |
| Respiratory medicine (per attendance) | 148 | Department of Health (2010) ⁴⁹ |
| Haematology (per attendance) | 152 | Department of Health (2010) ⁴⁹ |
| Nephrology (per attendance) | 156 | Department of Health (2010) ⁴⁹ |
| Neurology (per attendance) | 168 | Department of Health (2010) ⁴⁹ |
| Diagnostic imaging – MRI (per attendance) | 175 | Department of Health (2010) ⁴⁹ |
| Acute adult inpatient care (per bed-day) | 295 | Curtis (2010) ⁵⁰ |
| Elderly rehabilitation services (per bed-day) | 296 | Curtis (2010) ⁵⁰ |
| Admiral Nurse (per hour) | 31 | Curtis (2010) ⁵⁰ |
| Chiropodist (per hour) | 22 | Curtis (2010) ⁵⁰ |
| Counsellor (per hour) | 34 | Curtis (2010) ⁵⁰ |
| Dentist (per attendance) ^b | 87 | Curtis (2010) ⁵⁰ |
| GP (per consultation) | 28 | Curtis (2010) ⁵⁰ |

continued

TABLE 17 Unit costs of services (continued)

| Service | Unit cost (£) 2009–10 ^a | Source |
|---|---------------------------------------|--|
| NHS direct (per hour) | 3 | Curtis (2010) ⁵⁰ |
| Optician (per hour) | 29 | Curtis (2010) ⁵⁰ |
| Outreach worker (per hour) | 15 | Curtis (2010) ⁵⁰ |
| Home care worker/care attendant (per weekday hour) | 21 | Curtis (2010) ⁵⁰ |
| Physiotherapist (per hour) | 22 | Curtis (2010) ⁵⁰ |
| Psychotherapist (per hour) | 39 | Curtis (2010) ⁵⁰ |
| Hygienist (per hour) | 174 | Department of Health (2010) ⁴⁹ |
| Company medical check-up (per session) ^c | 175 | Marie Stopes International; www.mariestopes.org.uk/Womens_services/Well_Woman_screening/Company_health_screening.aspx |
| Nurse (advanced) (per hour) | 37 | Curtis (2010) ⁵⁰ |
| Occupational therapist (per hour) | 39 | Curtis (2010) ⁵⁰ |
| Community psychiatrist (per hour) | 22 | Curtis (2010) ⁵⁰ |
| Practice nurse (per hour) | 26 | Curtis (2010) ⁵⁰ |
| District nurse (per hour) | 31 | Curtis (2010) ⁵⁰ |
| Social worker (per hour) | 40 | Curtis (2010) ⁵⁰ |
| Speech and language therapist (per hour) | 22 | Curtis (2010) ⁵⁰ |
| Ambulance transport (per journey) ^d | 40–246 | Curtis (2010) ⁵⁰ |
| Dietician (per hour) | 22 | Curtis (2010) ⁵⁰ |
| Clinical support worker nursing (per hour) | 15 | Curtis (2010) ⁵⁰ |
| Support group (per hour) | 9 | Curtis (2010) ⁵⁰ |
| Community nurse (per hour) | 31 | Curtis (2010) ⁵⁰ |
| Orthodontist (per hour) | 174 | Curtis (2010) ⁵⁰ |
| Day care: NHS provision (per day) | 66 | Curtis (2010) ⁵⁰ |
| Day care: local authority provision (per day) | 43 | Curtis (2010) ⁵⁰ |
| Day care: voluntary provision (per day) | 42 | Curtis (2010) ⁵⁰ |
| Alzheimer's café (per hour) ^e | 6 | Curtis (2010) ⁵⁰ |
| Dementia course (per hour) ^f | 17 | Dementia UK; http://dementiauk.org/what-we-do/learning-partnerships-and-training/opencourses-2011/courses-by-huest-trainers |
| Alternative complementary therapies (per hour) | 40 | Professor Jennifer Beecham, PSSRU, London School of Economics and Political Science, 2012, personal communication |
| Yoga and pilates (per hour) | 7 | www.thetotalcareclinic.co.uk/yoga-pilates-classes-southampton.htm |

CT, computerised tomography; MRI, magnetic resonance imaging.

a 2008–9 prices updated to 2009–10 prices using the Hospital and Community Health Services Pay and Prices Index.

b Attendance assumed to last 30 minutes.

c Session is 30 minutes in duration.

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

e Weighted average of day care provision by NHS, local authority and voluntary provision per day divided by 8 hours.

f 1-day 6-hour course assumed.

Discounted treatment and cost effects and incremental cost-effectiveness ratios over 24 months

TABLE 18 Treatment and cost effects (with 95% CI) and ICERs

| Outcome | Incremental differences and ICERs 24-month evaluation time point (discounted 0%) | Incremental differences and ICERs 24-month evaluation time point (discounted 6%) |
|---|--|--|
| With QALY as outcome ($n = 144$) ^a | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £353 (–£223 to £929) | £325 (–£223 to £874) |
| Incremental QALY gain, mean (95% CI) | 0.03 (–0.01 to 0.06) | 0.03 (–0.01 to 0.06) |
| ICER (£ per QALY) | £11,767 | £10,833 |
| With HADS-T as outcome ($n = 156$) ^b | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £315 (–£210 to £840) | £295 (–£204 to £794) |
| Incremental HADS-T change (reversed so higher scores show better outcomes), mean (95% CI) | 1.63 (–0.61 to 3.88) | 1.45 (–0.55 to 3.45) |
| ICER (£ per unit change on HADS-T) | £193 | £203 |
| <p>a Sample size based on complete data for QALYs and cost measures.</p> <p>b Sample size based on complete data for HADS-T and cost measures.</p> <p>Discount rate = 3.5%; formula $1/(1+r)^n$; r = discount rate, n = years into the future.</p> | | |

TABLE 19 Treatment and cost effects (with 95% CIs) and ICERs following sensitivity analysis adjusting for significant predictors of missing values

| Outcome | Incremental differences and ICERs 24-month evaluation time point (discounted 0%) | Incremental differences and ICERs 24-month evaluation time point (discounted 6%) |
|---|--|--|
| With QALY as outcome ($n = 144$) ^a | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £308 (–£277 to £893) | £282 (–£277 to £842) |
| Incremental QALY gain, mean (95% CI) | 0.03 (–0.01 to 0.07) | 0.03 (–0.01 to 0.06) |
| ICER (£ per QALY) | £10,267 | £9400 |
| With HADS-T as outcome ($n = 156$) ^b | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £264 (–£298 to £825) | £245 (–£292 to £782) |
| Incremental HADS-T change (reversed so higher scores show better outcomes), mean (95% CI) | 2.15 (–0.06 to 4.38) | 1.92 (–0.05 to 3.90) |
| ICER (£ per unit change on HADS-T) | £123 | £128 |
| <p>a Sample size based on complete data for QALYs and cost measures.</p> <p>b Sample size based on complete data for HADS-T and cost measures.</p> <p>Discount rate = 3.5%; formula $1/(1+r)^n$; r = discount rate, n = years into the future.</p> | | |

TABLE 20 Treatment and cost effects (with 95% CIs) and ICERs, following sensitivity analysis adjusting for baseline imbalances

| Outcome | Incremental differences and ICERs 24-month evaluation time point (discounted 0%) | Incremental differences and ICERs 24-month evaluation time point (discounted 6%) |
|---|--|--|
| With QALY as outcome ($n = 144$) ^a | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £271 (–£336 to £877) | £248 (–£332 to £828) |
| Incremental QALY gain, mean (95% CI) | 0.03 (–0.01 to 0.06) | 0.03 (–0.01 to 0.06) |
| ICER (£ per QALY) | £9033 | £8267 |
| With HADS-T as outcome ($n = 156$) ^b | | |
| Incremental health and social care costs (£, 2009–10), mean (95% CI) | £293 (–£269 to £855) | £274 (–£262 to £810) |
| Incremental HADS-T change (reversed so higher scores show better outcomes), mean (95% CI) | 1.44 (–1.01 to 3.90) | 1.28 (–0.90 to 3.45) |
| ICER (£ per unit change on HADS-T) | £203 | £214 |
| <p>a Sample size based on complete data for QALYs and cost measures.</p> <p>b Sample size based on complete data for HADS-T and cost measures.</p> <p>Discount rate = 3.5%; formula $1/(1+r)^n$; r = discount rate, n = years into the future.</p> | | |

Appendix 2 Net monetary benefit graphs

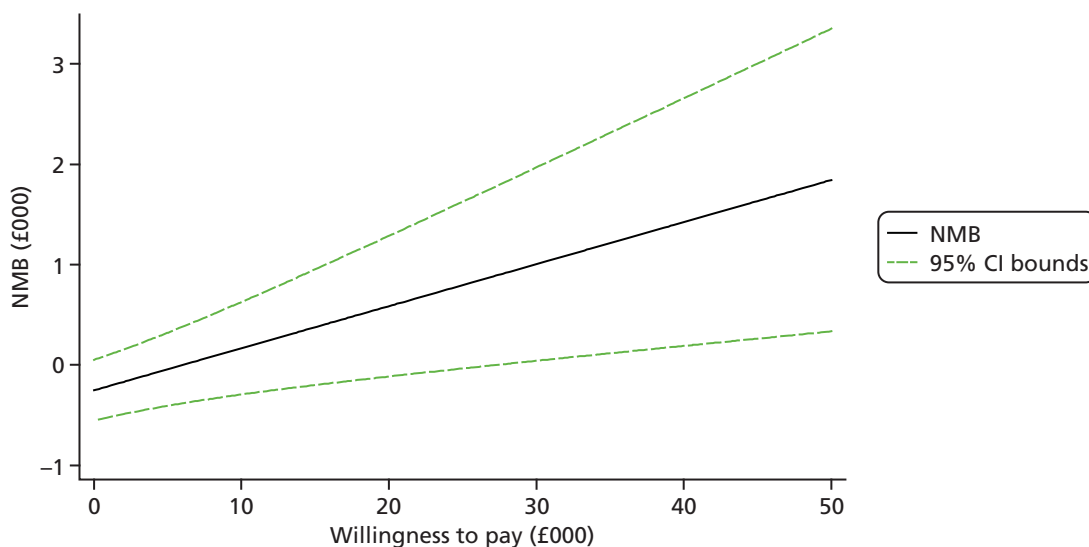


FIGURE 16 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU health and social care perspective, with effectiveness measured in QALY gain over 8 months.

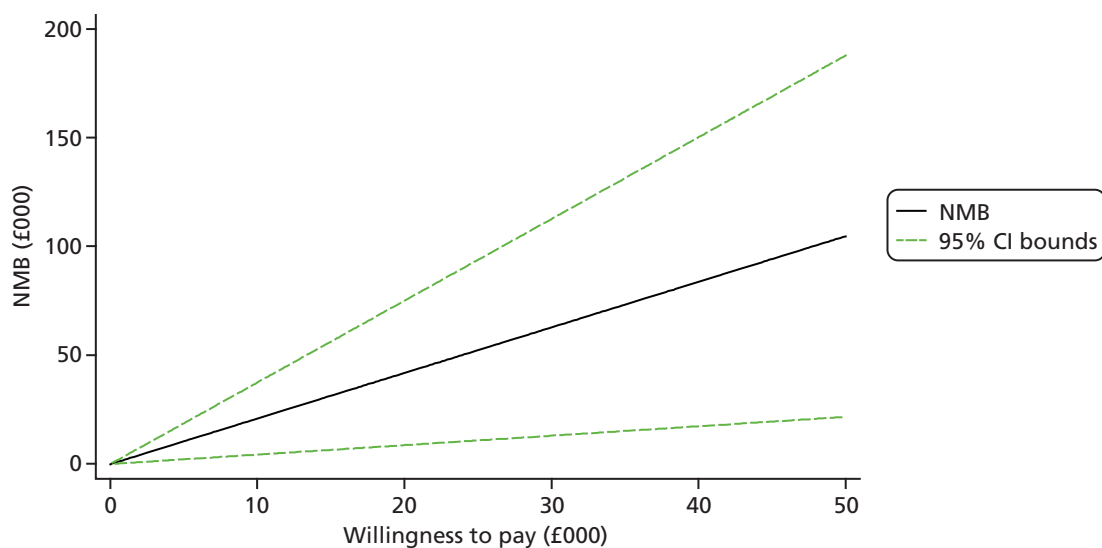


FIGURE 17 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured on HADS-T score over 8 months.

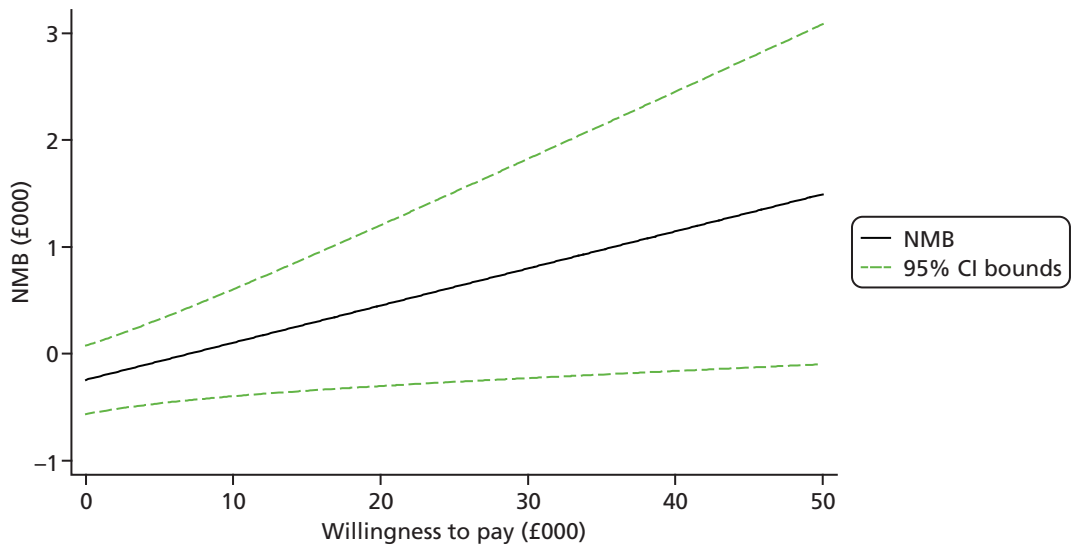


FIGURE 18 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 8 months following sensitivity analysis adjusting for significant predictors of missing values.

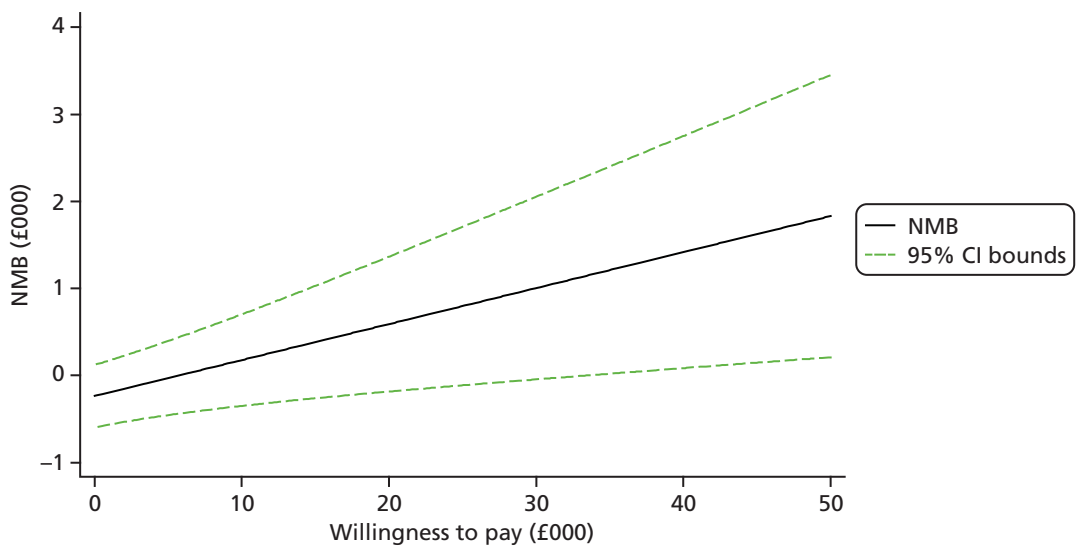


FIGURE 19 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 8 months following sensitivity analysis adjusting for baseline imbalances.

