

Clare L, Kudlicka A, Oyebode JR, Jones RW, Bayer A, Leroi I, Kopelman M, James IA, Culverwell A, Pool J, Brand A, Henderson C, Hoare Z, Knapp M, Morgan-Trimmer S, Burns A, Corbett A, Whitaker R, Woods B (2018). Goal-oriented cognitive Rehabilitation in Early-stage Alzheimer's and related dementias: a multi-centre single-blind randomised controlled Trial (GREAT). *Health Technol Assess.* Accepted for publication.

Version accepted for publication (4<sup>th</sup> January 2018)

---

## **Goal-oriented cognitive Rehabilitation in Early-stage Alzheimer's and related dementias: a multi-centre single-blind randomised controlled Trial (GREAT)**

Linda Clare<sup>1</sup>, Aleksandra Kudlicka<sup>1</sup>, Jan R. Oyebode<sup>2</sup>, Roy W. Jones<sup>3</sup>, Antony Bayer<sup>4</sup>, Iracema Leroi<sup>5</sup>, Michael Kopelman<sup>6</sup>, Ian A. James<sup>7</sup>, Alison Culverwell<sup>8</sup>, Jackie Pool<sup>9</sup>, Andrew Brand<sup>10</sup>, Catherine Henderson<sup>11</sup>, Zoe Hoare<sup>10</sup>, Martin Knapp<sup>11</sup>, Sarah Morgan-Trimmer<sup>12</sup>, Alistair Burns<sup>5</sup>, Anne Corbett<sup>1</sup>, Rhiannon Whitaker<sup>13</sup>, and Bob Woods<sup>14</sup>

<sup>1</sup>Centre for Research in Ageing and Cognitive Health, University of Exeter, Exeter, UK; <sup>2</sup>School of Dementia Studies, University of Bradford, UK; <sup>3</sup>RICE - Research Institute for the Care of Older People, Bath, UK; <sup>4</sup>Division of Population Medicine, Cardiff University, University Llandough Hospital, UK; <sup>5</sup>Department of Neuroscience and Experimental Psychology, University of Manchester, Manchester, UK; <sup>6</sup>Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience, Kings College London, St Thomas' Hospital, London, UK; <sup>7</sup>Centre of the Health of the Elderly, Northumberland Tyne and Wear NHS Foundation Trust, Newcastle upon Tyne, UK; <sup>8</sup>Kent and Medway NHS and Social Care Partnership Trust, St Martin's Hospital, Canterbury, UK; <sup>9</sup>Dementia Pal Ltd, Southampton, UK; <sup>10</sup>North Wales Organisation for Randomised Trials in Health, Bangor University, UK; <sup>11</sup>Personal Social Services Research Unit, London School of Economics and Political Science, London, UK; <sup>12</sup>Institute of Health Research, University of Exeter Medical School, Exeter, UK; <sup>13</sup>Whitaker Research Ltd, Bangor, UK; <sup>14</sup>Dementia Services Development Centre, Bangor University, Bangor, UK

Competing interests: MK Received funding from Lundbeck in relation to work on depression in younger adults and workplace mental health, and from Takeda for advice on measures of impact

on carers of people with dementia. ZH is a member of the HSDR Associate Board. Other authors reported no competing interests.

Address for correspondence:

Professor Linda Clare, Centre for Research in Ageing and Cognitive Health (REACH), School of Psychology, University of Exeter, Perry Road, Exeter EX4 4QG, United Kingdom.

[l.clare@exeter.ac.uk](mailto:l.clare@exeter.ac.uk)

Key words:

Alzheimer's disease; vascular dementia; mixed dementia; reablement; restorative care; tertiary prevention; functional ability; activities of daily living

Word counts:

Scientific abstract	521 words
Scientific summary	2,146 words
Plain English summary	299 words
Main text	49,191 words

## Scientific abstract

**Background:** Cognitive rehabilitation (CR) is an individualised, person-centred intervention for people with mild to moderate dementia that addresses the impact of cognitive impairment on everyday functioning.

**Objectives:** To determine whether CR is a clinically-effective and cost-effective intervention for people with mild to moderate Alzheimer's disease, vascular or mixed dementia and their carers.

**Design:** This multi-centre RCT compared CR with treatment as usual. Following baseline assessment and goal-setting to identify areas of everyday functioning that could be improved or managed better, participants were randomised (1:1) via secure web access to an independent randomisation centre to receive either treatment as usual (TAU) or CR, and followed up three and nine months post-randomisation.

**Setting:** Community.

**Participants:** Participants had an ICD-10 diagnosis of Alzheimer's, vascular or mixed dementia, had mild to moderate cognitive impairment (MMSE score  $\geq 18$ ), were stable on medication if prescribed, and had a family carer willing to contribute. Exclusion criteria were a history of brain injury or other neurological disorder, and inability to speak English. To achieve adequate power, we needed 350 people to complete the trial, 175 in each arm.

**Intervention:** CR consisted of ten therapy sessions over three months followed by four maintenance sessions over six months, delivered in participants' homes. The therapists were nine occupational therapists and one nurse.

**Outcome measures:** The primary outcome was self-reported goal attainment at three months. Goal attainment was also assessed at nine months. Carers provided independent ratings of goal attainment at both time-points. Secondary outcomes were participant quality of life, mood, self-efficacy and cognition, and carer stress, health status and quality of life. Assessments at three and nine months were conducted by researchers blind to participants' group allocation.

**Results:** 475 participants were randomised (CR n=239; TAU n=236), 427 (90%) completed the trial, and 426 were analysed (CR n=208, TAU n=218). At three months there were statistically-significant large positive effects for participant-rated goal attainment (mean change CR 2.57, TAU 0.86;  $d=.97$ , 95% CI .75-1.19), corroborated by carer ratings ( $d=1.11$ , .89-1.34). These effects were maintained at nine months for both participant ( $d=.94$ , .71-1.17) and carer ratings ( $d=.96$ , .73-1.2). There were no significant differences in secondary outcomes. In cost-utility analyses, there was no evidence of cost-effectiveness in terms of gains in person with dementia QALY (DEMQOL-U) or carer QALY (EQ-5D-3L) from either cost perspective. In cost-effectiveness analyses, by reference to the primary outcome of participant-rated goal attainment, CR was cost-effective from both the health and social care and societal perspectives at willingness-to-pay values of £2500 and above for improvement in the goal-attainment measure. There was no evidence for cost-effectiveness on the self-efficacy (GSES) measure from either cost perspective.

**Limitations:** Possible limitations arose from the non-feasibility of using observational outcome measures, lack of a general measure of functional ability and exclusion of people without a carer or with rarer forms of dementia.

**Conclusions:** Cognitive rehabilitation is clinically effective in enabling people with early-stage dementia to improve their everyday functioning in relation to individual goals targeted in the therapy.

**Future work:** Next steps will focus on implementation of CR into NHS and social care services and on extending the approach to people with rarer forms of dementia.

**Study registration:** ISRCTN21027481

**Funding details:** NIHR Health Technology Assessment Programme - HTA (UK) ref: 11/15/04

## Table of contents

Scientific abstract	3
List of appendices	8
List of tables	9
List of figures	23
List of abbreviations	26
Scientific summary	30
Plain English summary	37
Chapter 1. Introduction	38
Principles of cognitive rehabilitation	39
Cognitive rehabilitation in practice	42
Evaluating outcomes of cognitive rehabilitation	45
Development work undertaken prior to the GREAT trial	46
Lessons learned from the pilot trial	48
Aims of the GREAT trial	50
Chapter 2. Method	52
Design	52
Participants	54
Intervention	59
Comparator	65
Outcomes	66
Process evaluation measures	72
Data management	75
Outcome analyses	76
Process evaluation analyses	78

Feasibility of implementation	80
Economic analyses	80
Patient and Public Involvement	80
Changes to protocol	81
Chapter 3. Results	82
Recruitment and participant flows	82
Allocation	83
9-month follow-up	83
3-month follow-up	83
Enrollment	83
Sample characteristics	84
Intervention adherence in the CR group	89
Data collection	90
Adverse events	91
Numbers analysed	93
Missing data	93
Results for the primary outcome measure	94
Exploratory analyses for the primary outcome measure	98
Results for the secondary outcomes	101
Exploratory analyses for the secondary outcomes	106
Sensitivity analyses	107
Effectiveness of blinding	107
Associations between adherence and outcomes	108
Chapter 4. Process evaluation	109
Goal-setting and goal attainment	109
Intervention fidelity	114
Therapist views on factors associated with positive outcomes	117

Participant and carer experience of the intervention	132
Case studies	144
Feasibility of implementation	144
Chapter 5. Economic evaluation	145
Research question	145
Methods	145
Results	153
Conclusions	175
Chapter 6. Discussion	178
Evidence on clinical effectiveness	178
Evidence on cost-effectiveness	184
Implications for future implementation	186
Limitations	191
Next steps	195
Conclusions	195
Acknowledgements	196
Author contributions	198
Data sharing	199
Funding source	200
References	201
Appendices	217

## **List of appendices**

Appendix 1. Topics recorded by therapists in the therapy logs	218
Appendix 2. Interview schedule for exploring participant and carer experience of the GREAT intervention	219
Appendix 3. Participant recruitment	221
Appendix 4. Demographic and clinical characteristics of the sample: additional details	223
Appendix 5. Comparison of participants who did and did not complete the trial	231
Appendix 6. Summary of missing data for secondary outcomes	237
Appendix 7. Exploratory analyses for the primary outcome measure	242
Appendix 8. Exploratory analyses for the secondary outcomes	271
Appendix 9. Complete case analyses with no imputation	302
Appendix 10. Within-group analysis for the cognitive rehabilitation group	306
Appendix 11. Effectiveness of blinding	310
Appendix 12. Relationship of adherence to outcome	315
Appendix 13. Four case studies from the GREAT trial	317
Appendix 14. Feasibility of implementation	332
Appendix 15. Full unit costs	341
Appendix 16. Participant resource use and replacement costs	358
Appendix 17. Cost-effectiveness acceptability curves and cost-effectiveness planes	381

## List of tables

Table 1. Sample session-by-session cognitive rehabilitation protocol	62
Table 2. Summary of assessment measures by time-point	66
Table 3. Summary of process evaluation measures	74
Table 4. Demographic characteristics of the sample	84
(a) Participants with dementia	84
(b) Carers	85
Table 5. Baseline clinical characteristics of the sample	87
(a) Participants with dementia	87
(b) Carers	88
Table 6. Number of sessions completed by participants in the CR group (n=238)	90
Table 7. Serious adverse events	92
(a) Numbers of serious adverse events recorded for participants and carers at each site	92
(b) Classifications of the serious adverse events	92
Table 8. Missing data in the primary outcome measure (BGSI)	94
(a) Three month follow up	94
(b) Nine month follow up	94
Table 9. BGSI ratings at all time-points for CR and TAU groups, and statistical analysis of changes in BGSI ratings at three and nine months	96
(a) BGSI ratings for CR and TAU groups at baseline, three and nine months	96
(b) BGSI ratings at three months: ANCOVA adjusted for baseline score, allocation group and stratification variables, age, gender, MMSE score and site	96
(c) BGSI ratings at nine months: ANCOVA adjusted for baseline score, allocation group and stratification variables, age, gender, MMSE score and site	97
Table 10. Scores and statistical analyses for the secondary outcomes	102
(a) Scores for participants with dementia	102

(b) Scores for carers	103
(c) Statistical analyses at three month follow up	104
(d) Statistical analyses at nine month follow up	105
Table 11. Number of goals identified during baseline assessment	110
Table 12. In-session ratings of goal attainment	112
(a) Summary of in-session ratings	112
(b) Change from initial in-session ratings at sessions 10 and 14	113
Table 13. Therapists' goal attainment scaling following session 10	114
Table 14. Working with goals during therapy	115
(a) Number of goals identified at baseline that were introduced and addressed during therapy	115
(b) Stage of therapy at which work on each of the 590 goals commenced	116
(c) Extent to which goals were addressed exactly as set at baseline	116
Table 15. Demographic and clinical characteristics of participants in the 'poor outcome' and 'good outcome' groups, and BGSi ratings	122
(a) Demographic characteristics of the participants with dementia	122
(b) Demographic characteristics of the carers	123
(c) Clinical characteristics of the participants with dementia at baseline	123
(d) Clinical characteristics of the carers at baseline	124
(e) BGSi ratings at each time point	125
Table 16. Demographic and clinical characteristics, and BGSi ratings, of the participants and carers participating in the qualitative interviews	134
(a) Demographic characteristics of the participants with dementia	134
(b) Demographic characteristics of the carers	134
(c) Clinical characteristics of the participants with dementia	135
(d) Clinical characteristics of the carers	136
(e) BGSi ratings at each time point	137

Table 17. Unit costs in brief	148
Table 18. Mean costs for dyad: health and social care services for the person with dementia, unpaid carer costs, out-of-pocket costs and total health and social care and societal costs over prior three months, at baseline assessment (£, 2013-14). Sample: complete cases	156
Table 19. Cognitive rehabilitation delivery: cost elements (£, 2013/2014)	159
Table 20. Health professionals delivering cognitive rehabilitation <sup>a</sup> : visits and time (hours) per participant, over the three months to first follow up and over six months between first and second follow-up. Sample: complete cases [economic data available from person with dementia and unpaid carer dyad]	161
Table 21. Mean costs over the study period of nine months (£, 2013-14 prices). Sample: complete cases	162
Table 22. Summary statistics for outcomes: person with dementia and carer, at baseline, three-month and nine-month assessments. Sample: complete cases per assessment point	163
Table 23. Outcome scores and costs at nine months from regression estimates. Sample: complete cases	166
Table 24. Person with dementia and carer: Point ICER <sup>a</sup> for CR over TAU, from health and social care and societal perspectives	167
Table 25. Trial recruitment by site	222
Table 26. Full demographic characteristics of the sample	223
(a) Participants with dementia	223
(b) Carers	225
Table 27. Comorbid conditions	227
(a) Numbers of participants with comorbid conditions	227
(b) Frequency of comorbid health conditions	228

(c) Frequency of comorbid health conditions using the Charlson Comorbidity Weighted Index	228
(d) Number of participants scoring above and below the cut-off value of 5 on the Charlson Comorbidity Index	229
(e) Number of participants scoring at each level on the Age-Adjusted Charlson Comorbidity Index	229
Table 28. HADS scores for depression and anxiety at baseline and follow-up assessments	230
(a) HADS depression scores	230
(b) HADS anxiety scores	230
Table 29. Comparison of demographic characteristics of completers and non-completers who withdrew before the three-month follow-up	231
(a) Participants with dementia – continuous data	231
(b) Participants with dementia – categorical data	231
(c) Carers – continuous data	233
(d) Carers – categorical data	233
Table 30. Comparison of primary and secondary outcomes for completers and non-completers who withdrew before the three month follow up	235
Table 31. Missing data for the secondary outcome measures	237
(a) Baseline assessment	237
(b) Three-month follow-up	238
(c) Nine-month follow-up	239
Table 32. Missing data in the primary and secondary outcome measures in descending order of per cent missing, with participants who withdrew counted as missing data	240
Table 33. Linear mixed effects model fitted to identify potential participant characteristics as predictors of differences between the BGSi attainment ratings at baseline and three-month follow-up for participants in the CR group	242
(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline	242

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline 242

Table 34. Linear mixed effects model fitted to identify potential participant characteristics as predictors of differences between the BGSi attainment ratings at baseline and nine-month follow up 244

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline 244

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline 245

Table 35. Linear mixed effects model to identify potential carer factors as predictors of differences between the participants' BGSi attainment ratings at baseline and three-month follow-up for participants in the CR group 248

(a) ANOVA examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline 248

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline 249

Table 36. Linear mixed effects model to identify potential carer factors as predictors of differences between the participants' BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group 251

(a) ANOVA examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline 251

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline 252

Table 37. Linear mixed effects model fitted to identify potential carer factors as predictors of differences between the carers' BGSi attainment ratings at baseline and three-month follow-up for carers of participants in the CR group	254
(a) ANOVA examining the influence of carer characteristics as predictors of differences in carers' BGSi attainment ratings between three months and baseline	254
(b) Regression analysis examining the influence of carer characteristics in predicting differences in carers' BGSi attainment ratings between three months and baseline	255
Table 38. Linear mixed effects model to identify carer characteristics predicting differences between carers' BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group	256
(a) ANOVA examining the influence of carer characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline	256
(b) Regression analysis examining the influence of carer characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline	257
Table 39. Linear mixed effects model to identify participant characteristics predicting the difference between carer BGSi goal attainment ratings at baseline and at three-month follow-up for participants in the CR group	259
(a) ANOVA examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between three months and baseline	259
(b) Regression analysis examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between three months and baseline	259
Table 40. Linear mixed effects model to identify participant characteristics predicting the difference between the carer BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group	261

(a) ANOVA examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline

261

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline

261

Table 41. Linear mixed effects model to identify participant characteristics predicting the difference between BGSi satisfaction ratings at baseline and at three-month follow-up for participants in the CR group

264

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' ratings of BGSi satisfaction scores between three months and baseline

264

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi satisfaction ratings between three months and baseline

264

Table 42. Linear mixed effects model fitted to predict the difference between the participants' BGSi satisfaction ratings at baseline and nine-month follow-up for participants in the CR group

267

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' BGSi satisfaction ratings between nine months and baseline

267

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi satisfaction ratings between nine months and baseline

268

Table 43. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant DEMQOL scores at baseline and three-month follow-up

271

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between three months and baseline

271

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between three months and baseline

271

Table 44. Linear mixed effects model fitted to identify participant characteristics as predicting differences between participant DEMQOL scores at baseline and nine-month follow-up for participants in the CR group	272
(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between nine months and baseline	272
(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between nine months and baseline	273

Table 45. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS anxiety scores at baseline and three-month follow-up for participants in the CR group	274
(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS anxiety scores between three months and baseline	274
(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS anxiety scores between three months and baseline	274

Table 46. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS anxiety scores at baseline and nine-month follow-up for participants in the CR group	275
(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS anxiety scores between nine months and baseline	275
(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS Anxiety scores between nine months and baseline	275

Table 47. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS depression scores at baseline, and three-month follow-up for participants in the CR group	276
(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS depression scores between three months and baseline	276

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS depression scores between three months and baseline	277
Table 48. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS depression scores at baseline and nine-month follow-up for participants in the CR group	278
(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS depression scores between nine months and baseline	278
(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS Depression scores between nine months and baseline	278
Table 49. Linear mixed effects model fitted to identify carer characteristics predicting differences between participant total GSES scores at baseline and three-month follow-up for participants in the CR group	279
(a) ANOVA examining the influence of carer characteristics as predictors of differences in participant GSES scores between three months and baseline	279
(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participant GSES scores between three months and baseline	280
Table 50. Linear mixed effects model fitted to identify carer characteristics predicting differences between participant GSES scores at baseline and nine-month follow-up for participants in the CR group	281
(a) ANOVA examining the influence of carer characteristics as predictors of differences in participant GSES scores between nine months and baseline	281
(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participant GSES scores between nine months and baseline	281
Table 51. Linear mixed effects model fitted to identify carer characteristics predicting differences between carer RSS scores at baseline and three-month follow-up for carers of participants in the CR group	282

(a) ANOVA examining the influence of carer characteristics as predictors of differences in carer RSS scores between three months and baseline	282
(b) Regression analysis examining the influence of carer characteristics as predictors of differences in carer RSS scores between three months and baseline	283
Table 52. Linear mixed effects model fitted to identify carer characteristics predicting differences between carer RSS scores at baseline and nine-month follow-up for carers of participants in the CR group	286
(a) ANOVA examining the influence of carer characteristics as predictors of differences in carer RSS scores between nine months and baseline	286
(b) Regression analysis examining the influence of carer characteristics as predictors of differences in carer RSS scores between nine months and baseline	286
Table 53. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF physical scores at baseline and three-month follow-up for carers of participants in the CR group	290
(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between three months and baseline	290
(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between three months and baseline	290
Table 54. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF physical scores at baseline and nine-month follow-up for carers of participants in the CR group	291
(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between nine months and baseline	291
(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between nine months and baseline	292
Table 55. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF psychological scores at baseline and three-month follow-up for carers of participants in the CR group	293

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between three months and baseline 293

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between three months and baseline 293

Table 56. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF psychological scores at baseline and nine-month follow-up for carers of participants in the CR group 294

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between nine months and baseline 294

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between nine months and baseline 295

Table 57. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF social scores at baseline and three-month follow-up for carers of participants in the CR group 296

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between three months and baseline 296

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between three months and baseline 296

Table 58. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF social scores at baseline and nine-month follow-up for carers of participants in the CR group 297

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between nine months and baseline 297

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between three months and baseline 298

Table 59. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF environmental scores at baseline and three-month follow-up for carers of participants in the CR group	299
(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between three months and baseline	299
(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between three months and baseline	299
Table 60. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF environmental scores at baseline and nine-month follow-up for carers of participants in the CR group	300
(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between nine months and baseline	300
(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between nine months and baseline	301
Table 61. ANCOVA Summary table for BGSi ratings without imputations	302
(a) Three-month follow-up	302
(b) Nine-month follow-up	302
Table 62. ANCOVA summary table for analysis of secondary outcomes without imputations	303
(a) Three-month follow-up	303
(b) Nine-month follow-up	304
Table 63. ANCOVA Summary table for BGSi ratings without imputations	306
(a) Three-month follow-up	306
(b) Nine-month follow-up	306
Table 64. ANCOVA summary table for analysis of secondary outcomes without imputations	307

(a) Three-month follow-up	307
(b) Nine-month follow-up	308
Table 65. Researchers' accuracy in estimating group allocation at follow-up assessments	310
(a) Three-month follow-up (n=444)	310
(b) Nine-month follow-up (n=426)	310
Table 66. Researchers' responses regarding their estimations of group allocation for each participant at three-month follow-up	310
Table 67. Researchers' responses regarding their estimations of group allocation for each participant at nine-month follow-up	312
Table 68. Researchers' responses regarding blinding effectiveness at three months where blinding was either effective or ineffective	313
Table 69. Researchers' responses regarding blinding effectiveness at nine months where blinding was either effective or ineffective	314
Table 70. Analyses examining whether adherence (number of sessions completed) was associated with outcome	315
(a) Three-month follow-up	315
(b) Nine-month follow-up	316
Table 71. BGSi goal performance and goal satisfaction ratings during implementation at the Bangor site	335
Table 72. Unit costs	341
Table 73. Resources used by person with dementia over the prior 3 months, at baseline assessment. Sample: all available cases where CSRI was partially or wholly completed	358
Table 74. Resources used by person with dementia over the prior three months, at three months. Sample: all available cases. Sample: all available cases where CSRI was partially or wholly completed	362

Table 75. Resources used by person with dementia over the prior three months, at nine months. Sample: all available cases. Sample: all available cases where CSRI was partially or wholly completed	366
Table 76. Types of care and support tasks provided by the principal carer. Sample: complete cases	370
Table 77. Sensitivity analysis: replacement cost. Person with dementia: outcome scores and costs at nine months from regression estimates. Sample: complete cases	372
Table 78. Sensitivity analysis: replacement cost. Carer: outcome scores and costs at nine months from regression estimates. Sample: complete cases	373
Table 79. Sensitivity analysis: replacement cost. Person with dementia and carer: Point ICER <sup>a</sup> for CR over TAU, from health and social care and societal perspectives	374
Table 80. Sensitivity analysis: Exclusion of high-cost outliers from health and social care costs. Person with dementia: outcome scores and costs at nine months from regression estimates. Sample: health and social care costs outlier excluded	375
Table 81. Sensitivity analysis: Exclusion of high-cost outliers from health and social care costs Carer: outcome scores and costs at nine months from regression estimates. Sample: health and social care costs outlier excluded	376
Table 82. Sensitivity analysis: Exclusion of high-cost outliers from health and social care costs Person with dementia and carer: Point ICER <sup>a</sup> for CR over TAU, from health and social care and societal perspectives Sample: outliers excluded	377
Table 83. Sensitivity analysis: Imputed data. Person with dementia: outcome scores and costs at nine months from regression estimates	378
Table 84. Sensitivity analysis: Imputed data. Carer: outcome scores and costs at nine months from regression estimates	379
Table 85. Sensitivity analysis: Imputed data. Person with dementia and carer: Point ICER <sup>a</sup> for CR over TAU, from health and social care and societal perspectives Sample: Imputed data	380

## List of figures

Figure 1. Overview of trial design and planned flow of participants through the trial	53
Figure 2. CONSORT chart showing participant flow through the trial	83
Figure 3. Goal attainment ratings by participants and carers in CR and TAU conditions at baseline, three-month and nine-month follow-up. Data are mean scores and the error bars show the standard errors.	97
Figure 4. Attainment of therapy goals by session 10	114
Figure 5. Cost-effectiveness acceptability curve: BGSI, person with dementia	168
Figure 6. Cost-effectiveness plane: incremental costs and endpoint difference for BGSI at nine months, person with dementia	168
Figure 7. Cost-effectiveness acceptability curve: GSES, person with dementia	169
Figure 8. Cost-effectiveness plane: incremental costs and endpoint difference for GSES at nine months, person with dementia	169
Figure 9. Cost-effectiveness acceptability curve: QALY (DEMQOL-U), person with dementia	171
Figure 10. Cost-effectiveness plane: incremental costs and QALY (DEMQOL-U) at nine months, person with dementia	171
Figure 11. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer	172
Figure 12. Cost-effectiveness plane: incremental costs and QALY (EQ5D3L) at nine months, carer	172
Figure 13. Cumulative recruitment figures in relation to targets	221
Figure 14. Recruitment figures by month	221
Figure 15. Cost-effectiveness acceptability curve: BGSI, person with dementia; replacement costs of unpaid care	381

Figure 16. Cost-effectiveness acceptability curve: GSES, person with dementia; replacement costs of unpaid care	382
Figure 17. Cost-effectiveness acceptability curve: QALY (DEMQOL-U), person with dementia; replacement costs of unpaid care	383
Figure 18. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer; replacement costs of unpaid care	384
Figure 19. Cost-effectiveness plane: incremental costs and endpoint difference on BGSi at nine months, person with dementia; replacement costs of unpaid care	385
Figure 20. Cost-effectiveness plane: incremental costs and endpoint difference GSES at nine months, person with dementia; replacement costs of unpaid care	386
Figure 21. Cost-effectiveness plane: incremental costs and QALY (DEMQOL-U) at nine months, person with dementia; replacement costs of unpaid care	387
Figure 22. Cost-effectiveness plane: incremental costs and QALY (EQ5D3L) at nine months, carer; replacement costs of unpaid care	388
Figure 23. Cost-effectiveness acceptability curve: BGSi, person with dementia; excluding high-cost outliers	389
Figure 24. Cost-effectiveness acceptability curve: GSES, person with dementia; excluding high-cost outliers	390
Figure 25. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer; excluding high-cost outliers	391
Figure 26. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and endpoint difference on BGSi at nine months, person with dementia	392
Figure 27. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and endpoint difference GSES at nine months, person with dementia	393
Figure 28. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and QALY (DEMQOL-U) at nine months, person with dementia	394

Figure 29. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and QALY (EQ5D3L) at nine months, carer	395
Figure 30. Cost-effectiveness acceptability curve: BGSi, person with dementia; imputed data	396
Figure 31. Cost-effectiveness acceptability curve: GSES, person with dementia; imputed data	397
Figure 32. Cost-effectiveness acceptability curve: QALY (DEMQOL-U), person with dementia; imputed data	398
Figure 33. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer; imputed data	399
Figure 34. Cost-effectiveness plane: incremental costs and endpoint difference on BGSi at nine months, person with dementia; imputed data	400
Figure 35. Cost-effectiveness plane: incremental costs and endpoint difference GSES at nine months, person with dementia; imputed data	401
Figure 36. Cost-effectiveness plane: incremental costs and QALY (DEMQOL-U) at nine months, person with dementia; imputed data	402
Figure 37. Cost-effectiveness plane: incremental costs and QALY (EQ5D3L) at nine months, carer; imputed data	403

## **List of abbreviations**

<b>ACE-III</b>	Addenbrooke's Cognitive Examination – Third Revision
<b>AD</b>	Alzheimer's disease
<b>AfC</b>	Agenda for Change
<b>ANCOVA</b>	Analysis of covariance
<b>BCUHB</b>	Betsi Cadwaladr University Health Board
<b>BGSI</b>	Bangor Goal-Setting Interview
<b>CEA</b>	Cost-effectiveness analysis
<b>CEAC</b>	Cost-effectiveness acceptability curve
<b>CI</b>	Confidence intervals
<b>CONSORT</b>	Consolidated Standards of Reporting Trials
<b>COPM</b>	Canadian Occupational Performance Measure
<b>CPN</b>	Community Psychiatric Nurse
<b>CR</b>	Cognitive rehabilitation
<b>CSRI</b>	Client Services Receipt Inventory
<b>CT</b>	Cognitive training
<b>CTU</b>	Clinical Trials Unit
<b>DEMQOL</b>	People with DEMentia Quality Of Life questionnaire
<b>DEMQOL-U</b>	DEMQOL Utility score
<b>D-KEFS</b>	Delis-Kaplan Executive Function System
<b>EQ5D</b>	European Quality of Life 5 Dimensions questionnaire
<b>EQ5D3L VAS</b>	EQ5D 3-Level version – Visual Analogue Scale
<b>ETNA-3</b>	Évaluation de 3 Thérapies Non médicamenteuses dans la maladie d'Alzheimer – randomised clinical trial to evaluate the impact of cognitive training, reminiscence therapy and an individualised cognitive rehabilitation program on the progression rate of dementia

<b>fMRI</b>	Functional magnetic resonance imaging
<b>FTE</b>	Full-time equivalent
<b>GCBH</b>	Global Council on Brain Health
<b>GREAT</b>	Goal-oriented Cognitive Rehabilitation in Early-stage Alzheimer’s and Related Dementias: Multi-centre Single-blind Randomised Controlled Trial
<b>GSES</b>	Generalized Self-Efficacy Scale
<b>HADS</b>	Hospital Anxiety and Depression Scale
<b>HCHS Index</b>	Hospital and Community Health Services Index
<b>HTA</b>	Health Technology Assessment
<b>IADLs</b>	Instrumental activities of daily living
<b>ICD-10</b>	International Statistical Classification of Diseases and Related Health Problems (10 <sup>th</sup> edition)
<b>ICER</b>	Incremental cost-effectiveness ratio
<b>IHR</b>	International Health Regulations
<b>INDIGO</b>	A trial of a physical activity intervention for sedentary older people at risk of cognitive decline, based on INDIVIDUAL GOAL-setting.
<b>ITT</b>	Intention to Treat
<b>JDR</b>	Join Dementia Research
<b>M1, M2, M3, M4</b>	Maintenance Sessions 1, 2, 3 and 4
<b>MAGDR</b>	Ministerial Advisory Group on Dementia Research
<b>MMSE</b>	Mini-Mental State Examination
<b>NHS</b>	National Health Service
<b>NHS CCG</b>	National Health Service clinical commissioning groups
<b>NICE</b>	National Institute of Clinical Excellence

<b>NIHR</b>	National Institute of Health Research
<b>NIHR CRN</b>	NIHR Clinical Research Network
<b>NISCHR CRC</b>	National Institute of Social Care and Health Research Clinical Research Collaboration
<b>NWORTH</b>	North Wales Organisation for Randomised Trials in Health
<b>OT</b>	Occupational Therapist
<b>PAL</b>	Pool Activity Level Instrument
<b>PI</b>	Principal Investigator
<b>PSSRU</b>	Personal Social Services Research Unit
<b>PwD</b>	Person/people living with dementia
<b>QALY</b>	Quality-adjusted life year
<b>RBMT</b>	Rivermead Behavioural Memory Test
<b>RCT</b>	Randomised controlled trial
<b>REDALI-DEM</b>	Trial to study the effects of structured RElearning methods on DAily LIving task performance of persons with DEMentia
<b>RSS</b>	Relatives' Stress Scale
<b>SAE</b>	Serious adverse event
<b>SD</b>	Standard deviation
<b>SE</b>	Standard error
<b>SES</b>	Socio-economic status
<b>SMART</b>	Targets which are Specific, Measurable, Achievable, Realistic, Time-bound
<b>SMD</b>	Standardised mean difference
<b>SSD</b>	Local Authority Social Services Department
<b>TAU</b>	Treatment as usual
<b>TEA</b>	Test of Everyday Attention

<b>TI</b>	Technical Instructor
<b>UN</b>	United Nations
<b>VaD</b>	Vascular dementia
<b>WHOQOL- BREF</b>	World Health Organisation Quality of Life Instrument – brief version
<b>WTP</b>	Willingness-to-pay

## Scientific summary

### **Background**

Cognitive rehabilitation (CR) is an individualised, goal-oriented, problem-solving approach aimed at managing or reducing functional disability and maximising engagement and social participation. This intervention is intended to support everyday functioning by addressing the impact of cognitive impairment on functional ability. People with dementia and their family members or other supporters (here referred to as ‘carers’) work together with a CR therapist to identify personally-relevant and meaningful goals relating to their everyday activities. The therapist identifies the person’s intrinsic cognitive and functional capacity and current level of functioning, assesses the requirements of the task or activity outlined in the goal, pinpoints areas where the two are mismatched and problems arise, and helps devise a plan to overcome these problems using evidence-based rehabilitative methods. Participants and carers work together with the therapist to implement this plan over several sessions conducted in the home setting. Progress towards attaining the identified goals is evaluated through participant- and carer-reported levels of goal attainment. Building on a series of feasibility studies and a successful pilot trial, the multi-centre GREAT trial aimed to provide definitive evidence about the clinical and cost-effectiveness of CR for people with mild to moderate dementia.

### **Methods**

#### *Trial design*

Two-arm single-blind pragmatic randomised controlled trial comparing cognitive rehabilitation added to usual treatment with usual treatment alone. Participants were assessed at baseline and at three and nine months post-randomisation.

#### *Participants*

Participants were individuals of any age with an ICD-10 diagnosis of Alzheimer’s disease (AD), vascular dementia, or mixed AD and vascular dementia and in the relatively early stages as indicated by a Mini–Mental State Examination (MMSE) score of 18 or above. If taking dementia-specific medication, they had to be receiving a stable dose for at least one month before joining the trial, with no expectation of change in dose during the course of the trial. Participants had to have a carer who was willing to take part and provide collateral information, and had to be able to give informed consent. Exclusion criteria were a prior

history of stroke, brain injury or other neurological disorder and inability to communicate in English.

Participants were recruited in eight centres in England and Wales through NHS and voluntary sector services and Join Dementia Research over a 36 month period from 1<sup>st</sup> April 2013 to 31<sup>st</sup> March 2016. All assessments and intervention sessions were conducted in participants' own homes.

#### Sample size

To achieve 80% power to detect a medium effect size of 0.3, with alpha 0.05, in primary and secondary outcomes, 175 people with dementia, together with their carers, were needed to complete the trial in each arm. Allowing for potential attrition of 27%, it was necessary to randomise 480 people with dementia, each with a carer.

#### Randomisation

Participants were individually randomised by the Clinical Trials Unit (CTU) following consent and baseline assessment. Randomisation was stratified by centre, gender, age (under 75 vs. 75 and above), and MMSE score (under 24 vs. 24 and above).

#### Blinding

Trial researchers were blind to participants' group allocation.

#### ***Intervention***

The intervention was ten sessions of cognitive rehabilitation over three months, followed by four maintenance sessions over the next six months. This was provided in addition to usual treatment. The intervention was delivered by trained therapists (nine occupational therapists and one nurse) who received regular individual and group supervision to ensure fidelity to protocol.

#### ***Comparator***

The comparator was treatment as usual.

#### ***Outcomes***

The primary outcome was participant rating of goal attainment at three month follow up. All participants identified up to three goals at baseline. Goals were elicited using the Bangor Goal Setting Interview (BGSi), with goal attainment rated using a previously-validated

simple and accessible rating scale on which a two-point improvement is considered clinically significant. This measure also yielded secondary outcomes, as attainment ratings were made independently by participants and carers at each time-point, and participants rated their satisfaction with goal attainment at each time-point.

Other secondary outcomes were participant self-efficacy (Generalized Self-Efficacy Scale, GSES), depression and anxiety (Hospital Anxiety and Depression Scale, HADS), cognition (Rivermead Behavioural Memory Test (RBMT) story recall, Test of Everyday Attention (TEA) elevator counting and Delis-Kaplan Executive Function System (DKEFS) letter fluency), quality of life (People with DEMentia Quality Of Life questionnaire, DEMQOL), and service utilisation, and carer stress (Relatives' Stress Scale, RSS), health status (European Quality of Life 5 Dimensions questionnaire, EQ5D) and quality of life (World Health Organisation Quality of Life Instrument – brief version, WHOQOL-BREF).

Participant goals were recorded. Therapists recorded per cent attainment for all goals addressed in therapy. Therapists completed therapy logs with details of each session and contributed to a focus group discussion about perceived influences on outcome.