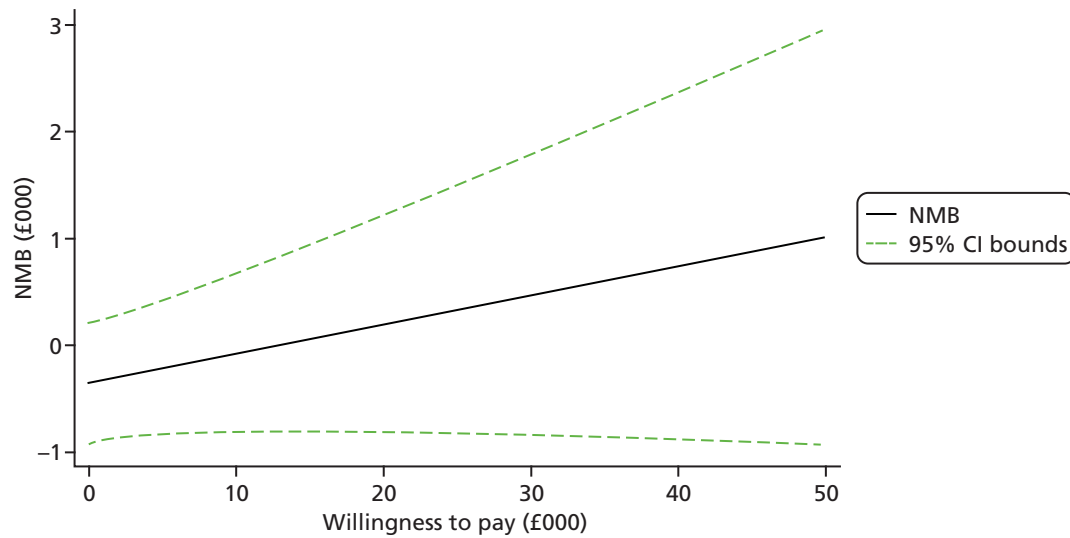


FIGURE 20 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months.

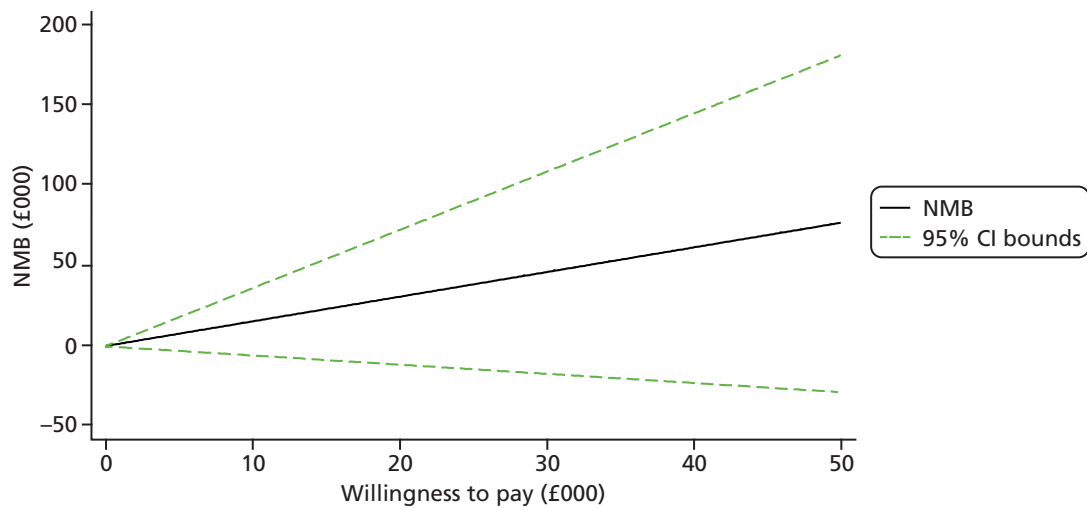


FIGURE 21 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured on HADS-T score over 24 months.

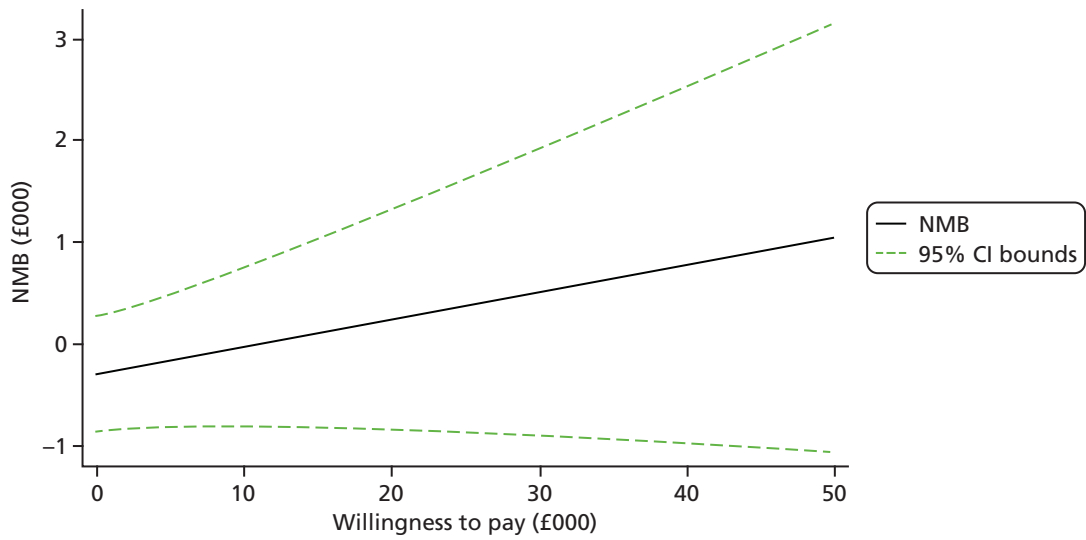


FIGURE 22 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months following sensitivity analysis adjusting for significant predictors of missing values.

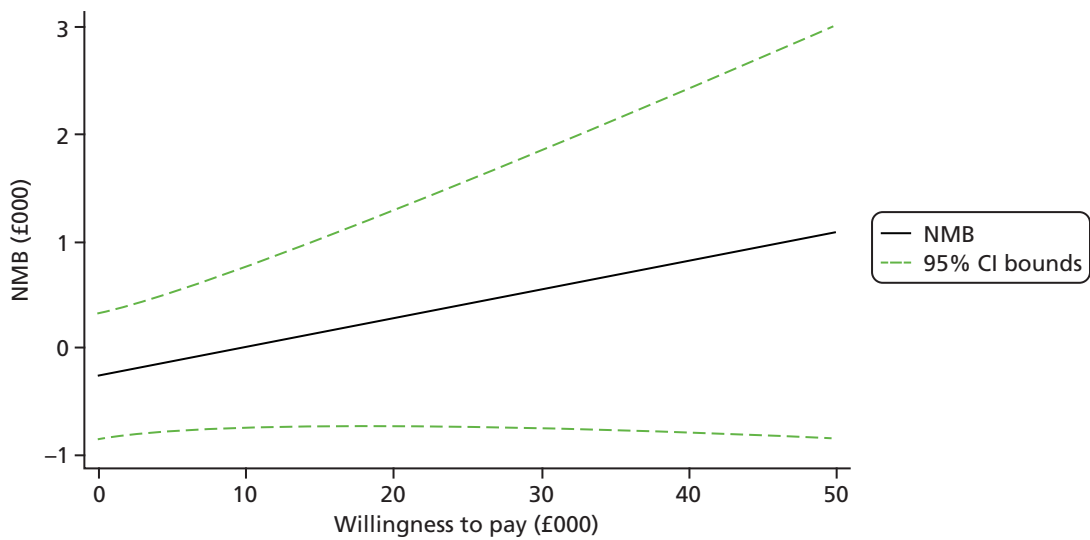


FIGURE 23 Net monetary benefit line (with 95% CI lines): START intervention vs. TAU; health and social care perspective, with effectiveness measured in QALY gain over 24 months following sensitivity analysis adjusting for baseline imbalances.

Appendix 3 The START manual

Leader Version

The START Manual: STrAtegies for RelaTives



Adapted from the original *Coping with Caregiving* with thanks to Dolores Gallagher-Thompson, Stanford University School of Medicine, for her kind permission.

Produced by MHSU UCL

Contents

| | |
|---|------------|
| Session 1: Stress and Well-Being | 5 |
| Session 2: Reasons for Behaviour | 23 |
| Session 3: Making a Behaviour Plan | 43 |
| Session 4: Behaviour Strategies and Unhelpful Thoughts | 61 |
| Session 5: Communication Styles | 83 |
| Session 6: Planning for the Future | 103 |
| Session 7: Introduction to Pleasant Events and your Mood | 133 |
| Session 8: Using your skills in the future | 153 |

Introduction

These sessions are about *you*, and how to maintain or improve your well-being when caring is stressful.

Some people find it helpful to think of themselves as a carer, others describe themselves as just acting the way a relative does.

How would you describe yourself?

Leader: Remember this and use their preferred description throughout if different to carer, the term used in this manual.

Caring is challenging, and many skills are needed. The sessions will focus on your thoughts, feelings, and reactions to looking after someone with memory loss. We will look at:

- Strategies to manage the difficult behaviours which are often associated with memory problems, so they are less upsetting.
- Strategies focusing on your sense of well-being, including ways to relax.

Although we can't guarantee that all difficult behaviours will change, we hope to provide you with some tools to improve your situation.

During my visits we will cover some strategies which help many people. You may be doing some already and not all will apply to you.

Here is an outline of what the programme covers:

Today is an introduction, in which we will discuss dementia, carer stress and understanding behaviours.

Throughout the sessions we will be focusing on:

- Providing you with skills to manage the problem behaviours that are associated with your relative's memory problems.
- Developing skills to take better care of yourself including changing unhelpful thoughts, communication, assertiveness, relaxation, and pleasant activities.
- Planning for the needs of your relative in the future
- Providing you with helpful hints for maintaining the skills you have learned over time.

After completing each session there will be a written exercise for you do at home, before the next session. Although you may find it difficult to find time, often people benefit from completing these exercises and are able to gain more from the session. It will allow you to become more aware of your own or your relative's behaviour and help you put into practice the tools, skills and techniques that we discuss.

This booklet is for you to keep and each time I visit I will give you more information covering what we talk about.



Session 1: Stress and Well-Being

Session Plan

1. Introduction to the Course
2. Overview of Memory Loss
3. Behaviour and Emotions
4. Managing the Stress that Caring brings
5. Stress
6. Stress Reduction Technique: *The Signal Breath*
7. Summary



Overview of Memory Loss

- Memory Loss is associated with more than 50 different disorders. The most common cause is Alzheimer's disease, followed by Vascular Dementia and then Lewy Body Dementia.
- Dementia is not a normal part of ageing. It is an illness.
- Memory loss and dementia can affect several areas of a person's life, making it difficult to function as usual. Some of these areas include:

Memory

Concentration

Thinking

Judgement

Behaviour

- Dementia affects the lives of many different people, including the individual with dementia and his or her family members. It can result in significant emotional and financial strain.
- Family carers can learn skills to manage the behavioural and emotional symptoms associated with dementia. Learning skills can allow carers to feel more able to manage and in control of their life circumstances.

- Each individual's experience and expression of dementia is different, because different areas of the brain are affected depending on the type of dementia and people are different to start with. Nearly everybody has difficulty in remembering and learning new things.
- Although dementia is very serious, and there is no known cure for it, there is *hope*. Research is being done all over the world. New treatments slow the progression of dementia, and are improving all the time.





Can you tell me the problems and symptoms you have noticed?

1.

2.

3.

4.

5.

Behaviour and emotion

A behaviour is something specific and observable that someone does. Some behavioural changes that can occur with memory loss include:

- Asking the same question repeatedly
- Accusing people of stealing when they forget where they have put things
- Wandering
- Doing embarrassing things in public
- Sleep difficulties

These behaviours are frustrating and difficult to manage. However, it is important to remember that they are the result of brain changes and not intentional.



Behaviours that you or your relative do are often related to feelings. It is important to understand that:

- Behaviours may not mean what you think
- Sometimes people cannot express what they feel in words as well as they used to. Sometimes what they do can be a clue to finding out what they are feeling

To illustrate this use the table below to identify behaviours that you or your relative do when experiencing the feelings (emotions) listed in the table.

| Feeling or Emotion | Related Behaviours |
|--------------------|-------------------------------------|
| Sad | 1. Talks less 2. |
| Pain | 1. Doesn't want to be touched 2. |
| Angry | 1. Shouts 2. |

Leader: If carer struggles to think of some behaviours you can prompt

- Loosing interest in family / hobbies
- Saying tactless / insensitive / uncharacteristic things
- Talking more / less / differently

Let's look at the problem behaviours on page 8.

Which of these most concern you?

Out of these, which one causes you the most stress?

If your relative does not have any problem behaviours you want to change, is there anything else about the situation that causes you stress?

Behaviour record

During the next week, please use this to write down the things your relative does (or you do in when caring for your relative) that you would like to change.

| Date/ Day of week | Time | Behaviour (what your relative does) | How did you feel when this happened? |
|-------------------------|------|--|---|
| | | | |

Managing the Stress that Caregiving Brings

We will now turn our focus to family and what they feel. Some common reactions include feelings of:

| | |
|--------------------|--------------------|
| <i>Sadness</i> | <i>Confusion</i> |
| <i>Anger</i> | <i>Grief</i> |
| <i>Despair</i> | <i>Guilt</i> |
| <i>Ambivalence</i> | <i>Frustration</i> |
| <i>Fatigue</i> | |



Do these describe how you have felt recently?

Stress describes a physical, emotional or mental strain which often results from difficult circumstances, many carers experience this.

We want to consider skills for coping with the difficulties that arise when caring for someone with memory problems, in order for you to take better care of both of you.

How stressed are you at the moment?

Caring for another person for a long period of time can be physically and emotionally draining. Over time, stress can impact on your health and well-being. Therefore, it is especially important for you to pay attention to your own physical and emotional health.

While the challenges cannot be avoided, you can take steps to manage them.



Stress and your body

There are a number of possible consequences of stress.

Physical Consequences of Stress

When a person is under stress, the body releases a stress hormone called cortisol. This explains why stress can cause symptoms such as sweating, breathlessness, nausea, and an increased heart rate.

Other Consequences of Stress

When left untreated, chronic stress can cause problems such as:

| | |
|--------------|---------------------|
| Depression | Changes in appetite |
| Anxiety | Sleep problems |
| Anger | Lack of energy |
| Irritability | Hopelessness |
| Helplessness | |

The psychological consequences of stress can take away your quality of life by lowering your ability to experience pleasure or a sense of accomplishment and can make it harder to care.

Social changes

The responsibilities of caring for someone can make it difficult to keep up with friends and relations. Talking things over can relieve stress by giving people a chance to discuss their thoughts and feelings. It is common to feel that no one understands what you are going through.

However, caring for someone with memory problems does not have to be a lonely experience.

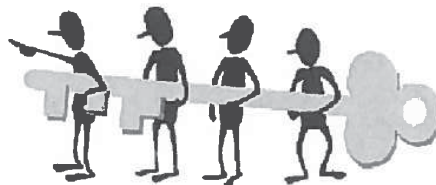
Let friends and family members know when you need help, or maybe just a break.

Caring is a very big job for a person. It can be particularly difficult if the person you are looking after is reluctant to accept help from anyone else. There are many local support groups, e.g. the Alzheimer's Society (for all carers of someone with memory problems) that can help you to meet others who have similar experiences. You probably find it difficult to have time for these kind of things, but it is important for your health and well-being.

Leader: Discuss with carer

- What social support do you have / find helpful?
- Have you thought about contacting the Alzheimer's Society?
- Would you ever consider it?

Seeing your friends and relatives socially can help you to feel less stressed.



Techniques for reducing stress

To help you reduce stress and tension, **I am going to show you some short techniques over the coming weeks** that you can use. Our aim is not to say, "When you are stressed, just relax". It is to help you gain control over stress, so you can concentrate your efforts on managing the stressful situation more effectively.

Of course, you may well have your own strategies for reducing stress that work for you already, such as listening to music, art or exercise. Our aim is to provide you with some new possibilities for reducing stress. As you try them out, you will come to find those that work best for you.

I will also ask you to practice them at home in stressful situations.



Stress reduction technique: *The signal breath*

Introduction

The Signal Breath is a simple stress reduction technique that can sometimes help you to cope better when stressful situations arise. It is useful because you can use it *anywhere*, at *any time*, and it is *quick*.

The Signal Breath is aimed at giving you immediate stress relief and is accomplished by creating a slight increase in tension in your body, by taking in a deep breath, and then letting go of the tension by breathing out. It also slows your breathing, which can become too fast when you are stressed. Slowing your breathing regulates the amount of oxygen and carbon dioxide in your blood. We will practice it in just a few moments.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now, before we practice the Signal Breath. On a scale of 1 to 5, how would you rate your tension?

Signal breath: Practice session

Script for Leader:

“The Signal Breath is very easy. It is a breathing technique that requires you to take in a deep breath.

When you will take this breath, you will need to tense your jaw, shoulders and arms... You will hold the breath for 2 to 3 seconds, then let the breath go and relax your jaw, shoulders and arms... As you exhale, you will mentally say a soothing word to yourself, such as ‘calm’ or ‘relax’...

Watch as I demonstrate....

Leader: Demonstrate a signal breath

Okay, now you try... Take in a deep breath, tightening your shoulders and arms, hold it for a few seconds...

[Pause for 2 or 3 seconds]

Now, let it go and say the soothing word you have chosen to yourself... Allow your jaw, shoulders, and arms to go loose and limp...

Are you happy? Or, shall we try it again?”

Tension rating after exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

Now, please rate your tension or stress level from 1 to 5. How would you rate your tension level now, after practicing the Signal Breath?

1. Did your level of tension change?

2. What was this experience like for you?

3. Can you think of a specific event when you think this technique might have been helpful during a stressful caregiving situation?

Please, practise this at least once a day. You can do it 2-3 times at once, but don't do it more than this, or it could make you dizzy.

Leader: Encourage carers to practise the Signal Breath at least one time each day this week.

Establish if they can make use of a CD, for next week. If they cannot use CDs, would they prefer a tape or mp3?

Summary

Today, we have talked about:

- **Memory loss**
- **How to define a behaviour and keep track of it**
- **Stress**
- **The relationship between stress and well-being**
- **The importance of taking care of oneself**
- **The Signal Breath**

FOR NEXT WEEK

It is important for you to practice what we have done. I really would like you to use these techniques in your everyday life, so they become almost second nature, helping both yourself and your relative.

√ **The signal breath:** Try to practice this every day and to use it in stressful situations. See if it helps.

√ **Behaviour record:** Please use the record **on page 12** to write down the things your relative does that upsets you. Please, try to use it **every day**.

When do you think you might have the opportunity to do these?

What might get in the way?

Session 2: Reasons For Behaviour

Session Plan

1. Review Behaviour Record from Last Week
2. Purpose of Behaviour
3. The “Trigger-Behaviour-Reaction” Chain
4. Stress Reduction Technique: *Focused Breathing*
5. Summary



Review Behaviour Record



Leader:

- Discuss their experience completing their first Behavioural Record. If they did not complete the record, ask them to think back on the week.
- Look at the Behavioural Record and read through it with them.
- Problem-solve any difficulties that might have occurred. For example:
 - “My relative did not have any behaviour problems this week.”
 - “There was no time to record in the log. I was too busy.”
 - “I didn’t understand what I was supposed to do.”
 - “There were too many problems, and I did not know what to record.”

Identify with them a recent problematical event and write it in.

- Encourage continued practice using the Behaviour Record

Why Is The Behaviour Occurring?

All behaviours have a purpose. For someone with memory problems, there may be several reasons why a difficult behaviour occurs.

Example: Some people with memory problems have trouble understanding their feelings or expressing themselves. Your relative may not like being on their own or may phone you repeatedly to check when you are coming home. This may be because your relative is feeling lonely, bored or worried about something. If we want to stop these behaviours, first we have to understand why they are happening.

All behaviours have a cause, it does not mean they are doing the behaviours on purpose.

Behaviours can have many purposes, and these may change over time and from person to person. For people with memory problems there can be many causes for difficult behaviours, some common examples are:

- Forgetfulness
- No longer knowing what is socially acceptable
- Frustration
- No longer being able to entertain themselves
- Difficulty communicating distress

Trying to make sense of why your relative does something can be hard. We will think first how their surroundings may affect them.

Understanding the Causes of Behaviour

Now let's look at the behaviour record again and try to answer these questions. Which behaviour would you like to focus on?

- Does the behaviour happen at the same time of the day?
 - If yes, what time is it?

 - What is usually happening at this time?

- Is your relative trying to communicate something (e.g. pain, thirst)?

- Is your relative frustrated, frightened or upset? (e.g. because they can't do something anymore or they do not know who someone is)

- Is your relative restless and trying to find something to do?

- Is your relative trying to get away from something you are asking her/him to do? (e.g. bathing, toileting, taking medications)
 - If yes, what activity is your relative trying to get away from?

Ruling out Medical Problems

Before trying to change your relative's problem behaviours, it is important to make sure that his/her behaviour changes are not related to a medical problem. Some common medical problems that can affect behaviour include:

1. Medical conditions e.g. urinary tract infections (symptoms are burning pain on passing urine, urinating more frequently, cloudy or different smelling urine), constipation, pain or fever. MS multiple sites



2. Medication side effects



3. Sensory impairments e.g. hearing loss or poor vision.



It is important that these conditions, as well as others, be adequately diagnosed and treated by your doctor, as there may be underlying sources to your relative's behaviour problems.

Important Note: Always contact your relative's doctor if there is any sudden change in their functioning.

Leader: It is important that you *do not* try to solve medical problems for carers. You should encourage them to seek medical attention for their relatives immediately if there is any concern.

The Trigger-Behaviour-Reaction Chain

The first step in identifying the cause of someone's behaviour is to pay attention to what happens before and after the behaviour.

TRIGGERS occur before the behaviour and can be any of the following:

- An event or activity, such as *noise* or a *demand* that is being placed on the person (e.g. bathing).



- General things that affect a person for a long period of time (e.g. time of day, season, and/or physical illness).



- Cues in the environment, such as keys to the car may remind someone of driving or the presence of another person.



BEHAVIOUR is what your relative does or what you do.

REACTIONS occur immediately after the behaviour.

- They include what you do, how you feel, what the person you care for does. In other words, what happens after the behaviour.

Reactions are very important to pay attention to, because they may cause, affect or change the problem behaviour.

It is helpful to think about the different phases of behaviour as a **Trigger-**

Behaviour-Reaction Chain:



A person with memory problems has a lot of difficulty learning new information or judging a situation.

The only things you as a carer have control over are triggers and reactions. Occasionally, we can't change the triggers. During these times, changing how *you* react to the behaviour may improve the situation.

Example:

When John goes to the shops with his brother Peter, it is often busy or loud. Peter finds this confusing, he becomes agitated and wants to go home. Although John may not be able to change the environment, he can reassure Peter and remain calm. As a result Peter is less distressed and able to continue shopping with John.

RECORDING the Trigger-Behaviour-Reaction Chain

We are now going to take a few moments to record a Trigger - Behaviour - Reaction Chain.

Example:

Every morning at 8am, Jim gets the car keys from the key hook and tells his wife, Pat, "I am going out for a drive."
Pat reminds him that he no longer has a driving licence and is not allowed to drive. Jim responds by shouting "I don't know what you are talking about" and walks towards the car. Pat says, "Alright, let's go for a ride, but let me drive." Jim lets Pat drive. Pat is upset with herself because she gave in to Jim's behaviour.

| Date/ Day of week | Time | Person Present | Trigger | Behaviour | Reaction |
|-------------------------|------|-------------------|---|---|---|
| Every morning | 8am | Pat Jim | Jim sees the car keys on the hook | Jim shouts and walks towards the car | Pat feels upset and gives in to Jim's behaviour Pat takes Jim for a drive |

Leader: Make sure that carer understands:

- Pat's reaction is reinforcing Jim's shouting and walking to the car as she is giving in to him when he does it
- Trigger is also important as not having keys on hook could solve problem

Exercise: Let's complete this Behaviour Record now, using the behaviour you identified earlier (see page 27). See the next page for helpful questions to refer to as you do this exercise.

| Date/ Day of week | Time | Person Present | Trigger | Behaviour | Reaction |
|-------------------------|------|-------------------|---------|-----------|----------|
| | | | | | |

When completing the Behaviour Record, keep in mind the following questions:

To work out the **triggers**:

1. What time of day was it?
2. Was the environment quiet or noisy?
3. Was the environment dark or bright?
4. Was your relative alone or was someone present? If so, who?
5. Was a particular event occurring, such as bathing, administering medications, or providing other direct care?
6. Did your relative want something such as food, a beverage, or keys?
7. How stressed did your relative feel?
8. Did your relative appear to be seeking attention?

To work out the **reaction**:

9. Did you stop the event (e.g. bathing, administering medications, or providing other direct care)?
10. Did your relative gain access to an object s/he wanted (e.g. food, beverage, keys)?
11. Did your relative receive attention?
12. Did your level of stress increase or decrease?

We will now discuss the different ways we can change behaviours. These include the following:

Changing the *trigger*

Changing our *reactions*

Changing the *trigger and our reactions*

We will begin with an example:

Example 1: Betty

Problem behaviour: Wandering at night

It is three o'clock in the morning and Betty wakes up and begins to walk around the house. Jane, her daughter, is sleeping. Betty paces throughout the house and wakes Jane up. Jane is upset, because she has a long day at work tomorrow. Jane says, "Mum, you need to go back to bed, it is 3 am." Betty says, "I am not sleepy." Jane shouts, "I can't take this anymore." Betty starts to cry.

| <u>Trigger</u> | <u>Behaviour</u> | <u>Reaction</u> |
|--|------------------------|--|
| Betty wakes up at 3 am. Jane is sleeping. Betty does not want to go to bed; she is not sleepy. | Betty wanders at 3 am. | Jane tells her Mum to go to sleep. Jane shouts. Betty cries. |

If Jane wants to keep her Mum from wandering at 3 am, what can she do?

1. Change the T (*trigger*) to prevent the wandering from occurring:

* Make an appointment with Betty's doctor to find out if there is a medical reason for her trouble sleeping (e.g. urinary tract infection, pain).

If there is no medical problem, then. . .

* Plan some activities to keep Betty awake during the day. Don't let her nap!

* Encourage Betty to exercise during the day (e.g., walking, stretching).

* Develop a bedtime routine that takes place at the same time every night.

* Do not allow Betty to have caffeine after lunch.

* As a LAST RESORT, talk to Betty's doctor, and ask her if there is anything Betty can take to improve her sleep.

2. Change the R (*reaction*) to prevent the behaviour from occurring again:

* Gently remind Betty that it is dark outside and time to go to sleep; lead her back to bed; play soothing music or do something else that will help Betty to relax.

* Jane could remind herself to approach the situation calmly and focus on the goal of the task (getting Betty back to sleep). This way, she will use her energy in a positive manner to problem-solve the situation, rather than reacting emotionally.

Leader:

- Remind carer this is how we will be developing strategies for them next session

Example 2: Joe**Problem behaviour: Asking the same question repeatedly**

After breakfast, Joe asks his wife, Sandy, "What are you doing?" Sandy says, "I am cleaning up." Five minutes later, Joe asks Sandy, "What are you doing?" Sandy says, "Washing the dishes." Five minutes later, Joe asks, "What are you doing?" Sandy begins to get annoyed and says, "I just told you, I am doing the dishes. Stop asking me the same question." Five minutes later Joe asks, "What are you doing?" Sandy is frustrated and feels helpless.

Using Joe's example, let's complete the following log and questions together:

First, identify the: **T**rigger **B**ehaviour **R**eaction

What could be the purpose of Joe's behaviour?

If Sandy wants to prevent the behaviour from occurring, what are some strategies she can use to prevent Joe's behaviour from being triggered?

How might Sandy react differently?

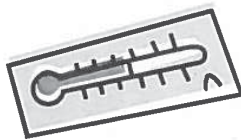
Stress Reduction Technique: *Focused Breathing*

Leader: Ask if they managed to try last weeks exercise, *the Signal Breath*. Ask what their experience was like. Discuss barriers that may have prevented practice. Praise all attempts.

Focused Breathing can be beneficial to carers for a number of reasons:

- It can be used to bring about a state of deep relaxation and ease the tension and stress that can be brought on by caring.
- It can help you learn to briefly focus your attention on something else, other than caring, allowing you time to focus on just you.
- Most importantly, through learning how to relax and take time for yourself, it will be easier to provide quality of care for the person you care for.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now before we practice the Focused Breathing. On a scale of 1 to 5, how would you rate your tension? _____

I am going to talk you through the Focused Breathing exercise now.

Focused Breathing: Practice Session

Script for Leader:

"You should begin this exercise by getting yourself into a comfortable position in your chair... Just settle back, and let the chair completely support your body...

Feel yourself sinking into the chair, allowing all of your muscles to go loose and floppy...

Now, take in a deep, signal breath, filling your lungs with air... holding it in until you notice a little tension building in your chest and then let the air out slowly, relaxing as you do...

Close your eyes and take in another breath, holding the air in until you feel the tension, and then relax, let go completely...

Now, let your breathing return to a normal and natural rhythm...

Start to focus your mind on your breathing... Become very aware of your breathing. Pay close and careful attention to each and every breath... Just watch it... Observe it...

Simply become aware of how easily and naturally your body breathes by itself, free and easy, in and out...

At all times your body is breathing by itself, you don't even have to think about it, your body breathes automatically, at all times, whether you are sound asleep or wide awake, aware or unaware... as long as you are alive, you are constantly breathing...

And all you have to do right now is to simply become aware of this process, this process of your body breathing by itself...

Notice the steady rhythm... the air coming in and going out again...

[Pause]

Allow your breathing to be natural and free... without trying to change and without trying to interfere... If your breathing is slow, let it be slow... If it is deep, let it be deep... If your breathing is shallow, let it be shallow... Just watch your body breathing by itself...

Be aware of the cool air coming in through your nostrils... and then the warm air flowing out...

Notice the slight pause between each inhalation and each exhalation...

Notice your chest as it ever so slightly rises and falls with each automatic breath... as your lungs expand when the air flows in and then contracts when the air flows out...

You may also notice your abdomen rising... and falling... each time you breathe in and breathe out... Experience the natural tides of your breath, the ebb... and the flow, as the air comes in... and flows out again...

If your mind should wander or your attention is pulled somewhere else, simply catch yourself and refocus on your breathing... refocusing again and again if necessary... Do your best to keep your mind focused on your breathing... Just watching and observing...

Nothing to change, nothing to hold onto, nothing to do... just awareness... watching... observing... and allowing your body to breathe free and easy... natural and automatic...

[Longer pause]

And now, as you continue to observe your body breathing by itself, you can begin to add a simple mental suggestion, a suggestion aimed at helping you experience even more relaxation and comfort...