Participant and carer experience of the intervention was explored through interviews with a sub-set of participants and carers. These were consecutive series of participants completing the trial in three sites. Interviews were conducted and data analysed by researchers not otherwise involved in the trial.

### ***Analyses***

Statistical analysis was conducted as an Intention to Treat (ITT) analysis. The main analysis for the primary outcome was an analysis of covariance (ANCOVA) adjusted for baseline score, allocation group and the stratification variables (age, gender, MMSE score and centre) which were treated as random effects. Analysis used a mixed-effects model. Additional regression modelling was undertaken to identify factors that could be important in attaining and maximising the observed effects. This was done separately for people with dementia and carers. Analyses for the secondary outcomes used ANCOVA adjusted for baseline score, allocation group and stratification variables.

Goals identified by participants were categorised descriptively. Therapists recorded the extent of attainment for all goals addressed in therapy as a percentage score using criteria identified

at the outset. Data from the therapy logs and focus group were examined in relation to factors perceived as affecting progress.

Participant and carer interviews were analysed thematically to identify key features of their experience of the intervention.

The main economic evaluation was a cost-effectiveness analysis (CEA), conducted first from a health and social care perspective and second from a societal perspective.

### ***Changes to protocol***

There were two changes to the protocol. The trial was initially set up in six centres, but two more centres were added in June 2015 to ensure recruitment targets were met. Interviews with participants and carers were added to the protocol following discussion with the trial steering group which included experts by experience.

## **Results**

### ***Recruitment***

A total of 583 participants were screened, of whom 475 were randomised to either CR (n=239) or treatment as usual (n=236). One participant in the CR group was incorrectly included and was removed from analyses. At three-month follow up 219 CR and 227 TAU participants were reassessed. At nine-month follow up, 209 CR and 218 TAU participants were reassessed. Retention in the trial was 94% at three months and 90% at nine months.

Participants' mean age was 78.56 years (range 53-95) and mean MMSE score was 23.82 (range 18-30). The majority (59.5%) had a diagnosis of Alzheimer's disease. Carers were mainly spouses or partners (69.8%).

### ***Primary outcome***

For the CR group, participant attainment ratings improved at the three month follow up by 2.57 points on average, and this improvement was maintained at nine months. Average ratings in the TAU group showed a negligible improvement of less than 1 point at three months. Analysis of covariance indicated that the differences between CR and TAU groups were significant at both three and nine months, with large effect sizes of 0.81 and 0.8 respectively.

The same pattern was observed for informant attainment ratings with the CR group improving by an average of 2.7 points and maintaining the improvement at nine months, while the TAU group ratings showed a negligible improvement of less than 1 point. Analysis of covariance indicated that the differences between CR and TAU groups were significant at both three and nine months, with large effect sizes of 0.93 and 0.79 respectively.

In the CR group average satisfaction ratings improved by 2.7 points at three months and increased further to give a 3 point improvement over baseline at nine months. Average satisfaction ratings for the TAU group improved by 1.2 points at three months with a further slight increase at nine months. Analysis of covariance indicated that the differences between CR and TAU groups were significant at both three and nine months, with large effect sizes of 0.7 and 0.67 respectively.

Few predictors were identified to indicate which participants were most likely to benefit, but more positive participant baseline ratings of readiness to change and a higher number of sessions completed were associated with greater gains, and at nine month follow-up, participants with higher MMSE scores had better outcomes.

### ***Secondary outcomes***

Following correction for multiple comparisons, there were no significant changes in any secondary outcome measures following intervention. Effect sizes were small to negligible, although in some cases with wide confidence intervals. Exploratory analyses examining whether benefits were seen for particular sub-groups yielded no statistically-significant models.

### ***Process evaluation***

Participants and carers engaged well in therapy, with 89% of CR participants completing at least ten sessions.

Goals addressed in therapy related to engaging in activities, managing everyday tasks and situations, using appliances and devices, being well-oriented, retaining or keeping track of information and events, locating belongings, recognising, identifying and naming people and objects, engaging in conversation, keeping in contact with family and friends, being organised, managing emotions and basic self-care. Therapists rated per cent attainment for each goal addressed; 54.8% of goals were rated as at least 75% attained, and 79.8% as at least 50% attained. Only 5% of goals showed no progress towards attainment. The therapists'

perception was that degree of impairment or dementia severity was the main determinant of progress.

Participants and carers were uniformly positive about the intervention and felt they experienced improvements in activities of daily living and in well-being. They found the intervention helped with the process of psychological adjustment to living with dementia, leading to feelings of greater confidence, less anxiety, and better coping skills. The relationship they built up with the therapist was important both as a vehicle for providing information, education and support and as the means by which rehabilitative strategies were developed, accepted and personalised.

### *Economic analyses*

Cost-effectiveness analyses: The cost of an increase of 1.32 points in the BGSi attainment rating was £1,296 from the health and social care perspective and -£9 from the societal perspective. The cost of attaining an increase of 1.53 points (ICER point estimate) on the GSES was £4470 from the health and social care perspective and -£2961 from the societal perspective.

Cost-utility analyses: The cost per DEMQOL-U-derived QALY was £1,110,000 from the health and social care perspective. The ICER was negative (-£1,052,000) from the societal perspective, the cost being somewhat lower in the CR than the TAU group (by £526, 95% CI -£3108 to £1927). There were no differences between groups in terms of QALYs derived from DEMQOL-U. It was not possible to be certain that either strategy (CR or TAU) is cost-effective at any level of WTP. The cost per carer QALY (from EQ-5D) was £632,000 from the health and social care perspective. The ICER was negative (-£902,000) from the societal perspective, costs being somewhat lower in CR than TAU (by £902, 95% CI -£3,616 to £1,705); there were no differences in EQ-5D-derived QALY between the groups.

Thus there was no evidence for cost-effectiveness in terms of gains in person with dementia QALY (DEMQOL-U), nor carer QALY (EQ-5D-3L) from either study perspective. By reference to the primary outcome of participant-rated goal attainment, CR was cost-effective from both the health and social care and societal perspectives at willingness-to-pay values of £2500 and above for improvement in the goal attainment measure equivalent to the standardised mean difference (1.32). There was no evidence for cost-effectiveness on the self-efficacy (GSES) measure from either cost perspective.

## **Conclusions**

Cognitive rehabilitation is clinically effective in enabling people with early-stage Alzheimer's, vascular or mixed dementia to improve their everyday functioning in relation to individual goals targeted in the therapy. CR was not cost-effective when gauged against QALY gains for either participants with dementia or carers, but would be cost-effective by reference to the primary outcome (goal-attainment) if decision-makers were willing to pay for gains in participant-rated goal attainment. Results showed improved functioning in the targeted areas in the CR group at three month follow up, and this improvement was maintained at the nine month follow up. Participants in the CR group were more satisfied with their ability to carry out the everyday activities targeted in the intervention, and participants and carers felt the intervention helped them develop and implement strategies and adjust to the challenges of living with dementia. CR may be a useful addition to care pathways for those people with mild to moderate dementia who would benefit from developing strategies to manage their everyday activities and maintain their engagement in life, and may be particularly valuable if offered in the months following a dementia diagnosis.

## **Plain English summary**

**Background:** Cognitive rehabilitation (CR) is a personalised intervention to help people with early-stage dementia manage everyday activities. This individualised therapy is conducted in people's own homes over several sessions. A therapist works with the person and the carer to identify realistic and relevant goals, plan how to tackle these, and support people in achieving them. Previous small studies suggested that CR could be beneficial.

**Methods:** The GREAT trial was run in eight centres to find out whether CR improves everyday functioning. Participants were in the early stages of Alzheimer's, vascular or mixed dementia, with a family carer involved. At the first assessment, participants identified areas where they would like to see improvements, and set goals. Participants and carers rated how well participants were currently doing in relation to these goals, and completed questionnaires, for example about mood and quality of life. Participants were then randomly selected to either receive CR or continue with treatment as usual (TAU). CR consisted of ten weekly sessions with the therapist over three months followed by four sessions over the next six months. Participants were re-assessed after three and nine months.

**Results:** We included 475 participants, and 427 (90%) completed the trial (209 in CR and 218 in TAU). After three months, ratings by both participants and carers in the CR group showed that participants were doing significantly better in relation to their goals, and this was maintained six months later. Ratings for TAU participants did not improve significantly. There were no other differences between the groups. There was a strong economic case for CR.

**Conclusions:** Cognitive rehabilitation is effective in enabling people with early-stage dementia to improve their everyday functioning in relation to individual goals targeted in the therapy. Next steps will focus on implementation of CR into NHS and social care services.

## Chapter 1. Introduction

There is a greater need than ever before to identify effective and beneficial interventions for people with early-stage dementia. Timely diagnosis of dementia creates an opportunity to equip people with dementia and carers to manage and live well with the condition. Psychological and social interventions can help to reduce or delay the development or progression of functional disability, depression or behavioural difficulties, maintain independence, support management of co-morbid health conditions and hence avoid or reduce hospitalisation, maintain quality of life, and ultimately delay institutionalisation.<sup>1</sup> At present, however, the chances of accessing psychological or social interventions following a diagnosis of dementia are limited<sup>2</sup>. There is a need to develop relevant and helpful interventions and to provide research evidence regarding the efficacy of these interventions. Research priorities set out by the Ministerial Advisory Group on Dementia Research (MAGDR) in 2011 emphasised the need to identify ways of enabling people with dementia and their family members or other supporters (here referred to as ‘carers’) to enjoy a better quality of life and to evaluate the effects of psychological and social interventions for people with dementia living in the community. Nevertheless there is still a significant ‘psychosocial intervention gap’ that remains to be addressed.<sup>2</sup>

What is needed is a range of accessible psychological and social interventions that are effective in supporting or enabling people to live well with dementia and tackling the specific challenges that people face in managing everyday life with the condition. In the early stages of dementia, this includes approaches that can enable people to function as well as possible and remain as independent as possible.<sup>3</sup> Neuropsychological and behavioural studies show that people with early-stage dementia have many retained cognitive and behavioural capacities and are capable of behaviour change and new learning, although this is likely to require extra support.<sup>4-7</sup> It should be possible to harness these retained capabilities to enable people to manage daily activities better and support engagement and participation. Models of disability<sup>8-10</sup> make an important distinction between underlying impairment, resulting from pathology, and disability, resulting from limitations on activity and restrictions on social participation. Furthermore, the possibilities for engaging in activity and participating in society are not solely determined by the extent of impairment, but are influenced by a range of other personal, relational, social and environmental factors. Unhelpful, unsupportive or negative influences can contribute to the development and maintenance of excess disability,<sup>11</sup> where functional disability is greater than would be predicted by the degree of impairment; an example would be where an unsupportive environment leads to

loss of confidence. This is similar to Kitwood's account of the way in which a negative social context can undermine well-being for people with dementia.<sup>12</sup> In contrast, facilitative and positive influences can enable a person to function optimally. A focus on supporting, and overcoming barriers to, activity and participation should therefore produce benefits for people with dementia and their family members.

Traditionally, however, and despite the expressed concerns of clinicians<sup>13</sup> considerable effort has been devoted to using non-pharmacological approaches to attempt to address the underlying impairments in memory and other cognitive functions which are a defining feature of mild dementia, rather than focusing directly on enabling people to function well in everyday life. An example is the use of cognitive (or 'brain') training, which involves repeated, structured practice of tasks targeting specific cognitive domains, such as working memory or attention. A Cochrane systematic review<sup>14,15</sup> found no evidence for significant benefits in early-stage dementia, and expert consensus endorses this finding.<sup>16</sup> A general issue with cognitive training that is a concern also in work with healthy older people or those with mild cognitive impairment is the lack of generalisation of benefits. Even in cases where improvements are observed in trained domains, there is no evidence that these generalise to other areas, improve the ability to undertake everyday activities, or have any beneficial impact in real life.<sup>17</sup> There is a need for more directly relevant approaches that can enable better functioning or reduce functional disability for people with dementia.

Interventions that aim to enable functional ability by targeting activity and participation, drawing on retained strengths to support adaptive behaviour, are typically described as forms of rehabilitation. The aim of rehabilitation is to enable people to function at their optimal level in the context of their intrinsic capacity and current health state.<sup>18</sup> The rehabilitation of people with cognitive impairments is termed cognitive (or neuropsychological) rehabilitation. The work described here has applied this approach in the care and support of people with early-stage dementia.

### **Principles of cognitive rehabilitation**

Cognitive rehabilitation is an individualised behavioural therapy based on a problem-solving approach.<sup>3,19,20</sup> It represents the application of rehabilitation principles to address the effects of cognitive impairment. Cognitive rehabilitation aims to address the impact of cognitive

disability by enabling people with cognitive impairments to function at the best possible level given the nature and extent of these impairments. Supporting optimal functioning means enabling people to manage their daily lives, engage in worthwhile and meaningful activities and sustain as much independence as possible. This in turn allows people to feel more in control of their lives and supports the continuing experience of a coherent sense of identity. Cognitive rehabilitation is person-centred, acknowledging that each person's combination of life experience, motivations, values, preferences, skills and needs is unique, and views the person holistically, taking account of the person's relationships and environment

Cognitive rehabilitation does not aim to train cognition or directly improve performance on cognitive tasks. Its goal is the *functional* rehabilitation of people with cognitive impairment. The focus is on better management of the functional disability that results from cognitive impairment and on reducing any excess, or unnecessary, disability resulting from secondary consequences such as loss of confidence. This is achieved by working with people on the goals that are important to them and that will make a difference in their daily lives.

### ***Concept and terminology***

Most people are familiar with the concept of rehabilitation following injury or illness, aiming to return the person to a former state of functioning, or if this is not possible then to enable the person to adjust to altered capacity and function at the best possible level given the residual impairments.<sup>18</sup> In the acute phase during recovery, intensive rehabilitation in specialist settings may be indicated, while at later stages, a less intensive community-based approach may be appropriate. Rehabilitation may target physical or cognitive functioning. The concept of rehabilitation is equally relevant for people with progressive impairments, who may benefit from episodes of community-based rehabilitation at various stages or as circumstances change.

In community settings, the term 'rehabilitation' is now sometimes replaced by 'reablement', which is derived from the same root and essentially shares the same meaning, but is perhaps viewed as a more readily understandable label. Rehabilitation can also be considered as related to the concept of 'tertiary prevention' used in public health. We will use the term 'rehabilitation' here. The key point is that rehabilitation (or reablement) is grounded in a philosophy of enablement reflecting a positive approach to finding solutions and encouraging optimal functioning. This philosophy emphasises a collaborative approach in service

delivery, which can be summarised as ‘doing with’ rather than ‘doing for’ or ‘doing to’<sup>21</sup> and which translates into specific individualised interventions aimed at optimising functioning.

### *Application to dementia*

Living with dementia means living with disability resulting from cognitive impairment. The UN Convention on the Rights of Persons with Disabilities sets out a range of rights, including the right to be able to attain and maintain as much independence as possible through the assistance of comprehensive rehabilitation services (Article 26(1)).<sup>22</sup> For people with dementia, rehabilitation has been proposed both as an overarching principle of care and service provision reflecting the aim of enabling optimal functioning,<sup>3,20,23,24</sup> and as a specific intervention approach that aims to support attainment of practical functional goals.

The principles of rehabilitation can be applied flexibly to address different types of need at various stages of dementia. These might include needs resulting from the impact on functioning of cognitive, behavioural, emotional, communication, relational, social or physical changes or difficulties. Cognitive rehabilitation for people with dementia focuses primarily on the effects on functioning of the cognitive, behavioural and social communication impairments which form the core symptoms of dementia and the emotional and relational impact of these. A person might have several episodes of rehabilitation over time as needs change or in response to particular circumstances such as being discharged after a period of hospitalisation. Cognitive rehabilitation is distinct from physical rehabilitation, but it is important to note that people with dementia can benefit from exercise-based interventions and should of course have access to intensive physical rehabilitation where needed following injury or illness.<sup>25</sup>

Rehabilitation, with its focus on optimising functioning, provides a highly relevant framework for supporting people with dementia and their carers, and for designing interventions to meet their needs. However, the term ‘cognitive rehabilitation’ (or ‘neuropsychological rehabilitation’), although familiar in areas such as brain injury research, needs to be better understood in the dementia field. ‘Rehabilitation’ signifies that the intervention aims to enable people to function optimally given any impairments they may have, and ‘cognitive’ signifies that the intervention specifically addresses the impact of cognitive impairment on functional ability. This impact may be the direct result of the cognitive impairment (for example, difficulty remembering) or may reflect secondary effects,

such as loss of confidence. Cognitive rehabilitation has a different focus and takes a different approach to other interventions that include the term ‘cognitive’ in their titles.<sup>15</sup> Cognitive training and cognitive stimulation focus on cognitive function and target specific domains or global functioning respectively; the term cognitive rehabilitation is sometimes incorrectly used to describe these types of interventions or as an umbrella term for them. Cognitive or cognitive behavioural therapy targets unhelpful or self-defeating thought patterns that may underlie mental health difficulties or adjustment issues. Cognitive rehabilitation is distinct from all of these other approaches which include the term ‘cognitive’, and should not be confused with them.

### **Cognitive rehabilitation in practice**

Cognitive rehabilitation is focused on the attainment of realistic personal goals<sup>26</sup> that are meaningful to the individual and address relevant needs. Goal-setting is a powerful behavioural strategy,<sup>27</sup> and goal-oriented approaches are widely used in rehabilitation interventions, including rehabilitation for people with brain injury,<sup>28,29</sup> stroke,<sup>30</sup> neurological illness,<sup>31</sup> memory difficulties,<sup>32</sup> physical disability,<sup>33</sup> chronic pain<sup>34,35</sup> and age-related frailty.<sup>36</sup> Goals for rehabilitation are expressed in a form that meets the description captured in the acronym SMART: specific, measurable, achievable, and realistic within a defined time-scale. The goal-oriented approach has hitherto rarely been used in dementia care but is consistent with person-centred principles.

Goals are identified collaboratively and realistic targets established, leading to generation and implementation of strategies to support goal attainment. This process is based on a formulation, or understanding, of the individual’s intrinsic capacity, current functioning, strengths and needs, which considers cognitive, behavioural, emotional, relational and environmental factors.

To arrive at a formulation reflecting this global level of understanding, the cognitive rehabilitation therapist assesses the person’s intrinsic cognitive and functional capacity and current level of functioning. This makes it possible to understand the person’s potential and to pinpoint any areas where the person is functioning below capacity. Understanding the reasons for this can indicate avenues that need to be addressed before specific rehabilitation goals are tackled. For example, depression or loss of confidence may lead to reluctance to

engage in activities with consequent loss of skills, creating an unnecessary burden of excess disability. An early stage of therapy may therefore involve addressing issues of this kind.

The overall formulation provides a framework for identifying specific areas of daily life that the person would like to manage better and establishing which of these may be amenable to change. Through a collaborative process, which can be facilitated by using a structured interview schedule, individual personally-meaningful and achievable goals are identified. These relate to particular activities or situations that give rise to concern for the individual. For each of these, the cognitive rehabilitation therapist assesses the demands of the activity or situation the person wishes to engage in or manage better, identifies any areas of mismatch between these demands and what the person is able to do, and pinpoints where difficulties are likely to arise and why. This is an important precursor to devising strategies for goal attainment. For example, a person could encounter difficulty with engaging in an activity due to not remembering what to do or being unable to concentrate (cognitive), lacking some of the skills needed (behavioural), feeling anxious or fearful (emotional), being in surroundings that are not conducive to carrying out the activity (environmental) or lacking someone to do the activity with (social), or some combination of these. Understanding where the difficulties arise provides a focus for the problem-solving process and for starting to work together to generate possible solutions that can support goal attainment. For example, if the difficulty arises from lack of necessary skills the solution may be to teach these skills or to modify the activity, if the difficulty is due to memory problems the solution may be to provide support for remembering, and if the difficulty is due to anxiety the solution may be to find ways of regulating emotions. The cognitive rehabilitation therapist can select from a range of methods and strategies, which could involve new learning, relearning, use of compensatory strategies, task modification, environmental modification, application of assistive technology, or some combination of these.

Once a possible solution is chosen, a plan for goal attainment is devised. Specific strategies that can help with implementing the solution are identified collaboratively, and tested out in practice. Evidence-based rehabilitative strategies include techniques such as spaced retrieval which support new learning or relearning of information or skills, techniques to support the introduction and use of compensatory aids, and introduction of environmental adaptations. Assistive technology may be used to augment the person's capacity.

Progress towards attaining therapy goals is reviewed continually and strategies are adjusted as needed. Throughout this process the therapist provides important psychological support and models a positive, problem-solving orientation. Alongside the focus on problem-solving, goal-setting and strategy application, cognitive rehabilitation incorporates other behavioural therapy methods. Firstly, many people with dementia experience low mood and apathy, and this may need to be addressed at the outset of therapy. Behavioural activation is used to increase engagement in activities that would usually be enjoyable, with the experience of engagement and pleasure providing a source of motivation to make changes and improvements. Secondly, tackling rehabilitation goals can trigger distress, including fear, despondency or frustration, and therapists provide important psychological support in acknowledging these emotions and helping people develop ways of dealing with them and overcoming the barrier they can present.

Rehabilitation interventions for people with dementia need to offer practical benefits in daily life. When providing behavioural interventions it is essential to consider firstly whether benefits will transfer from the specific situation to application in real life, and secondly whether these benefits generalise, for example to other similar activities. Potential for transfer and generalisation is often limited in the absence of specific efforts, and this is a particular concern in the context of cognitive impairment. For this reason, cognitive rehabilitation interventions for people with dementia are designed to circumvent the issue by being conducted in the person's everyday setting where the skills and strategies learned need to be applied. Wherever possible, carers and other family members are involved to help implement and maintain changes in daily life.

Supporting carers is an essential part of cognitive rehabilitation for people with dementia. For family carers, this includes both explaining and demonstrating the strategies and skills employed to promote goal attainment and attending to the carer's own needs and well-being by providing psychological support, discussing needs and signposting to appropriate sources of help. Where the needs and wishes of the person with dementia and family carer differ, resulting in tensions, the therapist has to negotiate a balance between the two perspectives, and this can be one of the most challenging aspects in delivering cognitive rehabilitation interventions, requiring sensitivity and skill.

## **Evaluating outcomes of cognitive rehabilitation**

For a behavioural intervention, the first requirement is to demonstrate change in the behaviour or behaviours targeted, and hence progress with therapy goals must be the primary outcome for cognitive rehabilitation.<sup>19</sup> As cognitive rehabilitation interventions are based on individual formulations and address personally-relevant goals, this has important implications for assessment of primary outcomes at a group level, for example in clinical trials. In a trial, the overall therapeutic approach and the structure of the intervention (e.g. number and duration of sessions) will be consistent across all participants receiving the intervention, but the content and focus of the intervention and the specific strategies applied will be different for each individual. This is typical for psychological interventions based on individual formulations, for example cognitive-behavioural therapy for depression. However, cognitive rehabilitation does not address a single defined clinical problem such as depression which can be clearly targeted as a common outcome across all participants. Instead, it aims to enable each individual to manage aspects of his or her daily life more effectively and with greater satisfaction. Therefore, the appropriate proximal outcome is the individual's performance in relation to these selected aspects of daily life.

In single-case designs outcome can readily be assessed directly in relation to the therapy goal – for example, whether a given activity is completed successfully or a desired behaviour is demonstrated. For effective outcome evaluation in large trials, however, there is a need for a standardised means of capturing individual functioning and changes in functioning.

Observational methods can be used in single-case or small group studies but are unlikely to be feasible for large trials. Patient-reported outcomes are increasingly understood to be not only valuable but indeed an essential component in evaluating the effectiveness of psychological and social interventions. This is particularly the case in rehabilitative interventions where the approach is one of collaboration in identifying and solving practical problems, and patient-reported outcome measures are central to researching rehabilitation outcomes. While goal attainment scaling<sup>37</sup> was developed as a means of evaluating the overall effectiveness of multi-component rehabilitation programmes,<sup>26,28,36</sup> client-centred performance measures have been developed that aim to identifying outcomes for individuals. The most widely-used example of such a measure is the Canadian Occupational Performance Measure,<sup>38</sup> which provides a structured format for identifying individual goals and rating

current performance in relation to these. Research using this measure has provided evidence for the reliability, validity and sensitivity to change of the rating method.<sup>30,39-42</sup>

Patient-reported outcomes may raise questions about the accuracy with which people rate specific aspects of their own experience. However, there is increasing recognition that people in the mild to moderate stages of dementia can provide meaningful accounts of their own experience.<sup>43</sup> This issue of awareness and accuracy in reporting rehabilitation outcomes stimulated our extensive investigations of awareness in people with early-stage dementia.<sup>44-46</sup> Evidence from these studies shows that while people with early-stage dementia are likely to overestimate cognitive abilities relative to objective test score,<sup>47</sup> they appear to be relatively accurate in estimating their functional ability in everyday tasks relative to objective test scores based on observation, and indeed may be more accurate than carers.<sup>48</sup> Therefore patient-reported outcomes in relation to performance of the activities that are the subject of rehabilitation goals can be considered an appropriate means of evaluating intervention effectiveness.

### **Development work undertaken prior to the GREAT trial**

Experience with cognitive rehabilitation for people with cognitive disability resulting from non-progressive acquired brain injury led to formulation of the research question: ‘Can cognitive rehabilitation be adapted to enable people with dementia and their carers to better manage the effects of cognitive disability?’ Literature searches identified a few examples of interventions for people with dementia consistent with principles of cognitive rehabilitation,<sup>49-51</sup> and some descriptions of the application of specific learning strategies, mainly using single-case designs.<sup>52</sup> We carried out a Cochrane systematic review<sup>14</sup> which confirmed that there were no relevant randomised controlled trials.

A series of feasibility studies conducted by our group demonstrated that it was possible for people with early-stage dementia themselves to identify personal rehabilitation goals and to apply rehabilitation strategies to change behaviour and improve functioning in relation to these goals. These were either single-case experimental designs<sup>53-56</sup> or small group pre/post comparisons.<sup>57</sup> Behavioural change was observed in relation to the identified goals, and sometimes this generalised to other situations. Secondary benefits included maintained social engagement and reduction in carer burden. Gains were maintained for several months and in

one case with long-term follow up over several years.<sup>58</sup> Additional work extended the evidence for efficacy, relevance and acceptability of specific rehabilitation methods, such as spaced retrieval or errorless learning.<sup>59,60</sup> These findings were supported by reports from other research groups.<sup>61,62</sup>

We next conducted a single-site pilot trial of individual, goal-oriented cognitive rehabilitation in North Wales from 2005 – 2009, funded by Alzheimer’s Society.<sup>63</sup> This was the first randomised controlled trial of cognitive rehabilitation for people with early-stage dementia. We anticipated that the CR intervention would result in improvements in participants’ functioning in the areas targeted in the intervention, but not in cognitive test scores. We included measures of mood and quality of life to explore whether the intervention had any effects in these domains, and to allow us to check that the intervention did not have any adverse effects, given the concerns expressed by clinicians that cognitive training interventions could adversely affect mood and well-being.<sup>13</sup>

The participants in the pilot trial were 69 people with dementia recruited from NHS memory clinics, of whom 44 had a family carer who also contributed. Participants had an ICD-10 diagnosis of Alzheimer’s or mixed Alzheimer’s and vascular dementia, were in the early stages as indicated by an MMSE score of 18 or above, and were receiving a stable dose of either donepezil (Aricept), galantamine (Reminyl) or rivastigmine (Exelon). All participants identified personal rehabilitation goals during baseline assessment, using the structured interview format of the Canadian Occupational Performance Measure (COMP).<sup>38</sup> Participants were then randomised to one of three arms: cognitive rehabilitation, relaxation therapy or treatment as usual. The cognitive rehabilitation intervention involved weekly one-hour home visits by the therapist for eight weeks. The main focus of the intervention was addressing the identified personal rehabilitation goals, and this was supported by improving strategies for emotion regulation, retaining information and enhancing concentration, and managing everyday activities. Carers were included in part of each session where available and willing. Selected goals related primarily to managing the impact of memory, communication or organisational difficulties, improving performance of practical skills and activities, learning new skills, regaining confidence and motivation to engage in activities, and increasing social interaction.<sup>64</sup> The relaxation therapy intervention, delivered by the same therapist, involved eight weekly one-hour home visits in which participants were taught progressive muscle relaxation and breathing exercises. Participants allocated to treatment as usual had no contact with the therapist.

The primary outcome was participant-reported goal performance using the COPM rating system. At post-intervention follow-up, ratings of goal performance and satisfaction with functioning in relation to goals improved significantly for the cognitive rehabilitation group and did not change for the other two groups; effect sizes in favour of cognitive rehabilitation were large. Behavioural changes in the cognitive rehabilitation group were corroborated by therapist ratings of performance and of the extent to which goals were attained. The average performance ratings made by participants and therapists improved by a magnitude greater than the two-point change required to indicate clinical significance.<sup>38</sup>

In secondary outcomes, cognitive rehabilitation produced benefits relative to the other two conditions in quality of life, mood and cognition for the person with dementia and stress, well-being and quality of life for the carer. Some of these secondary benefits were maintained six months later. There were no differences between the relaxation therapy and treatment as usual groups. A subset of participants underwent fMRI scanning using a recognition memory task;<sup>65</sup> at post-intervention follow up those from the cognitive rehabilitation group showed higher, and those from the control groups showed lower, brain activation in relevant areas, although neither group improved performance on the task. This was interpreted as suggesting that cognitive rehabilitation may have promoted a partial restoration of function in frontal brain areas.<sup>66</sup>

The intervention was acceptable to participants and carers. Attrition was low with 64 of the 69 randomised participants (93%) completing the post-intervention assessment and 56 (81%) completing the six-month follow-up (19% attrition overall). Reasons for loss to follow up included death (3), illness (1), moving out of area (3), and change of diagnosis (1), with elective withdrawal accounting for only 5 cases.

In summary, the pilot trial provided evidence to show that people with early-stage dementia can identify realistic goals and make significant improvements in functioning with regard to their chosen goals during a brief cognitive rehabilitation intervention.

### **Lessons learned from the pilot trial**

We used the experience gained during the pilot trial to develop plans for a large, definitive trial. We updated our Cochrane review during the course of the pilot trial in 2007<sup>67</sup> and

continued to monitor emerging literature, and found no other RCTs to inform our development work.

A key area of learning from the pilot trial related to outcome measurement. In the pilot trial we used the COPM which provides a pragmatic rating system based on a simple 0 – 10 scale. This is accessible for people with cognitive impairments and can be presented visually as well as verbally. There was consistency in ratings over time for the non-treated groups, and for the cognitive rehabilitation group the measure was sensitive to change, corroborated by therapist observation. This reflects similar findings from other clinical groups<sup>30,40-42,68,69</sup> and suggests that goal performance ratings made by people with early-stage dementia can be considered reliable and valid<sup>64</sup> and that changes in ratings are a valid indicator of treatment effectiveness, with improvements of 2 points being considered clinically-significant.

While the COPM rating system proved suitable in the pilot trial, the semi-structured interview format specified domains of self-care, leisure and productivity, reflecting its generic nature. These domains do not necessarily cover everything that might be relevant for specific groups such as people with early-stage dementia, or that might be addressed in individual research projects. We therefore developed a semi-structured goal-setting interview that used the same rating method but placed this within the context of a more directly relevant and targeted discussion and goal-setting process, which could be adapted to the needs of specific groups or projects. The measure we developed, the Bangor Goal-Setting Interview (BGSi), has been used to elicit goals and evaluate progress towards goal attainment in trials with cognitively-healthy older people<sup>70</sup> and people with mild cognitive impairment<sup>71</sup>, and is used in the GREAT trial described here.

In the pilot trial we included people who did not have a carer available to participate, as people living alone with dementia may be in particular need of support to manage everyday activities, and therefore carer ratings were not obtained for these participants. However, when conducting cognitive rehabilitation with people who have cognitive impairments it is good practice if possible to obtain a collateral perspective from a family carer,<sup>30,42</sup> and such a perspective is particularly valuable in research trials. For this reason we concluded that an inclusion criterion for participating in GREAT should be the availability of a carer willing to provide collateral information. The BGSi provides for the inclusion of parallel informant ratings. A further limitation in the pilot trial was that goal attainment ratings were only

obtained post-intervention and not at the six-month follow up. In GREAT we assessed goal attainment at each follow up.

In the pilot trial 46% of goals were rated as fully achieved, 50% as partially achieved, and 4% as not achieved within the eight week timeframe of the intervention. Reviewing the therapy logs kept by the therapist indicated that for most of the ‘partially achieved’ goals the therapist considered further improvements could have been achieved with a little more time. The therapist’s view was that a slightly longer intervention was needed in order to optimise and consolidate benefits. For GREAT we therefore decided on a 10 session intervention with four additional maintenance sessions.

Finally, the lack of observed differences between the relaxation therapy and treatment as usual groups suggested that in a further trial a two-arm design comparing cognitive rehabilitation to treatment as usual should be acceptable.

### **Aims of the GREAT trial**

Building on our extensive development work, we aimed to provide definitive evidence about whether goal-oriented cognitive rehabilitation is a clinically-effective and cost-effective intervention for people with early-stage Alzheimer’s disease, vascular or mixed dementia and their carers.

We hypothesised:

1. That this personalised intervention would improve functioning in areas directly targeted in the therapy, and that this would be reflected in self- and carer ratings.
2. That the intervention might impact on perceived self-efficacy, reflecting a possible psychological mechanism of action.
3. That carers of participants receiving the intervention, having learned new ways of supporting and enabling their relatives, might report feeling less stressed following the intervention.

In line with our theoretical model of cognitive rehabilitation, we did not anticipate changes in performance on cognitive tests, as CR does not directly target or train specific underlying cognitive processes. We did not plan to select participants on the basis of having clinical levels

of depression or anxiety, poor scores on quality of life measures, or carers who reported their quality of life as poor, although we expected that some participants would show these features. This would necessarily limit the potential for demonstrating improvements in these domains. Nevertheless, there were some improvements in these domains in the pilot trial,<sup>63</sup> and we therefore planned to include relevant measures in our assessment of secondary outcomes. This would also make it possible to identify any harms arising if the intervention had a negative impact on well-being.

We set the following specific objectives:

1. To compare the effectiveness of goal-oriented cognitive rehabilitation with that of treatment as usual with regard to: (a) improving self-reported and carer-rated functional performance in areas identified as causing concern by people with early-stage dementia; (b) improving quality of life, self-efficacy, mood and cognition of people with early-stage dementia; (c) reducing stress levels and ameliorating quality of life for carers of participants with early-stage dementia.
2. To estimate the incremental cost-effectiveness of goal-oriented cognitive rehabilitation compared to treatment as usual.
3. To examine how the goal-oriented cognitive rehabilitation approach could most effectively be integrated into routine NHS provision, to develop a pragmatic approach that could be directly applied within standard NHS services, and to develop materials to support the implementation of this approach within the NHS following trial completion.

## Chapter 2. Method

### **Design**

This was a multi-centre two-arm single-blind randomised (1:1) controlled trial comparing cognitive rehabilitation added to usual treatment with treatment as usual alone. The design and planned flow of participants through the trial is summarised in *Figure 1*.

### **Ethics**

The study was reviewed by Wales Rec 5, which issued a favourable opinion on 25<sup>th</sup> June 2012 (Reference 12/WA/0185), and was approved by the Bangor University School of Psychology Research Ethics Committee. Based on findings from the pilot trial, it was expected that participants and carers allocated to receive the cognitive rehabilitation (CR) intervention would derive some benefits, while people allocated to treatment as usual (TAU) would not be harmed by this allocation. As there was no existing large-scale evidence about the effects of CR, it was not considered unethical to withhold the treatment from those allocated to TAU. Also based on existing evidence, there were no known risks associated with cognitive rehabilitation. However, trial researchers and therapists were trained to be alert to any concerns about participants' well-being and to refer any serious concerns to the clinician responsible for the person's care, wherever possible with the knowledge and permission of the person and carer.

### **Governance**

The trial was sponsored first by Bangor University (from its start on 1<sup>st</sup> October 2012 to 28<sup>th</sup> February 2015) and then, following transfer of the co-ordinating centre, by the University of Exeter (from 1<sup>st</sup> March 2015 until its completion on 31<sup>st</sup> December 2016). Governance was overseen by a Trial Steering Committee which included two Alzheimer's Society research volunteers who were former carers and a sponsor's representative, and by a Data Monitoring and Ethics Committee.

### **Trial registration**

The trial was registered with Current Controlled Trials under reference ISRCTN21027481.