Right now, as you focus your mind on your breathing, you can begin to imagine that each time you breathe out, each time you exhale, you are letting go of unnecessary tension, letting go of negative thoughts or worries, letting go of more and more discomfort... Just let it all go...

Allow yourself to breathe in fresh, positive, and healthy thoughts and feelings... Breathe in the good... Breathe out the bad... And so with each complete breath cycle, you can allow and experience both your body and mind becoming more comfortable, more relaxed, and more at ease...

Enjoy the natural mental and physical cleansing that your breathing can bring you, letting it carry you into a deeper and deeper state of relaxation and comfort...

Enjoy the mental tranquility and the peacefulness that this breathing can bring to you...

[Longer pause]

In a moment, you are going to open your eyes and return to a more normal, alert, and wide-awake state...

[Pause]

Ok, I would like you to take in a nice, deep, refreshing, and energising breath, stretch comfortably and open your eyes, to end this relaxation..."

Tension Rating After Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

Now, please rate your tension or stress level from 1 to 5. How would you rate your tension level now after practicing the Focused Breathing exercise _____ ?

1. How are you feeling now?
2. Did your level of tension change?
3. What was this experience like for you?
4. Can you think of a specific event when you think this technique might have been helpful during a stressful caring situation?

Leader: Encourage carers to practice the Focused Breathing at least one time each day this week. Check that they have been able to make use of the CD and if so give them this week's. If they cannot use CD, would they prefer a tape?

Summary

Today we have talked about;

- The purpose of behaviour
- Ruling out medical problems
- Trigger-Behaviour-Reaction Chain
- Stress reduction technique: *Focused Breathing*



FOR NEXT WEEK

✓ **Focused Breathing:** Before next week try and do this stress reduction exercise.

✓ **Behaviour Record:** Complete this record, on the next page, when your relative's target behaviour occurs. We understand it may be difficult to complete the record each time the behaviour occurs, but please complete it as frequently as possible.

Behaviour Record

Please use this log to write down the things your relative does (or that you do) that upset you.

| Date/ Day of week | Time | Person Present | Trigger | Behaviour | Reaction |
|-------------------------|------|-------------------|---------|-----------|----------|
| | | | | | |

Session 3: Making a Behaviour Plan

Session Plan

1. Review Behaviour Record from Last Week
2. Behavioural Strategies
3. Changing Behaviours by Changing Reactions
4. Stress Reduction Technique: *Physical Grounding*
5. Summary



Review Behaviour Record

Leader:

Review the behaviour record from last week. Look at each trigger, behaviour and reaction in turn and allow carer to discuss and reflect on what happened.

Could they have avoided the trigger or changed the reaction to prevent the behaviour (or encourage a helpful behaviour?)

Developing Behavioural Strategies

Now that you have recorded triggers and reactions, we will discuss how we want the behaviour to change.

There are three different things that can happen:

1. The behaviour can increase.
2. The behaviour can be maintained (no change).
3. The behaviour can decrease.



Identifying a behaviour you would like to change

Your relative's behaviour (or your behaviour) has probably been going on for a while. It would be unrealistic for us to think we can change it right away. So, we want to start out small and we want to be as specific as possible. Remember to set a realistic goal or you may set yourself up to fail.

On the next page are some examples of behaviours some people want to change:

Examples:

If Mrs. Smith refuses to eat lunch, a possible strategy would be: *Mrs. Smith will eat a small plate of food you know she likes for lunch at least 3 times per week.*

If Mr. Johnson follows you around every afternoon, a possible strategy would be:

Mr. Johnson will engage in an activity for 20 minutes between 4 and 5 pm without following you around at least 3 times this week.

Individual Plan to Change Behaviour

Using Mr. Johnson's example:

The behaviour that I want to change is:
Following you around

Do I want to increase or decrease it?
Decrease



What is the strategy for a new behaviour?
You or family member will listen to music with Mr. Johnson for 20 minutes between 4 and 5 pm without him following you around

What is the goal for the frequency of this new behaviour?
At least 3 times this week

Leader:

Make sure that carer understands that it is what they do that will change the behaviour

YOUR TURN:

Please turn to the Behaviour Record you completed at home and pick the behaviour you want to focus on changing:

The behaviour that I want to change is:

Do I want to increase or decrease it?

What is the strategy?

Let's think about Triggers and Reactions

Could the problem behaviour be related to your relative's health?



Could the problem behaviour be related to triggers in the environment?



Could the problem behaviour be related to your reaction?



We will now develop a list of *strategies* that you can use to *prevent* the behaviour from occurring or to help you respond differently. Be creative, and write down at least two.

- 1.
- 2.
- 3.
- 4.

Which one do you think you might try first? Write it down in the space below.

- **Try to use this strategy and complete the behaviour log to find out if the behaviour has changed.** You may feel that you can “mentally” keep track of whether the behaviour has changed, but we would like you to keep the record. The reason for this is that it is helpful to write the information down.
- **It might feel hard to stick with a strategy when there are so many things to think about.** Regardless of which behaviour and strategies you choose, remember to try to be consistent and use the strategy every time even if you do not achieve your desired behaviour change each time.
- **Problem-solving is a process of trial and error. There is no right or wrong answers.** Once this problem is solved, another one may develop. It’s possible that the strategy that you came up with may work at some times and not others. Be flexible, patient and creative!

Behaviour Record

Please use this Behaviour Record to write down something your relative does (or that you do) that upset you and the strategy you used to change it.

| Date and time | People Present | Trigger | Behaviour | Reaction | The strategy you used to change the behaviour was: | What happened when you tried using this strategy? |
|---------------|----------------|---------|-----------|----------|--|---|
| | | | | | | |

Changing Behaviours by Changing Reactions

There are various ways we can react to behaviours:

A. Encourage desired behaviour

In our daily lives it is normal to pay more attention to negative events than positive ones. Therefore you may find yourself focusing on your relative's difficult behaviours. However, if you are thinking about your relative's behaviour it is important to notice when things are going well and to encourage them.

For example, if your relative has been refusing to eat lunch everyday, but on Monday s/he does, then encourage your relative by giving her/him something positive. A positive reaction would be:

- Giving her/him something s/he likes: attention, a smile, or something else they like
- Saying something positive, praising
- Doing something kind, assisting, comforting, hugging.

You can consider this as "rewarding".

Guidelines for rewarding desired behaviour

1. Give a reward immediately after the desired behaviour.
2. Give a reward every time the desired behaviour occurs.
3. Make sure the reward is personal and meaningful to your relative.
4. Do not give a reward unless the desired behaviour occurs.

B. Do not reward problem behaviours

When your relative's problem behaviour occurs, it is important not reward the behaviour. It is easy to make this mistake without meaning to. One example is providing attention when they don't eat lunch. The reason to avoid giving attention when they don't eat lunch is so they don't learn a link between refusing to eat and attention. Otherwise the most likely result will be that they do it again.

The best option is to not reward the problem behaviour.

- Ignore the problem behaviour, or

- Draw attention away from the upsetting situation.

It is not always easy to ignore problem behaviours – it can feel unfair or unkind, but you are doing this as part of a strategy to help.

Let's look back at your behaviour record from last week

A. Did you reward the problem behaviour? **Yes** **No**

B. If so, how did you reward it?

Can you think of a time during the last week when the problem behaviour did not happen or you noticed a more desired behaviour?

C. Did you reward the desired behaviour? **Yes** **No**

D. If so, how did you reward the desired behaviour?

Stress Reduction Technique: *Physical Grounding*

Leader: Ask if they managed to try last weeks exercise, *Focused Breathing*. Ask what their experience was like. Discuss barriers that may have prevented practice. Praise all attempts.



Introduction

Grounding can also be called “distraction.”

This technique is particularly powerful, because it can be used whenever you are caught in a stressful situation, and can be done anytime, anywhere, by yourself, without anyone else noticing it. With practice, it can help you control your reaction to stressful situations that can arise during caring. Even though this technique is simple, it is very important to practice it to get the maximum benefit.

It is important to note that grounding is not a relaxation exercise. It is an active strategy that works through distraction and connection with the world around you. Keep your eyes open, as you are being taught to notice everything about the world in front of you and about the present.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now before we practice Physical Grounding. On a scale of 1 to 5, how would you rate your tension?

Physical Grounding: Practice Session

Script for Leader:

“First, I want you to get into a comfortable position in your chair with your feet flat on the floor and your hands resting by your side. You should keep your eyes open during this exercise and look around the room if you want.

I will ask you some simple questions, which I would like you to answer silently to yourself. If you notice distracting feelings during this physical grounding technique, I want you to let the distractions go, like leaves in an autumn breeze. Turn away from them, focusing your attention on the world around you. Remember that you are always in control. And, try not to judge anything – just notice what there ‘is’.

[Pause for about 10 seconds].

Remind yourself that you are safe, and at home.

[Pause].

Now, we'll try to imagine putting a buffer between you and all of your uncomfortable thoughts and feelings; feelings that could lead to stress and tension. Imagine that your uncomfortable feelings are bundled up and put in a box.

[Pause for about 10 seconds].

Next, visualise something between you and the uncomfortable feelings stored in this box: perhaps a wall, a large lake, or a big open field in the country, anything that creates safe distance between you and your uncomfortable feelings.

[Pause for about 10 seconds].

Now we are going to try physical grounding. Please keep following along with me. Notice your feet on the floor. They are literally grounded, connected to the floor.

[Pause for 10 seconds].

Wiggle your toes. Dig your heels gently into the floor to ground yourself even more.

Now, touch your chair. Say everything you can about it silently to yourself. Concentrate on its physical properties.

[Pause for 30 seconds, with prompts: What is it made of? Is it cold, or warm? What colour is it?]

Now touch a different piece of furniture. What is it made of? Is it colder or warmer than the chair?

Now, find any object that is near you – perhaps a pen, or your keys, or anything else on the table or desk. Pick it up and hold it, and say everything you can about it.

[Pause for 30 seconds, with prompts: What is it made of? How heavy is it? Is it cold, or is it warm? What colour is it?]

Just experience it for a moment.

[Pause for 15 seconds].

Now put it down.

Now, slightly clench your fists; notice the tension in your hands as you do that.

[Pause for 20 seconds].

Now, release your fists. Notice the difference.

[Pause for about 7 seconds].

Now press your palms together, with elbows to the side; press as tightly as you can. Focus all of your attention on your palms.

[Pause for 7 seconds].

Now, let go. Grab onto your chair as tightly as you can.

[Pause for 15 seconds].

Now let go. Notice the difference.

Then, gently turn your head to the left.

[Pause for 5 seconds].

Now turn it to the right.

[Pause for 5 seconds].

Bring your head back to the centre and gently drop your chin to your chest, as far as you can.

[Pause for 5 seconds].

Take a deep breath.

[Pause].

Breathe Out.

Finally, bring your head up to your normal position, to bring this session to a close"

Tension Rating After Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

Now, please rate your tension or stress level from 1 to 5. How would you rate your tension level now after practicing the Physical Grounding exercise _____ ?

1. Did your level of tension change?
2. What was this experience like for you?
3. Can you think of a specific event when you think this technique might have been helpful during a stressful caregiving situation?

Leader: Encourage carers to practice the Physical Grounding at least once a day this week.

Summary

Today we have looked at:

- Identifying a problem behaviour that you want to change
- Developing a plan to try and do this
- Rewarding desired behaviour and not rewarding problem behaviour
- Stress reduction technique: *Physical Grounding*



FOR NEXT WEEK

✓ **Behaviour Record:** Please fill in the new Behaviour Record (on the next page) including your strategy for behaviour change.

✓ **Physical Grounding:** Before next week, try and do this stress reduction exercise.

Behaviour Record

Please use this Behavioural Record to write something your relative does (or that you do) that upset you and the strategy you used to change it.

| Date and time | People Present | Trigger | Behaviour | Reaction | The strategy you used to change the behaviour was: |
|---------------|----------------|---------|-----------|----------|---|
| | | | | | <p>What happened when you tried using this strategy?</p> |
| | | | | | |

Session 4: Behaviour Strategies and Unhelpful Thoughts

Session Plan

1. Review Behaviour Record from Last Week
2. Choosing a New Behaviour and Reviewing the Steps to Changing Behaviour
3. Changing Unhelpful Thoughts
4. Stress Reduction Technique: *Guided Imagery – Meadow and Stream*
5. Summary



Refining Behavioural Strategies

Please review the Behaviour Record you completed last week and fill in the following information.

The strategy I developed last week to prevent the problem behaviour from occurring is:

Did you use the strategy? Yes No

If **no**, why did you not use it?

If **yes**, was it effective? Why or why not?

Choosing a New Behaviour

We identified one problem behaviour in session 3 that you wanted to focus on first. However, **there are likely to be other behaviours that your relative is doing that are causing you stress that can be changed.**

If there is a new behaviour you would like to change in the person you care for or yourself, then we will help you develop a new behaviour plan.

If your relative does not have any other behaviours that you would like to change, then choose something about yourself to change. We will follow the same steps as last session.

Step one: Choose the behaviour to focus on

The new behaviour that I want to change is:

Do I want to increase or decrease it?



Step two: What are the triggers and reactions?

In order to answer this question, you can keep track of the behaviour for next week by using the behaviour record.

However, you may be aware of some of these already.

Possible triggers:

Possible reactions:

Thinking about these, what possible strategies can you use to decrease the problem behaviour?

Changing Unhelpful Thoughts

Looking after someone with dementia may make you feel overwhelmed and stressed. When anyone feels like this, it can be helpful to pay attention to our thoughts. In general, our feelings are linked to our thoughts. **The way you think about something directly affects the way you feel about it.** These thoughts may be unhelpful and make you feel worse.

The first step to changing this cycle is to **stop** and **focus**. When you are in a stressful situation, take a moment to think about the thoughts and feelings you are having.

To help you better understand the relationship between thoughts and feelings, let's review the following example:

Lydia and David

Lydia is providing care for her husband David, who has Alzheimer's disease. Although David can still take care of some of his own basic needs, he can't follow any of Lydia's instructions.

In this situation, Lydia's thoughts are:

"David refuses to listen to me, even though he is able to. He is purposely not following my suggestions."

Lydia then feels frustrated and sad.

What strikes you about this example?

Learning how to change the unhelpful thoughts people have in stressful situations can help reduce frustration and sadness.

What am I thinking?

There are three steps to changing your unhelpful thoughts:

- *Stop and identify your current thoughts.*
- *Challenge and replace your unhelpful thoughts with more helpful ones.*
- *Pay attention to how you feel now.*

We will start by focusing on step one, which is to stop and identify the thoughts that are contributing to your unpleasant feelings. This process often happens so quickly that you are unaware that you have thoughts that occur between a stressful event and your unpleasant feelings.

The way to stop and identify your thoughts is by keeping track of what you are thinking in a stressful situation. To do this we will use a Thought Record.



Thought Record

The Thought Record has **three** columns for the following information:

- a.) the stressful situation
- b.) the thoughts you had in connection with this
- c.) the feelings that you experienced in the situation

Recording the situation, your current thoughts and feelings may help you find new ways to cope with the stress.

Lydia is providing care for her husband David, who has Alzheimer's disease.

The Thought Record can be filled in as below.

Although David can still take care of some of his own basic needs, he can't follow any of Lydia's directions.

Lydia's Thought Record

| Situation | Current Thoughts | Feelings |
|---------------------------------------|--|-------------------|
| David is not following my directions. | 1. David refuses to listen to me, even though he is able to. 2. He is purposely not following my suggestions. | Frustrated Sad |

We will now try to practice this, thinking about things which have happened to you. It is natural to find it difficult when someone you care for has dementia and lots of things are outside your control, but there are some things that you can control and improve.

Think about this past week and tell me about a difficult or stressful situation where you felt that you would have liked to react differently. Try to complete a Thought Record using your own example.