### **Trial protocol**

The trial protocol was published in 2013.<sup>72</sup>

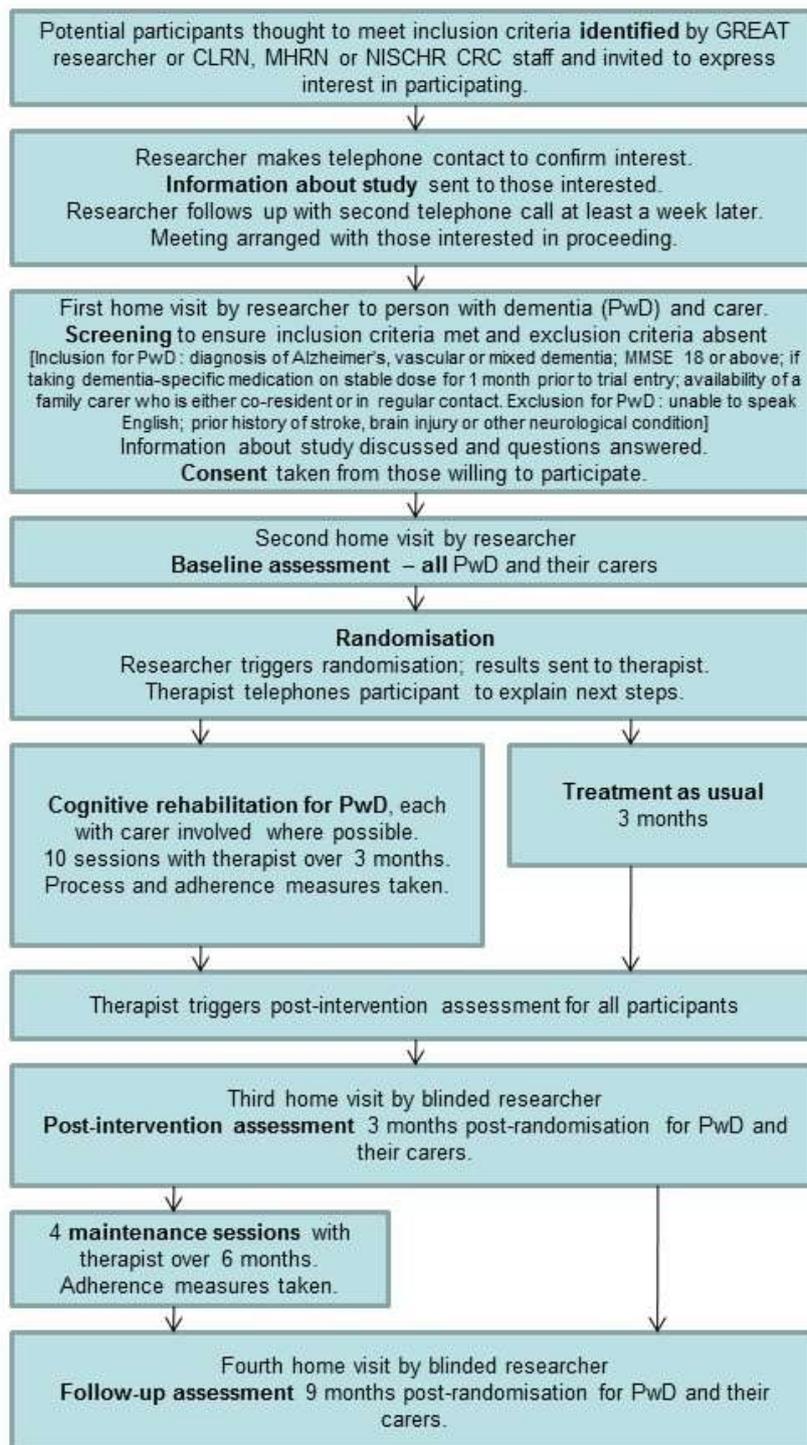


Figure 1. Overview of trial design and planned flow of participants through the trial

*PwD: person/people living with dementia*

## **Participants**

Participants were individuals of any age diagnosed with Alzheimer's, vascular or mixed dementia and in the mild stages of the condition. Each participant was recruited together with a carer.

### ***Eligibility***

Inclusion criteria:

- Participants had to have been assigned an ICD-10 diagnosis of Alzheimer's disease (AD), vascular dementia, or mixed AD and vascular dementia. These conditions are estimated to account for 89% of all dementia diagnoses.<sup>73</sup> While people with rarer sub-types of dementia could potentially benefit from CR, they might require an intervention tailored to take account of the specific profile of their condition, and we considered this would best be assessed in separate studies.
- Participants had to be in the relatively early stages of dementia, with mild to moderate cognitive impairment as indicated by an MMSE<sup>74</sup> score of 18 or above. While people with more advanced dementia could potentially benefit from CR, the focus and specific approach would differ, and using a cut-off score in this way provided a basic means of ensuring that the approach is appropriately targeted.
- It was acknowledged that some but not all participants would be receiving dementia-specific medication in accordance with standard practice guidelines. To ensure that results were not affected by changes in medication use, those participants taking dementia-specific medication, such as acetylcholinesterase inhibitors, must have been receiving a stable dose for at least a month before entering the trial, with no expectation that the dose would be changed during the course of the trial unless a specific clinical need emerged.
- Participants had to have a carer who was willing to take part. Having a carer involved is not essential, although helpful, for CR; however, for the purposes of the trial it was important to have collateral information and informant ratings of progress, and valuable to be able to determine whether CR provided any benefits for carers. By 'carer' we mean a family member or close friend who provides unpaid care and support; we acknowledge that some people undertaking this role may not use the term 'carer' to describe their role.

- Participants had to be able to give informed consent to participation. This CR intervention was aimed at people in the earlier stages of dementia and involved engaging the person with dementia in a collaborative process of identifying and addressing meaningful and personally-relevant goals. It was therefore essential for participants to understand the process and make a positive choice to engage with it.

Exclusion criteria:

- Potential participants were excluded if they had a prior history of stroke, brain injury or other significant neurological condition. Such conditions would be expected to affect cognitive, behavioural and emotional functioning, and people who have one of these conditions prior to developing dementia could have additional rehabilitation needs. While such individuals might benefit from CR, their inclusion would have represented a potential confounding factor.
- Participants were excluded if they were unable to speak English. This criterion was applied for practical reasons, because of the time and costs that would be involved in translating standardised measures and providing interpreters for assessment and therapy sessions. However, when setting this criterion we expected that no, or only very few, individuals would be excluded from participation due to inability to communicate in English.

Any cases where eligibility was unclear were referred to an eligibility panel consisting of four clinically-qualified co-investigators (two old age psychiatrists, one neuropsychiatrist and one clinical psychologist) for a decision.

### ***Recruitment***

Participants were recruited through NHS services such as memory clinics and old age psychiatry teams, carer and patient support groups led by NHS staff, support groups and networks run by Alzheimer's Society, and Join Dementia Research (JDR). Recruitment to the trial covered a 36 month period from 1<sup>st</sup> April 2013 to 31<sup>st</sup> March 2016.

Potentially-eligible individuals were initially identified either by GREAT trial researchers or by NIHR Clinical Research Network (NIHR CRN) staff in England and Health and Care Research Wales staff in Wales (previously National Institute of Social Care and Health

Research Clinical Research Collaboration, NISCHR CRC). GREAT trial researchers and research network staff visited clinics to provide information and ascertain interest in participating. Research network staff also identified possible participants through note-screening and wrote to them on behalf of the responsible clinician; they were invited to indicate interest by sending a reply slip directly to a GREAT trial researcher, who then made contact by telephone, sent written information and made a further telephone call to ascertain willingness to continue.

Where a possible interest in participating was identified, a GREAT trial researcher visited the potential participant and carer to explain the study in detail, answer any questions, re-check eligibility and ensure that the person with dementia had capacity to consent. Informed consent from both the person with dementia and the carer was taken at this visit or, if either required more time to decide, at a subsequent visit. As participants were in the early stages of dementia, we expected that they would continue to have capacity to consent throughout the period of participation. However, on entry to the trial, participants were asked whether, in the event that they did lose capacity, they would wish to continue to be included in the trial and to have their data used in the analysis.

Obtaining informed consent at the start of the trial was only the beginning of an ongoing process. This is particularly crucial in an intervention of this kind which requires the participant's active engagement. Trial researchers and therapists were trained to monitor ongoing consent and identify and respond to any indication of possible withdrawal of consent.

### ***Locations***

The trial was conducted in eight NHS sites throughout England and Wales. These were:

- North Wales - Betsi Cadwaladr University Health Board (Bangor site)
- South Wales - Cardiff and Vale University Health Board (Cardiff site)
- London – South London and Maudsley NHS Foundation Trust, with recruitment supported by Kings College Hospital NHS Foundation Trust, Guy's and St Thomas's NHS Foundation Trust, St George's Healthcare NHS Trust, and Oxleas NHS Foundation Trust (London site)
- South-East England – Kent and Medway NHS Partnership Trust (Kent site)

- South-West England – RICE - Research Institute for the Care of Older People, Bath, with recruitment supported by Royal United Hospitals Bath NHS Foundation Trust and by GP practices within the Wiltshire NHS CCG (Bath site)
- West Midlands - Birmingham and Solihull Mental Health NHS Foundation Trust, with recruitment supported by Black Country Partnership NHS Foundation Trust and Heart of England NHS Foundation Trust (Birmingham site)
- North-West England - Manchester Mental Health and Social Care NHS Trust, with recruitment supported by Pennine Care NHS Foundation Trust (Manchester site)
- North-East England – Northumberland, Tyne and Wear NHS Foundation Trust (Newcastle site)

### *Setting*

All assessments and intervention sessions were conducted in participants' own homes.

### *Sample size*

Power calculations were based on findings from the pilot trial. Improvement in goal performance was assessed in the pilot trial with the rating scale of the Canadian Occupational Performance Measure,<sup>38</sup> which is equivalent to the rating of goal attainment used as the primary outcome measure in GREAT. The effect size for improvement in goal performance was large, with a standardised effect  $>1$  at post-intervention assessment. However, it was important to be able to detect at least medium effect sizes of 0.3 for both primary and secondary outcomes. To achieve 80% power to detect a medium effect size of 0.3, with alpha 0.05, in primary and secondary outcomes, 175 people with dementia, together with their carers, were needed to complete the trial in each arm. Attrition in the pilot trial was 19% overall, but as the rate could be higher in a longer multi-centre trial we adopted a more conservative estimate of 27%. Allowing for potential attrition of 27%, it was necessary to randomise 480 people with dementia, each with a carer.

To meet this target, we calculated that each centre would need to recruit three participants per month over 27 months, a total of 80 participants per site. Experience suggested that one in three of the people with dementia identified as eligible and invited to participate would be successfully recruited; thus, each month, 9 potentially-eligible participants would need to be approached in each centre.

### ***Randomisation***

Participants were individually randomised following consent and baseline assessment. Randomisation was triggered by the trial researchers on completion of baseline assessment through secure web access to the remote randomisation centre, N.WORTH Clinical Trials Unit, at Bangor University. In this system, which was maintained and monitored independently of the trial statistician or other trial staff, the randomisation was performed by dynamic allocation<sup>75</sup> to protect against subversion while ensuring that the trial maintained good balance to the allocation ratio of 1:1 both within each stratification variable and across the trial. Participants were stratified by centre, gender, age (under 75 vs. 75 and above), and MMSE score (under 24 vs. 24 and above). For validation purposes, additional information was recorded including the participant's trial number, initials, and date of birth, and details of the person requesting the randomisation. Group allocation was notified to the trial therapists.

### ***Blinding***

The trial researchers were blind to participants' group allocation. The importance of maintaining blinding was emphasised in the training of both researchers and therapists. Potential for unblinding could arise through the researchers' contact with participants at the three- and nine-month assessments and through day-to-day contact between researchers and therapists at each site.

To address the potential for unblinding through day-to-day contact between researchers and therapists at each site, we ensured that they were based in different offices and did not share telephones or printers. Arrangements for the follow-up assessment visits by the researcher were made by the therapist for all participants. As the participants and carers could not be blinded to their group allocation, they were specifically asked not to comment at post-intervention and follow-up assessments on the nature of their involvement in the study and not to reveal to the researcher whether or not they had been visited by the therapist. This was explained by the researcher during baseline visits and included in the written information given to participants, and it was reiterated by the therapists when they contacted participants to confirm the dates of the three- and nine-month assessments.

Following each assessment at the three- and nine-month points, the blinded researcher noted to which condition s/he thought the participant had been allocated and how certain s/he was of the allocation.

Due to the nature of the intervention, it was not possible to blind participants and carers to group allocation.

## **Intervention**

Participants allocated to the intervention group received cognitive rehabilitation in addition to usual treatment. Cognitive rehabilitation is an individualised, goal-oriented, problem-solving approach aimed at managing or reducing functional disability and maximising engagement and social participation, in which people with dementia and their carers work together with a health professional over a number of sessions to identify personally-relevant goals and devise and implement strategies for achieving these. In this trial, CR was delivered by appropriately-qualified therapists with experience of rehabilitative interventions. We set out to recruit therapists with psychology, occupational therapy or nursing backgrounds. In the event, our therapists were from occupational therapy and nursing backgrounds. Ten therapists worked on the trial, nine occupational therapists and one nurse; two sites (West Midlands and North-West England) had a change of therapist during the trial.

CR was delivered in ten individual sessions over three months, followed by four maintenance sessions over six months. Carers were involved in part of each session wherever possible, and were kept informed where direct involvement was not possible (for example, because the carer was at work). Involvement of a carer helps to ensure that skills are maintained and applied to novel situations, and facilitates communication about how current or possible future difficulties might be managed.

Over the course of the ten weekly sessions, participants with dementia worked collaboratively with the therapist to address personal rehabilitation goals. Alongside the information from the initial assessment with the BGSi, therapists used the Pool Activity Level Instrument<sup>76</sup> to facilitate their understanding of participants' current level of functioning and potential for goal attainment and support development of a comprehensive formulation. The Pool Activity Level (PAL) instrument provides a framework for care planning with people who have cognitive impairments caused by conditions related to dementia, stroke and intellectual disability.<sup>76,77</sup> The PAL Instrument contains a valid and reliable tool for assessing functional ability in nine domains, with ability graded at one of four levels for each domain. It was recommended in the National Clinical Practice Guideline

for Dementia<sup>78</sup> for activity of daily living skill training and for activity planning. The instrument also contains profiling tools for interpreting the assessment in order to plan and deliver effective, enabling care and support. As part of the assessment for each participant, the therapist completed the PAL Checklist with the carer, and used the resulting profile in planning and implementing the intervention.

Drawing on the goals identified at baseline assessment, up to three behavioural goals were operationalised for each participant, and strategies for addressing these were devised and implemented. These strategies could include environmental adaptations and prompts, use of compensatory memory aids, procedural learning of relevant skills, supported learning of important new information, and restorative learning methods to reactivate prior knowledge. For each goal, a set of strategies was formulated into an individual plan, following discussion of the possible options and selection of the most promising solutions. Following introduction and modelling of strategies and skills during the therapy sessions, the participant and carer worked on the selected goal between sessions following an agreed schedule of activities. Progress was reviewed and the strategies adopted adjusted as necessary on a weekly basis. Goals were introduced one at a time, in a flexible manner depending on rate of progress. Performance for each goal was independently rated at the outset and in week 10 by the participant, carer and therapist.

Work on the identified goals was supplemented by four key therapy components which were considered at appropriate stages across the ten sessions:

1. Developing a problem-solving orientation. Introduction of, and practice in applying, a solution-focused problem-solving approach by following a short sequence of steps to specify and test possible solutions. This was emphasised at the start of therapy and provided a continued focus throughout.
2. Addressing motivational and affective issues. Strategies to tackle motivational and affective responses that could affect the progress of therapy were considered at an early stage:
  - (a) Emotion regulation strategies. Encountering problems with functioning in daily life can result in emotional reactions such as anxiety, distress or frustration. Tackling therapy goals and finding these challenging could potentially trigger similar responses. Therefore it was important to assess participants' strengths and needs in this area and where appropriate introduce, or enhance, emotion

regulation strategies for managing anxiety and other affective reactions, and provide practice in strategy use and application.

- (b) Behavioural activation strategies. Lack of interest, anhedonia, apathy and withdrawal are common and can lead to further loss of skills and confidence. Therefore it was important to assess participants' activity levels and where appropriate to identify plans for increasing engagement in meaningful and enjoyable activity and support implementation of these plans.
3. Addressing cognitive disability. A comprehensive set of skills and strategies was developed to help manage the effects of cognitive disability, complementing the goal-specific problem-solving work:
    - (a) The participant's use of compensatory strategies (e.g. calendars, diaries, reminder systems) was reviewed and a plan for improving strategy use was developed and implemented, which might include both increasing the efficiency of existing strategies and introducing new strategies.
    - (b) The participant's knowledge and use of strategies for retaining new information or improving recall was reviewed, and practice in applying key strategies (mnemonics, semantic association, and spaced retrieval) was provided, enabling the participant to identify a preferred strategy that could be used in everyday situations.
    - (c) Difficulties with attention and concentration can interfere with strategy application. Methods for maintaining or improving attention and concentration were taught and practised.
  4. Carer support. Specific support for the carer included discussion of the carer's well-being and sources of stress, and identification of strategies the carer could use, or enhance, to manage stress more effectively.
  5. Signposting to other sources of support. For both the carer and participant, the therapist explored options for further sources of help and support, and encouraged them to take advantage of these.

The four maintenance sessions were focused on supporting maintenance of gains and encouraging continued goal performance and strategy use.

It was acknowledged that participants' progress with goals would be variable and although it was suggested that participants work on three goals, the number of goals tackled was likely to vary.

Similarly, participants' needs with regard to the other therapy components were expected to vary, and hence both the amount of time spent on these and the stage at which they were introduced could also vary for different individuals. Therapists needed to be flexible in structuring the sessions in order to take account of individual differences. An example session-by-session protocol for the CR intervention, which assumes that three goals are addressed, is shown in *Table 1*.

Table 1. Sample session-by-session cognitive rehabilitation protocol

<b>Session</b>	<b>Participant with dementia</b>	<b>Carer</b>	<b>Between sessions</b>
1	Orientation to the intervention and explanation of between-session tasks; goal 1 selection and rating; emotion regulation strategies; activity monitoring exercise	Orientation and explanation; goal 1 rating; emotion regulation; activity monitoring	Monitor current activities using diary sheet; practise emotion regulation strategies
2	Review of activity monitoring and plans for increasing activities; introduction of solution-focused problem-solving approach; intervention plan for goal 1; emotion regulation	Problem-solving; goal 1 intervention; plans for increasing activities	Agreed tasks for goal 1; practice emotion regulation strategies; develop plans for increasing activities; practice solution-focused approach
3	Progress review for goal 1; progress review for increasing activities; review of adaptations and compensatory strategy use; emotion regulation	Progress review; review of adaptations and compensatory strategy use; increasing activities	Agreed tasks for goal 1; practice emotion regulation strategies; implement plans for increasing activities
4	Progress review for goal 1; progress review for increasing activities; goal selection and rating - goal 2; plan to improve compensatory strategy use	Progress review; goal 2 <sup>1</sup> rating; plan to improve compensatory strategy use	Agreed tasks for goal 1; implement changes to compensatory strategies

5	Progress review for goal 1; progress review for compensatory strategy use; intervention plan for goal 2; strategies for improving attention and concentration	Progress review; goal 2 intervention; strategies for improving attention and concentration	Agreed tasks for goals 1 and 2; changes to compensatory strategies; practice maintaining attention and concentration
6	Progress review for goals 1 and 2; progress review for compensatory strategy use; goal selection and rating - goal 3; improving attention and concentration	Progress review; goal 3 <sup>1</sup> rating; carer well-being	Agreed tasks for goals 1 and 2; practice in maintaining attention and concentration
7	Progress review for goals 1 and 2; intervention plan for goal 3; restorative strategies for taking in new information	Progress review; restorative strategies; carer well-being	Agreed tasks for goals 1, 2 and 3; practice of restorative strategies
8	Progress review for goals 1, 2 and 3; practice with restorative strategies	Progress review; application of restorative strategies	Agreed tasks for goals 1, 2 and 3; practise restorative strategies
9	Progress review for goals 1, 2 and 3; practice with restorative strategies; preparation for ending weekly sessions	Progress review; discuss other sources of help and support	Agreed tasks for goals 1, 2 and 3; practice of restorative strategies; investigate other sources of support
10	Progress review for goals 1, 2 and 3; review of strategy use for emotion regulation, attention and concentration strategies, compensatory strategies and restorative strategies; re-rating of goal performance	Progress review; re-rating of goal performance; review other sources of help and support	Review written information provided about strategies; monitor progress; where appropriate access other sources of support
M1	Re-orientation to problem-solving approach; review of progress with goals; review of strategy use	Problem-solving approach; progress review	Review information given; monitor progress

M2	Problem-solving; review of progress with goals; review of strategy use	Problem-solving; progress review	Review information given; monitor progress
M3	Problem-solving; review of progress with goals; review of strategy use	Problem-solving; progress review	Review information given; monitor progress
M4	Review of progress; goal ratings; reminder of problem solving approach and strategies; goodbyes	Progress review; goal ratings; future orientation; goodbyes	N/a

*M = maintenance session*

### ***Intervention fidelity***

In line with practice recommendations,<sup>79</sup> intervention fidelity was promoted through provision of initial training, a therapy manual, regular centralised supervision, and recording of information about each session in therapy logs:

1. Training. Therapists participated in a two-day training course to prepare them for delivering the intervention at the start of the trial and subsequently attended a refresher training day annually. Co-investigator Mrs Jackie Pool, an occupational therapist, specialist consultant and experienced trainer with expertise in applying rehabilitation in dementia care, delivered initial training to all the trial therapists and guided them throughout the trial in effective and consistent application of the therapy protocol.
2. Therapy manual. Therapists were provided with a detailed therapists' manual that included information about the principles and key elements of CR as well as session by session overviews and references to relevant literature.
3. Supervision. Therapists had monthly individual supervision via video-conferencing and three-monthly face-to-face group supervision meetings with Mrs Pool, with *ad hoc* advice available between meetings if needed. Supervision meetings offered detailed guidance on delivery of CR and enabled ongoing monitoring of fidelity to protocol, with potential concerns discussed and resolved as they were raised. Each supervision session was documented and notes were reviewed annually to ensure appropriate involvement of all therapists in the supervisory process. The Trial Manager attended the quarterly supervision meetings to review progress with therapy provision and regular updates were

given to the Chief Investigator and the Trial Management Group. The supervision meetings were focused on reviewing therapists' plans for achieving individual therapy goals, resolving any specific difficulties relating to individual participants, and reviewing overall progress with implementing the therapy protocol for current participants in the CR group. Advice was also given about achieving a positive therapeutic relationship with participants and managing caseloads. Group meetings provided a platform for sharing best practice and ensuring consistency across sites.

4. Therapy logs. Supervision was facilitated by the use of therapy logs summarising session content (with participant details anonymised). A therapy log was maintained for each participant receiving CR, with notes on session content added by the therapist after each session. The logs were submitted to the supervisor for review prior to supervision sessions and formed a basis for discussion during the sessions.

Treatment fidelity was considered in relation to form and function.<sup>80</sup> While the therapy protocol was prescriptive in relation to the number and length of sessions, and provided guidelines on the typical content of each session (form), a degree of flexibility was required in order to facilitate individual goal attainment, as this was a key aspect of the intervention (function). Therapists could therefore make adjustments to the content of therapy sessions in order to take account of participants' preferences, levels of cognitive and functional ability, and social and family context.

### **Comparator**

The comparator was treatment as usual (TAU). Participants allocated to the control group received usual treatment only, and had no contact with the research team between assessments. TAU consisted of dementia-specific medication where prescribed, and any other services normally provided apart from specific programmes of cognitive rehabilitation or other cognition-focused interventions. TAU could include, for example, routine monitoring by the Memory Clinic, information provision and attendance at drop-in groups or support groups, or carer participation in support groups, as well as receipt of any services provided by voluntary organisations.

## Outcomes

The assessment measures are summarised in *Table 2* which indicates which measures were administered at each time-point by the trial researchers. Assessments were completed by 15 trial researchers, all with backgrounds in psychology, nursing or clinical research. Some sites employed more than one researcher. There were changes of researchers during the trial at three sites (West Midlands, South-West England and London).

Table 2. Summary of assessment measures by time-point

Domain	Measure	Baseline	3 months post baseline	9 months post baseline
<b>Person with dementia</b>				
Goal attainment	BGSI	x	x	x
Satisfaction with goal attainment	BGSI	x	x	x
Quality of life	DEMQOL	x	x	x
Self-efficacy	GSES	x	x	x
Depression	HADS	x	x	x
Anxiety	HADS	x	x	x
Memory	RBMT story recall	x	x	x
Attention	TEA elevator counting	x	x	x
Executive function	DKEFS letter fluency	x	x	x
Co-morbid conditions	Charlson Index	x		
Service utilisation	CSRI	x	x	x
<b>Carer</b>				
Participant's goal attainment	BGSI	x	x	x
Stress	RSS	x	x	x
Quality of life	WHOQOL-BREF	x	x	x
Health status	EQ5D	x	x	x

### ***Demographic details***

At baseline assessment we collected demographic and background information for the person with dementia and carer, including gender, age, relationship between the person with dementia and carer and whether they live together, age at onset of dementia, educational level, social class, and co-morbid health conditions assessed using the Charlson Co-Morbidity Index<sup>81</sup> to provide both the number of conditions and the weighted co-morbidity score. A weighted score of five or more is used to indicate people with particularly high level of comorbidity translating into a high mortality risk. This was intended to provide a profile of the sample and allow us to examine effects of demographic and social variables on treatment efficacy.

### ***Primary outcome measure***

The primary outcome for GREAT was participant-reported goal attainment at three months post-randomisation (the three-month follow-up). Participant-reported goal attainment was also assessed at nine months post-randomisation (the nine-month follow-up). Parallel carer ratings of goal attainment were obtained at both the three-month and nine-month assessments. These ratings were obtained using the structured interview protocol of the Bangor Goal-Setting Interview. The trial researchers participated in a two-day initial training course to prepare them for conducting goal-setting using the BGSI, attended annual refresher training days, and participated in monthly telephone supervision with two of the investigators (from a rotating panel of four) focussed specifically on optimising the goal-setting process.

During initial assessment using the Bangor Goal Setting Interview, participants were asked how memory and other cognitive difficulties impact on (a) everyday tasks, activities and routines, (b) the possibility of engaging in pleasurable and meaningful activities, and (c) social contacts and relationships. For each of these domains, participants rated how important it was to them and how ready they were to try to make changes, in each case using a 1 – 10 scale. This provided a basis for identifying areas where participants would like to make changes or improvements and for setting specific goals. Participants could select up to three goals. Goals were expressed in behavioural terms using SMART principles: specific, measurable, achievable, realistic, and attainable within a defined period of time. Participants described what they want to be able to do and what they are currently doing, and made ratings of current level of goal attainment on a 1 – 10 scale where 1 was unable to do or not currently doing and 10 was able to do well with no difficulty. Participants also rated their satisfaction with this level of attainment on the same 1 –

10 scale where 1 was extremely dissatisfied and 10 was extremely satisfied. The scale was presented in visual format as well as through verbal explanation. Mean levels of attainment and satisfaction were calculated by summing the ratings across all the identified goals and dividing by the number of goals identified.

Carers provided their own descriptions of the person's current functioning and made parallel ratings of attainment on the same 1 – 10 scale. Mean ratings for attainment were calculated by summing the ratings across all the identified goals and dividing by the number of goals.

At the three-month and nine-month follow ups, participants and carers were shown the goal descriptions and baseline ratings for the originally-identified goals and asked to rate current attainment and satisfaction for each goal. Mean attainment and satisfaction ratings were calculated as before.

The key information that the performance and satisfaction ratings provide is an indication of the extent and direction of change. In clinical practice, it is usual for people to remember and consider previous ratings or previously-obtained information when making such ratings, and this can make current ratings more informative and the process of completing the ratings more transparent.<sup>82</sup> However, people with dementia may find it difficult to remember their previous ratings due to their memory difficulties. Various approaches to obtaining follow-up ratings are used in clinical trials, and one question that arises is whether or not participants should have access to their previous ratings when completing a new set of ratings at follow up. Evidence shows that participants prefer to be reminded of previous scores, and that for healthy adults being reminded of previous scores produces no significant differences in ratings compared to not being reminded.<sup>83</sup> People with dementia, due to their difficulties with memory, may benefit more than other groups from being reminded about the rating process and given access to their earlier ratings. Furthermore, in GREAT participants in the CR group made in-session ratings of goal attainment in the sessions prior to the three- and nine-month assessments, and providing a reminder of previous scores to all study participants removed this source of inequity.

### ***Secondary outcome measures for participants with dementia***

Secondary outcomes for the person with dementia at the three- and nine-month follow-ups were self-rated quality of life, self-efficacy and mood, cognitive test scores (memory, attention and executive function) and extent of service utilisation. The following measures were taken at baseline and follow-up.

DEMQOL.<sup>84</sup> DEMQOL is a measure of health-related quality of life of people with dementia, with good internal consistency (Cronbach's alpha 0.87) and test-retest reliability (ICC 0.76) in people with mild to moderate dementia. We used the 28-item interviewer-administered questionnaire for the person with dementia to obtain participants' ratings of their own quality of life. Items are rated on a 4-point scale with potential scores ranging from 28-112. This measure was also used in the economic evaluation, drawing on the algorithm that has been developed to generate quality-adjusted life year (QALY) scores from DEMQOL scores.<sup>85</sup>

Generalized Self-Efficacy Scale (GSES).<sup>86</sup> This 10-item scale assesses a general sense of perceived self-efficacy, which is the potential to influence one's situation through one's own actions. Responses are made on a 4-point scale. Responses to all 10 items are summed to yield the final composite score with a range from 10 to 40. Cronbach's alphas range from .76 to .90.<sup>87</sup>

Hospital Anxiety and Depression Scale (HADS).<sup>88</sup> The HADS contains 14 items forming subscales for anxiety and depression. Each item is rated on a four-point scale, giving maximum scores of 21 for anxiety and for depression. Scores of 11 or more on either subscale are considered to be a significant 'case' of psychological morbidity, with scores of 8–10 classified as 'borderline' and 0–7 'normal'. The HADS has been employed and validated in studies of people with dementia and carers.<sup>89,90</sup>

Brief cognitive assessment battery. This consisted of brief tests of memory, attention and executive function, suitable for people with early-stage dementia, each taking less than 5 minutes to administer:

(a) Memory: Rivermead Behavioural Memory Test (RBMT),<sup>91</sup> story recall sub-test. The RBMT is a well-established ecologically-valid test of everyday memory. In the story recall task the researcher reads out a short story, similar to a brief report of a newsworthy event in a daily newspaper, and the participant is asked for immediate and, after 20 minutes, delayed recall of the content. Recall is scored following a standard protocol (inter-rater reliability > 0.9) with a maximum possible score of 21 for the immediate and for the delayed component. Four parallel versions of equivalent difficulty are available to permit reassessment without the risk of practice effects; practice effects are not anticipated with test-retest intervals of three and six months, but as a precaution we used a different version at each time-point. Raw scores were used in the

analysis as they provide a greater range than the condensed standardised profile score that is used in calculation of the overall RBMT score.

(b) Attention: Test of Everyday Attention (TEA),<sup>92</sup> elevator counting and elevator counting with distraction subtests. The TEA is a well-established ecologically-valid test of everyday attention, with subtests assessing different components of attention. The elevator counting subtest assesses sustained attention. Participants are required to count a short string of monotonous tones and give the total number. Seven strings are presented, and the total score is the number of strings correctly counted. The elevator counting with distraction subtest assesses auditory selective attention. Ten strings of tones are presented, this time also including distractor (high-pitched) tones that are not to be counted. The total score is the number of strings correctly counted. Three equivalent versions of each subtest are available to permit reassessment without the risk of practice effects; as above, practice effects were not anticipated but as a precaution we used a different version at each time-point.

(c) Executive function: Letter fluency sub-test of the Delis-Kaplan Executive Function System (D-KEFS).<sup>93</sup> D-KEFS consists of a set of standardised tests of executive function. The verbal letter fluency task evaluates the executive sub-domains of initiation, response generation and inhibition<sup>94</sup> as well as drawing on semantic memory and language ability. In this task, the participant is asked to list as many words as possible beginning with a specific letter of the alphabet in a one-minute period, excluding proper nouns and repetitions. Three letters, F, A and S, are used. The total number of correct responses to the three letters is the unit of analysis. This task has been extensively examined in people with early-stage dementia.<sup>95</sup> Evidence suggests that even in healthy participants there are no practice effects for most components of this task even at test-retest intervals of less than two weeks; there are minimal practice effects for the switching component with test-retest intervals of less than two weeks, but not with longer intervals.

Client Services Receipt Inventory (CSRI),<sup>96</sup> completed by the person with dementia and carer together. The CSRI provides a template that can be adapted to the needs of each specific study. In GREAT, the CSRI focused on both the person with dementia and the carer. Respondents were asked about the use of health and social care services by the person with dementia in the three-month period preceding each assessment. The questions cover contact with a range of health and social care professionals, prescription of medications, hospital appointments and stays, participation in local authority funded activities such as day centres, participation in activities run by voluntary organisations, and the contribution of informal carers. Questions to examine the

nature and extent of any dementia-specific treatment received from the Memory Clinic were included. Carers were asked about their own accommodation, the impact of caring on employment (where applicable), involvement of others in the person's care, and costs involved in accompanying the person with dementia to appointments.

### *Secondary outcome measures for the carer*

Outcomes of interest for carers were stress, quality of life and health status, assessed with the following self-rated measures at baseline and at three- and nine-month follow-up.

Relatives' Stress Scale (RSS).<sup>97</sup> The RSS is a 15-item dementia-specific measure of caregiver stress with items rated on a 5-point Likert scale and summed (score range 0-60). A higher overall score indicates higher levels of caregiving-specific stress.

WHO Quality of Life – BREF (WHOQOL-BREF).<sup>98</sup> The WHOQOL-BREF is a 26-item scale assessing perceived quality of life, with each item scored on a 5-point Likert scale (low of 1 to high of 5) giving scores in four domains: environment (raw score range 8-40), social relationships (raw score range 3 - 15), psychological health (raw score range 6-30) and physical health (raw score range 7-35). Scores within each domain are summed and the mean domain score is calculated (range 1-5); this is multiplied by 4, giving a score in the range 4-20.

EuroQOL (EQ5D).<sup>99</sup> The EQ5D is a standardised measure of health status and health outcome, applicable to a wide range of health conditions. In the first section, the respondent is asked to select one of three options for each of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each dimension, the three response options are coded on a 3 point scale from 1 (no problems) to 3 (unable to perform/extreme problem). This yields a descriptive profile (e.g. 11232) across the five dimensions. Based on the EQ5D descriptive categories, a summary index can be calculated.<sup>100</sup> Each level in each dimension has a weight attached and the summary index is calculated by deducting the appropriate weights from 1. EQ5D3L has an index score from -0.594 to 1.0, with a higher index indicating a higher quality of life and a negative index indicating a quality of life that is considered by some respondents as 'worse than death'. The second part of the measure is a visual analogue scale for self-rating of health-related quality of life ('your health state today') on a 0 – 100 scale. This measure was included so that the EQ5D score could be used to generate QALY scores using societal weights.

## **Process evaluation measures**

Process evaluation addressed firstly the process of goal-setting and secondly the process of therapy. A summary of process evaluation measures is provided in *Table 3*.

### ***The goal-setting process***

All participants, irrespective of allocation, identified personal goals in the baseline assessment. For each goal they indicated how important it was to them and rated their readiness to change. We extracted details of the goals that participants identified at baseline, together with the corresponding ratings.

### ***The process of therapy***

For participants allocated to the cognitive rehabilitation intervention, we evaluated the process of therapy through several means, from the perspectives of the therapists and of the participants and carers.

#### Goals addressed in therapy

For every goal originally set at baseline by participants subsequently randomised to cognitive rehabilitation, we noted whether the goal was addressed in therapy, any adjustments to the original phrasing or modifications made by the therapist in order to operationalise the goal, and details of the corresponding ratings by the participant and carer.

#### Therapist perceptions of goal attainment

Therapist perceptions of goal attainment were captured in two ways.

Firstly, the therapist made in-session parallel ratings of goal attainment alongside the participant and carer when each goal was introduced, when work on therapy goals concluded (usually in session 10) and at the final maintenance session (usually session 14).

Secondly, the therapist applied a simplified goal attainment scaling procedure<sup>26</sup> for each goal addressed in the intervention. When starting work on the goal, clearly-specified behavioural indicators of full and partial goal achievement were established. The therapist subsequently rated progress according to these criteria following session 10 and again following session 14 (maintenance session 4).

### Effectiveness of supervision

The supervision process was reviewed through annual evaluation of supervision session attendance rates and rates of submission and review of therapy logs to ensure appropriate involvement of all therapists in the supervisory process.

### Therapist perspective on the process of therapy

Following each session, therapists noted relevant information in the therapy log. Therapy logs contained the therapists' notes from each session, with comments on participants' progress in relation to goals and other pre-specified topics relating to intervention delivery. The logs were not intended to provide a comprehensive summary of every session. Each therapist completed a separate record for each session. See *Appendix 1* for full details of the topics recorded in the therapy logs.

### Therapist experience of providing the intervention

A focus group was held with six therapists in June 2014, during an annual training event for the trial team held at the end of the therapists' first year. The aim was to explore their experience of delivering the intervention.

### Participant treatment compliance

Treatment compliance was indexed by the number of sessions completed for each participant, up to the maximum of 14 (ten therapy sessions and four maintenance sessions).

### Participant and carer experience of the intervention

In three sites where an independent researcher not involved in the trial was available to contribute, a consecutive series of participants and carers completing the trial in the CR arm were approached after the nine-month follow-up and invited to participate in an interview to reflect on their experience of the intervention. The sites were Bangor, Cardiff and Manchester. The interviews addressed the following questions:

- How did participants and carers experience the intervention?
- What were their overall perceptions, how useful did they find it, and what did they feel about the degree of effort required?
- What impact, if any, did the participants and carers feel the intervention had on their everyday life?

The interview schedule is presented in *Appendix 2*.

Table 3. Summary of process evaluation measures

Source	Measure	Time-point (where applicable)
Whole sample		
BGSi	Goals set	Baseline
	Goal ratings – importance	Baseline
	Goal ratings – readiness to change	Baseline
CR group		
Therapy logs	Goals addressed	
	Adjustments made to BGSi goal statements	
	Goal attainment ratings by person with dementia	When work on goal introduced and in session 10
	Goal attainment ratings by carer	When work on goal introduced and in session 10
	Goal attainment ratings by therapist	When work on goal introduced and in session 10
	Therapist selection of goal attainment scaling indicators	In sessions 10 and 14
	Therapist rating of carer involvement in therapy	Following session 14
	Therapist rating of confidence in addressing participants' goals	Following session 14
Compliance – number of sessions participant received	Following session 14	
Therapy logs and therapist supervision	Therapist adherence to protocol	
Focus group with therapists	Therapist experience of delivering the therapy	
Interviews with participants and carers	Participant and carer experience of CR	After the 9 month follow-up

## **Data management**

A detailed data management plan covering all the quantitative data gathered in the trial was developed in collaboration with the CTU and was followed throughout the trial. Quality assurance procedures included audit of sites, random checks of accuracy of data entry, and ongoing monitoring of scoring accuracy.

We used the online MACRO<sup>101</sup> data management system, managed by NORTHWORTH CTU. A range of built-in checks prevent the entering of invalid information into MACRO. Accuracy of data entry was examined during initial site visits and 5% of data at each time-point was cross-checked against hard copy case report forms. Additional checks were conducted centrally, including missing data verification, searches for unusual patterns, and identification of unexpected data ranges. These checks indicated a high level of accuracy in data entry. GREAT trial researchers received training in administering all outcome measures and in following data management procedures at the start of the trial and thereafter through annual refresher training days, and were provided with a detailed researcher's handbook together with a number of other resources: a guide to using the BSGI, an administration and scoring guide for all other measures, a MACRO user guide, randomisation instructions, details of the safety monitoring and reporting procedure, and template spreadsheets for recording and managing contact with participants. The researchers recorded assessment data manually during the participant visits and entered anonymised data item-by-item into MACRO. GREAT trial therapists received training in data management procedures and use of the MACRO system at the start of the trial and this was updated during their annual refresher training. In addition to the therapists' manual, they were provided with a MACRO user guide, randomisation instructions, details of the safety monitoring and reporting procedure, and template spreadsheets for recording and managing contact with participants. The therapists entered into MACRO basic information about the participant, details of the PAL assessment, date and length of each therapy session and details of any missed sessions, details of goals worked on, ratings of goal attainment, goal attainment scaling indicators, and ratings of participant awareness and response to therapy.

Information about adverse events was recorded in the MACRO system by both researchers and therapists or provided on paper-based forms to the co-ordinating centre where it was entered into the MACRO system.

A separate plan covered management of the data gathered by the therapists and of the qualitative interview data, and this was overseen by the trial manager. Therapy Record Sheets for each participant (Therapy log, Goal Rating sheet, and Goal Intervention sheet) were stored within a secure shared drive where the documents could be updated by the therapists following each therapy session and accessed by the supervisor to inform the monthly supervisory sessions. A similar data sharing strategy was used to manage interview sub-study data. In Bangor we used a shared drive accessed with WinSCP software (<https://sourceforge.net/projects/winscp>)<sup>102</sup> or an Oracle Secure Global Desktop platform (Oracle Corporation, Redwood Shores, California, USA),<sup>103</sup> and in Exeter we used an Alfresco web-based platform (Alfresco Software Inc., San Mateo, California, USA).<sup>104</sup>

### **Outcome analyses**

The primary statistical analysis was based on the treatment as allocated principle and conducted as an Intention to Treat (ITT) analysis. The trial statistician conducted analyses blind to allocation, not knowing which of the two groups had received the intervention. The statistician was unblinded only after the primary analysis had been completed and approved by the Trial Steering Committee. Analyses were conducted in R v.3.3.1 (R Foundation for Statistical Computing, Vienna, Austria)<sup>105</sup> and IBM SPSS v.22 (IBM Corp., Armonk, New York, USA).<sup>106</sup>

### ***Primary outcome***

The main analysis was an analysis of covariance (ANCOVA) adjusted for baseline score, allocation group and the stratification variables (age, gender, MMSE score and centre) which were treated as random effects. Analysis used a mixed-effects model. However, standardised effect size estimates (d) and confidence intervals (CIs) were based on a fixed effect size model as these parameters cannot be derived from a mixed-effects model. Effect sizes were calculated by converting eta squared to r and then converting r to d using the formula provided by McGrath and Meyer.<sup>107</sup>

Additional regression modelling was undertaken to identify factors that could be important in attaining and maximising the observed effects. This was done separately for people with dementia and carers. For the participants with dementia, in addition to the stratification variables (age, gender, MMSE score, and centre), the following factors were retained in the final model on a priori theoretical grounds: diagnosis, medication, education and comorbidity. The remaining factors (marital status, living situation, first language, ethnicity, socio-economic status and self-rated health) were each subjected to a simple regression analysis to determine whether the given factor was significantly associated with outcome; if so, that factor was added to the regression model. For the carers, the following factors relating to the carer were included in the final model on a priori theoretical grounds: relationship with the PwD, age, gender and education. The remaining factors (first language, ethnicity, socio-economic status and self-rated health) were each subjected to a regression analysis to determine whether the given factor was significantly associated with outcome; if so, that factor was added to the regression model.

### ***Secondary outcomes***

The main analyses for the secondary outcomes used ANCOVA adjusted for baseline score, allocation group and stratification variables.

We conducted exploratory analyses to examine the influence of demographic variables on key secondary outcomes at baseline and follow-up. For the person with dementia, we examined the influence on BGSi performance ratings at nine months, and BGSi satisfaction ratings, of centre, age, gender, educational level, social class, ethnicity, living situation, diagnosis, baseline MMSE score, whether taking medication for dementia, co-morbidity, and effectiveness of blinding. For the carer, we examined the influence on carer stress of age, gender, education, social class, ethnicity, relationship to the participant, whether co-resident with the PwD, and self-rated health status.

### ***Sensitivity analyses***

Sensitivity analyses for the primary and main secondary outcomes were planned based on:

1. Treatment received irrespective of group allocation. This analysis was planned in order to compare the outcomes of statistical analyses where the group allocation was determined by random assignment with the outcomes of statistical analyses where group allocation was based on the treatment received. Because the group allocation

and treatment received was 100% consistent, a treatment received analysis was not necessary.

2. Complete case with no data imputation. We compared the outcomes of statistical analyses that included both imputed and complete case data with the outcomes of statistical analyses that included complete cases only. This proposed comparison involved appraising whether the results from the complete case data analysis and the imputed data analysis are substantially different.

### ***Adherence***

For the cognitive rehabilitation group, we examined the impact of the ‘dose’ of treatment received on primary and secondary outcomes at three and nine month follow up. Adherence was calculated as the number of therapy sessions completed. The analysis was intended to be conducted on the basis of treatment received rather than group allocation.

### ***Effectiveness of blinding***

We examined whether the researcher’s ability to correctly surmise the participant’s group allocation was associated with primary and secondary outcomes at three and nine month follow-up, and whether this ability varied by centre or according to any participant characteristics.

### **Process evaluation analyses**

We undertook a range of process evaluation analyses. These are briefly detailed below. A fuller account of the methods is presented along with the findings in *Chapter 4*.

### ***Nature of goals identified***

To better understand the concerns of participants and the areas addressed by therapists in the intervention, we examined the goals set by participants in the trial and used descriptive content analysis to classify them into groups based on the content and focus of the goal.

### ***Goal-setting and goal attainment***

We compared the goal attainment ratings made by the participant, carer and therapist at each stage and the changes in these ratings between the point where work on the goal was introduced and sessions 10 and 14 in order to examine similarities and differences in

perspective regarding level of functioning and change in functioning. We also compared the goal attainment ratings with the therapists' goal attainment scaling process (which classified goals as fully or partially achieved, with a percentage score) to determine whether these two procedures yielded consistent information.

### ***Intervention fidelity***

Fidelity of form was evaluated in relation to the provision of core elements of the intervention. This was indexed by number and length of therapy sessions completed and number of goals operationalised and addressed.

Fidelity of function was considered in relation to the therapists' ability to deliver the intervention in a flexible, person-centred manner adapted to the needs of each individual participant. In order to evaluate the level of flexibility applied by the therapists we reviewed the times at which additional goals were introduced and the nature and extent of modifications to goals formulated in the baseline assessment. As fidelity of function was promoted through regular supervision, with the aid of the detailed therapy logs produced by therapists, we also assessed attendance at supervision sessions and rates of completion of therapy logs.

### ***Therapist perspectives on the intervention and factors associated with positive outcomes***

We explored what factors were thought to influence treatment outcome and the characteristics of participants who seemed most and least likely to benefit from the intervention, and why, with two sets of data: data from a focus group conducted with the therapists and a selection of therapy logs.

We analysed data from the focus group conducted with the therapists to identify their views about delivering the intervention and about what factors influence treatment outcome. From existing literature we identified a number of factors that we expected the therapists to consider; these were level of cognitive impairment, health status, awareness of difficulties, motivation, degree of carer involvement and family circumstances. We used a deductive approach, coding the data in relation to these factors, but also adopted an inductive perspective allowing new factors to emerge.

The therapy logs provided a rich source of data about the process of therapy for each individual participant and were analysed to identify significant features and processes of the intervention. We analysed therapy logs for the 25 participants with the best outcomes on the BGSi and the 25 participants with the worst outcomes on the BGSi using matrix analysis to examine which factors identified from the focus group data were noted as relevant in the therapy logs. This analysis was also inductive, allowing additional factors to emerge from the therapy logs. The aim was to understand more about which participants were or were not likely to benefit from the intervention.

### ***Participant and carer experience of the intervention***

We analysed the transcribed recordings of the interviews with participants and carers using thematic analysis. The aim was to identify level of satisfaction with the intervention, and any features that contributed to greater or lesser degrees of satisfaction.

### **Feasibility of implementation**

Towards the end of the trial, once recruitment had finished and therapists had completed the majority of the intervention work, sites were invited to consider examining the feasibility of future implementation of cognitive rehabilitation within their routine services. This was achieved by therapists offering training in the approach to groups of clinical staff and supporting these staff to use the approach. This initiative was evaluated informally through reports from the local Principal Investigators. The findings are described in *Appendix 14*.

### **Economic analyses**

The main economic evaluation was a cost-effectiveness analysis (CEA), conducted first from a health and social care perspective and second from a societal perspective. The methods and results for the economic analyses are described in *Chapter 5*.

### **Patient and Public Involvement**

Two Alzheimer's Society Research Network volunteers were involved as advisors to the pilot trial, contributed to development of the GREAT trial protocol, and served as experts by experience on the Trial Steering Committee (TSC), where they were joined by a third Research Network Volunteer.

## **Changes to protocol**

There were two changes to the protocol.

The trial was initially set up in six sites. To meet our recruitment target, each site was requested to randomise 80 participants, representing approximately three participants per month over a 27-month recruitment period. All centres regarded this recruitment target as feasible. However, it proved challenging for some sites, and although other sites did meet and in some cases exceed targets (Bangor and Bath agreed to increase their target to 90 participants each), under-recruitment was a concern. Attrition was lower than expected, suggesting that randomisation targets could be reduced, but the funder advised that the original estimate should be retained and no alteration made to the target sample size. To address the likely shortfall in recruitment, two additional sites were identified with a target of 25 randomisations each: Kent and Medway NHS Partnership Trust and Northumberland, Tyne and Wear NHS Foundation Trust. Inclusion of these sites was agreed with the funder and approved as an amendment by Wales REC 5. The two sites achieved their first randomisations in June 2015, allowing for a 10 month recruitment period in each site.

The process evaluation component of the data analysis plan was initially envisaged to include (a) convergent evidence about changes in goal performance in the cognitive rehabilitation group derived from in-session ratings and therapist assessment of goal attainment; (b) intervention fidelity on the part of the therapists; and (c) treatment compliance in terms of number of sessions received by the participant. This was expanded following discussion within the trial team and with the steering group. Qualitative interviews were added in order to capture the experience and perspectives of participants, carers, therapists and researchers; this was approved as an amendment by Wales REC 5. A subset of participants and carers was interviewed following completion of the trial after the nine-month follow-up by an independent researcher who was not part of the trial team in order to elicit the participants' and carers' experience of the intervention, and a focus group was conducted with the therapists to capture their experience of delivering the therapy.

## Chapter 3. Results

### Recruitment and participant flows

The flow of participants through the GREAT trial is shown in the CONSORT diagram in *Figure 2*.

Participants were recruited in eight NHS sites in England and Wales: Bangor, Cardiff, London, Kent, Bath, Birmingham, Manchester and Newcastle. Recruitment began on 1<sup>st</sup> April 2013 and was completed by 31<sup>st</sup> March 2016. Follow up assessments were completed by 31<sup>st</sup> December 2016. Cumulative recruitment figures are provided in *Appendix 3*.

Overall, 1731 participants were identified as potentially eligible, of whom 583 (34%) were screened for eligibility and 538 (31%) were seen for baseline assessment. Following baseline assessment, 475 participants (88% of those assessed) were randomised to either CR (n = 239) or TAU (n = 236). Of those who did not proceed, a small proportion had difficulty identifying any goals to work on as they felt content with their current situation and did not think they had any particular needs. One participant who did not meet diagnostic criteria was incorrectly randomised (to CR) and was withdrawn from the analysis; this participant had a diagnosis of Parkinson's disease dementia. All other participants received their allocated condition. Six participants in the CR group requested withdrawal from the intervention after at least two sessions but remained in the trial to complete follow-up assessments. One person withdrew after two sessions, three people withdrew after four sessions, one person withdrew after ten sessions and one person withdrew after 11 sessions. Reasons for withdrawal were stressful life circumstances, lack of motivation to engage in therapy, comorbid health problems and rapid cognitive decline.

Retention in the trial was 94% at three months and 90% at nine months. The overall figure of 10% attrition was considerably lower than the conservative 27% estimate used in the sample size calculation. The trial was adequately powered, and would have been adequately powered even with a smaller sample size consisting of 385 participants randomised.

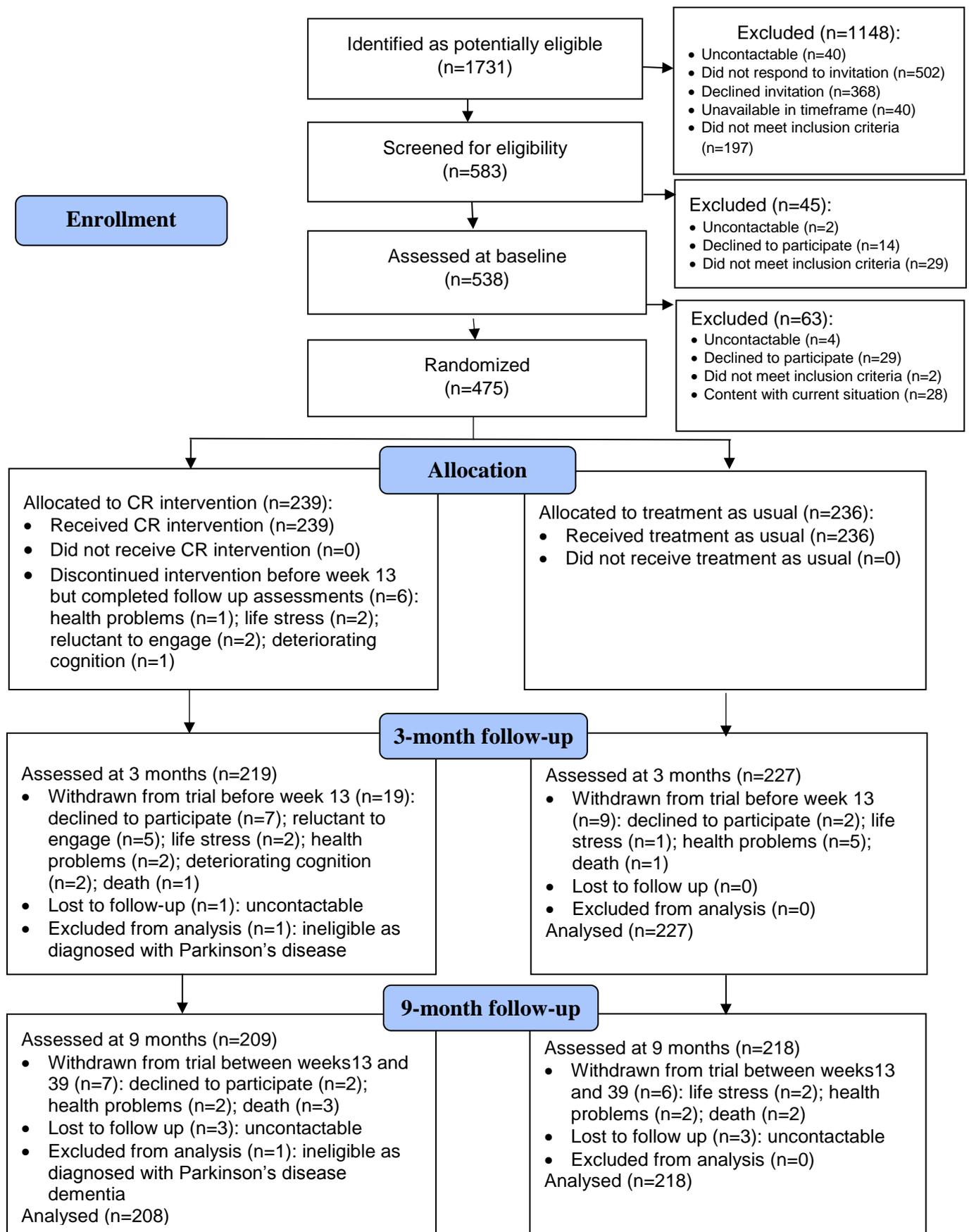


Figure 2. CONSORT chart showing participant flow through the trial

## Sample characteristics

The demographic characteristics of participants and carers are summarised in *Table 4*. Details are provided for the sample as a whole and separately for CR and TAU groups. Demographic characteristics are presented in more detail in *Appendix 4*.

Table 4. Demographic characteristics of the sample

### (a) Participants with dementia

Measure	Whole sample n=474	CR n=238	TAU n=236
Age	78.56 (7.07); 53 to 95	78.25 (7.13); 53 to 95	78.87 (7.01); 55 to 95
Sex (male)	248 (52.3)	124 (52.1)	124 (52.5)
Ethnicity:			
White	457 (96.4)	226 (95.0)	231 (97.9)
Mixed / Multiple ethnic group	2 (0.42)	2 (0.84)	0 (0)
Asian / Asian British	6 (1.27)	3 (1.26)	3 (1.27)
Black / African / Caribbean / Black British	7 (1.48)	5 (2.10)	2 (0.85)
Other ethnic group	2 (0.42)	2 (0.84)	0 (0)
First language (English)	445 (93.9)	222 (93.3)	223 (94.5)
Marital status (married)	330 (69.6) n=474	167 (70.2) n= 238	163 (69.1) n=236
Years of education	12.57 (3.37); 5 to 33 n=471	12.57 (3.33); 6 to 24 n=236	12.58 (3.42); 5 to 33 n=235
Occupational status:			
I Professional	52 (11)	23 (9.7)	29 (12.3)
II Managerial/technical	157 (33.1)	81 (34)	76 (32.2)
III N Skilled, non-manual	103 (21.7)	54 (22.7)	49 (20.8)
III M Skilled, manual	80 (16.9)	41 (17.2)	39 (16.5)
IV Partly skilled	50 (10.5)	24 (10.1)	26 (11)
V Unskilled	32 (6.8)	15 (6.3)	17 (7.2)

*Data are mean (SD) range, or n (%)*

## (b) Carers

<b>Measure</b>	<b>Whole sample n=474</b>	<b>CR n=238</b>	<b>TAU n=236</b>
Relationship to participant with dementia:			
Spouse/partner	331 (69.8%)	167 (70.2%)	164 (69.5%)
Adult child (including in-law)	118 (24.9%)	58 (24.3%)	60 (25.4%)
Other	25 (5.3%)	13 (5.5%)	12 (5.1%)
Age	68.74 (13.01); 17 to 92	68.45 (13.76); 17 to 92	69.04 (12.24); 23 to 92
Sex (male)	142 (30%)	75 (31.5%)	67 (28.4%)
Ethnicity:			
White	449 (94.7)	224 (94.1)	225 (95.3)
Mixed / Multiple ethnic group	5 (1.1)	4 (1.7)	1 (0.42)
Asian / Asian British	10 (2.1)	4 (1.7)	6 (2.5)
Black / African / Caribbean / Black British	8 (1.7)	6 (2.5)	2 (0.85)
Other ethnic group	2 (0.42)	0 (0)	2 (0.85)
First language (English)	443 (93.5%)	222 (93.3)	221 (93.6%)
Marital status (married)	393 (82.9%)	187 (78.6%)	206 (87.3%)
Years of education	13.49 (3.52); 4 to 26; n=472	13.67 (3.45); 5 to 25; n=237	13.32 (3.58); 4 to 26; n=235
Occupational status:			
I Professional	49 (10.3%)	30 (12.6%)	19 (8.1%)
II Managerial/technical	158 (33.3%)	74 (31.1%)	84 (35.6%)
III N Skilled, non-manual	137 (28.9%)	64 (26.9%)	73 (30.9%)
III M Skilled, manual	47 (9.9%)	24 (10.1%)	23 (9.7%)
IV Partly skilled	55 (11.6%)	27 (11.3%)	28 (11.9%)
V Unskilled	20 (4.2%)	14 (5.9%)	6 (2.5%)
NA	8 (1.7%)	5 (2.1%)	3 (1.3%)

Data are mean (SD) range, or n (%)

We examined whether participants who were randomised but dropped out before the three-month follow up had different demographic characteristics and substantially different scores on the primary outcome to the participants who completed the three-month follow-up. None of the comparisons between non-completers and completers were statistically significant ( $p < 0.05$ ) after correcting for multiple comparisons (see *Appendix 5*).

The participants' mean age was 78.56 years, with the age of individual participants ranging from 53 to 92 years. Only 20 (4.2%) were aged under 65 on entry to the trial, and 4 (0.8%) were aged under 60. Most (69.6%) were currently married, and 21.3% were widowed. Just over half were male (52.1%) and the overwhelming majority were of white ethnicity (95%) and had English as their first language (93.3%). On average they had 12.57 years of education, but nearly half (42.2%) had left education by the age of 16 and only 19% had completed higher education. Two-thirds had a previous occupational background that was professional, managerial/technical or skilled non-manual.

The majority of carers were spouses or partners of the participants (70%) and another 25% were adult children (or sons or daughters-in-law). The carers' mean age was 68.74 years. They were predominantly female (70%), currently married (82.9%), and of white ethnicity (94.8%) with English as their first language (93.5%). They were a relatively well-educated group with a mean of 13.49 years of education, although one-third (32.9%) had left education by age 16 and only a quarter (25.3%) had engaged in higher education, and 72.5% had a current or previous occupational background classed as professional, managerial/technical or skilled non-manual. Counter to protocol, there were four paid carers in the sample. One was a long-term, live-in housekeeper with a longstanding knowledge of the participant, who was not specifically employed to provide dementia care and was considered appropriate for inclusion. Three were paid dementia care workers, of whom two, a support worker and an activities co-ordinator, provided both baseline and follow-up data; these data were retained in the analyses on the advice of the trial statistician.

Clinical characteristics are shown in *Table 5*. Over half the sample (59.5%) had a diagnosis of Alzheimer's disease, around a quarter had a diagnosis of mixed Alzheimer's and vascular dementia (24.5%), and the remainder (15.6%) had a diagnosis of vascular dementia.

Table 5. Baseline clinical characteristics of the sample

(a) Participants with dementia

Measure	Whole sample n=474	CR n=238	TAU n=236
Diagnosis:			
Alzheimer's disease	284 (59.9)	139 (58.4)	145 (61.4)
Vascular dementia	74 (15.6)	43 (18.1)	31 (13.1)
Mixed	116 (24.5)	56 (23.5)	60 (25.4)
MMSE	23.82 (3.02); 18 to 30	23.89 (3.04); 18 to 30	23.75 (3.02); 18 to 30
Charlson Co-Morbidity Index weighted score	2.52 (1.47); 1 to 11	2.49 (1.47); 1 to 11	2.55 (1.48); 1 to 10
Subjective rating of health:			
Excellent	39 (8.2)	20 (8.4)	19 (8.1)
Very good	125 (26.4)	65 (27.3)	60 (25.4)
Good	159 (33.5)	77 (32.4)	82 (34.7)
Fair	121 (25.5)	61 (25.6)	60 (25.4)
Poor	30 (6.3)	15 (6.3)	15 (6.4)
DEMQOL	92.3 (12.33); 39 to 112; n=472	92 (12.9); 39 to 112; n=237	92.61 (11.75); 39 to 112; n=235
GSES	30.94 (5.09); 11 to 40; n=469	30.75 (4.81); 13 to 40; n=237	31.13 (5.35); 11 to 40; n=232
HADS:	n=472	n=238	n=234
Depression	3.77 (2.79); 0 to 14	3.87 (2.83); 0 to 12	3.67 (2.75); 0 to 14
Anxiety	5.14 (3.64); 0 to 16	5.29 (3.67); 0 to 16	4.98 (3.62); 0 to 16
RBMT:	n=473	n=237	n=236
Immediate recall	2.66 (2.11); 0 to 11.5	2.58 (2.1); 0 to 9.5	2.73 (2.12); 0 to 11.5
Delayed recall	0.38 (1.96); -1 to 9	0.39 (1.94); -1 to 8	0.37 (1.97); -1 to 9
TEA:			
Elevator counting	6.39 (1.16); 0 to 7 n=463	6.35 (1.27); 0 to 7 n=232	6.42 (1.05); 1 to 7 n=231
Elevator counting with distraction	4.55 (2.72); 0 to 9; n=448;	4.39 (2.68); 0 to 9; n=223	4.72 (2.75); 0 to 9; n=225

DKEFS verbal fluency	26.27 (11.82); 2 to 64; n=470	25.78 (11.61); 2 to 64; n=235	26.77 (12.03); 3 to 58; n=235
----------------------	----------------------------------	----------------------------------	----------------------------------

Data are mean (SD) range, or n (%)

(b) Carers

Measure	Whole sample n=474	CR n=238	TAU n=236
Stress (RSS)	18.96 (9.44); 0 to 52; n=471	18.85 (9.04); 2 to 46; n=236	19.08 (9.83); 0 to 52; n=235
Subjective rating of health:			
Excellent	68 (14.3)	30 (12.6)	38 (16.1)
Very good	113 (23.8)	59 (24.8)	54 (22.9)
Good	179 (37.8)	89 (37.4)	90 (38.1)
Fair	83 (17.5)	42 (17.6)	41 (17.4)
Poor	31 (6.5)	18 (7.6)	13 (5.5)
WHOQOL domains:			
Physical	15.34 (2.95); 5 to 20; n=470	15.3 (3.0); 5 to 20; n=237	15.37 (2.9); 7 to 20; n=233
Psychological	15.14 (2.15); 8 to 20; n=470	15.13 (2.19); 8 to 20; n=237	15.15 (2.1); 8 to 20; n=233
Social	n=468; 15.13 (2.66); 5 to 20; n=468	15.19 (2.67); 5 to 20; n=235	15.07 (2.66); 7 to 20; n=233
Environmental	16.43 (2.15); 10 to 20; n=470	16.35 (2.3); 10 to 20; n=237	16.52 (1.99); 10 to 20; n=233
EQ5D3L:			
Index	0.78 (0.25); -0.18 to 1; n=468	0.77 (0.25); -0.18 to 1; n=235	0.79 (0.24); -0.07 to 1; n=233
VAS	74.48 (19.95); 0 to 100; n=467	73.52 (20.95); 1 to 100; n=234	75.44 (18.9); 0 to 100; n=233

Data are mean (SD) range or n (%)

Participants' mean MMSE score was 23.82, with a range from 18 to 30. Over two-thirds of participants (68%) rated their health as good, very good or excellent, and only 6.3% rated their health as poor. However, levels of co-morbidity were high with 312 participants (65.8%) having at least one other condition in addition to dementia. The mean Charlson Co-Morbidity weighted score was 2.52, with 44 participants (9.28%) identified as having a high mortality risk, which is a score of five or more.<sup>81</sup> Full details of comorbidity are presented in *Appendix 4*. Three-quarters of the carers (75.9%) rated their health as good, very good or excellent, and only 6.5% rated their health as poor. On average the carers recorded low levels of stress and good scores for quality of life, although there was individual variability.

Eight participants with dementia (1.7%) had a HADS Depression score of 11 or above, indicating clinical levels of depression (6 in the CR group (2.5%) and 2 in the TAU group (0.9%). Forty-seven participants with dementia (10%) had a HADS Depression score of 8 to 10, indicating possible depression (22 in the CR group (9.2%) and 25 in the TAU group (10.7%). Forty-one participants with dementia (8.7%) had a HADS Anxiety score of 11 or above, indicating clinical levels of anxiety (23 in the CR group (9.7%) and 18 in the TAU group (7.7%). Sixty-six participants with dementia (14%) had a HADS Anxiety score of 8 to 10, indicating raised anxiety levels (33 in the CR group (13.9%) and 33 in the TAU group (14.1%). Full details of HADS depression and HADS anxiety scores are shown in *Appendix 4*.

### **Intervention adherence in the CR group**

The CR intervention consisted of ten weekly sessions followed by four maintenance sessions given at 6-week intervals; all sessions were conducted in participants' own homes. Details of the number of sessions completed are summarised in *Table 6*.

Ninety percent of participants randomised to CR completed at least ten sessions, with 166 (70%) completing all 14 sessions. Another 46 participants (19.32%) completed between 10 and 13 sessions; sessions were missed due to difficulty in scheduling therapy sessions in the available timeframe (n=40), for example due to sickness of the participant, carer and/or therapist, or therapist annual leave, or because they withdrew from therapy (n=2) or from the trial entirely (n=4). Only 26 participants (10.92%) completed fewer than ten sessions: 20 of these withdrew from the trial (3 of these before the first session), and six remained in the trial

to complete follow up assessments (4 participants discontinued therapy, one completed only eight sessions due to the delayed start of a new therapist following a staff change at the site, and one participant did not receive any sessions due to the therapist being on sick leave for an extended period). One ineligible participant with a diagnosis of Parkinson’s disease dementia, who was excluded from the analysis due to not meeting inclusion criteria, completed all sessions but is not included in *Table 6*.

Table 6. Number of sessions completed by participants in the CR group (n=238)

<b>Number of sessions completed</b>	<b>Number of participants</b>	<b>%</b>
0	1	0.4
1	2	0.9
2	2	0.9
3	5	2.1
4	4	1.7
5	4	1.7
6	2	0.9
7	0	0
8	1	0.4
9	2	0.9
10	7	3
11	8	3.4
12	10	4.3
13	21	8.9
14	166	70.6

### **Data collection**

The three-month follow-up assessments were scheduled within a four-week window from weeks 14 – 17 week post-randomisation. The assessments were completed within this timeframe for 420 participants (94%); 5 participants (1%) completed the assessment more than 1 month late. The nine-month follow-up assessments were scheduled within a four-week

window in weeks 39 – 42 post-randomisation. The assessments were completed within this time-frame for 367 participants (86%), with 2 participants (0.5%) completing the assessment more than a month late.

### **Adverse events**

Details of serious adverse events (SAEs) recorded for participants and carers at each site are summarised in *Table 7*. The majority involved hospitalisation. There were 111 serious adverse events reported at eight sites. Sixty-eight participants and 26 carers were involved in 83 and 28 SAEs respectively.

Of the 111 events, 66 were reported in the CR group (54 different individuals), and 36 in the TAU group (32 different individuals); nine SAEs occurred prior to randomisation.

SAEs were reported in one of seven categories: death, a life threatening event, hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, an event otherwise considered clinically significant by the principal investigator, and alleged or suspected abuse or neglect. Within the 111 SAEs, 98 were recorded as a single classification SAE and 13 had multiple classifications. Hospitalisation or prolongation of existing hospitalisation was the most frequently reported type of SAE (82%). Eight deaths were notified to the trial team.

None of these events were considered to be related to participation in the trial. The SAE reports were reviewed biannually by the Data Monitoring and Ethics Committee, which concluded that the nature of the SAEs appeared to reflect health problems commonly seen in an older population. An increased number of SAEs in the CR group was seen as an artefact of the reporting procedure, as the CR group received 14 additional visits from the therapist over a nine-month period.

Table 7. Serious adverse events

(a) Numbers of serious adverse events recorded for participants and carers at each site

Site	Participant			Carer			Total
	Therapy	TAU	Before randomisation	Therapy	TAU	Before randomisation	
Bath	7	3	0	2	0	0	12
Birmingham	6	2	0	3	2	0	13
Cardiff	9	5	3	4	1	1	23
Kent	3	0	0	0	0	0	3
London	9	0	1	0	0	0	10
Manchester	8	10	3	5	3	0	29
Newcastle	2	1	0	0	0	0	3
North Wales	5	6	0	3	3	1	18
Total	49	27	7	17	9	2	111

(b) Classifications of the serious adverse events

Classification	Individual classification reported			Reported within a multiple classification			Total per classification
	Participant	Carer	Total	Participant	Carer	Total	
Death	7	1	8	0	0	0	8
Life threatening	0	2	2	5	0	5	7
Hospitalisation or prolongation of existing hospitalisation	62	19	81	8	2	10	91
Persistent or significant disability or incapacity	1	1	2	9	2	11	13
Otherwise considered	1	3	4	5	0	5	9

clinically significant by the investigator							
Alleged/suspected abuse or neglect	0	0	0	1	0	1	1
Total	71	26	97	28	4	32	129

*Note: 13 serious adverse events were assigned to more than one SAE type.*

### **Numbers analysed**

The analysis, by assigned group, included data from 474 participants at baseline (CR n=238; TAU n = 236), 445 participants at three months (CR n=218; TAU n = 227) and 426 participants at nine months (CR n=208; TAU n = 218).

### **Missing data**

Details of missing data for the primary outcome at the three-month and nine-month follow-ups are shown in *Table 8*; there were no missing data on this measure at baseline. Details of missing data for the secondary outcomes are provided in *Appendix 6*.

Multiple imputation of missing values was conducted using the mice R package.<sup>108</sup> For all the measures, a predictive mean matching algorithm was used. The missing outcome measures at baseline were imputed using the centre-level factors and the participant's gender, age and baseline MMSE scores. The missing outcome measure scores at the three-month and nine-month assessments were estimated based on centre-level factors, baseline characteristics and scores for the same outcome at the earlier time point(s). In line with the Grund et al.<sup>109</sup> simulation-based observations of the D2 statistics performance for pooling p values, 25 sets of imputations were generated using the method described above.

Table 8. Missing data in the primary outcome measure (BGSI)

(a) Three month follow up

	Whole sample			CR			TAU		
	Missing	%	Total	Missing	%	Total	Missing	%	Total
Participant rating of attainment	0	0.00%	445	0	0.00%	218	0	0.00%	227
Participant rating of satisfaction	0	0.00%	445	0	0.00%	218	0	0.00%	227
Carer rating of attainment	6	1.27%	439	2	0.84%	216	4	1.69%	223

(b) Nine month follow up

	Whole sample			CR			TAU		
	Missing	%	Total	Missing	%	Total	Missing	%	Total
Participant rating of attainment	10	2.11%	416	3	1.26%	205	7	2.97%	211
Participant rating of satisfaction	14	2.95%	412	5	2.09%	203	9	3.81%	209
Carer rating of attainment	11	2.32%	415	4	1.67%	204	7	2.97%	211

**Results for the primary outcome measure**

The primary outcome was participants' goal attainment ratings on the BGSI at three month follow up. Participants' goal attainment ratings were also obtained at nine-month follow up, and carers provided informant ratings of attainment at the three and nine month points. Participants gave ratings of satisfaction with their goal attainment at both time points. For convenience, all these BGSI measures will be considered together here. Participant attainment and satisfaction ratings, and carer attainment ratings, across all time points are summarised in Table 9 and shown graphically in Figure 3. Table 9 also summarises the statistical analyses of changes in the BGSI ratings at three and nine months.