Your Thought Record

| Situation | Current thoughts | Feelings |
|--|---------------------------------|--|
| Describe the events that led to your unpleasant feelings | What did you think at the time? | What were you feeling? (sad, angry, anxious, etc.) |
| | | |

Leader: Did you think about (the person, the action, yourself). Other useful prompts for identifying thoughts and emotions: "Can you tell me a bit more?" "Anything else?"; also saying – "Can I see if I've got this right?" Then summarising what you understand they have said back to them.

We are now going to add two more columns to the Thought Record.

The additional steps we are adding are:

- 4.) **Challenge and replace** unhelpful thoughts with more helpful thoughts
- 5.) Describe any change of **feelings** you have as a result

This is the five column Thought Record.

| Situation | Current thoughts | Feelings | Challenge and replace with more helpful thoughts | New feelings |
|-----------|------------------|----------|--|--------------|
| | | | | |

Challenging and replacing your thoughts can be difficult at first, but with practice you may find it **useful**. There are common patterns of thinking called “automatic thought patterns”. To change these, there are some techniques.

Some require you to perform actual behaviours in challenging your thoughts and others ask you to analyse the thoughts from a different perspective.

1. Look at it from someone else’s point of view.
2. Ask other people what they think or get more information.
3. Change how you talk to yourself.
4. Try not to jump to conclusions.

Consider the following example while going through the list below.



MS

Alice is a 64 year old woman caring for her 90 year old mother. She believes that she is not a dependable carer. She feels guilty when she wants to visit her friends. Alice thinks, "I should always stay with my mother because something bad will happen to her when I leave. Other people can't take care of her the way I do. If something happens I will never forgive myself for not being a good daughter."

Look at it from a different point of view: Talk to yourself as if someone who cares about you is talking to you.

In our example, as Alice blames herself for wanting to spend time away from home, she could ask herself: "How would my close friend Marie view this - and what would she have to say about my situation?" Alice could also imagine what her friend (who cares about her) would think about her leaving her mother for short periods.

Discussion

1. What do you think Alice's friend Marie would say?

2. If your friend was here what would they say to you?

3. What if your friend was in your situation, what would you say to them?

Take action/ Ask others:

Some carers find it helpful to get additional information to challenge their unhelpful thoughts.

Alice could challenge her thoughts about “not being a dependable carer” by talking to other carers about how they handle similar situations.

Alice could also plan to leave her mother with someone she trusts for a short period, to test out her concerns that her mother will have a crisis when she is gone.

Discussion

1. Have you ever talked to other carers? Is this something you have considered?
2. What do you believe you need to do, to be a dependable carer?
3. Do you have any concerns? What could you do to test out your concerns?

Change how you talk to yourself:

We often create negative labels for others or ourselves without realising what we are doing, for example thinking "If I can't be there all the time, I am not a good enough carer, I am not giving what my relative deserves".

We also may believe that we must behave, think, or feel a certain way. This might often include us saying things to ourselves like "I must/ I should do ...". Allowing yourself to think "It's OK not to be perfect" and "It's also important I look after myself" can help you see the situation from a different point of view.

If Alice tried to think about what her label of "Not being a dependable carer" really meant, she would see that she was expecting the impossible and this expectation would set herself up to fail.

She could also change, "I should always stay with mother" to, "My mother likes me being there, but she could enjoy being with others too, and it would be good for both of us if I get a break and feel a bit better".

Discussion

1. Do you ever have these kinds of thoughts?
2. How else could you think about your situation? Is there any other way you could think about your situation?

Try not to think of things as all or nothing:

Remind yourself to think of different options. Don't assume that if you can't do something perfectly; it is not worth doing at all.

Could Alice consider other alternatives to never going out? Must she think of herself as either a dependable carer **OR** *not* a dependable carer?

It's important Alice recognises all the good things she is doing and how much she is coping with.

Discussion

1. Do you ever have these kinds of thoughts?
2. Tell me some of the positives about caring for your relative

PRACTISING THE THOUGHT RECORD Let's use the 5-column Thought Record to expand the example that you thought of earlier, or, if you prefer, choose a new example.

| Situation Describe the events that led to your unpleasant feelings | Current thoughts Identify your thoughts in the situation | Feelings What are you feeling? (sad, angry, anxious, etc.) | Challenge and replace with more helpful thoughts What is a more helpful way of thinking about the situation? | New feelings What are you feeling now? (sad, angry, anxious, etc.) |
|--|--|--|--|--|
| | | | | |

Stress Reduction Technique: *Guided Imagery - Meadow and Stream*



Leader: Ask if they managed to try last week's exercise, *Physical Grounding*. Ask what their experience was like. Discuss barriers that may have prevented practice. Praise all attempts.

Introduction

Guided Imagery is a stress reduction technique that allows one to have a "time out" from daily concerns. It should be done in a quiet setting where you will not be disturbed. Some carers find that this type of exercise works best when they do it right before they go to bed in the evening, when all is quiet around them. Practice is important in order to maximize your benefits from this exercise.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now, before we practice the Guided Imagery exercise. On a scale of 1 to 5, how would you rate your tension? _____

Guided Imagery: Practice Session

Script for Leader:

"This is a guided relaxation imagery exercise. First of all, get yourself into a comfortable position. Just settle back into your chair.

Close your eyes and take in a deep signal breath, holding the breath for a few moments, and then let it out slowly, feeling relaxation as you do so.

And now take in another deep breath... hold it ... until you feel a little tension in your chest and then let go... relax... allow all the muscles in your body to become loose, limp, soft like a rag doll;

Just allow pleasant waves of relaxation to flow through you, soothing and relaxing each and every part of your body... including your arms and hands... your neck and shoulders... your scalp and all the muscles in your face...

And as you rest there quietly, breathing freely and evenly, allow the muscles of your chest to become loose and relaxed... and then your stomach and your back... both your upper back and lower back... your hips and legs... allow the relaxation to flow through your legs all the way down your feet and ankles...

And as I continue talking to you, these waves of relaxation can continue to spread throughout your body... penetrating deeply into every cell... but no matter how relaxed you feel right now, it is possible to become even more deeply relaxed and yet awake and aware of my voice."

"Now, ... even though your attention may wander from time to time, simply bring it back to the images that I am going to describe.

Imagine yourself about to open a very large door...

and as the door opens, you find yourself transported to another place.
You step out into a grassy meadow ...a peaceful, quiet meadow.

And flowing through the meadow is a small winding stream,
and on each side of the stream are tall, shady trees...

Now picture yourself, right now, sitting down... along the bank of this stream.
You sit and rest against the trunk of one of the trees...

notice the pale blue sky and the white clouds,....feel the warmth of the sun
with pleasant rays shining down, ... sparkling as it reflects on the flowing water...
it is a beautiful, pleasant,... peaceful day,....not too warm or too cold... the
air is fresh and clean and you are aware of sounds of birds chirping...of the
sound of the water, as it flows along the stream...

It is so peaceful here... so calm and tranquil... just look around you... taking it all
in... enjoy the simple beauty of this place..."

[Long pause]

"And now look more closely at the stream... notice the clear, cool water as it
flows by... wondering where the water comes from and where it goes..."

Then, as you look upstream you notice a very large leaf, floating on the water,

and your eyes observe this leaf as it is getting closer, closer and closer to the
place where you are sitting...

and then, the leaf is in front of you...

Now you find yourself transferring to this leaf all of your concerns, and all of your discomfort ...

All of your cares, all of your worries are transferred to the leaf.

...and so the leaf continues, floating down the stream, floating away,....
the leaf carries away all of your discomfort,... all of your cares and worries...

just watch it float along... Watch it getting further, and further away from you...

until it finally disappears completely and you are left feeling even more relaxed, more comfortable, and more at ease than you have felt for a long time..."

[Longer pause]

"For in this state of deep relaxation all parts of your body are working together harmoniously, smoothly, and healthily...

a deep sense of well-being fills your mind... a feeling of healthy energy and vitality fills your body...

and as you prepare to eventually leave this special place of relaxation, you can carry back with you many of these pleasant feelings and sensations, knowing that as you practice this exercise and similar exercises, it will become easier... to use the powers of your mind...to experience these positive effects..."

"And now I will bring you back slowly from this relaxation by counting backwards from 3 to 1. When I get to 1, you will be alert, refreshed, and comfortable. Okay: "3," much more alert; "2," feeling refreshed and comfortable; and "1," as you open your eyes and return your awareness to the room you are in."

Tension Rating After Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

Now, please rate your tension or stress level from 1 to 5. How would you rate your tension level now, after practicing the Guided Imagery exercise? _____

1. Did _____ your level of tension change?
2. What was this experience like for you?
3. Do you think that the person you care for might like to try listening _____ to a tape of this exercise with you?

Leader: Encourage carers to practice the Guided Imagery at least one time each day this week.

Summary

Today we looked at:

- Choosing a new behaviour to change and revising the steps that need to be followed when developing a new plan
- How unhelpful thoughts contribute to how we feel
- How to identify automatic thoughts and complete a record of unhelpful thoughts
- Strategies for challenging these thoughts and trying to change them
- Stress reduction technique: *Guided Imagery – Meadow and Stream*



FOR NEXT WEEK:

✓ **Thought Record:** Please complete this (on the next page).

✓ **Behaviour Record:** You may also like to complete the behaviour record (on page 79).

✓ **Stress Reduction:** Please try to practice one of the stress reduction exercises.

Thought Record

| Situation Describe the events that led to your unpleasant feelings | Current thoughts Identify your thoughts in the situation | Feelings What are you feeling? (sad, angry, anxious, etc.) | Challenge and replace with more helpful thoughts What is a more helpful way of thinking about the situation? | New feelings What are you feeling now? (sad, angry, anxious, etc.) |
|---|---|---|---|---|
| | | | | |
| | | | | |

Optional Exercise: Behaviour Record

Please use this Behavioural Record to write down something your relative does (or that you do) that upsets you and the strategy you used to change it.

| Date and time | People Present | Trigger | Behaviour | Reaction | The strategy you used to change the behaviour was: |
|---|----------------|---------|-----------|----------|--|
| | | | | | |
| <p style="text-align: center;">What happened when you tried using this strategy?</p> | | | | | |

Session 5: Communication Styles

Session Plan

1. Review Thought Record and Behaviour Record, if completed
2. How to Express Yourself Effectively
3. Practicing Assertiveness Skills
4. Communicating with Someone with Memory Problems
5. Stress Reduction Technique: *Meditation*
6. Summary



Review

Leader.

Behaviour Record

Review the Behaviour Record completed last week. Ask if they used the strategy?

If **no**, why not?

If **yes**, was it effective?

Why or why not?

Thought Record

Did they have any trouble filling out the Thought Record? Was it helpful?

Why or why not?

If there is a problem, spend some time thinking about a solution.

How to Express Yourself Effectively

We all communicate in different ways. We are going to talk about three styles of communicating today: We will call these passive, aggressive and assertive. Most people use these different styles at different times or in different situations.

Passive Communication

EXAMPLE: Passive Communication

Sylvia takes care of her husband, who has memory problems. She has arranged for her husband to stay with her brother, Daniel, while she attends a weekly exercise class. An hour before the class, Daniel calls to say that he has changed his mind and doesn't want to take care of her husband after all. Sylvia responds by saying, "That's okay, I really didn't need to go after all."

Discussion

How might you feel after this kind of experience?



Passive Communication

- Can involve communicating thoughts and feelings indirectly and apologetically, allowing others to easily disregard them
- Can involve reluctance to express difficult feelings openly
- Puts other peoples needs above your own
- Seeks to please others and to avoid conflict at any cost
- Sends the following message:

"I don't count. My feelings don't matter; only yours do. I'm not important."

Aggressive Communication

EXAMPLE: Aggressive Communication

Sylvia responds to Daniel's decision not to take care of her husband by saying, "I'm sick and tired of you not thinking of me. You promised to take care of him, and I'm going to hold you to that promise whether you like it or not! I'm not interested in hearing any excuses!"

Discussion

How might Daniel react?
 How might you feel after this kind of experience?
 What might be the effect?



Aggressive Communication

- Can involve standing up for personal rights and expressing thoughts in an unhelpful way (e.g., becoming angry, verbally attacking)
- Can ignore other people's points of view
- Seeks to force the other person to agree with you
- Sends out the following message:

"This is what I think; you're wrong to think differently. This is what I want; what you want doesn't matter. This is what I feel; I don't care about your feelings."

Assertive Communication

EXAMPLE: Assertive Communication

Sylvia responds to Daniel's statement that he doesn't want to take care of her husband by saying, "It's important that I get a break. I know you're busy, but can you find time to give me a break even if its not today."

Discussion

How might the effects of this interaction be different from the previous examples?

Assertive Communication

- Can involve expressing your own opinions while respecting the views of others
- Can involve expressing your thoughts directly and honestly
- Can increase the chance that your requests are understood, and that you will have a better result
- Leads to problem solving and negotiation
- Communicates the following message:

"This is what I think. This is what I feel. This is how I see the situation. Your thoughts and feelings are also important."



Leader: Ask carer "Which do you think is the most useful method of communication?"

How do you communicate?

1. How do you think you communicate with doctors, health care workers or with other service professionals?
2. What about in situations with family members or friends? Or when trying to obtain help from others?
3. What about with the person you care for with memory loss?
4. Would you like to change your communication pattern in any of these situations (e.g., with family, friends, health care professionals, or the person you look after with memory loss)?

Practicing Assertiveness Skills

Analysing the situation

We are going to look at how you communicate with your relative a little later. Now we are going to be looking at asking for help. Think of a situation you were recently in where you asked someone for help with or information relating to your relative and things didn't go right.



Practicing assertive communication

In a minute, we will talk through a situation that occurred with someone you have asked for help when it didn't go as you would have liked.

Try to be aware of how to be effective and assertive in your approach. On the next page are some tips to consider first.

Leader:

- Ask carer to think of a specific situation relating to their relative and create a simple description of the scene. Be very specific! You take the role of the person the carer is negotiating with.
- Prior to this session, think of an example the carer has told you about recently that would be a good example to use for this exercise.
- Try prompting e.g. "If you were to ask 'x' for help, what would you say?"
- If carers do not have an example, use this alternative role play:

"If you cannot think of a specific example to role play, try to imagine this scene:

You are in need of a "break" (to go shopping, go to the dentist, pay bills, etc.), so you can get things done without your relative coming along and distracting you. You want to ask your sister (or whoever is appropriate) to come over and be with the person you care for 4 hours while you go out. Your relative usually doesn't agree when you've asked for this kind of help in the past, or usually says yes and then cancels at the last minute. This time you really want a solid yes."

TIPS TO REMEMBER FOR ASSERTIVE COMMUNICATION

1. Think about what do you want or need
2. What exactly is the problem? Formulate this in one or two sentences
3. Try to describe your thoughts and feelings clearly
4. Give detailed information about what you need. E.g. Taking care of Mum for two hours involves feeding her a snack, turning the radio to her favourite station, and taking her to the bathroom
5. Be persistent and flexible: Maybe you won't get exactly what you asked for, but you will get something that will be helpful
6. Break it down into smaller parts or ask for things one at a time – it's usually easier for people to say yes to a little request than to a big one!
7. If you feel stuck – agree to think about it and talk again
8. Recognise that sometimes there isn't a solution
9. Remember to recognise the difference between what you want and what the person you care for wants. They might not always be the same
10. DON'T GIVE UP! It may take many attempts before things change

Discussion:

How did you find practicing assertive communication?

What could you have done differently?

What went well and what techniques would you use again?

Leader: Discuss whether they found it difficult to communicate assertively?
What are the barriers to doing this in real life situations?

Communicating with Someone with Memory Problems

Communicating with someone with memory problems can be challenging. You may now or in the future, feel as if you have to jump over many hurdles. When we feel frustrated it can be even harder to communicate clearly.

You may know some of the following already, or it may be new information:

Memory problems affect communication in a number of ways:

- They may affect your relative's ability to understand what you say.
 - They may limit your relative's ability to express what he or she wants to say.
- Increased memory problems may lead to an inability to remember thoughts from one moment to the next.