For the CR group, participant attainment ratings improved at the three month follow up by 2.57 points on average, and this improvement was maintained at nine months. Average ratings in the TAU group showed a negligible improvement of less than 1 point at three months. Analysis of covariance indicated that the differences between CR and TAU groups were significant at both three and nine months, with large effect sizes of 0.81 and 0.8 respectively.

The same pattern was observed for informant attainment ratings with the CR group improving by an average of 2.7 points and maintaining the improvement at nine months, while the TAU group ratings showed a negligible improvement of less than 1 point. Analysis of covariance indicated that the differences between CR and TAU groups were significant at both three and nine months, with large effect sizes of 0.93 and 0.79 respectively. Carers' informant ratings of attainment were slightly lower on average than participants' attainment ratings, but followed similar trajectories. Participant and carer attainment ratings were highly correlated at all time-points, with Pearson's product-moment correlation coefficients of 0.68 at baseline, 0.77 at three month follow-up and 0.81 at nine month follow up.

In the CR group average satisfaction ratings improved by 2.7 points at three months and increased further to give a 3 point improvement over baseline at nine months. Average satisfaction ratings for the TAU group improved by 1.2 points at three months with a further slight increase at nine months. Analysis of covariance indicated that the differences between CR and TAU groups were significant at both three and nine months, with large effect sizes of 0.7 and 0.67 respectively.

These results demonstrate that, according to the patient- and informant-reported outcomes assessed by the BGSI, the CR intervention was effective in improving functioning in the targeted areas. Furthermore, participants in the CR group were more satisfied with their ability to carry out the everyday activities targeted in the intervention.

Table 9. BGSi ratings at all time-points for CR and TAU groups, and statistical analysis of changes in BGSi ratings at three and nine months

(a) BGSi ratings for CR and TAU groups at baseline, three and nine months

Measure	CR			TAU		
	Baseline (n=238)	3 months (n=218)	9 months (n=205)	Baseline (n=236)	3 months (n=227)	9 months (n=211)
Participant rating of attainment	3.53 (1.74)	6.10 (1.99)	6.05 (2.21)	3.55 (1.59)	4.41 (1.84)	4.22 (2.00)
Participant rating of satisfaction	3.76 (1.76)	6.47 (1.88)	6.75 (1.97)	3.86 (1.49)	5.05 (1.94)	5.26 (2.05)
Carer rating of attainment	2.76 (1.43)	5.46 (1.94)	5.21 (2.33)	2.72 (1.32)	3.55 (1.73)	3.31 (1.96)

Data are mean (SD)

(b) BGSi ratings at three months: ANCOVA adjusted for baseline score, allocation group and stratification variables, age, gender, MMSE score and site

Measure	p	Bonferroni adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
Participant rating of attainment	<0.001	NA	1.58	1.27 to 1.9	0.81	0.62 to 1
Participant rating of satisfaction	<0.001	<0.001	1.34	1.01 to 1.66	0.7	0.51 to 0.88
Carer rating of attainment	<0.001	<0.001	1.75	1.42 to 2.07	0.93	0.74 to 1.12

(c) BGSi ratings at nine months: ANCOVA adjusted for baseline score, allocation group and stratification variables, age, gender, MMSE score and site

Measure	p	Bonferroni adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
Participant rating of attainment	<0.001	<0.001	1.71	1.35 to 2.08	0.8	0.61 to 0.99
Participant rating of satisfaction	<0.001	<0.001	1.36	1 to 1.73	0.67	0.49 to 0.86
Carer rating of attainment	<0.001	<0.001	1.7	1.32 to 2.09	0.79	0.6 to 0.97

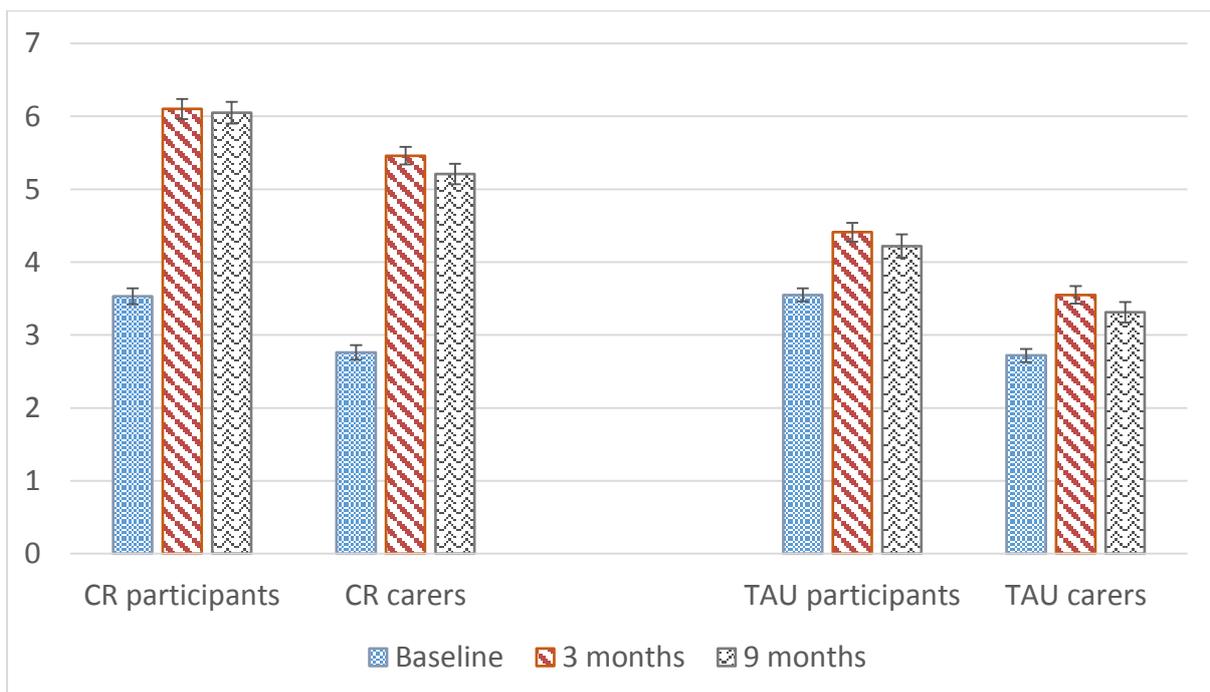


Figure 3. Goal attainment ratings by participants and carers in CR and TAU conditions at baseline, three-month and nine-month follow-up. Data are mean scores and the error bars show the standard errors.

## **Exploratory analyses for the primary outcome measure**

Linear mixed effects models were fitted to identify factors predicting change in BGSi ratings from baseline to follow up for participants in the CR group. There were no significant group by centre interactions in any of the models, indicating that results did not differ across centres. Details of these analyses are provided in *Appendix 7*.

### ***Participants' goal attainment ratings***

A linear mixed effects model was fitted to identify whether any factors predicted the difference in participants' goal attainment ratings at baseline and three-month follow up. Centre was treated as a random effect and the following factors were treated as fixed effects: gender, age (stratified), MMSE score (stratified), diagnosis, medication use, education, comorbidity, socio-economic status (SES) and blinding efficiency. At three-month follow up the model was not statistically significant (Chi-square(18) = 41.74,  $R^2 = 0.19$ ,  $p = 0.001$ ). Two factors within the model had a statistically significant effect in predicting a change in BGSi attainment ratings, blinding efficiency ( $b=1.24$ ,  $SE=0.30$ ,  $t(216.87)=4.12$ ,  $p<0.001$ , CI [0.54 ,1.76]) and participant SES (Chi-square(5) = 16.66,  $p= 0.005$  ). Greater improvement was seen where blinding was ineffective. For SES, there was a statistically significant difference in the change in BGSi attainment rating between professionals and non-manual skilled workers ( $b =-1.66$ ,  $SE = 0.65$ ,  $t(214.71) = -2.55$ ,  $p = 0.012$ , 95% CI [-3.39, -0.56]), professionals and manual skilled workers ( $b = -2.11$ ,  $SE = 0.65$ ,  $t(216.57) = -3.28$ ,  $p = 0.001$ , 95% CI [-4.17, -1.05]) and professionals and partly skilled workers ( $b = -1.93$ ,  $SE = 0.75$ ,  $t(216.88) = -2.58$ ,  $p= 0.011$ , 95% CI [-3.83, -0.67]). These observed differences show that CR was more effective at improving BGSi performance ratings at three-month follow-up for professionals than for non-manual skilled workers, manual skilled workers or non-skilled workers.

A linear mixed effects model was fitted to identify whether any factors predicted the difference between the BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group. Centre was treated as a random effect and following factors were treated as fixed effects: blinding effectiveness, participant's age (stratified), gender, education, social status, ethnicity, living situation (alone or with others), diagnosis, MMSE score (stratified), medication use and co-morbidity. The model was statistically significant (Chi-square(28) = 68.61,  $R^2 = 0.32$ ,  $p <0.001$ ). Factors within the model that were

individually statistically significant were participant's age, MMSE score and blinding efficiency. Greater improvement was seen in participants who were younger ( $b = -0.05$ ,  $SE = 0.02$ ,  $t(200.60) = -2.08$ ,  $p = 0.038$ , 95% CI [-0.09, -0.00]) and had higher MMSE scores ( $b = 0.16$ ,  $SE = 0.05$ ,  $t(199.31) = 3.06$ ,  $p = 0.002$ , 95% CI [0.06, 0.26]) and where the researcher was able to correctly identify the participant's group allocation ( $b = 1.35$ ,  $SE = 0.32$ ,  $t(199.86) = 4.21$ ,  $p < 0.001$ , 95% CI [0.71 1.99]).

Linear mixed effects models were fitted to identify whether any carer factors predicted the difference between the participants' BGSi attainment ratings at baseline and the three-month and nine-month follow-up for participants in the CR group. Centre was treated as a random effect and the following factors were treated as fixed effects: carer's gender, carer's age, carer's education, hours spent helping the PwD per day and the relationship between the carer and participant. The models were not statistically significant and no factors within the models were statistically significant.

#### ***Carers' ratings of participant goal attainment***

Linear mixed effects models were fitted to identify whether any carer factors predicted the difference between carers' BGSi attainment ratings at baseline and at the three-month and nine-month follow ups. The models were not statistically significant and no factors within the models were statistically significant.

Linear mixed effects models were fitted to identify whether any participant characteristics predicted the difference between carers' BGSi attainment ratings at baseline and three-month follow up. The overall model included centre as a random effect and the following factors as fixed effects: MMSE score (stratified), diagnosis, medication use, education, comorbidity, socio-economic status (SES). The model was not statistically significant (Chi-square(17) = 27.24,  $R^2 = 0.12$ ,  $p = 0.055$ ) Within the model, SES was statistically significant (Chi-square(5) = 14.54,  $p = 0.013$ ). There was a statistically significant difference in the change in carer BGSi attainment rating between professionals and non-manual skilled workers ( $b = -1.83$ ,  $SE = 0.68$ ,  $t(214.14) = -2.70$ ,  $p = 0.007$ , 95% CI [-3.15, -0.50]), professionals and manual skilled workers ( $b = -1.63$ ,  $SE = 0.67$ ,  $t(214.99) = -2.46$ ,  $p = 0.015$ , 95% CI [-2.94, -0.33]). These results mirror the findings for participant goal attainment ratings at three-month follow up.

Linear mixed effects models were fitted to identify whether any participant characteristics predicted the difference between carers' BGSi attainment ratings at baseline and nine-month follow-up. The overall model included centre as a random effect and the following factors as fixed effects: MMSE score (stratified), diagnosis, medication use, education, comorbidity, socio-economic status (SES). The model was not statistically significant (Chi-square(17) = 31.18,  $R^2 = 0.15$ ,  $p = 0.019$ ). Within the model, MMSE (stratified) was a statistically significant factor (Chi-square(1) = 7.91,  $p = 0.005$ ). This shows that there was a statistically significant difference in carer attainment ratings for participants with MMSE scores of 24 or above compared to participants with MMSE scores below 24 ( $b=0.96$ ,  $SE = 0.34$ ,  $t(202.98) = 2.81$ ,  $p = 0.005$ , 95% CI [0.29, 1.63]). Improvement in carer attainment ratings was greater where participants had higher MMSE scores.

### ***Participants' ratings of satisfaction with goal attainment***

A linear mixed effects model was fitted to identify whether any participant characteristics predicted the difference between the BGSi satisfaction ratings at baseline and three-month follow-up for participants in the CR group. Centre was treated as a random effect and the following factors were treated as fixed effects: gender, ethnicity, age (stratified), MMSE score (stratified), diagnosis, medication use, education, comorbidity and socio-economic status (SES). The model was statistically significant (Chi-square(28) = 49.89,  $R^2 = 0.21$ ,  $p = 0.007$ ). Factors within the model that were individually statistically significant were participant social status (Chi-square(5) = 16.82,  $p = 0.005$ ) and blinding efficiency (Chi-square(1) = 10.30,  $p = 0.001$ ). There was a statistically significant difference in the change in BGSi satisfaction rating, showing that satisfaction ratings improved more in professionals compared to non-manual skilled workers ( $b = -1.73$ ,  $SE = 0.65$ ,  $t(217) = -2.67$ ,  $p = 0.008$ , 95% CI [-3.01, -0.46]), manual skilled workers ( $b = -2.10$ ,  $SE = 0.63$ ,  $t(217) = -3.34$ ,  $p = 0.001$ , 95% CI [-3.33, -0.86]) and partly skilled workers ( $b = -1.92$ ,  $SE = 0.75$ ,  $t(217) = -2.57$ ,  $p = 0.011$ , 95% CI [-2.93, -0.26]). There was greater improvement in BGSi satisfaction ratings from baseline to three-month follow up when blinding was ineffective and the researcher was able to correctly identify that the participant belong to the CR group compared to when blinding was effective ( $b = 0.96$ ,  $SE = 0.30$ ,  $t(217) = 3.21$ ,  $p = 0.002$ , 95% CI [1.04, 9.49]).

A linear mixed effects model was fitted to predict the difference between the BGSi satisfaction ratings at baseline and nine-month follow-up for participants in the CR group. Centre was treated as a random effect and following factors were treated as fixed effects:

blinding efficiency, participant's age, gender, education, social status, ethnicity, living situation (alone or with others), diagnosis, MMSE score, medication use and co-morbidity. The model was statistically significant (Chi-square(27) = 54.26,  $R^2 = 0.25$ ,  $p = 0.001$ ). The only effects that were statistically significant were MMSE score (Chi-square(1) = 15.79,  $p < 0.001$ ) and blinding efficiency (Chi-square(1) = 14.35,  $p < 0.001$ ). Participants with higher MMSE scores at baseline showed greater improvement in BGSi satisfaction ratings from baseline to nine-month follow-up than those with lower MMSE scores ( $b = 0.20$ ,  $SE = 0.05$ ,  $t(199.45) = 3.97$ ,  $p < 0.001$ , 95% CI [0.22, 0.27]). There was greater improvement in BGSi satisfaction ratings from baseline to nine-month follow up when blinding was ineffective and the researcher was able to correctly identify that the participant belong to the CR group compared to when blinding was effective ( $b = 1.23$ ,  $SE = 0.33$ ,  $t(200.33) = 3.79$ ,  $p < 0.001$ , 95% CI [0.58, 1.88]).

### ***Ratings of importance and readiness to change***

We examined whether participants' BGSi ratings of importance of the functional domain addressed by each goal and ratings of readiness to change made at baseline were associated with attainment ratings at three-month follow up. Participants' baseline ratings of the importance of the functional domain addressed by each goal did not predict improvement. Participants' ratings of readiness to change at baseline, however, were significantly associated with improvement in attainment ratings at three-month follow-up ( $t(403) = 2.66$ ,  $r = 0.13$ ,  $p = 0.008$ ).

Participants' ratings of readiness to change remained significantly associated with improvement in their BGSi attainment ratings at nine-month follow-up ( $t(379) = 2.79$ ,  $r = 0.14$ ,  $p = 0.005$ ).

### **Results for the secondary outcomes**

Scores on secondary outcome measures at all time-points and the ANCOVA results are summarised in *Table 10*. Following Bonferroni correction of the  $p$  values for the secondary outcomes, there were no significant between-group differences in any secondary outcome measures at three- or nine-month follow-up. Effect sizes were small to negligible, although in some cases with wide confidence intervals.

Table 10. Scores and statistical analyses for the secondary outcomes

(a) Scores for participants with dementia

Measure	CR			TAU		
	Baseline	3 months	9 months	Baseline	3 months	9 months
DEMQOL	n=237 92 (12.9) 39 to 112	n=218 92.79 (11.95) 51 to 112	n=204 92.36 (12.00) 54 to 112	n=235 92.61 (11.75) 47 to 111	n=227 93.198 (12.00) 51 to 111	n=213 92.25 (12.82) 45 to 112
GSES	n=237 30.75 (4.81) 13 to 40	n=215 30.98 (4.62) 18 to 40	n=194 30.76 (4.91) 15 to 40	n=232 31.13 (5.35) 11 to 40	n=224 30.59 (5.61) 11 to 40	n=207 30.62 (5.60) 10 to 40
HADS depression	n=238 3.87 (2.83) 0 to 12	n=218 3.90 (2.86) 0 to 15	n=194 4.19 (3.23) 0 to 17	n=234 3.67 (2.75) 0 to 14	n=226 3.74 (2.69) 0 to 12	n=210 3.83 (2.82) 0 to 17
HADS anxiety	n=238 5.29 (3.67) 0 to 16	n=216 5.13 (3.66) 0 to 17	n=193 5.63 (3.83) 0 to 18	n=234 4.98 (3.62) 0 to 16	n=226 4.61 (3.41) 0 to 15	n=210 4.88 (3.37) 0 to 20
RBMT immediate recall	n=237 2.58 (2.1) 0 to 9.5	n=218 2.88 (2.16) 0 to 10.0	n=200 2.34 (2.09) 0 to 10.0	n=236 2.73 (2.12) 0 to 11.5	n=226 2.79 (2.12) 0 to 11.0	n=211 2.37 (1.96) 0 to 10.0
RBMT delayed recall	n=237 0.39 (1.94) -1 to 8	n=217 0.94 (2.31) -1.0 to 8.5	n=200 0.23 (1.97) -1.0 to 8.5	n=236 0.37 (1.97) -1 to 9	n=225 0.66 (2.16) -1.0 to 11.0	n=210 0.36 (1.97) -1.0 to 9.5

TEA elevator counting	n=232 6.35 (1.27) 0 to 7	n=210 6.31 (1.23) 0 to 7	n=191 6.21 (1.41) 0 to 7	n=231 6.42 (1.05) 1 to 7	n=219 6.36 (1.22) 0 to 7	n=206 6.24 (1.32) 1 to 7
TEA elevator counting with distraction	n=223 4.39 (2.68) 0 to 9	n=198 4.62 (3.08) 0 to 10	n=177 4.66 (3.11) 0 to 10	n=225 4.72 (2.75) 0 to 9	n=208 4.90 (3.15) 0 to 10	n=193 4.52 (3.07) 0 to 10
DKEFS verbal fluency	n=235 25.78 (11.61) 2 to 64	n=217 26.29 (12.56) 0 to 58	n=198 26.30 (13.32) 0 to 62	n=235 26.77 (12.03) 3 to 58	n=227 26.80 (12.38) 3 to 68	n=211 25.9 (12.36) 1 to 67

Data are mean (SD) range

(b) Scores for carers

Measure	CR			TAU		
	Baseline	3 months	9 months	Baseline	3 months	9 months
RSS	n=236 18.85 (9.04) 2 to 46	n=212 19.42 (9.62) 2 to 46	n=200 21.23 (9.92) 2 to 51	n=235 19.08 (9.83) 0 to 52	n=221 20.42 (10.33) 1 to 54	n=211 21.65 (10.74) 2 to 50
WHOQOL physical	n=237 15.3 (3.00) 5 to 20	n=212 15.20 (2.93) 5 to 20	n=199 14.95 (3.14) 6 to 20	n=233 15.37 (2.9) 7 to 20	n=220 15.07 (2.86) 6 to 20	n=210 14.78 (2.97) 6 to 20
WHOQOL psychological	n=237 15.13 (2.19) 8 to 20	n=212 14.98 (2.21) 7 to 20	n=199 14.74 (2.41) 7 to 20	n=233 15.15 (2.1) 8 to 20	n=220 14.74 (2.20) 7 to 20	n=210 14.53 (2.38) 7 to 20
WHOQOL social	n=235 15.19 (2.67) 5 to 20	n=211 15.03 (2.47) 7 to 20	n=197 15.04 (2.72) 8 to 20	n=233 15.07 (2.66) 7 to 20	n=219 14.80 (2.58) 7 to 20	n=210 14.51 (2.83) 5 to 20

WHOQOL environmental	n=237 16.35 (2.3) 10 to 20	n=212 16.33 (2.26) 9 to 20	n=199 16.00 (2.40) 9 to 20	n=233 16.52 (1.99) 10 to 20	n=220 16.18 (2.04) 10 to 20	n=210 16.04 (2.05) 11 to 20
EQ5D3L index	n=235 0.77 (0.25) -0.18 to 1	n=209 0.75 (0.24) -0.18 to 1	n=196 0.73 (0.27) -0.18 to 1	n=233 0.79 (0.24) -0.07 to 1	n=217 0.74 (0.25) -0.24 to 1	n=211 0.75 (0.23) -0.07 to 1
EQ5D3L VAS	n=234 73.52 (20.95) 1 to 100	n=208 74.13 (18.92) 0 to 100	n=198 74.14 (19.16) 10 to 100	n=233 75.44 (18.9) 0 to 100	n=217 73.14 (18.95) 0 to 100	n=211 72.42 (19.13) 0 to 100

Data are mean (SD) range

(c) Statistical analyses at three month follow up

Measure	p	Adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
Participants with dementia						
DEMQOL	0.738	1	0.24	-1.27 to 1.75	0.02	-0.16 to 0.2
GSES	0.126	1	0.58	-0.16 to 1.32	0.11	-0.07 to 0.29
HADS Depression	0.861	1	0	-0.42 to 0.41	0.02	-0.16 to 0.2
HADS Anxiety	0.478	1	0.17	-0.3 to 0.65	0.06	-0.12 to 0.24
RBMT immediate recall	0.189	1	0.19	-0.1 to 0.48	0.1	-0.08 to 0.28
RBMT delayed recall	0.096	1	0.24	-0.04 to 0.52	0.12	-0.06 to 0.3
TEA elevator counting	0.799	1	0.01	-0.19 to 0.21	0.02	-0.16 to 0.2
TEA elevator counting with distraction	0.784	1	0.01	-0.45 to 0.47	0.03	-0.15 to 0.21

DKEFS verbal fluency	0.794	1	0.15	-1.12 to 1.41	0.02	-0.16 to 0.2
<b>Carers</b>						
RSS	0.382	1	-0.5	-1.61 to 0.62	0.05	-0.13 to 0.23
WHOQOL physical	0.431	1	0.12	-0.18 to 0.42	0.04	-0.14 to 0.22
WHOQOL psychological	0.214	1	0.18	-0.1 to 0.47	0.08	-0.1 to 0.26
WHOQOL social	0.572	1	0.1	-0.25 to 0.45	0.05	-0.13 to 0.23
WHOQOL environmental	0.05	0.947	0.26	0 to 0.51	0.13	-0.06 to 0.31
EQ5D3L index	0.295	1	0.02	-0.01 to 0.05	0.07	-0.11 to 0.25
EQ5D Visual Analogue Scale	0.286	1	1.58	-1.31 to 4.47	0.09	-0.09 to 0.27

(d) Statistical analyses at nine month follow up

<b>Measure</b>	<b>p</b>	<b>Adjusted p</b>	<b>Mean difference</b>	<b>95% CI for mean difference</b>	<b>d</b>	<b>95% CI for d</b>
<b>Participants with dementia</b>						
DEMQOL	0.215	1	1.08	-0.62 to 2.78	0.09	-0.09 to 0.27
GSES	0.38	1	0.37	-0.45 to 1.18	0.07	-0.11 to 0.25
HADS Depression	0.614	1	0.12	-0.35 to 0.6	0.05	-0.13 to 0.23
HADS Anxiety	0.334	1	0.26	-0.26 to 0.77	0.08	-0.1 to 0.26
RBMT immediate recall	0.496	1	0.1	-0.19 to 0.4	0.06	-0.12 to 0.24
RBMT delayed recall	0.466	1	-0.1	-0.37 to 0.17	0.06	-0.12 to 0.24
TEA elevator counting	0.718	1	-0.01	-0.27 to 0.25	0.04	-0.14 to 0.22
TEA elevator counting with distraction	0.334	1	0.23	-0.23 to 0.69	0.09	-0.09 to 0.27

DKEFS verbal fluency	0.342	1	0.71	-0.75 to 2.16	0.06	-0.12 to 0.24
Carers						
RSS	0.808	1	0.08	-1.09 to 1.25	0.02	-0.16 to 0.2
WHOQOL physical	0.399	1	0.14	-0.19 to 0.47	0.05	-0.13 to 0.23
WHOQOL psychological	0.346	1	0.15	-0.16 to 0.45	0.06	-0.12 to 0.24
WHOQOL social	0.049	0.93	0.41	0 to 0.81	0.15	-0.03 to 0.33
WHOQOL environmental	0.371	1	0.13	-0.15 to 0.4	0.06	-0.12 to 0.24
EQ5D3L index	0.547	1	-0.01	-0.04 to 0.02	0.04	-0.14 to 0.22
EQ5D Visual Analogue Scale	0.071	1	2.6	-0.22 to 5.42	0.14	-0.04 to 0.32

### Exploratory analyses for the secondary outcomes

As there were no overall effects on secondary outcomes, we examined whether benefits were seen for particular sub-groups on key outcome measures. The sub-groups reflected centre, age (under 75; 75 and above), gender, SES, diagnosis, and MMSE score (under 24; 24 and above). Details of these analyses are provided in *Appendix 8*.

For the person with dementia, the measures examined were DEMQOL, HADS anxiety and depression, and GSES at three-month and nine-month follow-ups. No statistically significant models or individual factors were observed for DEMQOL or HADS at either time-point. For GSES the overall models were also not significant, but at three months, gender was significant ( $p=0.044$ ) and at nine months, diagnosis was significant ( $p=0.021$ ).

For the carer, the measures examined were RSS and WHOQOL-BREF. No statistically significant models or individual factors were observed for RSS. For WHOQOL-BREF, there were no statistically significant models. The only significant individual factor was in the WHOQOL-BREF physical scale, where centre was significant at three-month follow up (Chi-square(1) = 4.48,  $p=0.034$ ). The model containing this factor was not itself significant, (Chi-

square(12) = 8.12,  $R^2 = 0.07$ ,  $p = 0.775$ ) and the centre factor was not statistically significant at nine-month follow up.

### **Sensitivity analyses**

As all participants received the allocated condition, it was not necessary to conduct the planned analysis based on treatment received irrespective of group allocation.

Results from the analysis of complete case data were very similar to those of the multiple imputation analysis and did not alter the overall picture in any way. A summary of the statistical analyses for the primary and secondary outcome measures using the full data set with no imputations is shown in *Appendix 9*.

Examination of change from baseline at three and nine month follow-up in the CR group alone using analysis of variance demonstrated the same pattern as the main analysis, with significant changes in participant and carer BGSi attainment ratings and participant BGSi satisfaction ratings, all with large effect sizes, and no significant changes in other outcomes. Details are shown in *Appendix 10*.

### **Effectiveness of blinding**

At the three-month and nine-month follow-ups, researchers recorded their estimations of group allocation for each participant. In the majority of cases, researchers were able to correctly guess the participant's allocation (see *Appendix 11*).

At the three-month follow-up, researchers were very certain about the accuracy of their estimations in 16.6% of cases, quite certain in 31.7%, uncertain in 33.3% and very uncertain in 18.2%. Participants explicitly disclosed their group allocation to the researchers in 14.8% of cases, while in 8.3% of cases researchers noticed some indirect clues, such as the presence of memory aids and adaptations. In 48.4% cases researchers acknowledged that their guesses were influenced by the presence or absence of change in the participant's goal performance rating. Researchers were more often very certain about their estimations for participants in the CR group (20.6% of CR participants) than those in the TAU group (12.8% of TAU participants), and they were more likely to be directly unblinded by participants in the CR group (20.2% of CR participants) than by those in the TAU group (9.7% of TAU participants). The picture at the nine-month follow up was similar.

Binomial tests to assess the difference in proportions between group allocation identified by researcher and group allocation not identified by researcher showed a statistically significant difference for all sites and follow up combinations ( $p < 0.001$ ). As noted above under the exploratory analyses for the primary outcome measure, the researcher's ability to correctly surmise the participant's group allocation was associated with participant attainment and satisfaction scores at the three-month and nine-month follow-ups.

### **Associations between adherence and outcomes**

For the CR group, we examined the association of number of sessions completed with all primary and secondary outcomes at three and nine months. These analyses are summarised in *Appendix 12*.

At three month follow up, adherence was significantly associated with BGSi participant ( $b = 0.17$ ,  $SE = 0.09$ ,  $t(215) = 2.01$ ,  $p = 0.046$ , 95% CI [0,0.34]) and carer ( $b = 0.21$ ,  $SE = 0.08$ ,  $t(213) = 2.46$ ,  $p = 0.015$ , 95% CI [0.04, 0.37]) attainment ratings. At nine month follow up, adherence was significantly associated with BGSi participant ( $b = 0.24$ ,  $SE = 0.10$ ,  $t(202) = 2.36$ ,  $p = 0.019$ , 95% CI [0.04, 0.44]) and carer ( $b = 0.28$ ,  $SE = 0.10$ ,  $t(201) = 2.68$ ,  $p = 0.008$ , 95% CI [0.07, 0.48]) attainment ratings, with participant BGSi satisfaction rating ( $b = 0.25$ ,  $SE = 0.11$ ,  $t(200) = 2.33$ ,  $p = 0.021$ , 95% CI [0.04, 0.47]) and with carer EQ5D3L VAS ( $b = -1.55$ ,  $SE = 0.78$ ,  $t(193) = -1.98$ ,  $p = 0.049$ , 95% CI [-3.09, -0.01]).

These adherence analyses indicate that attending more sessions was associated with more positive ratings of goal attainment. For each therapy session attended the participant's BGSi attainment rating increased on average by 0.24 at nine month follow-up.

## Chapter 4. Process evaluation

We undertook a range of process evaluation analyses to gain a better understanding of how the intervention was delivered, influences on treatment outcome and the mechanisms of action through which the intervention operated. We also undertook work to assess the feasibility of implementation in NHS services. As outlined in *Chapter 2*, we explored the following areas:

- Goal-setting and goal attainment
- Intervention fidelity
- Factors associated with positive outcomes and therapist perspectives on delivering the intervention
- Participant and carer experience of the intervention
- Feasibility of implementation

### Goal-setting and goal attainment

The use of individual goals was central to the intervention and a range of process evaluation analyses was undertaken to explore aspects of goal-setting and the goals chosen.

#### *Goal-setting*

All participants were invited to identify up to three therapy goals. Researchers were encouraged to ensure that at least two goals were identified, to ensure the participant understood the aims of the therapy and was motivated to participate. In total 1358 therapy goals were identified by 474 randomised participants. The majority of participants (411, 86.7%) identified three therapy goals, 62 participants (13.1%) identified two therapy goals, and one participant (0.2%) identified one goal. Details are provided in *Table 11* for further details.

Table 11. Number of goals identified during baseline assessment

<b>Number of goals set by participants</b>	<b>Whole sample (n=474)</b>	<b>CR (n=238)</b>	<b>TAU (n=236)</b>
One goal identified	1 (0.2)	0	1 (0.4)
Two goals identified	62 (13.1)	35 (14.7)	27 (11.4)
Three goals identified	411 (86.7)	203 (85.3)	208 (88.1)
Total number of goals in the group	1358	679	679

### ***Goal selection***

The 1358 goals identified by participants were listed and the content and focus analysed to identify the areas that were of concern to participants. This built on a preliminary analysis of 591 goals set by the first 209 participants enrolled into the trial by December 2014 <sup>110</sup>. In the current analysis, the first 300 goals were reviewed in detail and grouped thematically to form the basis of a detailed coding system. This system was then applied to the remaining goals.

Goals were grouped into the following categories:

- Engaging in activities and personal projects (21%). This included planning and engaging in enjoyable activities, taking up new activities, re-starting previously-enjoyed activities, doing activities regularly or more often, doing activities independently, practising skills, keeping occupied, undertaking personal projects, and doing things for others.
- Using appliances, devices and the internet (17%). This category focused on the use of household appliances such as washing machines or microwave ovens, devices such as mobile phones, smartphones, tablets or iPads, TVs, computers, laptops, cameras, CD or DVD players, iPods and sat-navs, and personal safety aids such as wristbands or pull cords. Participants wanted to learn to use, or be able to use, appliances and devices, to feel confident using them, or to use them independently. This was for a range of purposes including completing household tasks, communication, entertainment and occupation, obtaining information, and staying safe.
- Managing everyday activities, tasks and situations (16%). This included managing money, shopping, cooking and baking, correspondence and phone calls, carrying out household tasks, going out, wayfinding, using transportation, telling time, and staying safe.

Participants wanted to feel confident doing their everyday activities or to be able to do them independently or safely.

- Knowing what is happening (9%). Participants wanted to know the day and date, the schedule for the day or the week ahead, and the timing of any appointments. They were keen to know without asking others or having to check repeatedly, and sometimes mentioned particular strategies they wished to use, such as a whiteboard, calendar or diary.
- Retaining or keeping track of information and events (8%). Participants wanted to find ways of remembering important information, information they were recently given, information they had told others, events and activities, and messages to pass on. They wanted to be able to retain key elements of the plot of a novel or TV programme, or to keep the score when watching or playing sport or games.
- Locating belongings (7%). This category was about finding personal items and items around the house, knowing where things had been left, and putting things back in the right place.
- Recognising, identifying, and naming (6%). Participants wanted to remember names of family, friends, people they met, and prominent people involved in current affairs, as well as information about these people. They wanted to be able to recognise and identify people and objects.
- Engaging in conversation (5%). This category was about being able to engage in and participate in conversation, follow the thread of a conversation and retain key points, find words, keep conversation going, and speak without repetition. Participants wanted to be able to contribute confidently, in a range of settings, for example at family mealtimes or when walking with a group.
- Organising, improving and finishing (4%). Some participants emphasised a wish to organise aspects of their lives or their environment, to complete tasks they had set themselves, and to improve their performance in areas like handwriting, spelling or vocabulary.
- Caring for self (3%). Participants wanted to be able to do some basic life tasks regularly or independently. These included shaving, bathing, changing dirty clothes, and eating and drinking regularly.
- Keeping in contact and staying engaged with family and friends (2%). In this category participants specifically mentioned wanting to keep in contact with family and friends through various means, to take an interest in and remember what is going on in their lives, and to attend family gatherings.

- Managing emotions (2%). Participants wanted to manage anxiety or frustration, be more patient, and worry less, or to cope better with changes in routine.

***Goal attainment in the CR group***

Participants randomised to the CR group had previously identified 679 goals at baseline. Of these, 591 were introduced in therapy sessions by the therapist, initial in-session goal attainment ratings were made for 590, and follow-up ratings were made for 563. In-session goal attainment ratings showed a similar pattern to the ratings made at baseline and follow-up assessments (details are shown in *Table 12*). Correlations between the goal attainment ratings made by the participant, carer and therapist at each stage were large, ranging from .665 to .934, and were significant at  $p < .0001$  (two-tailed), indicating a high degree of consistency among the three raters. All ratings improved on average by over 2 points, reflecting a clinically-significant change. Change scores are shown in *Table 12*; correlations among the change scores for participants, carers and therapists were large, ranging from .679 to .861, and were significant at  $p < .0001$  (two-tailed), again reflecting a high degree of consistency.

Table 12. In-session ratings of goal attainment

(a) Summary of in-session ratings

<b>In-session attainment ratings</b>	<b>On introduction of goal</b>	<b>Session 10</b>	<b>Session 14</b>
Participant rating of attainment (n=232)	4.09 (1.79), 590	6.75 (1.68), 554	6.96 (1.91), 494
Carer rating of attainment (n=232)	3.21 (1.58), 584	6.24 (1.75), 550	6.29 (2.14), 484
Therapist rating of attainment (n=232)	3.03 (1.50), 590	6.36 (1.69), 557	6.55 (2.06), 496

*Data are mean (SD), number of goals rated. Session 10 participant ratings n = 212, carer ratings n = 211. Session 14 participant ratings n = 196; carer ratings n = 192*

(b) Change from initial in-session ratings at sessions 10 and 14

<b>Change from initial in-session attainment ratings</b>	<b>Session 10</b>	<b>Session 14</b>
Participant attainment rating	2.66 (1.95)	2.87 (2.08)
Carer attainment rating	3.03 (1.74)	3.07 (2.14)
Therapist attainment rating	3.33 (1.66)	3.52 (2.02)

*Data are mean (SD)*

On introducing goals, therapists also independently established indicators to classify the extent of goal attainment in percentage terms. On completion of the therapy they rated the extent of attainment for each goal. In total 54.8% of goals were rated as at least 75% attained, and 79.8% as at least 50% attained. Only 5% of goals showed no progress towards attainment. *Figure 4* provides a summary of the therapists' goal attainment ratings made after session 10 and *Table 13* breaks this down by order of introduction of the goals.