IMPORTANT POINT: Because people with memory problems often cannot change their communication patterns, we need to find other ways to communicate with them.

Let's look at an example.



Gloria wants her husband John to go to bed. He is watching television. She shouts from the kitchen that it's time for bed. He ignores her. She shouts louder for him to turn off the television and get ready for bed. John continues to ignore her so she begins to cry and locks herself in the bathroom.

How could Gloria have done things differently?

How to talk to someone with memory problems

Helping you or your relatives listening and understanding

Attention

- Try to catch the attention of your relative before beginning to speak.
- Reduce distractions when talking to your relative, e.g. switching off the television.
- Position yourself so that your relative can see you clearly and make eye contact.
- Touching your relative may help you to attract their attention.

Environment

7. Sit closely, ensure that background noise is minimal and that lighting is good.

Aiding understanding / listening

- Try to listen carefully to what your relative is saying and gently encourage them.
- If they find it difficult to communicate what they mean, listen for clues, allow plenty of time, encourage them to explain in other ways.
- If you have had to guess what they mean, check out with your relative that you have understood them correctly.
- If you become frustrated or irritated, change the subject or take a break and talk about it later.

Being understood

- Speak clearly, slowly and calmly, try not to raise your voice.
- Try counting to ten in your mind after asking your relative a question, to allow them time to answer.
- Make instructions clear and simple, using short sentences.
- Try to ask only simple questions, one at a time, allowing for yes/no answers or try to avoid questions.
- If you are not being understood, try again in a different way, perhaps using actions, objects or signs as well as words.

You may have to try some different communication techniques and see what works for both of you. You may also have to change and adapt your communication over time.

Discussion

What changes have you noticed in your relative's ability to express themselves?

How have you changed the way you communicate with him/her?

Which of these tips do you already use?

Which of these tips do you think you will start using?

Communication Record

If you would like we can record an example of difficult communication with your relative.

| Situation | What I said or did in the situation | How the situation turned out | How I felt |
|-----------|-------------------------------------|------------------------------|------------|
| | | | |

Stress Reduction Practice: *Meditation*

Leader: Ask if they managed to try last week's exercise, *Guided Imagery- Meadow and Stream*. Ask what their experience was like. Discuss barriers that may have prevented practice. Praise all attempts.

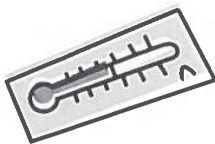


Introduction

Today we are going to do a meditation technique. This technique will involve combining pleasant imagery with various physical sensations. The theory behind this technique is that visualizing yourself in a relaxing scene (e.g. a beach, forest, etc...) helps you to become less tense and focus better. Focusing on pleasant images will make it easier for you to focus on the relaxing physical sensations that I am going to repeat to you.

Throughout this procedure adopt a relaxed, passive and casual attitude. You can't force relaxation to occur. Try to give up conscious control of your body and allow your physical processes to flow naturally.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now, before we practice the Meditation. On a scale of 1 to 5, how would you rate your tension? _____

Meditation: Practice Session

Script for Leader:

“Let’s begin... Settle comfortably in your chair and take in a deep, cleansing breath...

When you are ready, close your eyes and feel yourself becoming more and more relaxed with every breath...

Continue to breathe normally, as you picture yourself in a relaxing setting... You may be at the beach, or in a forest, or wherever you feel comfortable and at ease...

Take a moment to notice the details around you in this peaceful place and notice that you are becoming more and more relaxed...

Once you feel at ease in your special place, think to yourself, *‘I am at peace... My right arm is heavy... My left arm is heavy...’*

Now continue on your own, noticing your calm breathing and heartbeat, and the heavy, warm sensation in your arms and legs...

‘I am at peace... My arms and legs are heavy and warm, my heartbeat is regular and calm... My breathing is calm... My breathing is calm... My abdomen is warm... I am at peace... My abdomen is warm... My abdomen is warm... I am at peace... My arms and legs are heavy and warm... my heartbeat is calm and regular... My breathing is calm... My abdomen is warm... My abdomen is warm...’

Now, continue to notice the heaviness and warmth in your legs, and your calm and regular heartbeat and breathing and the warmth of your abdomen...

‘I am at peace... My arms and legs are heavy and warm... my heartbeat is calm and regular... My breathing is calm... My breathing is calm... My abdomen is warm... My forehead is cool... My forehead is cool... I am at peace... My forehead is cool... My forehead is cool... I am at peace...’

Now, continue to notice the sensations you feel throughout your body as you relax in your peaceful place...

Now, I am going to count from 3 to 1, and as I do, you will open your eyes and become more alert and aware of your surroundings... By the time I say 1, your eyes will be completely open, and you will feel alert, refreshed, and relaxed...

Here we go... Three... two... one... Your eyes are open and you are awake, alert, relaxed and aware of your surroundings...”

Stress Rating after Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

On a scale of 1 to 5, how would you rate your tension? _____

1. Did your level of tension change?
2. What was this experience like for you?
3. Can you think of a specific event when this technique might have been helpful during a stressful caregiving situation?

Leader – Encourage carers to practice this exercise, or another one of their choice, at least one time each day this week.

Summary

Today we looked at:

- Different communication styles
- Passive communication
- Aggressive communication
- Assertive communication
- Communicating with someone with memory problems
- Stress reduction technique: *Meditation*

For next week:

✓ **Planning for the Future:** Please read over the material for next week. It will help you to process this important information. Feel free to invite another family member who is helping you care to come to the session if you would like to.

✓ **Communication Record:** Please use the sheet on **page 97** to monitor your verbal and non-verbal communication style over the next week.

✓ **Stress Reduction Exercises:** Please carry on regularly practicing your preferred stress reduction exercises.

Optional Exercises (Recommended):

✓ **Behaviour Record:** Please complete the Behavioural Record on **page 98** when your relative's target behaviour occurs. We understand it may be difficult to complete the Record each time the Behaviour occurs, but please complete it as frequently as possible.

✓ **Thought Record:** When a situation occurs that stresses you, please record your unhelpful thoughts and challenge and replace them with more helpful thoughts. Use the Thought Record on **page 99**.

Communication Record

Use this sheet to write down difficulties with communicating both verbally and nonverbally with your relative this week.

Write down a specific situation, how you communicate, how it turned out and what your feelings were. Try to complete this once a day, if you see them.

| Situation | What I said or did in the situation | How the situation turned out | How I felt |
|-----------|-------------------------------------|------------------------------|------------|
| | | | |

Optional Exercise: Behaviour Record

Please use this Record to write something your relative does (or that you do) that upset you and the strategy you used to change it.

| Date and time | People Present | Trigger | Behaviour | Reaction | The strategy you used to change the behaviour was: |
|---------------|----------------|---------|-----------|----------|--|
| | | | | | What happened when you tried using this strategy? |

Optional Exercise: Thought Record

| Situation Describe the events that led to your unpleasant feelings. | Current thoughts Identify your thoughts in the situation. | Feelings What are you feeling? (sad, angry, anxious, etc.) | Challenge & replace with more helpful thoughts What is a more helpful way of thinking about the situation? | New feelings What are you feeling now? (sad, angry, anxious, etc.) |
|---|---|--|--|--|
| | | | | |

Session 6: Planning for the Future

Session Plan

1. Review Communication, Thought and Behaviour Records from last week
2. Introduction to Planning for the Future
3. Options for Care
4. Managing Your Relative's Physical Health
5. Legal Issues in Care Planning
6. Making a Plan
7. Stress Reduction Technique: *Guided Imagery – Ocean Escape*
8. Summary



Review Home Practice

Leader:

A. Communication Record

What was your experience of using communication skills with the person you care for? What happened?

Did you use the strategy? **Yes** **No**

If **no**, why did you not use it?

If **yes**, was it effective?

Why or why not?

Discuss what worked and what might be helpful in the future.

If carer completed the Behaviour or Thought Record, go through it:

B. Behaviour Record

Did you use the strategy? **Yes No** If **no**,
why did you not use it?

If **yes**, was it effective?

Why or why not?

C. Thought Record

Did you have any trouble filling out the Thought Record? Was it helpful? Why or why not?

Planning for the Future

In this session, we will discuss some of the issues surrounding planning for the future care of your relative. We realise that these issues are hard to talk about, but it can be helpful to plan ahead.

Families often find themselves making important decisions when a crisis occurs. However, making decisions when you are under stress can be more difficult.

Planning before a crisis can help your family prepare for potentially difficult decisions you might face. Of course, you can always change these plans as things change.

We will discuss some of the most common concerns that relatives express including the following:

- Options for care
- Managing the physical health of someone with dementia
- Legal issues

You may have other concerns, if so let me know and we can talk about these. The goal is to help you feel more confident and informed when making difficult decisions about care.

Talking About the Future

I would like you take a moment to think about your concerns regarding the future.

1. What concerns do you have about caring for your relative in the future?

Is there anything else?

Leader:

If carer can't think of any concerns, prompt:

"Some people worry about caring in the future if things become more difficult, for example if they become ill or the person with memory problems get worse? Are these things that worry you?"

2. Have you discussed these concerns and how you plan to handle them?

If **yes**, what decisions have you made?

If **no**, who would you want to include in a discussion of these issues?

Options for Care

In this section, we will discuss some of the options available for caring for someone with memory problems over the course of their illness. We will discuss the advantages and disadvantages of each option.

The Present Situation

We will start by looking at the table on the next page and thinking about any help that you have now and the resulting advantages and disadvantages.

1. Could you tell me what help your relative receives from family friends, or local community?

2. What other support is your relative receiving, from NHS, social services, or voluntary services?

Leader:

Go through the types of help the carer has mentioned in the last two questions and fill in the advantages and disadvantages in the table on the next page.

Use *Descriptions: Options for Care* section on the following pages to augment participants' answers to the previous questions.

The goal is to provide them with an understanding of the different options available for their situations. If they are unsure or decline a service go over the section so they are fully aware of what is on offer.

If you have gone over a particular section in detail or they already know about it, there is no need to repeat it. Just fill in the gaps with this material.

PULL OUT THIS PAGE

| Care Options | Advantages | Disadvantages |
|---|-------------------|----------------------|
| Family/Friends help | | |
| Health care | | |
| Home care | | |
| Telecare | | |
| Day centres and lunch clubs | | |
| Respite care including sitting services | | |
| Care home | | |

BLANK PAGE

Health Care Options



Specialist health services for dementia

GPs refer people with memory problems to memory clinics or other dementia services with psychiatrists (or, less often, neurologists or geriatricians).

If your relative has been seen and discharged from these specialist services, the GP is able to re-refer them if further advice is needed in the future.

Your relative will continue using their usual services for other health issues.

Social Care Options

Home care services

Range from reminders, e.g. to eat or change clothes, to the care workers doing the task.

- Included are bathing, grooming, dressing, and cooking.
- Home carers can remind someone to take their tablets if they are in a blister pack.
- Care workers have training in dementia and how to provide care safely, effectively and safeguarding the person's dignity.
- They can come in up to 4x a day depending on what is needed.

Telecare

Is an electronic monitoring system that social services can provide, that allows people to remain independent for as long as possible. This could be helpful if your relative is at risk of falling, leaves the gas or water on, or if you are concerned about them leaving the house alone.

Day centres and lunch clubs

Some are for all older people; others are for people with dementia.

- They focus on keeping the body and mind active, and social contact to improve quality of life.
- They can give carers a break.
- They often provide transport to and from home.

Respite care

Allows a carer to have some time off.

- *Residential* respite care is at a care home or hospital.
- *At home* respite is where someone sits with your relative in their own home, or takes them out for a few hours, while you have a break.

Sometimes the budget for social care is handled by the person with dementia and their family, deciding what to buy themselves. This is called "direct payments".

Residential Care Options



Sheltered housing

This enables people to continue to live independently but with the reassurance that help is at hand. It may be suitable for some people with memory problems.

Long term care

If you or a relative can no longer manage at home, you may want to consider long term residential or nursing care.

- A *residential* home can offer assistance with personal care,
- Whereas a *nursing* home can provide specialised nursing care.

The decision about whether someone should move to a care home is very personal and complicated.

We have included some fact sheets in the appendix that give comments and advice from family members who have made these decisions.

Leader:

Ask if they have any questions about care options available. Talk about any concerns they have.

If they ask a question you can't answer, tell them you will try and find the answer and ring them or tell them next time. You won't be able to answer questions specific to the person they care for, but you can suggest to them who can.

We have included some sheets, produced by our team which you may find helpful. These are:

- When does the local authority pay for care?
- Choices in care
- How to select a care home

Managing Your Relative's Physical Health

Now, we will move on to talk about physical health and pain management.

As anyone (including people with dementia) gets older, they are more likely to experience physical illnesses. People with memory problems often need help to look after their physical health. This support can include:

- Reminding them about medical appointments
- Attending appointments with them
- Helping them to make decisions about medical care, or giving your opinion or advice, or
- Making these decisions on their behalf.

For example, as a carer you may be asked whether you think your relative should have an operation or receive certain treatments.

Some points to consider

- Some people with dementia continue to make (or at least contribute to) decisions about their own health.
- You can always discuss these issues with friends, family members and healthcare professionals. If you are asked to make decisions like this, you will be given information about the advantages and disadvantages of any treatment.
- It can be helpful to discuss these issues with your relative in the early stages of their illness.

We have included some fact sheets that give comments and advice from family members who have made these decisions.

Pain management



Although dementia does not cause pain, like all of us people with dementia can become physically unwell.

- Sometimes people with dementia are not able to tell you that they are in pain. You may notice instead that their behaviour changes, they become irritable or agitated, or they do not seem themselves.
- In most cases, severe pain and physical discomfort can be managed through effective use of painkillers and non-medical means, such as relaxation therapies, massage and good nursing care.

Ways to ensure good pain management

- Don't be afraid to tell professional carers that your relative is in pain. You probably know them best.
- Consider the compromises you and your relative are willing to make for pain management. Some people would rather be sedated and in less pain and others would not.

What if something happens to me?

Some carers make a plan in case something happens to them, and they can no longer provide care for their relative.

- If you suddenly could not provide care (perhaps because you were taken ill) and there was no plan, Social Services would arrange any necessary emergency care for your relative.
- You can discuss with your family what would happen to your relative, so that you can make a decision together for this eventuality.
- The **Carers Emergency Card** Scheme operates in most areas, allowing carers to draw up and register a plan. The carer has a card, and in emergencies they (or someone with them) can call the 24-hour helpline, who will make the agreed arrangements. Details of where to find out about the scheme are in the CHOICE factsheets provided with this session.

Decisions for the future

Planning for a time when a person with memory problems cannot make their own decisions about physical health care is difficult.

Let's read the following conversation between two sisters whose mother has memory problems:

83-year-old Gloria has had memory problems for many years. She has two daughters, Paula and Mary. Gloria's doctor told Mary that Gloria's memory is likely to get worse. Mary decides it's time to talk with her sister, Paula, about future decisions for their Mum.



Leader: Suggest carer reads Mary in the following script

Mary: I saw Mum's doctor last week and he told me that Mum's memory will probably get worse.

Paula: You know, doctors aren't always right. I don't think you should worry.

Mary: But the doctor said we will need to make some decisions pretty soon. It would make me feel better if we could discuss this.

Paula: I don't think there is anything to talk about. We can handle things as they come up.

Mary: I'd prefer to discuss it now. I think that if we wait till the last minute, it will be too late. I know it's not easy, but ignoring it won't make it go away.

Discussion questions:

- Have you thought about or discussed similar issues?
- If so, was this helpful?

Legal Issues in Care Planning

In this third section, we will introduce some legal issues that may come up in the future. Please tell me if you already know of, or have dealt with, these issues, and we can move on.

What is mental capacity?

Legally, people who make decisions must be able to understand what they are doing. If someone cannot make a particular decision for themselves, they are said to lack the **mental capacity** to make that decision.