We compared the therapists' goal attainment scaling with the in-session goal attainment ratings made by participants, carers and therapists in or following both sessions 10 and 14 to determine whether these two procedures yielded consistent information. For session 10 goal attainment scaling, correlations were .557 with participant ratings, .786 with carer ratings and .862 with therapist ratings, and for session 14 goal attainment scaling, correlations were .652 with participant ratings, .881 with carer ratings and .932 with therapist ratings. All correlations were significant at  $p < .0001$ , two-tailed. This indicates generally good consistency.

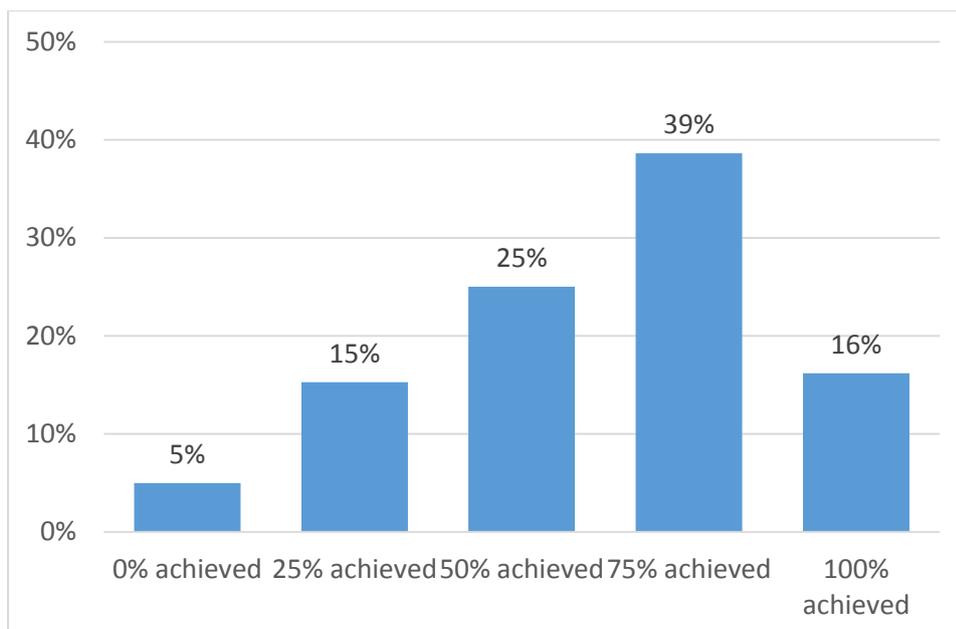


Figure 4. Attainment of therapy goals by session 10

*Proportion of therapy goals rated as fully achieved (100%), partially achieved (25%, 50%, or 75%) and not achieved (0%) after session 10*

Table 13. Therapists' goal attainment scaling following session 10

% achieved	All goals		Goal 1		Goal 2		Goal 3	
	n	%	n	%	n	%	n	%
0% achieved	27	5.0	7	2.9	10	4.2	10	4.2
25% achieved	83	15.3	27	11.3	33	13.9	23	9.7
50% achieved	136	25.0	51	21.4	53	22.3	32	13.4
75% achieved	210	38.6	72	30.3	86	36.1	52	21.8
100% achieved	88	16.2	49	20.6	25	10.5	14	5.9

### Intervention fidelity

We evaluated fidelity of form<sup>80</sup> in relation to the provision of core elements of the intervention, completion of therapy sessions (in terms of number and length of sessions) and the number of therapy goals identified at the baseline assessment that were introduced and addressed in the therapy.

As presented in *Table 6 (Chapter 3)*, the majority of participants (70%) received all 14 sessions, and only 26 participants (11%) completed fewer than ten sessions. Therapy sessions lasted between 43 and 120 minutes, with an average of 75.5 minutes (SD=12.4) per session.

Out of 679 goals identified at baseline assessment, as noted above, therapists discussed and confirmed with the participants 591 therapy goals. Initial in-session ratings were completed for 590 goals and 563 goals were subsequently re-rated at a later stage of therapy (details are shown in *Table 14*). Some goals were not introduced, either because the participants withdrew from the study, because the goals were no longer seen as suitable or relevant by the participant and no replacement was identified, or because there was not enough time to work on them.

In order to evaluate fidelity of function<sup>80</sup> we assessed the level of flexibility applied by the therapists in relation to timing of introducing additional therapy goals (as goals identified at baseline were introduced one at a time during the course of therapy) and the extent to which goal statements formulated at baseline were modified, for example to make them more specific, realistic, or achievable (see *Table 14*). In the majority of cases the first goal was introduced in the first session, with other goals being brought gradually in the subsequent sessions. Only a small proportion of participants had more than one goal introduced at the first session.

Table 14. Working with goals during therapy

(a) Number of goals identified at baseline that were introduced and addressed during therapy

Therapy goals at baseline	All goals		Goal 1		Goal 2		Goal 3	
	n	%	n	%	n	%	n	%
Goal confirmed by therapist	591	100	232	100	217	100	142	100
Initial goal rating completed	590	99.8	232	100	217	100	141	99.3
Goal re-rated during therapy	563	95.3	214	0.9	213	98.2	136	95.8

(b) Stage of therapy at which work on each of the 590 goals commenced

Session number	Goal 1		Goal 2		Goal 3	
	n	%	n	%	n	%
1	207	89.2	33	15.2	29	20.6
2	20	8.6	6	2.8	4	2.8
3	4	1.7	15	6.9	4	2.8
4	1	0.4	100	46.1	12	8.5
5			43	19.8	9	6.4
6			10	4.6	42	29.8
7			8	3.7	28	19.9
8			1	0.5	10	7.1
10			1	0.5	2	1.4
11					1	0.7
Total introduced	232	100	217	100	141	100

(c) Extent to which goals were addressed exactly as set at baseline

Approach taken	All goals		Goal 1		Goal 2		Goal 3	
	n	%	n	%	n	%	n	%
Goal was addressed exactly as set at baseline or very slightly modified	525	88.8	213	89.5	193	81.1	119	50.0
Goal set at baseline was used, but significantly modified	21	3.6	8	3.4	7	2.9	6	2.5
New goal was developed with the therapist	36	6.1	8	3.4	13	5.5	15	6.3
Other	9	1.5	3	1.3	4	1.7	2	0.8

As summarised in *Table 14*, the majority (89%) of the goals introduced in therapy sessions were used exactly as formulated during baseline assessment or very slightly modified. This attests to the skill the researchers developed in supporting participants to identify goals that were both meaningful and realistic – a process that in routine practice would be undertaken by the therapist. However, therapists showed flexibility in cases where modification was required, and a small proportion of goals was significantly modified (4%) or replaced (6%).

In 36 cases where no third goal was identified at baseline, or where a goal set at baseline was no longer felt to be relevant, therapists were able to agree and introduce a new goal. In 2 instances two goals were amalgamated into one, in six instances participants decided during the initial discussion that they did not want to work on a particular goal and no other goal was introduced, and in one case it was not possible to address the goal due to changed circumstances.

As fidelity of function was promoted through regular supervision with the aid of the detailed therapy logs produced by therapists, we also reviewed attendance at supervision sessions, rates of completion of therapy logs, and therapists' confidence in their ability to address participant's goals. Therapists had 16 hours of face-to-face group supervision per year with an average attendance rate of 90%. In addition, therapists had on average seven hours of individual supervision each year, conducted via telephone or Skype. Therapy logs were compiled for every participant in the CR group.

Therapists' evaluation of their confidence in addressing participants' therapy goals indicated that overall they felt fairly confident, with a mean score of 7 (SD=2.31) on a scale from 1 to 10, where 1 is not at all confident and 10 is completely confident.

### **Therapist views on factors associated with positive outcomes**

We explored the therapists' views about what factors influence treatment outcome and what groups of participants were most and least likely to benefit from the intervention, and why. Two sets of data were analysed: data from a focus group conducted with the therapists and a selection of therapy logs. The focus group was analysed using thematic analysis,<sup>111</sup> with NVivo 11 (QSR International; Doncaster, Victoria, Australia).<sup>112</sup> The focus group analysis and stage 1 of the therapy log analysis informed the development of a list of significant features of the therapy experience. Stages 2 and 3 of the therapy logs analysis involved exploration of the factors influencing good and poor therapy outcomes, and potential causal relationships contributing to outcomes, in more depth.

### *Focus group conducted with the therapists*

#### Methods

A focus group was conducted with the trial therapists to examine how the intervention was delivered, the nature of participant and carer engagement, and the mechanisms of action through which the intervention operated. The focus group was conducted in June 2014 with six therapists from the original research sites, and lasted one hour. The focus group was digitally recorded and transcribed verbatim.

Focus group data were analysed by a qualitative researcher who had not been otherwise involved in the trial and was independent of the trial team. The analysis was conducted by first developing a codebook based on two initial readings of the focus group transcript, using a combined deductive and inductive approach. In the deductive approach, aspects of the intervention which were already thought to be critical to success at the intervention development stage - participant motivation, participant acknowledgement of difficulties, cognitive impairment, health status, and carer involvement - were included as initial codes in the analysis. Data were also coded inductively, where codes were identified in a 'bottom up' way from the data rather than being pre-determined. Fourteen codes were identified, including the four deductive codes. One deductive code, 'overall health status', was dropped as no data were associated with this code. Data were then coded in NVivo 11<sup>112</sup> using the resulting 14 deductive and inductive codes, which were subsequently grouped into five descriptive themes: trajectory of the intervention; characteristics and role of the participant; characteristics and role of the carer; role of the therapist; and contextual factors affecting the intervention. The five themes and 14 codes were summarised in a report and translated into two graphics to further explore the relationships between them. Data for each code were re-read at each stage of the analysis, to ensure that the groupings and interpretation of the data retained validity.

The two graphics and the summary of the themes and codes were then reviewed and discussed in a meeting between the researcher and trial manager to reflect on the findings, including consideration of any surprising results, how the findings related to the intervention design and intervention manual, and any hypotheses about implications of the findings. This formed the basis for reporting the findings.

## Findings

There were several different aspects to the work that therapists conducted, including: engaging carers; tailoring the intervention according to participant capacity; and developing relationships and providing support to both carers and participants. The participation of carers and participants' cognitive and functional ability and readiness to acknowledge difficulties emerged as important factors affecting the success of the intervention. The development of relationships and working with goals flexibly over time was a feature of how the intervention was implemented, and it was clear that achievements could create a positive cycle over time, though not all 'small' achievements were necessarily formally noted. These key findings are presented below.

Therapists commented on several ways in which carers were important for the success of the intervention, and also described how they worked with carers to facilitate their involvement. The role of carers in the intervention was regarded as important by therapists because their facilitation of the intervention (such as prompting the participant between sessions) was thought to impact on participant motivation and engagement. Therapists thought carers were more likely to engage with goals if the goal affected the carer as well as the participant, and that carers' engagement was negatively impacted by carer beliefs in a participant's lack of functional ability, though this could change if participants made progress. Therapists would adapt visit times to ensure they met with carers who could be limited by other commitments (such as work) and also made efforts to identify and meet the carers who were most involved in the participant's life, who were not always the same person as the nominated carer for the intervention. Therapists additionally provided support for carers which included education, socio-emotional support (which one therapist commented could be the primary benefit for the carer) and referral to other services.

Therapists commented on different participant profiles. Some had busy and active lives. Of concern, however, were those participants who were functioning less well. Therapists felt that a goal-centred therapy was more difficult for this group because they could be less likely to engage with goals in the first place due to limited acknowledgement of difficulties, could have difficulty setting relevant goals or remembering them, and could find it hard to complete goal ratings. Lack of awareness of particular difficulties resulted in lower motivation to engage in the intervention. Therapists also commented that it was difficult for some participants to absorb all the information that they wanted to deliver in the time allocated for

the session, and that it was important to be able to present concepts in an accessible manner. Therapists responded to differences in participant ability levels by tailoring the timing of material and highlighting the most relevant sections in the session handouts provided.

The therapists described various ways in which they tried to engage participants and carers in the intervention and help them progress to achieving goals. In some cases they explained the evidence-based nature of the intervention in order to engage carers. They thought that participants who had a relatively recent diagnosis, and their carers, were easier to engage because they were still adapting to the diagnosis and more open to change. The relationships created and support provided by therapists seemed to be an element that supported their work with participants and carers, and promoted effective working towards goals. Therapists worked with goals flexibly, as sometimes the goals set at baseline were not optimal and therapists needed to get to know carers and participants in order to adapt and operationalise them or, if necessary, identify a more relevant goal. Goals could also change in response to an event in a participant's life. Therapists reflected on the way in which goals could sometimes appear to reflect small issues, but these could make a significant difference to the participant's life. Achieving goals could be motivating for participants and carers, although sometimes this could make them too ambitious, and achieving goals could also have beneficial effects in other areas of their lives, for example through promoting social engagement.

Therapists described elements of the intervention they were delivering that were or were perceived to be additional to the intervention protocol. These included social support, relationship building, managing relationship conflict between carers and participants, contacting social services to enable carers to have a break, and extending the length of their visits. For example, a few therapists mentioned evening visits or additional hours, or made referrals to social services for specific needs.

In talking about the participants, therapists appeared to focus on several dichotomies. They compared participants with lower and higher cognitive and functional ability, and felt the approach was more relevant for, or easier to apply with, those who were functioning better. They made a distinction between those participants who had received a diagnosis relatively recently and those who had had a diagnosis for longer, and felt that those currently adapting to a recent dementia diagnosis were more likely to engage well with the intervention. These

two categories, higher levels of functioning and recency of diagnosis, naturally tended to overlap. They also differentiated those needing longer and shorter maintenance visits, where participants who were doing well needed shorter visits.

A limitation of these findings is that they are from one focus group of six therapists, and some comments were made only by one or two individuals. Further, these findings only reflect the perspectives of therapists on how the intervention operated.

To summarise the findings, a number of features were perceived by the therapists as influencing the outcomes of therapy:

1. Participants' level of functioning. Participants who were functioning better were more likely to engage well in setting goals and working on goals, and were more motivated to make changes.
2. Proximity of diagnosis. Participants who had been diagnosed more recently, and their carers, tended to be more motivated to engage in the intervention.
3. Individual tailoring. Therapists tailored the intervention to individual goals and needs, and greater individual tailoring was thought to be related to better outcomes.
4. Carer engagement. Low levels of carer engagement were thought to be linked with outcomes, but could be mitigated by the therapists working to engage carers more fully.
5. Therapeutic relationship. The relationships that the therapists developed with participants and carers were very important influences on outcome, and these relationships changed over time as therapy progressed.
6. Positive cycles. Achievement of goals led to greater carer engagement and other benefits

### ***Therapy logs analysis***

Following the analysis of the focus groups, a set of therapy logs was analysed. Findings from the focus group analysis informed the analysis of therapy logs data, as described below.

#### **Methods**

Two subsets of CR group participants were identified, representing the 25 participants with the best goal attainment outcomes and the 25 participants with the poorest outcomes. Therapy outcome was operationalised for this analysis as change in the BGSi participant goal

attainment ratings between baseline and three-month follow-up. Scrutiny of demographic and clinical characteristics of the two groups showed no evident differences. *Table 15* summarises demographic and clinical characteristics and mean BGSi ratings for the two groups.

Table 15. Demographic and clinical characteristics of participants in the ‘poor outcome’ and ‘good outcome’ groups, and BGSi ratings

(a) Demographic characteristics of the participants with dementia

<b>Measure</b>	<b>Poor outcome n=25</b>	<b>Good outcome n=25</b>
Age	79 (5.5); 66 to 90	77.36 (6.8); 62 to 91
Sex (male)	11 (44.0)	16 (64.0)
Ethnicity:		
White	23 (92.0)	24 (96.0)
Mixed / Multiple ethnic group	1 (4.0)	0
Black / African / Caribbean / Black British	1 (4.0)	0
Other ethnic group	0	1 (4.0)
First language (English)	25 (100)	23 (92.0)
Marital status (married)	19 (76.0)	18 (72.0)
Years of education	12.1 (3.1); 8 to 20	12.3 (3.3); 8 to 21.5
Occupational status:		
I Professional	1 (4.0)	4 (16.0)
II Managerial/technical	7 (28.0)	13 (52.0)
III N Skilled, non-manual	8 (32.0)	3 (12.0)
III M Skilled, manual	5 (20.0)	1 (4.0)
IV Partly skilled	4 (16.0)	1 (4.0)
V Unskilled	0	3 (12.0)

*Data are n (%) or mean (SD) and range*

(b) Demographic characteristics of the carers

<b>Measure</b>	<b>Poor outcome n=25</b>	<b>Good outcome n=25</b>
Relationship to participant with dementia:		
Spouse/partner	18 (72.0)	19 (76.0)
Adult child (including in-law)	5 (20.0)	6 (24.0)
Other	2 (8.0)	0
Age	70.1 (10.5); 50 to 89	68.4 (13.9); 29 to 82
Sex (male)	10 (40.0)	6 (24.0)
Ethnicity:		
White	25 (100.0)	23 (92.0)
Mixed / Multiple ethnic group	0	1 (4.0)
Other ethnic group	0	1 (4.0)
First language (English)	24 (96.0)	25 (100.0)
Marital status (married)	18 (72.0)	24 (96.0)
Years of education	12.0 (3.1); 5 to 20	13.8 (3.6); 8 to 22
Occupational status:		
I Professional	3 (12.0)	(24.0)
II Managerial/technical	9 (36.0)	(24.0)
III N Skilled, non-manual	7 (28.0)	10 (40.0)
III M Skilled, manual	3 (12.0)	0
IV Partly skilled	2 (8.0)	1 (4.0)
V Unskilled	1 (4.0)	2 (8.0)

*Data are mean (SD) range or n (%)*

(c) Clinical characteristics of the participants with dementia at baseline

<b>Measure</b>	<b>Poor outcome (n=25)</b>	<b>Good outcome (n=25)</b>
Diagnosis:		
Alzheimer's disease	16 (64)	16 (64)
Vascular dementia	4 (16)	2 (8)
Mixed AD and vascular	5 (20)	7 (28)
MMSE	23.08 (2.27); 18 to 26	24.92 (3.0); 20 to 29

Charlson Co-Morbidity Index weighted score	2.7 (2.1); 1 to 10	2.8 (2.2); 1 to 11
Subjective rating of health:		
Excellent	1 (4.0)	0
Very good	8 (32.0)	5 (20.0)
Good	7 (28.0)	7 (28.0)
Fair	8 (32.0)	11 (44.0)
Poor	1 (4.0)	2 (8.0)
DEMQOL	90.5 (18.0); 39 to 109	92.28 (10.8); 68 to 112
GSES	29.7 (4.5); 14 to 36; n=24	30.20 (4.1); 18 to 36; n=25
HADS:		
Depression	4.2 (2.9); 1 to 10	3.75 (2.3); 0 to 8
Anxiety	5.6 (3.7); 0 to 15	5.76 (3.5); 0 to 14
RBMT:		
Immediate recall	2.3 (2.0); 0 to 9.5	3.08 (2.1); 0 to 6.5
Delayed recall	-0.4 (1.0); -1 to 2.5	1.16 (2.1); -1 to 5
TEA:		
Elevator counting	6.2 (1.1); 3 to 7; n=22	6.36 (0.9); 4 to 7; n=25
Elevator counting with distraction	4.8 (2.8); 1 to 9; n=21	5.26 (2.9); 0 to 9; n=23
DKEFS verbal fluency	27.6 (11.6); 2 to 51; n=24	22.24 (8.5); 7 to 43; n=25

*Data are mean (SD) range or n (%)*

(d) Clinical characteristics of the carers at baseline

Measure	Poor outcome (n=25)	Good outcome (n=25)
<b>Subjective rating of health:</b>		
Excellent	0	1 (4.0)
Very good	3 (12.0)	8 (32.0)
Good	12 (48.0)	10 (40.0)
Fair	8 (32.0)	5 (20.0)
Poor	2 (8.0)	1 (4.0)
RSS	19.69 (8.0); 6 to 44; n=24	19.06 (7.2); 6 to 35

WHOQOL domains:		
Physical	14.58 (3.1); 9 to 20	14.56 (3.3); 6 to 19
Psychological	15.13 (2.1); 11 to 20	15.20 (2.0); 11 to 18
Social	14.42 (2.4); 11 to 20	15.32 (2.2); 11 to 20
Environmental	15.75 (2.2); 12 to 20	16.24 (2.5); 10 to 20
EQ5D3L:		
Index	0.69 (0.29); -0.02 to 1; n=24	0.79 (0.1); 0.5 to 1
VAS	72.48 (22.3); 8 to 99; n=23	73.52 (19.5); 30 to 100

Data are mean (SD) range

(e) BGS1 ratings at each time point

Measure	Poor outcome (n=25)			Good outcome (n=25)		
	Baseline	3 months	9 months	Baseline	3 months	9 months
Participant rating of attainment	4.55 (2.30)	3.94 (2.08)	4.94 (2.55) n=24	1.91 (0.83)	8.13 (0.94)	7.86 (1.64)
Participant rating of satisfaction	4.09 (1.86)	4.91 (1.99)	6.24 (2.05) n=23	2.71 (1.34)	8.01 (0.71)	8.12 (1.39)
Carer rating of attainment	3.37 (1.85)	3.35 (1.63)	3.79 (2.27)	1.96 (1.18)	7.09 (1.62)	6.99 (1.90)

Data are mean (SD)

Therapy logs were maintained by the therapists in Word document format, and for the analysis these documents were used to create two parallel summary Excel spreadsheets, one for the 'best outcome' group and one for the 'poor outcome' group. Each file contained 15 tabs; the first tab contained information about the participant's current functional ability and therapy goals, and each of the remaining 14 tabs referred to one therapy session. Within each tab, each row contained data for one participant and each column contained comments about one topic relating to the treatment delivery (e.g. goal progress, use of restorative and compensatory strategies, anxiety management strategies applied, etc.), with 6-7 columns in each tab. The trajectories of participants' progress through the intervention were analysed to identify factors that could help to explain good or poor outcomes.

The analysis was conducted through several stages, using an adapted framework analysis method,<sup>113</sup> by a researcher who was not otherwise involved in the trial and was independent of the trial team.

- In stage 1, therapy logs were analysed by session, according to the pre-existing topics. This was to provide a perspective on the intervention according to how the intervention was structured and the progress recorded after each session.
- In stage 2, therapy logs were analysed by participant, in order to identify critical factors affecting involvement and progress. This stage was informed by findings from the stage 1 analysis and findings from the therapists' focus group.
- In stage 3, a 'negative case analysis' was conducted in order to explore in more depth secondary factors influencing therapy outcomes for those participants who did not fit with the general patterns emerging from the analysis.

In the stage 1 analysis, the therapy logs for each participant were summarised using an adapted framework analysis approach, with the framework categories representing pre-existing categories in the therapy logs rather than being identified as themes in the data by the researcher. Summaries were produced for each component of the intervention delivery (i.e. each column in the matrix), for each of the 14 therapy sessions. The summaries produced were sub-divided into different themes depending on the content, for example 'carer stress.' Summaries included details such as frequencies, for example numbers mentioning particular types of goals at this stage, to avoid impressionistic bias in the analysis. These summaries also used the voice of the therapist, such as terms employed, as much as possible to maintain the validity of the analysis. The summaries were then further summarised into short versions according to key content and themes in order to identify patterns in how participants engaged with and benefited (or not) from different aspects of the intervention. The findings for the two participant groups were then compared, to identify any differences in treatment and treatment experience between the two groups, and to identify and refine explanatory themes emerging from the analysis. Memos reflecting other features of the intervention and participants' experiences were also recorded, to help in identifying factors that appeared to be important but which were not captured by the therapy log categories; the factors noted were:

- Progression or stage of dementia
- Physical health of participants
- Participants' anxiety

- Carer engagement – commitment to the intervention and participation in the sessions
- Carer difficulties (e.g. stress, health problems)
- Adaptation of goals, for example where participants rejected previously-chosen goals; extension of goals or strategies where original aims were surpassed
- Life events, holidays or family visits
- Type of goal – for example whether the goal related to household chores, personal projects or social activities.

Factors emerging from the focus group analysis and from the stage 1 therapy log analysis were combined into the following final list of eight significant features of therapy experience that was used for stage 2 of the therapy log analysis:

1. Stage or severity of dementia
2. Participants' physical health
3. Low mood or depression
4. Anxiety
5. Carers' difficulties (e.g. stress, health problems)
6. Carer engagement
7. Type of goal
8. Changes in goals (either rejecting, changing or surpassing original goals)
9. Life events, holidays or family visits

In stage 2, a summary for each of these categories was produced for each participant, identifying the therapist comments made for each domain (if any). The summaries for both groups were then compared, to identify any differences in the experiences between the two groups of participants. The initial analysis examined frequencies to identify broad differences between groups and then explored potential explanations of why groups were different. This included consideration of differences with regard to specific factors (for example, the type of problematic carer engagement), and exploration of links between initial findings (for example, whether participants whose dementia had progressed further tended to select different types of goals to work towards).

Summaries of key findings from the therapy log analysis included a comparison of the findings from each of the three main stages of analysis and further refinement of themes. The

findings were discussed by the researcher and trial manager to confirm the basis for and discuss the implications of the findings.

Stage 3 analysis built on stages 1 and 2, to investigate negative cases where participants did not fit the general pattern for their group, for example where participants who had lower functional ability achieved good BGSi outcomes. The analysis focused on therapy log entries from three milestone sessions where therapists summarised goal progress and factors affecting progress: session 10 (the end of the main phase of the intervention), session 11 (the beginning of the maintenance phase) and session 14 (the end of the maintenance phase). Similarities between negative cases in the 'poor outcome' and 'good outcome' groups were investigated to try to identify factors contributing to participant outcomes.

A limitation of the analysis is that both the therapy logs and the focus group data only represent views of the therapists of how the intervention operated, and the therapy logs were notes made by therapists about significant events or issues rather than a systematic summary of each session. There were also aspects of the log entries that could be unclear:

- Some entries were ambiguous; for example, some noted strategies without being clear about whether these were being suggested by the therapist or were actually being applied by the participant/carer.
- Some entries implied rather than explicitly stating the presence of features such as anxiety (for example references were made to '*frustration*' or '*stress*') or dementia symptoms (such as lack of motivation, which could be caused by several quite different types of difficulties).
- Some entries noted 'nil'/none and it was not clear whether this referred to lack of progress or whether it indicated that this topic was not covered in the session.

Where data were unclear they were not included in the data reduction summaries for the analysis.

## Findings

The analysis identified differences between the two groups in relation to two areas: level of functioning and anxiety, and there were also secondary factors influencing outcomes.

## 1. Level of functioning

The initial stage of the therapy logs analysis found that participants in the poor outcome group were more likely to be described as experiencing greater cognitive difficulties, as being less likely to acknowledge difficulties, and as having limited motivation to engage in therapy. Cognitive decline over the study period was noted for participants in both groups to an equal extent, but therapists were more likely to comment on lack of acknowledgement of difficulties in the group with poorer outcomes. This overarching difference between the groups was reflected in several important themes evident in the therapy logs.

*The nature of therapy goals:* While there was some similarity in the type of goals identified by participants in both groups (e.g. similar numbers of participants in both groups wanted to improve their use of mobile phones), there were also marked differences. Participants in the poor outcome group tended to select more basic goals such as knowing the date, while participants in the best outcome group tended to identify more recreational goals, such as engaging in social activities outside the house. In the poor outcome group notes from the initial therapy sessions contained more concerns about the person's ability to carry out basic daily activities, such as dressing.

*Changing goals:* The frequency with which therapists amended the goals identified during the researchers' visit was the same for both groups. Participants in the best outcome group were more likely to extend their goals and aim for more ambitious targets, while those in the poor outcome group were more likely to give up on a goal entirely. This could be linked to lower motivation or to difficulties identifying suitable objectives, or could possibly be seen as a way to avoid confronting difficulties.

*Goal progress:* Differences in rates of progression appeared following the first three sessions. In the best outcome group, the first three sessions were often enough for the participants to start making noticeable progress and there was an increase in positive comments about progress towards achieving therapy goals from the third session onwards. In contrast, for participants in the poor outcome group there were comments about low levels of engagement with working on goals and insufficient between-session practice. The poor outcome group were also less likely to engage with a third goal, if they had one, or else they started working on it later. As expected, participants in the best outcome group gave more positive in-session ratings for goal attainment, and both participants and therapists made more positive comments about progress toward achieving the goals than in the poor outcome group. Therapists made more comments on wholly positive progress for the best outcome group at

the end of the maintenance phase. The lack of progress in the poor outcome group was attributed by therapists to some participants not acknowledging difficulties.

*Activity levels:* Participants in the best outcome group had slightly higher levels of functioning as indicated by the PAL<sup>76</sup> score, and were more likely to report interest in increasing their activity levels and to make plans to do so than those in the poor outcome group, who were more likely to be described as inactive.

*Compensatory strategies:* The types of strategies adopted were similar for both groups, although participants in the best outcome group were often already using some strategies and were more likely to make positive progress with new ones.

*Restorative strategies:* Participants in the best outcome group were also more likely to be already using some restorative strategies to remedy their cognitive difficulties and were more likely to use new ones successfully and to apply them to a wider range of areas. Participants in the poor outcome group were less likely to engage with these strategies or to even have a discussion about using them.

*Attention and concentration:* While there were similar types of strategies adopted in both groups to support attention and concentration, participants in the best outcome group appeared to have adopted strategies earlier in the course of therapy, and made more positive comments about using the strategies.

*Perspectives of participants:* Participants in the poor outcome group tended to engage less with therapy, expressed more reluctance, appeared withdrawn during sessions, and had more difficulty recalling previous sessions. At the end of the intervention, they were more likely to refer to the relational or social aspect of the therapist visiting them as a positive element of the intervention, or to make very general positive comments. Participants in the best outcome group were more likely to give examples of specific elements of the intervention that had benefitted them.

*Relationship between participant and carer:* In the poor outcome group, relationships between the participant and the carer appeared more unbalanced, with dominant carers and/or more passive or dependent participants, although it was not clear to what extent this reflected participants' cognitive or functional ability and to what extent it was a more intrinsic characteristic of the relationship. Relationship strains were mentioned for both groups, but therapists were slightly more likely to report wholly positive relationships for the participants in the best outcome group.

*External support:* Toward the end of therapy, the plans for ongoing support differed between the good and poor outcomes groups. Participants in the poor outcome group tended to

consider whether additional external support, such as day care or respite, would be helpful, while those in the best outcome group were more likely to discuss getting involved in social activities such as support groups or dementia choirs.

## 2. Anxiety

In both groups, therapists noted a range of psychological difficulties experienced by participants, including low confidence, agitation, frustration, and low mood. However, anxiety problems were more often noted for participants in the best outcome group, while participants in the poor outcome group and their carers were more likely to report that anxiety was not a problem.

## 3. Secondary factors influencing therapy outcomes

Stages 2 and 3 of the analysis explored in more detail secondary factors influencing therapy outcomes. In the second stage, therapy sessions were examined with regard to the final list of eight significant features of therapy experience thought likely to influence outcome. The list included cognitive difficulties as discussed above, as well as factors that did not appear to differentiate the groups clearly, such as participants' health, carer engagement in therapy and support provided by the carer. To further investigate the impact of these factors on therapy a negative case analysis explored potential relationships in more depth. Specifically, therapy logs for participants who had poor outcomes but for whom no particular dementia-related problems were noted were reviewed as a group (n=11), and therapy logs for participants who had good outcomes but for whom specific dementia-related problems were noted (n=6) were reviewed as a group.

The negative case analysis of the six participants who were in the 'good outcome' group despite particular dementia-related problems being noted indicated that their symptoms were milder than those in the 'poor outcome' group or their symptoms fluctuated, creating opportunities for more effective therapy work. The analysis of this group of participants therefore supports the view that the extent of cognitive difficulties or dementia-related problems is associated with outcome.

For the 11 participants in the 'poor outcome' group for whom no particular dementia-related problems were noted, progress with therapy appeared to be affected by several secondary factors. The most significant of these factors were either not engaging with goals or setting an

inappropriate goal, lack of carer support for between-session practice, and significant health problems or additional disability such as visual impairment. Several participants in this subgroup had a combination of two or three of these factors hindering therapy progress. It is important to note, however, that these secondary factors appear to have less impact on the therapy outcome than their level of functional ability, as discussed above.

There were a number of factors that did not appear from the therapists' records to have any consistent relationship with therapy outcomes, such as therapeutic alliance, number of sessions attended, carer health and wellbeing, and therapist support in the areas not related to goals.

### Summary

The main findings indicate that the intervention appears to be more effective for participants with less severe cognitive difficulties and with better functional ability. This concurs with findings from the therapist focus group. While other factors such as carer support and participant health influence participants' behaviour, such as levels of between-session practice, these factors do not seem to be linked to overall intervention outcomes.

### **Participant and carer experience of the intervention**

A subset of participants and carers from the CR group was interviewed about their experience of the intervention to gain insight into the way in which they experienced the therapy, and what aspects of the therapy were found particularly challenging or helpful. In-depth understanding of the participants' subjective experience of the intervention is important for understanding the mechanisms of therapy. It also enables participants to formally contribute their views and experiences to the therapy evaluation

### ***Method***

Three sites were able to contribute to this component of the evaluation as they each identified an independent researcher not involved in the trial who could conduct detailed interviews. Interviews were conducted in the Bangor (21st March 2014 - 20th January 2015), Cardiff (31st July 2015 – 9th December 2015) and Manchester sites (1st April 2015 – 28th May 2015). In each site, a consecutive series of participants and carers was approached following the nine-month follow-up assessment and invited to participate in the interview to discuss

their experiences of the therapy. The Trial Manager issued the researchers with site-specific lists of all participants in the CR group that were due to complete their final follow-up assessment in the designated recruitment period. In total 36 couples were approached and 26 agreed to be interviewed although in the case of one couple only the carer participated in the interview. We interviewed 12 carers and 11 participants at Bangor (100% of those approached), ten carers and ten participants at Cardiff (50% of those approached), and four carers and four participants at Manchester (100% of those approached). Demographic and clinical characteristics of these participants, and BGSi ratings, are shown in *Table 16*. Of note, six of the participants were also included in the therapy logs analysis, two in the poor outcome group and four in the good outcome group.

The interviews followed a semi-structured schedule, and interviewers encouraged the participants and carers to talk freely about their experience of the intervention (see *Appendix 2* for the interview schedules). The interviews covered the following topics:

- How did participants and carers experience the intervention?
- What were their overall perceptions, how useful did they find it, and what did they feel about the degree of effort required?
- What impact, if any, did the participants and carers feel the intervention had on their everyday life?

The interviewers had an overall understanding of what the intervention involved, but no specific knowledge of the individual participants' therapy goals or the therapy process in order to avoid bias. Participants and carers were interviewed separately wherever possible, starting with the person with dementia. Interviewers took a photograph of the therapist on the visit to prompt the participant's memory of the therapy sessions. If the participant was struggling to recall the therapy sessions the interview was completed jointly with the carer. The first interview conducted by each interviewer was reviewed at the co-ordinating centre to ensure adherence to the interview schedule. Interviews were found to have been conducted satisfactorily in each case. All interviews were audio-recorded, transcribed verbatim and anonymised.

Table 16. Demographic and clinical characteristics, and BGSi ratings, of the participants and carers participating in the qualitative interviews

(a) Demographic characteristics of the participants with dementia

<b>Measure</b>	<b>Interviewed n=25</b>
Age	76.64 (5.7) 66 to 87
Sex (male)	13 (52.0)
Ethnicity:	
White	24 (96.0)
Mixed / Multiple ethnic group	0
Asian / Asian British	0
Black / African / Caribbean / Black British	1 (4.0)
Other ethnic group	0
First language (English)	23 (92.0)
Marital status (married)	21 (84.0)
Years of education	12.74 (2.7); 10 to 21.5
Occupational status:	
I Professional	3 (12.0)
II Managerial/technical	6 (24.0)
III N Skilled, non-manual	6 (24.0)
III M Skilled, manual	5 (20.0)
IV Partly skilled	4 (16.0)
V Unskilled	1 (4.0)

*Data are n (%) or mean (SD) and range*

(b) Demographic characteristics of the carers

<b>Measure</b>	<b>Interviewed n=26</b>
Relationship to participant with dementia:	
Spouse/partner	21 (80.8)
Adult child (including in-law)	5 (19.2)
Other	0
Age	70.38 (11.2); 46 to 85
Sex (male)	8 (30.8)

Ethnicity:	
White	26 (100)
Mixed / Multiple ethnic group	0
Asian / Asian British	0
Black / African / Caribbean / Black British	0
Other ethnic group	0
First language (English)	24 (92.3)
Marital status (married)	25 (96.2)
Years of education	14.40 (3.1); 10 to 20.5
Occupational status:	
I Professional	6 (23.1)
II Managerial/technical	7 (26.9)
III N Skilled, non-manual	6 (23.1)
III M Skilled, manual	2 (7.7)
IV Partly skilled	4 (15.4)
V Unskilled	1 (3.8)

*Data are n (%) or mean (SD) and range*

(c) Clinical characteristics of the participants with dementia

<b>Measure</b>	<b>Interviewed n=25</b>
Diagnosis:	
Alzheimer's disease	19 (76.0)
Vascular dementia	3 (12.0)
Mixed Alzheimer's and vascular dementia	3 (12.0)
MMSE	23.40 (2.3); 19 to 28
Charlson Co-Morbidity Index weighted score	2.1 (1.2); 1 to 6
Subjective rating of health:	
Excellent	2 (8.0)
Very good	8 (32.0)
Good	7 (28.0)
Fair	8 (32.0)
Poor	0
DEMQOL	91.84 (12.3); 53 to 106

GSES	31.84 (3.7); 24 to 39 n=25
HADS:	
Depression	3.28 (2.6); 0 to 9
Anxiety	4.88 (3.2); 1 to 14
RBMT:	
Immediate recall	2.84 (2.3); 0 to 7.5
Delayed recall	0.34 (1.9); -1 to 5
TEA:	
Elevator counting	6.6 (0.8); 4 to 7
Elevator counting with distraction	5.36 (2.7); 1 to 9
DKEFS verbal fluency	25.04 (13.2); 2 to 55

*Data are mean (SD) and range*

(d) Clinical characteristics of the carers

<b>Measure</b>	<b>Interviewed n=26</b>
Subjective rating of health:	
Excellent	1 (3.8)
Very good	9 (34.6)
Good	13 (50.0)
Fair	3 (11.5)
Poor	0
RSS	17.02 (7.7); 5 to 36
WHOQOL domains:	
Physical	16.00 (2.4); 10 to 19
Psychological	15.58 (1.4); 12 to 18
Social	15.19 (2.3); 11 to 20
Environmental	17.15 (1.7); 13 to 20
EQ5D3L:	
Index	0.82 (0.2); 0.09 to 1
VAS	80.42 (11.0); 60 to 100

*Data are mean (SD) and range*

(e) BGS ratings at each time point

<b>Rating</b>	<b>Baseline</b>	<b>3 months</b>	<b>9 months</b>
Participant rating of attainment (n=25)	3.37 (1.74)	6.10 (1.67)	6.66 (1.94)
Participant rating of satisfaction (n=25)	3.57 (1.82)	6.54 (1.31)	7.06 (1.70) n=24
Carer rating of attainment (n=26)	2.59 (1.21)	5.49 (1.76)	5.72 (2.33)

*Data are mean (SD)*

Thematic analysis started from a critical realist position and was based on an inductive approach to identifying and exploring patterns of meaning in relation to the research question.<sup>111,114</sup> Four researchers who were not involved in conducting the interviews analysed the interviews; three of these were independent from the trial and one was the Trial Manager. The process was overseen by the Chief Investigator. Initially, two researchers read and re-read the first five transcripts to familiarise themselves with the data and then identified and coded (briefly summarised and characterised) units of meaning within each transcript. Codes were listed separately, reviewed, and organised into meaningful groups representing initial themes for each interview. The resulting lists of themes were compared and discussed by the two researchers until consensus was reached about content and organisation, after which each researcher re-coded the transcripts. Related themes were clustered together and the clusters ordered into group-level themes and sub-themes, and the two researchers worked together to integrate these into an overall thematic map. The remaining transcripts within the set were then coded by a single researcher using the identified list of themes

### ***Findings***

Overall, the therapy was received positively by both carers and people with dementia, and generally, there were very few criticisms of the therapy. Participants mostly said that they had nothing negative to report about the experience. Several key themes emerged reflecting factors that influenced the experience of the intervention and whether it was considered beneficial.

#### **Therapeutic relationship**

The relationship with the therapist played an important role in participants' perceptions of the intervention, especially as the participants with dementia were often unable to recall the specific goals that they had been working towards in the therapy. The therapeutic relationship was what both carers and people with dementia enjoyed about their experience of the

intervention. They looked forward to the therapist visits, and they said that they would miss the visits now the therapy had ended.

A positive interaction with the therapist was believed to be very important for the therapy by people with dementia and carers. The therapists were described as being pleasant, nice, responsive, knowledgeable, and professional. People with dementia described feeling comfortable, relaxed and at ease when talking to their therapists. Moreover, they also said they did not feel distressed or disturbed during these interactions. Carers and people with dementia believed that the therapeutic relationship was the foundation for several aspects for the intervention. The three most commonly reported aspects were education for carers and people with dementia about the dementia experience, provision of social support, and provision of information or resources that could help with daily functioning in the future.

The information and explanations that therapists gave about dementia were considered to be very beneficial for both carers and people with dementia, who found it helpful to have written information and educational materials about living with and caring for someone with the condition. Both carers and people with dementia valued the chance to have any questions answered by the therapist. In particular, the relationship with the therapist made asking questions and communication easy and less frightening, as one person with dementia described below:

**Person with dementia 1:** *Oh fine, yeah fine, got on well ... Easy, yeah she explained everything and, you know, it was no hardship (laughs)...That's right, yeah, well sometimes when people come to see you, ... you're afraid to talk, you know, afraid to say anything when it's a little bit dumb. But she made me feel so, er, comfortable and within a couple of minutes we were just like as though we'd been friends for a long time.*

The educational component was related to several perceived positive outcomes for people with dementia and their carers:

**Person with dementia 1:** *Yeah, she was very good explaining things and, you know ... I did become very positive ... after she'd been.... Cos she, she did, she made me feel good.*

Particularly, it increased their understanding and awareness of dementia, to which they attributed their resulting better psychological adjustment. Some participants reported a new and more positive perspective on the diagnosis which resulted in less worry. One person with dementia described how the therapist increased awareness and reduced worry:

**Person with dementia 2:** *She explored areas, you know that I hadn't thought about, and...I found a great help. I think it, uh... I don't think I've been sort of ... on edge about the Alzheimer's ... But ... it showed me to be less worried about it ...*

People with dementia described being wary of or worrying about performing tasks or coping in some situations prior to the therapy. Participants discussed how the therapist empowered them to make their own decisions about what they wanted to do and about working towards their goals. Person with dementia 1 described how the therapist improved her self-view and made her feel better about herself: *'I'm not as soft as I think I am.'* They went on to describe how they had changed their self-view by enabling them to make more decisions for themselves.

Carers also related this increased awareness and understanding to having more patience with the person with dementia and to other improvements in their relationship (e.g., less conflict, more affection, and thoughtfulness). An increase in patience and reduction in frustration with the person with dementia was mentioned by several carers. For example, they reported 'yelling' less at the person with dementia, and doing tasks more slowly to help the person with dementia understand. This increase in patience was seen as reducing conflicts and misunderstandings. Additionally, a few people with dementia commented that they had greater self-awareness and better social awareness. They said that they would now think before saying something in social situations, and they would consider how others (particularly, their carer) would perceive what they wanted to say before saying it. This change also seemed to benefit the relationship.

Social support and contact seemed to be important elements provided by the therapist. Carers reflected on how the participants with dementia *'enjoyed the company'*, suggesting they do not have visitors who engage with them regularly.

**Carer 1:** *I think my mum just enjoyed it more that somebody was, the social aspects of it, that somebody was coming.*

They described the visits as helpful because they offered opportunities to talk and provided support, which was something that they described as lacking in their lives. These discussions were often conducted with humour and included shared interests. The visits also became part of the routine for the person with dementia, which was viewed positively.

Several carers described how the therapist gave them a recognition that their experience was shared, as described below:

**Carer 2:** *And she made you feel that ...this was a problem that other people have and in a way it sort of normalises what is not a normal problem and she sort of made you feel it's ... something that other people experience, that there are ways through it...*

Other people who were also caring for a person with dementia were talked about as being ‘*in the same boat*’. This knowledge helped the carers feel they were not alone or ‘*neglected*’ and ‘*ignored*,’ which was what they mostly experienced in relation to others or society as a whole. In a few cases, the carer described how the therapist acted as a mediator, or neutral person, for conflicts between the carer and person with dementia. Therapists could provide suggestions without seeming confrontational or prompting other negative feelings (e.g., embarrassment). Sometimes, the carer reported that the person with dementia would respond better to the therapist than to the carer or other people.

#### Strategies to improve functioning

Through the therapeutic relationship, carers and people with dementia learned about strategies to improve functioning and how to implement these. One carer described how the input from the therapist helped develop ideas that were used to achieve goals:

**Carer 3:** *It was a great help really to talk to somebody other than [person with dementia], obviously, and [the therapist] gave us some ideas about goals which [person with dementia] couldn't remember but they were [about] your calendar and your medication. And we found that the calendar has worked very well.*

Participants discussed the effectiveness of a variety of different strategies such as simple instructions, memory prompts or reminders. For carers, these strategies were deemed especially helpful for functioning if they eased the burden of caregiving (e.g., by supporting dressing or cooking). Trying out these strategies and practising them was key to improvements for the person with dementia. Carers expressed how the intervention needed the investment of time and effort from the participants to gain any benefit. If the strategies were too challenging, effortful or repetitive, the carers believed that the people with dementia would get bored, ‘*worn down*’ or frustrated and no longer continue to use them.

Carers and people with dementia both mentioned improvements as a result of the strategies. These improvements related to general, daily functioning, and the strategies that were put into place were deemed helpful for the person with dementia. For example, the new strategies helped with remembering to take medication (as illustrated in the quote above) or knowing what activities were planned for the day without prompting. Often, the improvements were in small tasks, but some were deemed ‘vital’ for relieving some of the burden for the carer or were things that brought the person with dementia enjoyment, which seemed to enhance wellbeing.

Many carers described how they developed a more problem-focused and practical viewpoint as a result of the therapy, which enabled them to create new goals and strategies:

**Carer 4:** *[Therapist] made you think about things that you thought you perhaps knew, but think about them in a different way ... And approach them in a different way... That made it in a very practical way.*

This perspective was considered valuable as it would help in coping with future decline or challenges. There was also a shift in thinking that emphasised the ‘value [of] little things’ and enjoyment. Both carers and people with dementia got great pleasure from small and simple tasks (e.g., trips into town, a walk and a meal in a pub or restaurant), and these tasks were thought to improve wellbeing.

Participants also discussed how the strategies had positive psychological outcomes—that is, they led to greater confidence, autonomy and empowerment. People with dementia found a sense of achievement when they were able to remember or do something as a result of the intervention. One carer expressed how the act of achieving the goal was beneficial.

**Carer 3:** *I should think sometimes just reaching his goal, being able to do it after a few days. Something like that, you know, seeing that he can do it and just putting whatever [therapist] said into place... Just little things like that, they help I think.*

Both carers and people with dementia described how the therapy had improved the confidence of the person with dementia. Carers noted that the strategies and aids were helpful for improving or supporting independence. Carers remarked how the person with dementia was more willing to try different things and initiate conversations as a result of the enhanced confidence. For carers, perceiving any improvements or achievements was a source of motivation to continue with the intervention.

While the changes and strategies encouraged in the therapy were generally felt to be useful, a very small number of carers commented that these were a ‘*hindrance*’ to an established routine.

#### Person-centred approach

Carers and people with dementia both appreciated the person-centred approach of the intervention. The individual tailoring and flexibility that this approach provided was crucial for developing and implementing strategies and gaining confidence with problem-solving and finding solutions. As one carer describes below, there was flexibility to ensure that what was covered was relevant to the person and this was done at the right pace:

**Carer 5:** ... *they were always relevant to ... obviously relevant to the issues that [therapist] wanted to raise ... And also relevant to, the issues that were important for [person with dementia] ... And, the issues that were - she worked at a pace that was good for him as well.*

For people with dementia, this meant that time was taken for understanding their needs and preferences as well as personalising intervention components to suit their interests, abilities and needs. That is, the specific goal or task preferences of the people with dementia were considered and acknowledged. By individualising goals and strategies, people with dementia gained more enjoyment, empowerment and sense of achievement from completing them and therefore this potentially produced more positive outcomes for both the person with dementia and carer.

The flexibility of this approach also allowed for the adaption and modification of tasks or goals over time, which was deemed important by people with dementia and their carers. These changes made the tasks ‘*fit in*’ to their lives, and alterations could be made to manage changes in cognitive or physical health. This flexibility was closely related to the therapist’s responsiveness and the ability to address certain challenges in order to accomplish the goals.

#### Dementia-related beliefs

A few carers and people with dementia were not sure whether the therapy had been truly beneficial, and noted that it did not improve memory as such. This uncertainty about the impact of therapy was due to the progressive nature and inevitable decline associated with the

condition. This was illustrated by the response of one carer when asked about the impact of the therapy:

**Carer 6:** *...now, we come onto the issue of ... the problem of Alzheimer's itself, so that, to be honest, is very, very difficult to answer... Certain things have slipped away, but is that the fault of the programme or the fault of the condition? And so it's really difficult to equate what the programme has done and what the condition has not allowed it to do...*

A few carers questioned to what extent the intervention was worthwhile given that normal functioning could not be restored and decline was inevitable. Furthermore, there was a concern about the lasting benefit of the therapy. A couple of carers and people with dementia believed that the future deterioration would possibly undo any improvements from the therapy. With this thought, a few carers suggested that the intervention may be most relevant and beneficial in the earlier stages of dementia.

## Summary

The main findings can be summarised as follows:

- The relationship with the therapist played a major role in the therapy. It was the vehicle for providing information, education and support and was the means by which rehabilitative strategies were developed, accepted and personalised.
- The most frequently reported impact of the therapy was improved psychological adjustment to dementia and a more positive perspective, reflected in greater confidence, less anxiety, better coping, empowerment, and improved wellbeing.
- Participants and carers found the intervention effective in supporting activities of daily living, and improving psychosocial wellbeing and quality of life.
- The perceived effect of the therapy on cognition and memory was mixed. Some carers and people with dementia were not sure whether the therapy was beneficial for cognition due to the believed progressive nature and inevitable decline associated with the condition. It should be noted that the therapy was not expected to benefit cognition as such and was not presented to participants as a treatment to improve cognition.
- People with dementia and carers expressed an overarching need for social contact and support.

## **Case studies**

People living with early-stage dementia face many challenges in everyday life as cognitive impairments and other changes impact on functioning. The exact nature of these challenges is different for each individual, depending on personal characteristics, circumstances, interests and preferences. *Appendix 13* presents four illustrative case studies from the GREAT trial showing the kinds of needs and concerns that prompted participants and carers to choose particular goals and demonstrating how the therapists worked with participants and carers to address their goals during the cognitive rehabilitation intervention.

## **Feasibility of implementation**

In the later stages of the trial the GREAT team undertook to explore the feasibility of implementing the CR approach within NHS services. This was an opportunity to examine the challenges that could arise when translating the intervention to a real-world setting, and consider how these might be overcome to facilitate successful implementation. The results are presented in *Appendix 14*.

## Chapter 5. Economic evaluation

### Research question

Using a multi-centre pragmatic randomised controlled design, the study compared goal-oriented cognitive rehabilitation (CR) with treatment as usual (TAU). The aim of the economic evaluation was to examine whether CR is a cost-effective intervention, compared to TAU, for people with early-stage Alzheimer's disease, vascular or mixed dementia and their carers over a nine-month period post-randomisation.

### Methods

#### *Form of evaluation*

The economic evaluation included cost-effectiveness and cost-utility analyses.

#### *Effectiveness*

The economic evaluation examined four outcome measures, three for participants with dementia and one for carers.

Cost-effectiveness measures:

- Incremental cost of achieving a standardised mean difference (SMD) of 1.32 points in the participant-reported goal attainment measure (Bangor Goal-Setting Interview; BGSi), the primary outcome for the trial
- Incremental cost of achieving a difference in effect of 0.30 in the Generalized Self-Efficacy Scale (GSES), which assesses a participant's general sense of perceived self-efficacy

Cost-utility measures:

- Incremental cost per quality-adjusted life year (QALY) assessed by the participant-rated DEMQOL
- Incremental cost per QALY for carers' self-rated health-related quality of life, using EQ5D3L

A standardised mean difference for the GSES was calculated by multiplying the effect size of 0.3 by the (non-imputed) standard deviation of the mean across sample participants at baseline following Samsa et al.<sup>115</sup> The second outcome in the list above thus equates to an

incremental cost of achieving a SMD of 1.53 points in the GSES. These outcome measures are described in more detail in *Chapter 2*.

We calculated utility scores for participants with dementia from the DEMQOL instrument (the DEMQOL-U index), using published societal weights.<sup>116</sup> We derived QALYs from these scores using the area-under-the-curve method, with linear interpolation between the three assessment points. We calculated carers' utility scores from the EQ5D3L with published societal weights.<sup>117</sup>

### ***Perspective***

The economic evaluation first took a health and social care perspective, and second a societal perspective. Broadly speaking, the health and social care perspective took into account those costs falling to the NHS and to local authority social services departments (SSDs). Most service costs (e.g. hospital, community healthcare, community day and home-based care) were considered to fall entirely to these agencies. However, only adaptations and equipment reported as provided by NHS or SSDs were considered within this perspective. The societal perspective was considered to encompass not only health and social care costs but also the costs to the participant-carer dyad: lost production in terms of carer's wages forgone because of providing care; costs of providing care in terms of hours of care provided; out-of-pocket payments (privately purchased equipment and travel costs of attending appointments related to dementia treatment).

### ***Time horizon***

The outcomes and costs considered in the economic evaluation were measured at the baseline, three-month and nine-month assessment points. Costs collected using the Client Services Receipt Inventory (CSRI) covered the three-month period prior to each assessment point. Nine-month costs were calculated from these three data collections. The costs of services between three months post-baseline and six months post-baseline were assumed to be the same as the costs in the three months prior to the nine-month follow-up. In other words, to calculate nine-month costs, we estimated three-month costs based on data from the second follow-up, multiplied this estimate by two and added this to the costs in the three months prior to the first follow-up. It was not necessary to apply discount rates to either costs or outcomes because the time horizon was shorter than one year.

## *Costs*

The analysis considered comprehensive costs of care and support to the person with dementia. Costs were calculated drawing on the following collections:

- Data on services used by the person with dementia, as observed and reported by carers using the CSRI.<sup>118</sup>
- Data on carer time spent on care and support activities and lost employment, using the CSRI.
- Data on time spent by professionals in delivering the intervention, using the therapy logs.
- Data on professionals' labour costs, using a pro forma distributed to therapists.
- Costs of training (fees, materials) supplied by the project management team.

Costs of *health and social care services* were calculated from service-use data by applying relevant, nationally generalizable unit costs: NHS reference costs<sup>119</sup> and figures in the Personal Social Services Research Unit (PSSRU) costs compendium.<sup>120</sup> We calculated the costs of carers' inputs using opportunity costs (base case) and replacement costs (sensitivity) methods.<sup>121-123</sup> The opportunity costs approach involved attaching a value to each hour of unpaid carer time in providing care and support equal to the minimum wage. In the replacement cost approach, the cost of an hour of home care was used to value unpaid carer time spent providing care. The unit costs used in valuing resource use<sup>124-149</sup> are summarised in *Table 17* and reported in full in *Appendix 15*.

Costs are reported in the following categories: hospital services; primary and community health; mental health services; overnight respite care; community social care; day services; equipment and adaptations; mental health medication; costs of the CR intervention; unpaid care. Costs are also reported as aggregated total costs from the health and social care and from the societal perspective.

Table 17. Unit costs in brief

<b>Service use item</b>	<b>Unit cost (£, 2013/2014)</b>
Inpatient bed-day, per specialty	Range: 324-896
Inpatient bed-day, weighted average across adult specialities	495
Day attendances, per specialty	Range: 374-1333
Day case, weighted average across specialties	698
Outpatient attendances	Range: 42 - 271
A&E attendances, admitted and non-admitted	124
Outpatient, weighted average of follow-up attendances across adult specialities	102
Primary, community and community mental health services - contacts	Range: 0.5 - 221
Primary and community health services – minutes	Range: 0.5 – 4.43
Residential care, per day	Range: 79 - 157
Nursing home care, per day	104
Community-based social care, minutes	Range: 0.33
Day services, per session/day	Range: 3 - 146
Medications, standard quantity units	Range: 0.029 - 8.45
Equipment and adaptations, cost over 3 months per item	Range: 0.22 - 106
Carer hour, valued at replacement cost – home care worker, per hour	19.64
Carer hour, valued at opportunity cost - minimum wage, per hour	6.31

The costs of the *CR intervention* were calculated by drawing on a number of sources. We gathered comprehensive information on the time spent by therapists delivering the CR intervention. The intervention time consisted of three elements:

- *Direct (face to face) contact time with participants*: Therapists entered their contact time per visit in ‘therapy logs’ in the MACRO database system.
- *Indirect contact time (planning, travel) with participants*: The set-up time was estimated by the GREAT project team as 10-15 minutes. Therefore 12.5 minutes of indirect time was allocated per visit. Therapists estimated the time taken to make a one-way journey to the participant as an average and entered this into the MACRO database system.

- *Non-contact time (general training and individual training/supervision)*: A pro forma collected non-contact costs (supervision and training of therapists) from the project team. These included: numbers of hours spent in general training sessions; cost of providing general training sessions (trainers' fees, venue & materials costs); travel costs of attending general training sessions; numbers of hours spent in individual training sessions; cost of providing individual training sessions (trainers' fees, venue & materials costs); and travel costs of attending individual training sessions

Therapists also completed a pro forma providing information on Agenda for Change (AfC) band, the proportion of full-time equivalent (FTE) worked, start and end dates on the project, usual mode of transport, average miles travelled by car, average parking charges and the average cost of a public transport fare.

To value time spent by therapists in direct, indirect and travel activities, we calculated comprehensive therapy staff costs including salary costs (by median FTE earnings per AfC band, including on-costs: superannuation at 14% of salary, and national insurance contributions); administrative overheads (management and non-staff costs) and capital overheads calculated as a percentage of salary cost. Staffing costs were weighted by salary band and time contributions (FTEs at each band) to estimate a weighted cost per hour of therapy time. To value the costs of therapy journeys made to participants, we estimated the costs of public transport or car travel per centre using the data from each therapist-completed pro forma.

The study ran over four years: pro formas were issued every financial year. The costs of general training and supervision in years following the base year (2013-14) were deflated to 2013-14 prices using the Hospital and Community Health Service (HCHS) index.<sup>150</sup> The total across all years was divided by the number of CR participants (N=238) multiplied by 14 sessions to give a per-session overhead to be attached to each session attended by participants.

### ***Missing data***

Resource use data collected using the CSRI may be missing for any use of a service, for the frequency of using the service or for the duration of a service (e.g. length of a home care visit). Where service use was indicated but frequency was missing, a suitable nationally

applicable unit cost was used if available (e.g. cost per visit). For each case, items in each cost category were added together to give the total cost for the category. Category-level costs were then summed to give a total overall cost per case. If all costs in the category were missing, the category total (per case) was calculated as missing; if some items were missing, these were treated as zeros and the case was assigned the cost of the sum of available costs in the category.

Missing category-level costs were multiply-imputed by predictive mean matching (k=5 nearest neighbours) in a regression model that included demographic variables of the dyad, centre and stratified MMSE and the outcome measures to be used in the cost-effectiveness analysis, using the Stata programme *MI impute* (StataCorp LP, College Station, Texas).<sup>151</sup> Whether people with dementia who had been lost to follow-up or withdrew prior to the nine-month follow-up had died during this time was unknown. The model therefore also included the survival of the person with dementia to the end of the nine-month assessment as an imputation variable. Carers who were part of a dyad that had been lost to follow-up or withdrawn were assumed to have survived. Costs and outcomes were imputed separately by allocation and were imputed conditional on survival.<sup>152</sup> The number of imputations was guided by White, Royston, and Wood's<sup>153</sup> rule of thumb that the number of imputations should be set at the percentage of incomplete cases for variables to be used in the analyses.

### ***Analyses***

Use of services and mean use of services within allocation groups were compared descriptively with no tests of between-group differences given the large numbers of potential comparisons. Descriptive statistics of costs and outcomes are presented in terms of the mean and standard error in each group and the between-group difference and the standard error of the difference. All service use, costs and outcomes data are summarised in terms of the sample of dyads where unpaid carers were available for the completion of CSRI section of the assessment at each time point. All analyses were conducted using Stata 14 (StataCorp LP, College Station, Texas, USA).<sup>154</sup> Costs outliers were identified by following the adjusted boxplot technique described by Vanderviere and Huber<sup>155</sup> and recommended for skewed data. This involved calculating the medcouple, a measure of skewness (using a user-written programme *medcouple* in Stata),<sup>156</sup> establishing the upper fence of a boxplot interval and defining the observations falling above the upper fence as high-cost outliers.

### *Cost-effectiveness*

CR was to be defined as cost-effective if it was:

- either less costly and more effective than TAU;
- or more costly and more effective than TAU, and society is willing to pay the additional cost in order to achieve the gain in outcome;
- or less costly and less effective than TAU, and society is willing to sacrifice some of the outcome difference in order to make a saving.

The intervention was to be defined as *not* cost-effective if it was both significantly more costly and less effective than TAU, or where society was not willing to pay the cost of a gain in outcome. The criteria for this decision were based on the following rule:

$$\Delta C / \Delta E < \lambda \quad (1)$$

Here  $\Delta C$  represents the additional cost,  $\Delta E$  is the gain in outcome associated with the treatment, and  $\lambda$  is the willingness to pay for that outcome gain.<sup>157</sup> The incremental cost effectiveness ratio (ICER) ( $\Delta C / \Delta E$ ) must be below the decision-maker's willingness to pay ( $\lambda$ ) to be considered cost-effective.

The ICER was calculated as the difference in the mean costs of the CR and TAU groups over the period of follow-up (nine months) divided by the difference in the mean endpoint outcome measure (BGSI and GSES for participants with dementia) between groups. In the case of the ratio of incremental costs and QALYs (based on DEMQOL-U for participants with dementia and EQ5D for carers), the denominator was the difference in mean QALY. ICER point estimates presented in the tables are based on the ratio of the costs results rounded to one decimal place and outcomes results rounded to two decimal places.

The cost-effectiveness decision rule can be rearranged in terms of the net monetary benefit, the monetary value of a gain in effect associated with the treatment at a given willingness-to-pay, net of the additional cost of the treatment:<sup>157</sup>

$$\lambda \Delta E - \Delta C > 0 \quad (2)$$

The net monetary benefit must be greater than zero if the costs associated with the intervention are not to outweigh the benefits of the intervention.

### *Cost-effectiveness analyses*

Incremental costs and outcomes were estimated by seemingly-unrelated regressions.<sup>158</sup> This approach was combined with non-parametric bootstrapping. The estimates were adjusted by

centre, baseline outcome measures and baseline costs, as well as demographic variables (gender, age and stratified MMSE score). The regression coefficients on the allocation term were used to calculate net monetary benefit over a range of societal willingness-to-pay (WTP) levels for incremental differences in the primary outcome measures and for QALY gains.

The number of bootstrap samples used in the analyses was determined by a method suggested by Gould and Pitblado.<sup>159</sup> This involves examining the bootstrap variance estimates for the variable of interest plotted against the number of replications. The bootstrapped standard error for the allocation term in the cost regression was examined in this way. At the point when consecutive standard errors produced by the bootstrap samples (increasing from a base of 1000 replications by 1000 additional replications) differed by less than 1%, this was considered to be an adequate number of replications. The complete cases analyses used 60,000 replications; analyses with multiply imputed data used 3000 replications.

The proportion of bootstrap replicates in which the net benefit was greater than zero was plotted over a range of WTP values to produce cost-effectiveness acceptability curves. These illustrate the probability of making a correct decision to fund the intervention,<sup>157</sup> and also the sampling uncertainty around the point estimate of the ICER.<sup>160</sup> The cost-outcome difference pairs were plotted as points on the cost-effectiveness plane as a further means to illustrate sampling uncertainty while providing graphical information on the joint distribution of costs and outcomes across the quadrants of the plane. For instance, cost-outcome differences that fall into the north-east quadrant of the plane indicate that CR is associated with higher costs and better outcomes compared to TAU.<sup>161</sup> Points falling into the south-east quadrant indicate that lower costs and better outcomes are produced by the new intervention relative to the old (in which case the new intervention is said to ‘dominate’ the old). Points falling into the north-west and south-west quadrants represent situations where the new intervention respectively costs more (in which case the new intervention is ‘dominated’) and where the intervention costs less than the alternative; in either case the new intervention produces worse outcomes.

The analyses took into account the data of those participants and carers with information sufficient to calculate both service costs and carer costs. Thus the analyses did not consider data where only one member of the dyad had contributed information. Also, given the need to

reflect the societal perspective, data from participants with only *paid* carers were not analysed. This was for two reasons: first, paid carers were not providing unpaid care; and second, the reason that the informant was a paid carer was likely to reflect the absence of an unpaid carer who would incur any unpaid care costs.

## Results

### *Sample numbers*

The numbers of people who formally participated in assessments were:

- at baseline, 474 people with dementia and their carers (238 CR; 236 TAU)
- at three months, 445 people with dementia (218 CR; 227 TAU) and 442 carers (217 CR and 225 TAU)
- at nine months 426 people with dementia (208 CR; 218 TAU) and 422 carers (207 CR; 215 TAU).

In terms of *complete dyads* who formally participated in the assessment:

- at baseline, 474 complete dyads participated (238 CR; 236 TAU)
- at three months, 442 participated (217 CR; 225 TAU)
- at nine months 422 participated (207 CR; 215 TAU).

As regards CSRI questionnaires that were partially or wholly completed by dyads consisting of a person with dementia and an unpaid carer, the numbers were:

- at baseline, 469 CSRI questionnaires (236 CR; 233 TAU)
- at three months 437 CSRI questionnaires (215 CR; 222 TAU)
- at nine months 415 CSRI questionnaires (205 CR; 210 TAU).

Information from complete dyads (who had not withdrawn or been lost to follow-up) and had an unpaid carer participating that was sufficiently complete to calculate health and social care and societal costs were available:

- at baseline for 469 dyads (236 CR; 233 TAU)
- at three months for 435 dyads (213 CR; 222 TAU)
- at nine months from 414 dyads (204 CR; 210 TAU).

The outcomes data available at each assessment point are described in *Chapter 3*. Numbers of dyads included in the cost-effectiveness analyses varied depending on the measures; the

relevant valid numbers of observations associated with each measure are presented with the results of the analyses. There were four paid carers who completed the CSRI (see *Chapter 3*). At the end of the study, seven participants with dementia had died and one carer had died.

The complete case sample of economic data available for analysis at nine months (those with data from complete dyads across the three assessment points who had not withdrawn or been lost to follow-up and had an unpaid carer participating) was 412 (203 CR; 209 TAU). The numbers of cases available for the cost-effectiveness analyses varied depending on the outcome:

- for QALY calculated using DEMQOL-U, there were 401 cases available (CR 196; TAU 205)
- for BGSII 407 cases were available (201 CR; 206 TAU)
- for GSES 389 cases were available (CR 190; TAU 199)
- for carers' QALY calculated using EQ5D3L, there were 390 cases (CR 192; TAU 198).

The sample of cases available in the analysis of complete datasets as a product of the multiple imputation process was 462.

#### ***Use and costs of care and support services at each assessment point***

At baseline, both CR and TAU groups used a wide variety of services (*Appendix 16, Tables 73 to 75*). The groups exhibited high use of services such as outpatient appointments, GP and practice nursing contacts. In both groups, 11% of participants received some form of home help or home care, and roughly the same number attended a day centre. A fifth of the dyads had cleaning services. The proportions using these services remained relatively stable over the course of the study. Proportions reporting taking any mental health medications were stable over the three assessment points; approximately three-quarters of both groups took anti-dementia medications.

The mean number of home care contacts and hours demonstrates a problematic feature of the data. There were small numbers receiving very high levels of home care at each assessment point and these were concentrated in the TAU group. At baseline and nine months, the average number of contacts and hours of home care in the TAU group were twice those in the CR group. However the variation in contacts and hours was higher in the TAU group, as

evidenced by larger standard errors relative to the means. This complicates an assessment of the size of these differences: a unit-free measure is useful in these circumstances. The standardised mean difference (the mean CR-TAU difference divided by the standard deviation across the groups) in homecare hours between CR and TAU was -16% at baseline, 14% at three months and -33% at nine months (not presented in the table). This suggests very substantial variability in receipt, or reporting of receipt, of homecare over the study period and also a large difference in home care received at nine months in the TAU vs. CR comparison. The same pattern occurred in unpaid care time of the principal carer: unpaid care hours at baseline and nine months were greater in CR relative to TAU, but vice versa at three months.

The types of care and support provided by carers are described in *Appendix 16, Table 76*. A majority of carers reported providing social support (keeping the person with dementia company) and taking the person to appointments, helping with medications, providing practical help and supervision. Fewer than a third of carers in either group reported assisting with personal care at baseline or three-month assessments. At the nine-month assessment point, however, the proportion of carers providing personal care was 38% in the CR group and 43% in the TAU group.

The raw costs of health and social care services, unpaid care and out-of-pocket expenses in the three months prior to assessment are presented in *Table 18*. Total health and social care and societal costs are also given. Mean differences in costs between groups exhibited wide confidence intervals. The pattern of apparently higher costs in the CR group at baseline and nine months echoed that seen in utilisation of home care and unpaid care hours; however, the unadjusted differences were not significantly different from zero at any point, as evidenced by confidence intervals crossing zero.

Table 18. Mean costs for dyad: health and social care services for the person with dementia, unpaid carer costs, out-of-pocket costs and total health and social care and societal costs over prior three months, at baseline assessment (£, 2013-14). Sample: complete cases<sup>a</sup>

	CR (N=238)			TAU (N=236)			CR-TAU	
	N	Mean	SE	N	Mean	SE	Mean difference	95% CI
Hospital	236	426	91	233	276	44	151	-50 to 351
Primary and community health	236	153	11	233	164	14	-11	-46 to 25
Respite residential/nursing home	236	3	3	233	0	0	3	-3 to 9
Community care	236	203	52	233	458	177	-255	-615 to 105
Community mental health	236	58	11	233	51	10	8	-21 to 36
Day care (any provider)	236	107	25	233	85	19	22	-40 to 83
Medications <sup>b</sup>	236	182	10	233	181	9	1	-26 to 27
Equipment & adaptations <sup>b</sup>	236	10	2	233	10	2	0	-6 to 6
Health & social care <sup>d</sup>	236	1142	116	233	1224	194	-82	-524 to 360
Unpaid care <sup>e</sup>	236	5899	401	233	5632	369	267	-806 to 1340
Out-of-pocket <sup>f</sup>	236	53	5	233	71	6	-18	-33 to -3
Societal <sup>g</sup>	236	7041	422	233	6857	418	185	-983 to 1352
Sensitivity: unpaid care <sup>h</sup>	236	15236	1128	233	13497	982	1739	-1202 to 4681
Sensitivity: societal <sup>i</sup>	236	16378	1143	233	14721	1007	1657	-1339 to 4653
<b>3 months</b>								

Hospital	213	292	53	222	310	77	-18	-203 to 168
Primary and community health	213	131	10	222	144	18	-14	-54 to 27
Respite residential/nursing home	213	62	55	222	0	0	62	-45 to 168
Community care	213	423	157	222	387	182	36	-439 to 510
Community mental health	213	43	15	222	24	5	18	-12 to 48
Day care (any provider)	213	112	23	222	107	22	5	-59 to 68
Medications <sup>b</sup>	213	174	11	222	192	10	-18	-48 to 12
Equipment & adaptations <sup>b</sup>	213	13	3	222	11	2	2	-5 to 9
Health & social care <sup>d</sup>	213	1250	186	222	1177	234	73	-518 to 665
Unpaid care <sup>e</sup>	213	5985	385	222	6199	397	-214	-1303 to 875
Out-of-pocket <sup>f</sup>	213	56	5	222	66	6	-9	-25 to 6
Societal <sup>g</sup>	213	7235	462	222	7376	452	-141	-1411 to 1130
Sensitivity: unpaid care <sup>h</sup>	213	14846	1099	222	15026	1061	-181	-3182 to 2820
Sensitivity: societal <sup>i</sup>	213	16096	1162	222	16203	1080	-107	-3221 to 3007
<b>9 months</b>								
Hospital	204	424	114	210	308	69	116	-144 to 376
Primary and community health	204	129	9	210	168	14	-39	-72 to -5
Respite residential/nursing home	204	69	48	210	154	63	-86	-243 to 71
Community care	204	317	88	210	622	243	-305	-819 to 209
Community mental health	204	34	11	210	63	20	-29	-75 to 16
Day care (any provider)	204	123	24	210	133	29	-10	-84 to 63

Medications <sup>b</sup>	204	172	11	210	184	10	-12	-41 to 17
Equipment & adaptations <sup>b</sup>	204	15	3	210	14	3	0	-8 to 9
Health & social care <sup>d</sup>	204	1282	155	210	1647	299	-365	-1033 to 303
Unpaid care <sup>e</sup>	204	6317	428	210	6276	410	41	-1123 to 1205
Out-of-pocket <sup>f</sup>	204	61	5	210	73	6	-12	-27 to 4
Societal <sup>g</sup>	204	7599	490	210	7923	494	-324	-1691 to 1043
Sensitivity: unpaid care <sup>h</sup>	204	16110	1198	210	15695	1131	415	-2821 to 3650
Sensitivity: societal <sup>i</sup>	204	17391	1249	210	17342	1160	50	-3299 to 3398

*a Dyads completing baseline assessments: 236 CR; 233 TAU; dyads completing three month assessments: 213 CR; 222 TAU; dyads completing 9 month assessments: 204 CR; 210 TAU*

*b drugs for dementia, anti-epileptics, hypnotics and anxiolytics, antipsychotics and antidepressants*

*c Provided by NHS or Social Services*

*d person with dementia's health and social care costs*

*e unpaid carers' time in care and support to participant with dementia, lost production; time valued at minimum wage*

*f expenditure on travel to appointments, equipment purchases*

*g person with dementia's health and social care costs; unpaid carers' time in care and support to participant with dementia, lost production; time valued at minimum wage; expenditure on travel to appointments, equipment purchases*

*h unpaid carers' time in care and support to participant with dementia, lost production; time valued at hourly cost of home care worker*

*i person with dementia's health and social care costs; unpaid carers' time in care and support to participant with dementia, lost production; time valued at time valued at hourly cost of home care worker; expenditure on travel to appointments, equipment purchases*

Health and social care costs were on average relatively modest, being substantially lower than societal costs at each assessment point. These averages mask some extremely high-cost cases, particularly in the TAU group. At the nine-month follow-up, maximum total health and social care costs over the prior three months reached £18,063 (vs. the mean of £1282) in the CR group and £42,504 (vs. the mean of £1647) in the TAU group. The data were highly skewed: on a test for normality, the hypothesis that the data were distributed normally was rejected ( $p=0.000$ ) for both health and social care and societal costs.