This is one reason why someone might set up a Lasting Power of Attorney (which will be explained on the next page), so that if someone with dementia is not able to make an important decision in the future, they have already chosen someone who can make that decision for them.

Leader:

Be aware: LPAs replaced enduring power of attorney in October 2007 when the Mental Capacity Act (2005) came into effect. Enduring power of attorney (EPA) completed before this date are still valid. Any existing EPA only applies to finance and property matters, so even if someone already has one, they can also make an additional LPA for personal welfare decisions under the Act.

Ask the carer if they have ever considered a power of attorney. If they would like more information, you can give them a fact sheet. **Encourage them to think about Power of Attorney.**

Lasting Power of Attorney (LPA)



Anyone who still has capacity can complete legal documents giving another person (who is then called the *attorney*) the authority to act on their behalf.

People with memory problems usually appoint a family member or close friend as their attorney.

There are two types of Lasting Power of Attorney (LPA):

Property and Affairs LPA

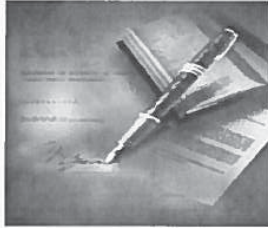
Gives the attorney the power to make decisions about financial and property matters, such as managing a bank account and paying bills.

Personal Welfare LPA

Gives the attorney the power to make decisions about health and personal welfare, such as day-to-day care, medical treatment, or where the person should live.

A Personal Welfare LPA only ever takes effect when the person with memory problems lacks capacity to make decisions.

A Property and Affairs LPA can take effect as soon as it is registered, even while the person with memory problems still has capacity, unless they specify otherwise.



Advance Decisions

Many people think about how and where they would like to be cared for if they became very unwell in the future. For example, whether they would prefer to be at home if at all possible, or in a hospital, nursing home or a hospice.

Discussing this with family and friends can be difficult. Many people with memory problems and their families find it helpful to have these discussions, while others prefer not to.

As well as talking with family and friends, the Mental Capacity Act allows anyone with capacity to make an **Advance Decision**. This specifies particular types of treatment they do not want should they lack the mental capacity to decide in the future.

The advance decision will only be used if the person making it is not capable of deciding at the time that the treatment is needed.

Tips for Planning for the Future

GATHER the information you need to make informed choices for you and your family as early as you can. If possible, discuss the following questions:

- How do you want to be treated at the end of your life?
- Are there treatments you want to receive or refuse?
- What are you afraid might happen if you can't make decisions yourself?
- Do you have any particular fears or concerns about medical treatments?

TALK about decisions with your family, friends, doctor, and any others close to you to help with decisions that are important to you and the person you care for.

PREPARE and sign Lasting Power of Attorney or advance directives that accurately reflect your decisions.

INFORM the person you care for and doctor about your preferences and give them copies of your advance directives.

If your relative cannot talk about these issues:

Think about what he or she may have said in the past on this topic.

Think about his or her values.

Making a Plan

For next week, think about a possible stressful situation that may occur in the next few months.

What information from this session might help?

Is there any further information you need to help cope with this situation?

FOR NEXT WEEK



✓ **Planning for the future:** Think about the questions we covered on **page 118** and read through the CHOICE factsheets. These were written after interviewing family members of people with memory problems, about decisions they found difficult. Make a note of any questions you have and we can discuss these next week.

✓ **Relaxation:** At home, please practise the **Guided Imagery–Ocean Escape** exercise that we will do shortly, or a relaxation exercise of your choice.

Optional Exercises (Recommended):

✓ **Behaviour Record:** Please complete the Behavioural Record on **page 126** when your relative's target behaviour occurs. I understand it may be difficult to complete the Record each time the Behaviour occurs, but please complete it as frequently as possible.

✓ **Thought Record:** When a situation occurs that stresses you, please record your unhelpful thoughts and challenge and replace them with more helpful thoughts. Use the Thought Record on **page 127**.

Leader: If they do not have time to do all of these tasks, tell them the most important task is to read over the information from this session and in the CHOICE factsheets.

Stress Reduction: *Guided Imagery– Ocean Escape*

Leader: Ask if they managed to try last week's exercise, Meditation. Ask what their experience was like. Discuss barriers that may have prevented practice. Praise all attempts.

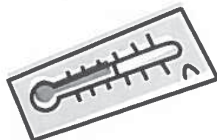


Introduction

Today we are going to do another Guided Imagery exercise. This exercise will involve imaging your experience at the ocean, far away from the cares of everyday life.

I am providing you with a wide range of options, as different people find different images or scenes relaxing. We hope this one will be helpful for you.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now, before we practise the Guided Imagery. On a scale of 1 to 5, how would you rate your tension? _____

Stress Reduction Technique: *Guided Imagery - Ocean*

Script for Leader:

We are about to begin the guided relaxation imagery exercise. Soon, I will be describing a relaxing scene for you.

But first of all, make sure you get yourself into a comfortable position in your chair, with your arms by your side.

Close your eyes, and take in a deep signal breath, holding it for a few moments... and then let go, relaxing as you do so.

Now as I continue talking to you, you can allow a calm relaxed feeling to settle over your body and mind.

Let go of any unnecessary tension in your shoulders, arms, and hands.... As your shoulders and arms hang loosely by your side, let all of the tension drain out through the tips of your fingers.

Let the relaxation flow from your shoulders into the back of your neck, ... as the tension dissolves and melts away... relaxing your neck and scalp...

... and also your face, including your mouth, tongue, and jaw.

Let the relaxation flow down the rest of your body... your chest... abdomen... and back.

Feel all the muscles of your body becoming loose and relaxed.

Letting the relaxing feelings flow into your legs, ankles, and feet.

Just allow your entire body to become loose, heavy, and relaxed.

And now... picture yourself somewhere by the ocean.

Just project yourself to any relaxing place along the ocean... perhaps a place you have been to or a place you would like to go...

It may be a sandy beach or a rocky beach... you may be on a pier or even on a cliff, overlooking the ocean... any place you choose is fine.

Look around... what do you see?

Can you see it clearly in your mind? ... Do you notice the vastness of the ocean... stretching out as far as you can see?

Perhaps you see a dolphin or whale swimming by...

Now inhale deeply, smelling the fresh sea air....

Feel the warmth of the sun,... the cool breeze. How peaceful and relaxing it is...

And now listen more closely to the sounds... especially the sound of the waves. Pay close attention to the sound of the waves and notice how soothing and relaxing the sound is...

...as you hear the waves roll in... and out again...

In... and out...

the constant rhythm of the waves... the ebb... and flow...

And each time the waves flow in... and out, you find yourself becoming more deeply relaxed...

deeper... and deeper... as your muscles go loose... and limp... and the tranquility of this place surrounds you.

[Long pause]

And now spend a few minutes doing whatever you would like.
You may just want to lie on the sand and soak up the sun...
you may want to walk along the beach... or swim in the cool water...
perhaps you would like to do some fishing... go sailing...

Whatever you would like to do at the ocean is okay... but no matter what you do,
just continue being aware of this relaxation...

[Allow participants a few minutes to enjoy this imagery].

And now. I will bring you back slowly from this relaxation by counting backwards
from 3 to 1. When I get to 1, you'll be alert, refreshed, and comfortable.

Okay,

"3" much more alert;

"2" feeling refreshed and comfortable,

and

"1" as you open your eyes and return your awareness to the room you are in."

Stress Rating after Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

On a scale of 1 to 5, how would you rate your tension? _____

1. Did your level of tension change?
2. What was this experience like for you?
3. Can you think of a specific event when you think this technique might have been helpful during a stressful caregiving situation?

Leader:

Encourage carers to practise the Guided Imagery, or an exercise of their choice, at least one time each day this week.

Summary

Today, we have talked about:

- Planning for the future
- Options for care
- Managing your relative's physical health
- Legal issues in care planning
- Stress reduction technique: *Guided Imagery–Ocean Escape*

Remember, if you only have time for one exercise over the next week, please read over the information from this session and have a look at the CHOICE factsheets.

Optional Exercise: Behaviour Record

Please use this Record to write something your relative does (or that you do) that upset you and the strategy you used to change it.

| Date and time | People Present | Trigger | Behaviour | Reaction | The strategy you used to change the behaviour was: |
|---------------|----------------|---------|-----------|----------|--|
| | | | | | <p>What happened when you tried using this strategy?</p> |
| | | | | | |

Optional Exercise: Thought Record

| Situation Describe the events that led to your unpleasant feelings. | Current thoughts Identify your thoughts in the situation. | Feelings What are you feeling? (sad, angry, anxious, etc.) | Challenge & replace with more helpful thoughts What is a more helpful way of thinking about the situation? | New feelings What are you feeling now? (sad, angry, anxious, etc.) |
|---|---|--|--|--|
| | | | | |

Session 7: Introduction to Pleasant Events and your Mood

Session Plan

1. Review of Planning for the Future
2. How Events Affect Your Mood
3. How to Identify Pleasant Events
4. Creating a List of Pleasant Events
5. Pleasant Events Planning
6. Monitoring Your Mood
7. Relaxation: *Stretching*
8. Summary



Review of Planning for the Future

Leader:

- Review Planning for the Future – review future possible stressful situation from last week.
- If they have indicated they need more information, talk with them about from where this could be obtained.
- Review Thought and Behaviour Records

How Events Affect Your Mood

Although being a carer is time consuming, it is important that you make the time for activities you enjoy. This is because if all your activities are limited to caring, you may begin to feel burned out and frustrated.

For example, feeling down is often related to having too few pleasant events. A lack of balance between unpleasant and pleasant events can make you feel like you have no control. You may think "It seems like there's nothing I can do to make things better." However, you can feel better by making sure your day has a few events that bring you pleasure

Rollercoaster of Moods

Pleasant
events



Unpleasant
events

We can make choices about many of the events that occur in our lives. Increasing pleasant events can help reduce stress and therefore make you feel more able to care.

What Counts As A Pleasant Event?

Pleasant events don't have to be long or need a lot of planning. They aren't just big events like holidays. Reading the newspaper, a leisurely cup of coffee, gardening or talking to a friend can all be pleasant activities.

Key Point: Anything you like to do is a pleasant event

List two activities that are pleasant for you:

- a.
- b.

Adding pleasant events to your daily life can be difficult. You may think "I don't have the time to do pleasant activities!" or feel guilty about making time for yourself or having time apart from the person you care for. These can be barriers but it is important to overcome them. **Being a good carer means taking care of yourself too!**

Pleasant Events for You and Your Relative

Pleasant events can be for you alone or for you and your relative. It is important to have pleasant activities to do with the person you care for. This can be hard since you may have many tasks to do as a carer, but it is valuable if you can continue to enjoy each other's company.

I'd like to work with you to develop a list of pleasant events that you can enjoy together, and things you can enjoy by yourself.



Here are some examples of pleasurable events, not all of these activities will be for you. Take a few moments to look over this list and tick the activities you think you would enjoy either together or separately.

| Activities | You | You and your relative |
|--|-----|-----------------------|
| Listen to music | | |
| Go to the shops | | |
| Go for a walk | | |
| Read/listen to books, newspapers, magazines or spiritual texts | | |
| Go out for coffee or to eat with friends or family | | |
| Cook or bake | | |
| Write letters or cards etc. | | |
| Drawing, painting, doing crafts | | |
| Exercise e.g. jogging, yoga, cycling, football | | |
| Go to the cinema or watch a film | | |
| Go for a drive | | |
| Go to the park with a picnic | | |
| Have friends over | | |
| Gardening / DIY | | |
| Be with children / grandchildren | | |
| Listen to the radio | | |
| Watch your favourite TV programme | | |
| Watch wildlife or be around animals or pets | | |
| Look at photos | | |
| Go to place of worship | | |
| Watch sports | | |
| Recall or discuss happy memories | | |
| Dance | | |
| Have a leisurely bath | | |
| Chat to friends or family on the phone | | |
| Spend time on the computer | | |
| Play cards, computer games, crosswords or puzzles | | |
| Talk about family or current events | | |
| Buy a ready prepared meal or take away | | |
| Get your hair / nails done | | |
| Massage | | |
| Have a glass of wine or beer | | |
| Bingo | | |
| Other activity: | | |
| Other activity: | | |

Highlighting these activities and doing two or three of them each day can make a huge difference to how you feel.

Creating a List of Pleasant Events

Rule A: *Start small and be simple.* The most important thing to remember is to choose events that you can do everyday or a few times a week. You may enjoy travelling, but realistically you cannot take a trip every day. A smaller and more realistic activity would be going to the shops, cycling or walking.

Rule B: *Focus on events you want to do more often.*

Let's think of four pleasant activities for you

Leader: use list from page before if necessary

1

2

3

4

Creating a List of Pleasant Events for You and Your Relative

It can be helpful to plan activities or events that are manageable and achievable. Think about events you used to enjoy together in the past.

Is it possible to still do those activities? If not, can they be changed in any way? For example, if you used to take long walks together, can you now take short walks? As long as you find things your relative enjoys and is able to do, you will be helping them to feel better. Things to remember when selecting and planning activities for your relative:

- Don't force them to participate: Encourage or reward him/her often.
- Try to think of things that are similar to some hobbies, interests, or games they used to enjoy.
- Have a few activities available, so if they become bored you can switch easily.
- Plan to do activities in short bursts.
- Try to involve other friends or family if at all possible.
- Activities that involve movement can be good, since people are often restless and have relatively short attention spans.
- There is no harm if your relative enjoys crafts, games, or music that are simpler than before.

Let's think of four pleasant activities for you and your relative

Leader: use list from page before if necessary

1

2

3

4

Pleasant Events Planning

Some activities require more planning than others. Because we want you to be successful in planning pleasant events for both you and your relative, we have put together a list of questions you may ask yourself beforehand so that things will go as smoothly as possible. It may be that planning beforehand will help you manage to do pleasant activities. Take a look at these questions:

Leader: Encourage carer to work through the questions for one activity they plan to do in the next week.

Pleasant Activity:

Materials or preparation needed

When it will take place?

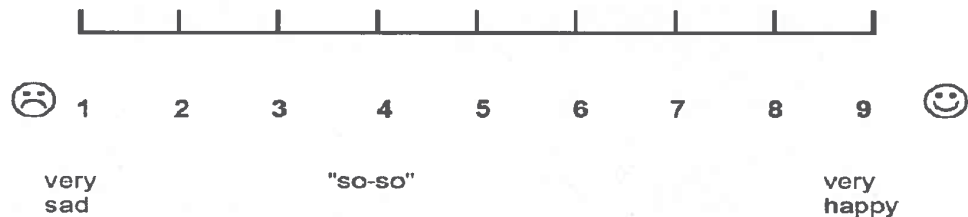
How often can it be done?

How much time will it take?

Monitoring Your Mood

In order to understand the difference pleasant events make to you, I want you to keep track of how you are feeling. This means asking yourself, "How am I feeling today?"

By keeping a daily record of your feelings, this will allow you to identify whether your mood follows a particular pattern.



The number 1 represents the lowest you could possibly feel.

The number 9 represents the best you could possibly feel.

Record a number on your pleasant events sheet (on the next page) at the end of each day. This number will represent the way you felt on that day. You will rate your mood on a scale 1 to 9.

When you fill in this number at the end of each day, think about how you felt *overall*. Most of us have lots of ups and downs over the course of the day, so try to take an average of these feelings.

Next to your mood score for each day, is a space for any comments about that day's events that may have contributed to your mood.

Leader: Fill in the days and events you wrote down before for the table on the next page now. Ask them to use these during the week. Complete the first line as an example.

Pleasant Events For My Relative and Me

| Day | Events for Me | Events for My Relative and Me | Total Events Today | My Mood Score (1-9) | Comments |
|---------|--|--|--------------------|---------------------|----------|
| | a..... b..... c..... d..... Which events (a,b,c, or d) | a..... b..... c..... d..... Which events (a,b,c, or d) | | | |
| Example | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

BLANK PAGE

Relaxation: Stretching

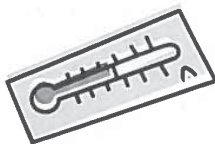
Leader:

- Ask if they managed to try last week's exercise. Ask what their experience was like. Discuss barriers that may have prevented practice. Praise all attempts.
- Check with the person that you are working with that they are fit and well enough to do these exercises i.e. do not feel dizzy or have funny turns when standing. **If so do it all sitting or another relaxation exercise**

Introduction

Simply stretching tired muscles can go a long way toward reducing tension and stress. Stretching exercises can be used almost anywhere, at any time, for as long as you want, so they can be an especially convenient relaxation technique for carers. It is important to do stretching exercises that feel good to you. As we practise this today, please tell me if you experience any discomfort and we will stop and try something else.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now, before we practise the Stretching Exercise. On a scale of 1 to 5, how would you rate your tension?

Stretching: Practice Session

Script for Leader:



"Today, we will do a few stretching exercises that will help you relax. First, let's start by standing up, or if you prefer, you may choose to do this exercise in your chair. Whatever is the most comfortable for you is all right.

Take a deep signal breath, all the way down to the bottom of your stomach, (pause 2s) and slowly let it out. Feel the tension drain from your body. (*pause*) Take one more breath and hold it for a moment (*pause 2s*) and let it out slowly. With each breath you are becoming more and more relaxed.

Now, gently reach your arms out to the sides, as though you were trying to touch the walls. Relax your shoulders and stretch yourself a little.

Gently reach your arms out in front of you. Feel the muscles in your back and shoulders loosen up. Stretch out in front a little further.

And now reach up as high as you can. Push up your arms towards the sky, as if you were trying to reach the sun.

Again, reach your arms out to the sides as though you were trying to touch the walls, as though you were trying to push the walls outward.

Reach out in front of you. Feel your muscles in your back and shoulders become looser and less tense.

Reach up toward the sky one more time. Reach as high as you can. Try to touch the sun.

Lower your arms to your sides.

Now, roll your shoulders back. Feel the tension drain from your body. Roll your shoulders back again. One more time roll your shoulders back.

Now roll them forward. Roll them forward again. One more time forward.

Now shrug your shoulders, lifting them up and then pushing them down. Shrug your shoulders again. Shrug them one more time.

Now another take in a deep and refreshing breath, and exhale all of the tension in your body. To complete this session, take one more breath... and exhale, letting go of any remaining tension..

Are you feeling calmer and more relaxed now? If not, consider completing this exercise a second time.”

Stress Rating after Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

Now rate your level of stress or tension after practicing the Stretching Exercise. On a scale of 1 to 5, how would you rate your tension?

1. Did your level of tension change?
2. What was this experience like for you?
3. Can you think of a time when you could use the stretching exercise (i.e., during a stressful caregiving situation)?

Leader:

- Praise carers for any success they had with the exercise
- Encourage carers to practise stretching at least once per day this week

Summary:

Today we have talked about:

- Being aware of your feelings/mood.
- The connection between mood and Pleasant Events.
- Increasing Pleasant Events as a way to improve your mood.
Relaxation: Stretching.

FOR NEXT WEEK:

✓ **Pleasant Events Tracking Form:** Please complete the form on **page 140** each day this week. Try to fill it out at the end of each day. Feel free to add new Pleasant Events or change the ones you have written down.

✓ **Relaxation:** Please try to practise the **Stretching** exercise that we have just done.

✓ **Optional Exercises (recommended):**

Behaviour Record: Please complete the Behavioural Record, on **page 147**, when your relative's target behaviour occurs. We understand it may be difficult to complete the record each time, but please complete it as frequently as possible.



Thought Record:

When a situation occurs that stresses you, please record your unhelpful thoughts and challenge and replace them with more helpful thoughts. Use the Thought Record on **page 148**.

Optional Exercise: Behaviour Record

Please use this Record to write down something your relative does (or that you do) that upsets you.

| Date and time | People Present | Trigger | Behaviour | Reaction | The strategy you used to change the behaviour was: |
|---------------|----------------|---------|-----------|----------|--|
| | | | | | |
| | | | | | What happened when you tried using this strategy? |
| | | | | | |

Optional Exercise: Thought Record

| Situation Describe the events that led to your unpleasant feelings. | Current thoughts Identify your thoughts in the situation. | Feelings What are you feeling? (sad, angry, anxious, etc.) | Challenge & replace with more helpful thoughts What is a more helpful way of thinking about the situation? | New feelings What are you feeling now? (sad, angry, anxious, etc.) |
|---|---|--|--|--|
| | | | | |

Blank Page

Session 8: Using your Skills in the Future

Session Plan

1. Review Pleasant Events Tracking Form
2. Review Relaxation
3. Review Behavioural Records
4. Review Thought Records
5. Review Assertive Communication
6. Review Communicating with Your Relative
7. Review Planning for the Future
8. Putting it all Together
9. Relaxation: *Mountain Cabin*
10. Summary



Leader: Prior to Session 8

Look at your notes from all prior sessions with carer before session 8 so that you are able to suggest review ideas around each of the sessions.

e.g. "Do you think that using this strategy helped to change this behaviour"

Leader: Review Pleasant Events Tracking Form

Please take out the Pleasant Events Tracking Form you completed last week.

Ask if their mood follows any patterns? Did they feel better on certain days versus others?

Ask about their Pleasant Events Tracking Form:

1. How many were you able to do?
2. How did you feel **during** and **after** your pleasant activities?
3. Looking at your mood scores 1-9, how do you think your pleasant activities affected your mood?

Are there any new events that you would like to **add** or **remove** from your list? If so, you can make these changes on the blank form on the following page. Please continue to use this new form next week - and in the future.

Pleasant Events for My Relative and Me

| Day | Events for Me | Events for My Relative and Me | Total Events Today | My Mood Score (1-9) | Comments |
|---------|---|---|--------------------|---------------------|----------|
| | a..... b..... c..... d..... Which events (a,b,c or d) | a..... b..... c..... d..... Which events (a,b,c or d) | | | |
| Example | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

BLANK PAGE

Reviewing Pleasant Events

Overcoming Obstacles

Although you might have completed the pleasant events you scheduled last week, you may find problems in the future. Adding pleasant events into your daily life can be difficult.

1. An obstacle that keeps me from increasing pleasant events into my life is:

2. How might you be able to overcome this?

Leader: If carer cannot think of an answer to question Q1, prompt:

Is there an obstacle related to money, guilty feelings, stress, or a physical limitation?

Leader: The purpose of the rest of the session is to give carers a structure/techniques which they will use in the future. If they haven't completed/agreed with/found useful certain aspects of the manual then move on to the next review.

Review of Relaxation

We have looked at different stress reduction/relaxation exercises each week. You also have these on a CD or tape to use.

Leader: If carer has not liked using the relaxation CD or tape. Use this time to reflect with carer how they do like to relax

Have you had a chance to use any of these? If so, which have you found helpful?

Do you have set times when you use them?

Do things get in the way? If so, how could you overcome them?

How do you think you will use these in future?

Leader: Encourage carer to continue using the relaxation techniques that have worked best for them and to use them in stressful situations.

Review of Behaviour Records (Session 1 onwards)

We are now going to review the Behaviour Records that you have been keeping (pages 12, 32/42, 50/59).

Leader: Have a look at the Behaviour Records the carer has completed.

Have you had a chance to use any of these? If so, which have you found helpful?

Have you been using the strategies we developed?

Have they been helpful? Do things get in the way? If so, how could you overcome them?

Have you developed any new strategies?

How do you think you will use these in future?

Leader: Encourage them to continue using these and the skills acquired.
Draw their attention to the blank Behaviour Records at the end of this session.

Review of Thought Records (Session 4 onwards)

We are now going to review the Thought Records that you have been keeping (pages 73/80).

Leader: Have a look at the Thought Records the carer has completed over the course.

Have you found completing these helpful? If so, how?

Do you feel you have used some of the techniques to challenge unhelpful thoughts? (e.g. looking at it from a different point of view or trying not to think of things as all or nothing)

Can you identify any thoughts that you have changed?

How will you continue thinking in this changed way in the future?

Leader: Encourage them to continue using these and the skills acquired. Draw their attention to the blank Thought Records at the end of this session.

Review of Assertive Communication (Session 5)

We have looked at different communication styles. This has included assertive communication and how to use these skills when asking for help from others.

Have you had a chance to use assertiveness skills? If so, have you found it helpful?

Do you use these skills in certain situations?

Do things get in the way? If so, how could you overcome them?

How do you think you will use these skills in future?

Leader: Encourage carer to continue using these skills.

Review of Communicating with Someone with Memory Problems (Session 5)

We have looked at how memory problems can affect your relative's communication in a number of ways. We have also looked at some techniques for you to consider in aiding clearer communication with them.

Have you had a chance to use any of these techniques? If so, which have you found helpful?

Have you had any difficulties using these techniques? If so, how could you overcome them?

How do you think you will use these techniques in the future?

Leader: Encourage carer to continue using these techniques and to refer back to Session 5 if they need to use other techniques.

Review of Planning for the Future (Session 6)

We have discussed different issues surrounding planning for your relative's future care, and how hard it can be to talk about important decisions with your relative and other family members.

Have you had a chance to think about or have these discussions with your relative or other family members? If so, have you found this helpful?

If not, what gets in the way? How could you overcome them?

Have you made any decisions or taken any actions?

How do you think you will discuss other difficult decisions about the care of your relative in the future with them or other family members?

Leader: Encourage carer to continue discussing the future and to refer back to Session 6 if they need to think more. If they say they still require more information, signpost them to the relevant resource (e.g. Choice leaflets, GP, local memory service).

Putting it all Together



Now, let's make a list of the things you found most helpful in the sessions:

Leader: You can remind them of things that helped. You can add more, but it's better not to pressurise by having too many.

1.

2.

3.

4.

Using the list on the page before, let's make a list of skills/techniques/strategies that you intend to keep using in the future:

1

2

3

4

1. What stressful situation do you anticipate occurring in the next few months?

2. Of the skills you have learned, which will help you with the stressful situation you described above?

IMPORTANT POINT: The key to understanding the concepts discussed in these sessions is to practice. With practice, you can then share these techniques with your family members or friends.

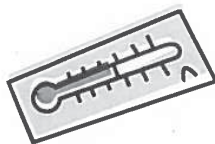
Relaxation: *Guided Imagery - Mountain Cabin*



Introduction

Today we are going to do another guided imagery exercise. This exercise will involve imagining your experience in a relaxing cabin, high up in the mountains, far away from the cares of everyday life. We are providing you with a wide range of options, as different people find different images or scenes relaxing. We hope this one will be helpful for you.

Stress Rating Before Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

First, please rate your level of stress or tension right now, before we practice the Guided Imagery exercise. On a scale of 1 to 5, how would you rate your tension? _____

Guided Imagery: Practice Session

Script for Leader:

“This is a guided relaxation imagery exercise. Soon I shall describe a relaxing scene. First of all, make sure you get yourself into a comfortable position in your chair.

Close your eyes, and take in a deep signal breath, holding it for a few moments... (*pause*) and then let go, relaxing as you do so. Now as I continue talking to you, you can allow a calm, relaxed feeling to settle over your body and mind.

Let go of any unnecessary tension in your shoulders, arms, and hands. As your shoulders and arms hang loosely by your sides, let all of the tension drain out through the tips of your fingers.

Let the relaxation flow from your shoulders, into the back of your neck (...), as the tension dissolves and melts away, relaxing your neck and scalp, and also your face, including your mouth, tongue and jaw.

Let the relaxation flow down the rest of your body... your chest... abdomen... and back. Feel all the muscles of your body becoming loose and relaxed.

Let the relaxing feelings flow into your legs, ankles and feet. Just allow your entire body to become loose, heavy and relaxed.

And as your body is becoming more and more relaxed, you can now picture yourself inside a log cabin, (*pause*) somewhere high in the mountains. (..) It's wintertime. Even though it is very cold outside, you can enjoy the warmth and comfort of the cabin... inside this cabin is a large fireplace with a blazing fire, providing just the right amount of heat. You can feel so comfortable, so peaceful and so deeply relaxed inside of this cabin.

Now, look around this cabin. Scan the layout and contents of the room (*pause*). You can go up to one of the windows. Notice the frost

on the window pane... you can even put your warm hand on the cold, hard glass of the window pane. Feel the heat from your hand melting the frost... and then look outside, you see many tall evergreen trees, and lots of snow on the ground...

To get an even better view, you can begin to open the window, (...) feeling it give way against the pressure of your hand. As the window opens, you take in a deep breath of that pure, fresh, cool mountain air (...) It feels so good, so healthy, so alive.

Then look outside, seeing more clearly the green trees against the whiteness of the snow... looking out and seeing a beautiful view, perhaps of the valley down below (..), the mountain peaks far off in the distance. (*pause*)

And now, you can close the window and walk over to the fireplace, feeling its relaxing warmth as you get closer... you can go ahead and sit back in a comfortable chair facing the fire, (...) or you may even want to lie down next to the fire on a soft blanket, feeling the soothing warmth of the fire against your skin... let your body absorb the warmth, bringing you deep relaxation and comfort...

You can enjoy watching the flames, (...) seeing the burning logs, (...) hearing the crackling of the logs (..), smelling the smoke from the logs. (..) You can even look around you, noting what the room looks like, as it is illuminated by the fire. Notice the flickering shadows on the walls... notice the furniture in the room... just look around you, taking in all the sights, the sounds, the smells... feeling so peaceful, so calm and so deeply relaxed in this place. (*pause for 10 seconds*)

As your attention returns to the fire, you can feel so comfortable and so relaxed... even though the cold wind is howling outside, you feel so warm inside... nothing to worry about, nothing to concern you... (*pause*) all that really matters, is that you allow yourself to enjoy the peace, (...) the comfort (...), the deep tranquility of being in this relaxing place. (*pause for 10 seconds*)

And now, I shall bring you back slowly from this relaxing place by counting backwards from 3 to 1. When I get to 1, you'll be alert, refreshed, and comfortable.

Okay: '3', much more alert; '2', feeling refreshed and comfortable; and '1', as you open your eyes and return your awareness to the room you are in."

Stress Rating after Exercise



- 1 = Not at all tense
- 2 = Slightly tense
- 3 = Moderately tense
- 4 = Really tense
- 5 = Terribly tense

Now, please rate your level of stress on a scale of 1 to 5, how would you rate your tension level now after practicing the Guided Imagery exercise? _____

1. Did _____ your level of tension change?
2. What was this experience like for you?
3. Do you think that the person you care for might like to try listening to a tape of this exercise with you?

Leader: Encourage carers to practice a relaxation/stress reduction technique at least once each day this week.

Summary

We have now looked back at the skills covered in these sessions.

- How to relax in stressful situations.
- How to identify and change problem behaviours.
- How to challenge your own negative thoughts and replace them with more helpful thoughts.
- How to ask for help from others.
- How to communicate better with the person with memory problems you look after.
- How to plan for the future and talk to your family about difficult decisions.
- How to increase and maintain a happier and healthier mood by engaging in more pleasant activities.

We hope you have found these sessions helpful and will in future keep using the skills you have listed as useful in this session.

Please try to keep using the skills that work for you and refer back to this manual to remind yourself of the techniques discussed in these sessions. There are blank copies of the Thought, Behaviour and Pleasant Event records in the appendix for you to use in the future. Please also feel free to share this manual with anyone else involved in the care of your relative.

Thank you for taking part

Leader: Highlight to carer that there are blank copies of the Thought, Behaviour and Pleasant Event Records in the Appendix for continued use.



End of Manual

Produced by: Mental Health Science Unit UCL

Contact details: g.livingston@ucl.ac.uk

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

**EME
HS&DR
HTA
PGfAR
PHR**

Part of the NIHR Journals Library
www.journalslibrary.nihr.ac.uk

This report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health

Published by the NIHR Journals Library