### ***Unit costs and per-participant costs of the CR intervention***

The cost components used to value the CR intervention are given in *Table 19*. CR-specific training and supervision costs per session were substantial at £33 and may not reflect the level of supervision and support that would be available in routine clinical practice. The mean number of visits in the three months after baseline in the economic evaluation sample ( $N=215$ ) was 9.61 (SE 0.09) as shown in *Table 20*; costs in the first three months were £1259 (SE £18). In the period between three-month and nine-month assessment in the economic evaluation sample ( $N=204$ ), the mean number of visits was 3.74 (SE 0.07) and costs were £474 (SE £10).

Table 19. Cognitive rehabilitation delivery: cost elements (£, 2013/2014)

<b>Training and supervision costs for professionals delivering CR</b>	<b>Total costs</b>	
Spend in Year 1	23,347	
Spend in Year 2 <sup>a</sup>	26,153	
Spend in Year 3 <sup>a</sup>	39,549	
Spend in Year 4 <sup>a</sup>	9,702	
4-year total	98,751.01	<b>Unit costs</b>
4-year total divided by 2 970 (total sessions provided to participants) <sup>b</sup>		33.25
Weighted cost per hour of professionals delivering CR		42.70
Mileage cost of a one-way journey, per centre		Range: 3-19

*a* Deflated to 2013-14 prices with HCHS

*b* Source: therapy log data

*c* Source: professional-completed pro-forma

### *Use and costs of care and support services over the period of the study*

Over the nine-month period of the study, the total cost of the CR intervention (as shown in *Table 20*) was £1736 (SE £25) per participant. The average total estimated health and social care costs, including the costs of CR over nine months were £3998 (SE £539) in CR and £4556 (SE £815) in TAU. Societal costs were of the order of five times higher. Again, while mean health and social care costs over nine months were quite modest, there were a small number of high-cost cases in the TAU group, with costs exceeding £130,000. A total of eight outliers were identified following the adjusted boxplot method; three in TAU ranging from approximately £28,000 to £133,000 and five in CR, ranging from approximately £31,000 to £63,000. In contrast, no outliers were identified by this method in the societal costs.

### *Cost-effectiveness analyses*

#### *Outcomes and costs for the person with dementia*

Examining the raw mean outcome scores in the economic evaluation sample (details are shown in *Table 21*), the CR and TAU groups had similar scores on the BGSi attainment ratings outcomes at baseline. At three months, the CR group mean score was 1.63 (95% CI 1.27 to 1.99) higher than that of the TAU group. The CR group mean score at nine months was also higher than in TAU by 1.79 (95% 1.38 to 2.20). The groups did not differ on any other measure.

Adjusted differences in outcomes (derived from SUR models) between groups are given in *Table 22*. The BGSi attainment ratings were significantly higher in the CR group, by 1.35 points (95% 1.09 to 1.64). The adjusted differences in other outcomes were not significantly different from zero.

Adjusted health and social care costs differences varied substantially depending on the number of complete cases available. In the case of the BGSi attainment ratings, costs were significantly higher in the CR group than in the TAU group (£1 474; 95% CI £59 to £2 646). In the slightly smaller samples available in the case of the GSES and the QALY (DEMQOL-U), the adjusted costs did not differ between groups. In contrast, the between-group difference in societal costs was not significantly different from zero in the case of any of the outcome measures; the sign on the difference was negative.

Table 20. Health professionals delivering cognitive rehabilitation<sup>a</sup>: visits and time (hours) per participant, over the three months to first follow up and over six months between first and second follow-up. Sample: complete cases [economic data available from person with dementia and unpaid carer dyad]

	<b>Valid n</b>	<b>Mean (CR, N=238)</b>	<b>SE</b>
<b>3 months</b>			
Number of visits <sup>b</sup>	213	9.61	0.09
Total hours of visits <sup>b</sup>	213	20.17	0.33
Mean duration per completed visit (hours) <sup>c</sup>	213	2.10	0.03
<i>Costs (£)</i>			
a) Face-to-face visits	213	523	7
b) Preparation	213	85	1
c) CR training & individual supervision	213	320	3
d) Travel (time and mileage)	213	331	12
Mean cost per person (includes a-d)	213	1259	18
<b>9 Months</b>			
Number of visits <sup>b</sup>	204	3.74	0.07
Total hours of visits <sup>b</sup>	204	7.46	0.17
Mean duration per completed visit (hours) <sup>c</sup>	197	2.00	0.03
<i>Costs (£)</i>			
a) Face-to-face visits	204	188	4
b) Preparation	204	33	1
c) CR training & individual supervision	204	124	2
d) Travel (time and mileage)	204	128	5
Mean cost per person (includes a-d)	204	474	10

*a data from therapy log data collection*

*b includes 12.5 minutes' preparation time per visit, time spent travelling to visits*

*c summarised hours of contact where contact occurred (participants who did not engage in sessions over the period are excluded)*

Table 21. Mean costs over the study period of nine months (£, 2013-14 prices). Sample: complete cases

	<b>CR</b>	<b>(N=238)</b>		<b>TAU</b>	<b>(N=236)</b>		<b>CR-TAU</b>	
	<b>n</b>	<b>Mean CR</b>	<b>SE</b>	<b>n</b>	<b>Mean UC</b>	<b>SE</b>	<b>Mean difference</b>	<b>95% CI</b>
Health & social care <sup>a</sup>	203	3 787	455	209	4 485	796	-698	-2 514 to 1 119
CR <sup>b</sup>	203	1 736	25	209	0	0	1 736	1 687 to 1 784
Health & social care+CR <sup>ab</sup>	203	5 523	453	209	4 485	796	1 038	-777 to 2 853
Societal <sup>c</sup>	203	22 417	1 356	209	23 290	1 335	-873	-4 614 to 2 868
Societal + CR <sup>bc</sup>	203	24 153	1 355	209	23 290	1 335	863	-2 877 to 4 602

*a Health and social care costs for the person with dementia. The costs of the interval between three and six months within the study period was assumed to be constant with the costs in three months prior to second (nine-month) follow-up*

*b Costs of CR intervention include costs of face-to-face visits, preparation time, travel time and mileage and CR-specific training and individual supervision. Data collected covered the full nine-month study period.*

*c Health and social care costs for the person with dementia; unpaid carers' time in care and support to participant with dementia, lost production; time valued at minimum wage; expenditure on travel to appointments, equipment purchases. The costs of the interval between three and six months within the study period was assumed to be constant with the costs in three months prior to second (nine-month) follow-up*

Table 22. Summary statistics for outcomes: person with dementia and carer, at baseline, three-month and nine-month assessments. Sample: complete cases per assessment point<sup>a</sup>

	CR (N=238)			TAU (N=236)			CR-TAU	
	n	Mean	SE	n	Mean	SE	Mean difference	95% CI
Person with dementia: baseline								
BGSI-attainment	236	3.51	0.11	233	3.56	0.1	-0.05	-0.35 to 0.25
GSES	235	30.74	0.31	229	31.07	0.35	-0.33	-1.25 to 0.60
DEMQOL-U	235	0.61	0.01	232	0.59	0.01	0.02	-0.00 to 0.03
Carer:								
EQ5D3L	233	0.76	0.02	230	0.78	0.02	-0.02	-0.07 to 0.02
Person with dementia: 3 months								
BGSI-attainment	213	6.06	0.14	222	4.43	0.12	1.63	1.27 to 1.99
GSES	211	30.94	0.32	219	30.5	0.38	0.45	-0.53 to 1.42
DEMQOL-U	212	0.6	0.01	222	0.59	0.01	0.01	-0.01 to 0.03
Carer:								
EQ5D3L	207	0.75	0.02	215	0.74	0.02	0.01	-0.04 to 0.06
Person with dementia: 9 months								
BGSI-attainment	202	6.04	0.16	207	4.25	0.14	1.79	1.38 to 2.20
GSES	191	30.72	0.36	202	30.62	0.4	0.1	-0.95 to 1.15
DEMQOL-U	199	0.59	0.01	207	0.59	0.01	0	-0.02 to 0.02
QALY (DEMQOL-U)	197	0.45	0	206	0.44	0	0.01	-0.01 to 0.02

Carer								
EQ5D3L	194	0.72	0.02	207	0.75	0.02	-0.03	-0.08 to 0.02
9-month QALY (EQ5D3L)	192	0.56	0.01	198	0.56	0.01	0	-0.04 to 0.03

*a Dyads completing baseline assessments: 236 CR; 233 TAU; dyads completing three month assessments: 213 CR; 222 TAU; dyads completing nine month assessments: 204 CR; 210 TAU*

## Outcomes and costs for carers

There was no difference in carer QALY (EQ5D3L) between groups, as shown in *Table 23*. The groups did not differ in terms of health and social care costs or societal costs, with wide confidence intervals around the differences.

## Incremental costs and outcomes: person with dementia

### Cost-effectiveness

The ICER point estimates are given in *Table 24*. The cost of an increase of 1.32 points in the BGSi attainment rating was £1296 from the health and social care perspective and -£9 from the societal perspective. The probability of cost-effectiveness (shown in *Figure 5*) was over 99% at a WTP of £2500 from the health and social care perspective and from the societal perspective, and over 50% at a WTP of £1300 or more. The distribution of costs and BGSi attainment rating differences on the cost-effectiveness plane is illustrated in *Figure 6*.

Because the difference in health and social care costs was significantly greater than zero and the difference in the outcome was also significantly greater, the cloud of cost-outcome pairs lies mostly in the northeast quadrant.

On the GSES, the cost of attaining an increase of 1.53 points (ICER point estimate) was £4470 from the health and social care perspective and -£2961 from the societal perspective. The probability of cost effectiveness (shown in *Figure 7*) was 76% at a WTP of £50,000 from the health and social care perspective and 79% at the same WTP value from the societal perspective. However, as can be seen in *Figure 8*, the position of the cloud of societal cost-outcome difference pairs covers all four quadrants of the cost-effectiveness plane such that in any quadrant, no line drawn from the origin could exclude 2.5% of the joint cost-outcome distribution. There is no WTP at which it would be possible to be confident that CR would be more cost-effective than TAU (or vice versa) on this measure.<sup>160</sup>

Table 23. Outcome scores and costs at nine months from regression estimates. Sample: complete cases

	<b>CR<sup>a</sup></b>	<b>95% CI<sup>b</sup></b>	<b>TAU<sup>a</sup></b>	<b>95% CI<sup>b</sup></b>	<b>CR-TAU Mean Difference</b>	<b>95% CI<sup>b</sup></b>	<b>p value</b>
Person with dementia	n=201		n=206				
BGSI <sup>c</sup>	4.57	4.36 to 4.79	3.21	3.02 to 3.41	1.37	1.09 to 1.64	0.000
Health & social care <sup>d</sup>	5 502	4 683 to 6 587	4 027	3 126 to 5 355	1 474	59 to 2 646	0.024
Societal <sup>d</sup>	23 366	21 229 to 25 665	23 379	21 186 to 25 774	-13	-2 661 to 2 628	0.896
Person with dementia	n=190		n=199				
GSES <sup>c</sup>	20.14	19.71 to 20.56	19.92	19.45 to 20.37	0.23	-0.32 to 0.78	0.427
Health & social care <sup>d</sup>	5 197	4 415 to 6 151	4 169	3 219 to 5 576	1028	-454 to 2 067	0.109
Societal <sup>d</sup>	22 703	20 603 to 24 976	23 384	21 249 to 25 765	-681	-3 259 to 1 796	0.626
Person with dementia	n=196		n=205				
QALY <sup>ce</sup> (DEMQOL-U)	0.45	0.44 to 0.46	0.45	0.44 to 0.46	0.00	-0.01 to 0.01	0.906
Health & social care <sup>d</sup>	5 397	4 563 to 6 388	4 286	3 353 to 5 672	1 110	-382 to 2 187	0.091
Societal <sup>d</sup>	23 271	21 104 to 25 538	23 798	21 662 to 26 179	-526	-3 108 to 1927	0.684
Carer	n=192		n=198				
QALY <sup>ef</sup> (EQ5-3L)	0.56	0.54 to 0.58	0.56	0.54 to 0.58	0.00	-0.02 to 0.02	0.893
Health & social care <sup>g</sup>	5 146	4 504 to 6 006	4 514	3 316 to 6 210	632	-1 058 to 1 880	0.389

Societal <sup>g</sup>	22 896	20 912 to 24 943	23 798	21 503 to 26 361	-902	-3 616 to 1 705	0.592
-----------------------	--------	---------------------	--------	---------------------	------	-----------------	-------

*a Estimated marginal means*

*b bias-corrected bootstrapped 95% confidence intervals (60000 replications)*

*c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome*

*d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.*

*e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points*

*f Estimates from outcome equation: adjusted for centre, age and sex of carer, stratified MMSE score, allocation to treatment, baseline outcome*

*g Estimates from costs equation: adjusted for centre, age and sex of carer, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.*

Table 24. Person with dementia and carer: Point ICER<sup>a</sup> for CR over TAU, from health and social care and societal perspectives

	<b>BGSI<sup>a</sup></b> (N=407)	<b>GSES<sup>b</sup></b> (N=389)	<b>QALY (DEMQOL-U)<sup>c</sup></b> (N=401)	<b>QALY (EQ5D3L)<sup>c</sup></b> (N=390)
Person with dementia: 9 months				
Health and social care	1 474/1.37 =1 296	1 028/0.23=4 470	1 110/0.001=1 110 000	NA
Societal	-13/1.37=-9	-681/0.23=-2 961	-526/0.0005=-1 052 000	NA
Carer: 9 months				
Health and social care	NA	NA	NA	632/0.001=632 000
Societal	NA	NA	NA	-902/0.001=-902 000

*a Cost of achieving a 1.32 points difference between groups at nine months*

*b Cost of achieving a 1.53 points difference between groups at nine months*

*c Cost of achieving a QALY gain over nine months; difference in QALY rounded to first non-zero decimal place*

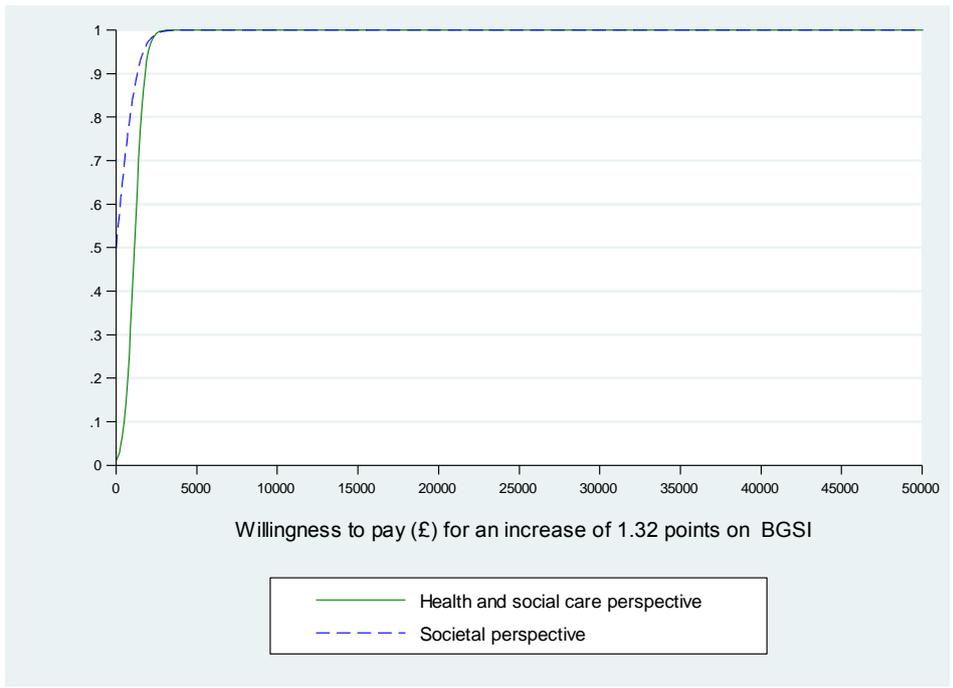


Figure 5. Cost-effectiveness acceptability curve: BGSi, person with dementia

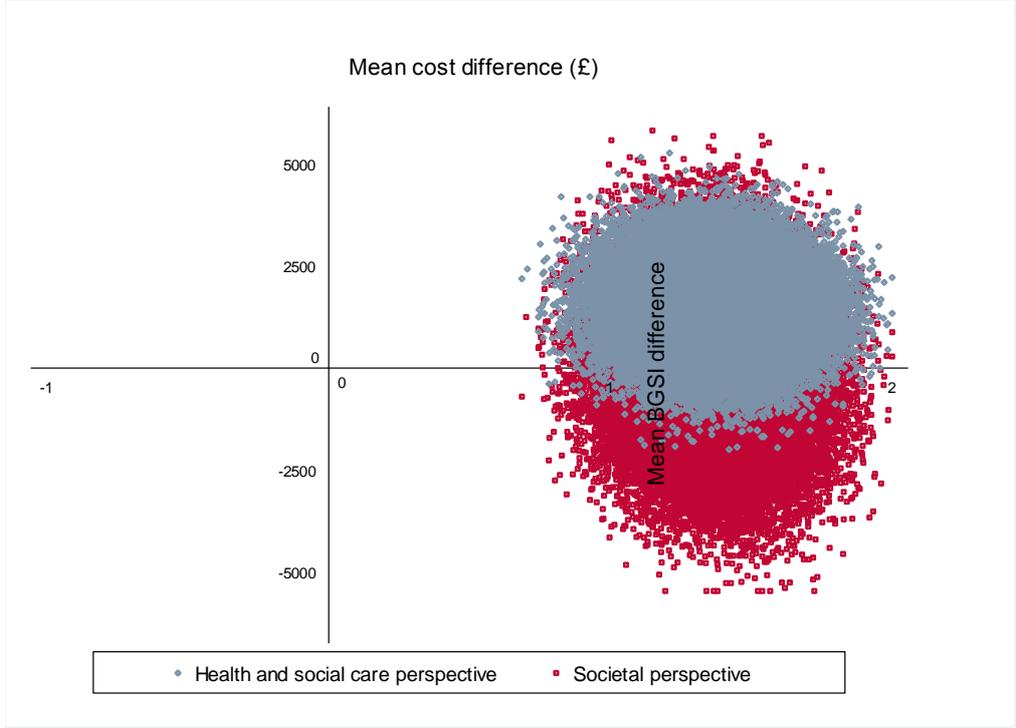


Figure 6. Cost-effectiveness plane: incremental costs and endpoint difference for BGSi at nine months, person with dementia

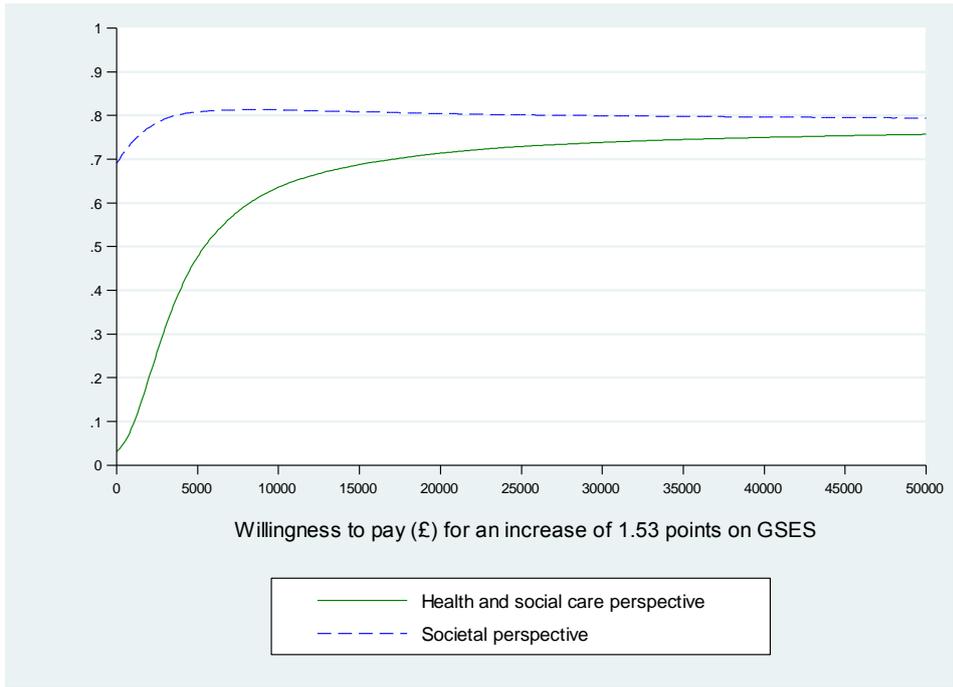


Figure 7. Cost-effectiveness acceptability curve: GSES, person with dementia

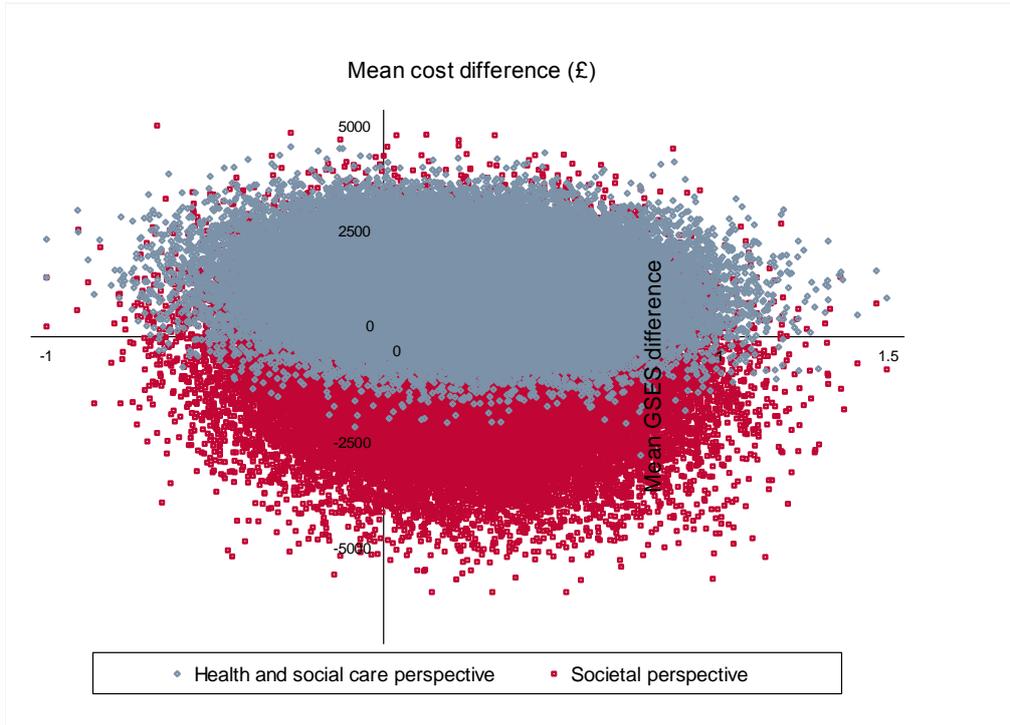


Figure 8. Cost-effectiveness plane: incremental costs and endpoint difference for GSES at nine months, person with dementia

### Cost-utility

The cost per QALY derived from DEMQOL-U (ICER point estimate) (Table 24) was £1,110,000 from the health and social care perspective. The ICER was negative (-£1,052,000) from the societal perspective, the cost being somewhat lower (difference of £526, 95% CI -£3 108 to £1927) in the intervention group from this perspective. There were no differences between groups in terms of QALY gain. The probability of cost-effectiveness on the QALY (DEMQOL-U) (shown in *Figure 9*) was very low at all WTP values (from £0 to £50,000) from the health and social care perspective; the probability of cost-effectiveness was just at or under 65% for all values of WTP over the same range. As illustrated in *Figure 10*, the cloud of societal cost-outcome difference pairs covers all four quadrants of the plane in approximately equal proportions, indicating that it is not possible to be certain that either strategy is cost-effective by reference to QALY gains at any level of WTP.

Incremental costs and outcomes: carers

### Cost-utility

The cost per QALY for the carer, derived from the EQ-5D-3L (Table 24) was £632,000 from the health and social care perspective; the ICER was negative (-£902,000) from the societal perspective, costs being somewhat lower in the CR than the TAU group (by £902, 95% CI -3,616 to 1,705). There were no differences in terms of QALY between CR and TAU groups. The probability of cost-effectiveness on the QALY (EQ5D3L), shown in *Figure 11*, was between 17% and 22% at a range of WTP values between £0 and £50,000 from the health and social care perspective, and approximately 74% across this range from the societal perspective. The cloud of cost-outcome pairs (shown in *Figure 12*) is fairly evenly distributed across all four quadrants of the plane, suggesting no certainty in the cost-effectiveness of the intervention vs. TAU (or vice versa) at any WTP from this perspective.

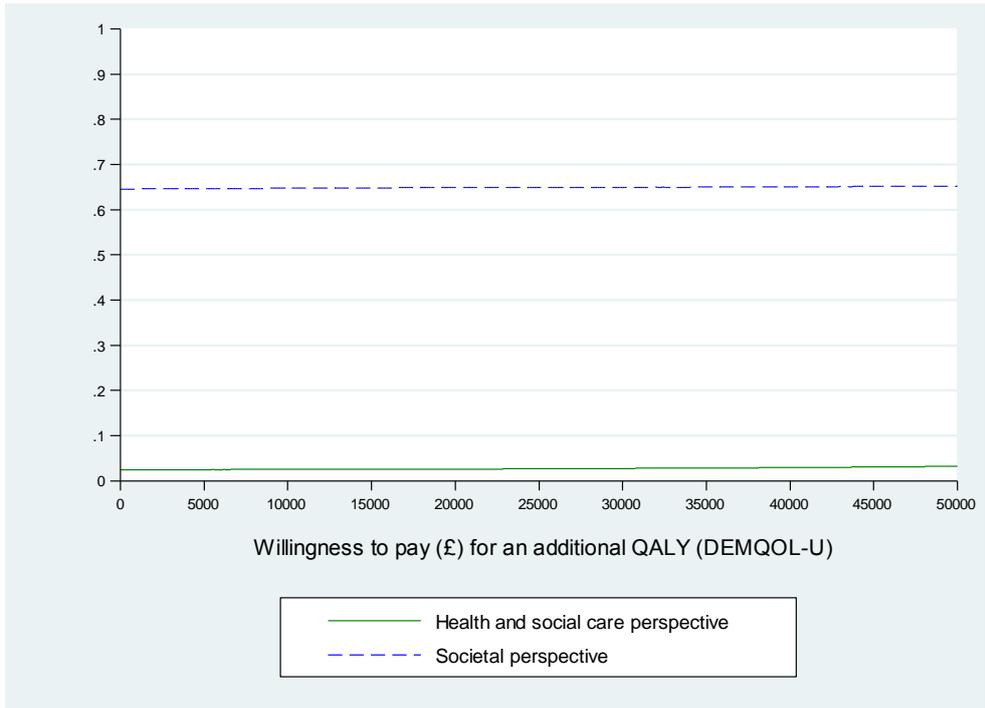


Figure 9. Cost-effectiveness acceptability curve: QALY (DEMQOL-U), person with dementia

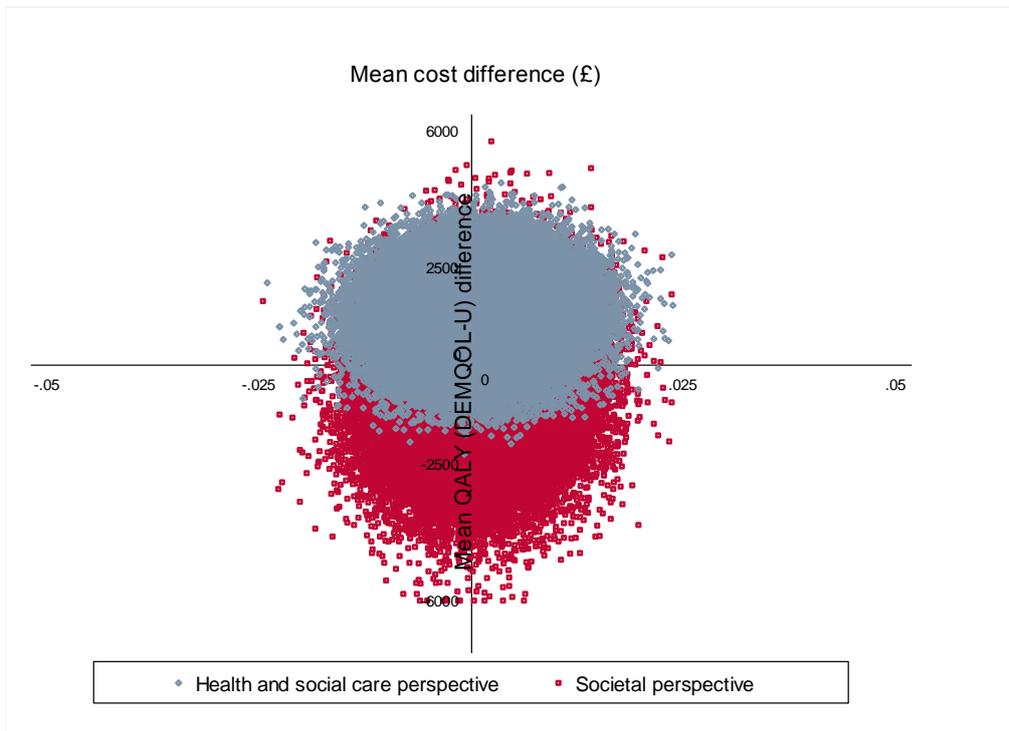


Figure 10. Cost-effectiveness plane: incremental costs and QALY (DEMQOL-U) at nine months, person with dementia

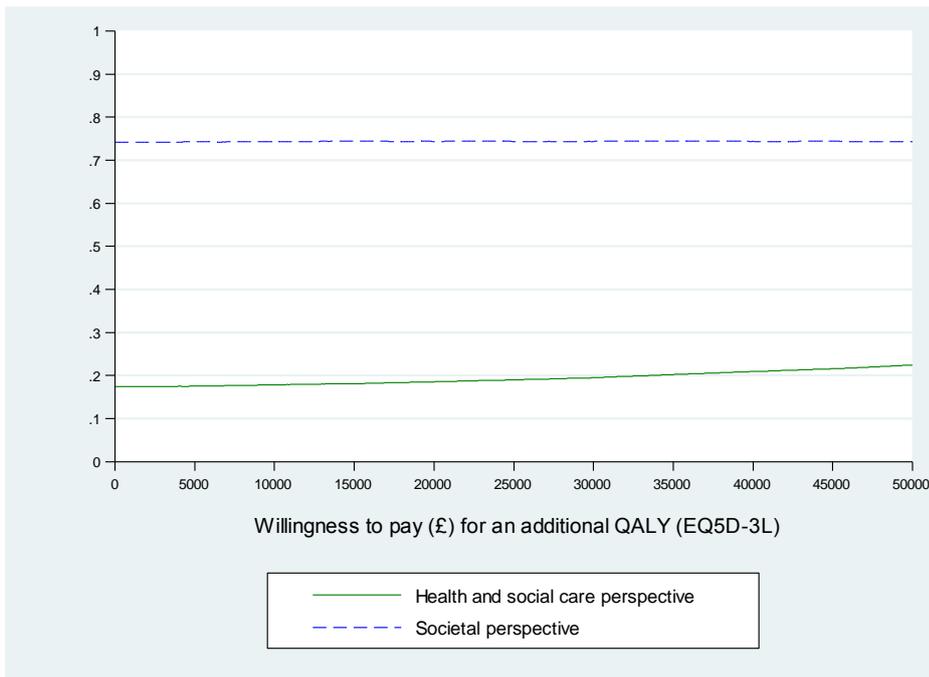


Figure 11. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer

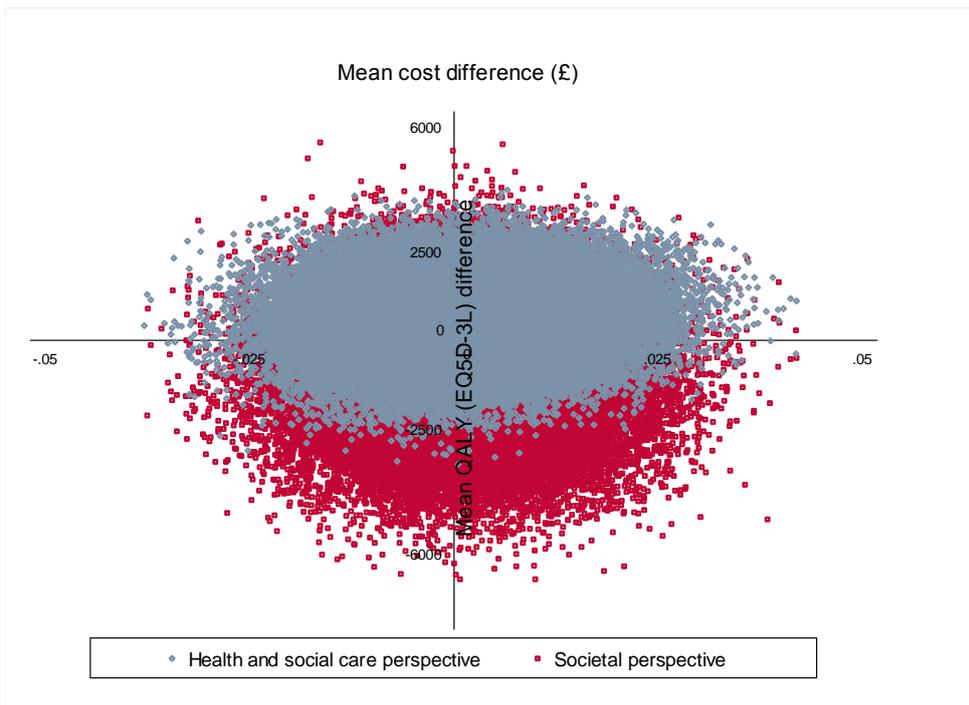


Figure 12. Cost-effectiveness plane: incremental costs and QALY (EQ5D3L) at nine months, carer

### *Sensitivity analyses*

We investigated the robustness of results to several key assumptions made in the base-case analyses.

#### Replacement costs of unpaid care

We took a replacement costs approach to calculating societal costs, valuing unpaid carer time at the hourly cost of a home care worker (raw mean costs are given in *Table 18*; regression results are given in *Appendix 16, Tables 77 to 79*). The groups did not significantly differ in societal costs, with wide confidence intervals of the mean difference, across samples associated with all outcome measures. However, the size of the differences (across samples associated with the outcome measures) was much greater than in the base case; the sign on the differences remained negative. Point ICERs were much larger for each outcome measure. In terms of the uncertainty around the point estimates (see *Appendix 17, Figures 15 to 18*) for GSES and QALY (DEMQOL-U and EQ5D3L), while the probability of cost effectiveness over the £0 to £50,000 WTP range was higher than in the base case estimates, we could not be confident that the intervention was more cost-effective, given that the CEAC cuts the y-axis at the 80% or 90% level and remains relatively flat (or declines, in the case of the GSES) over the whole range. This point is illustrated in the cost-effectiveness plane (see *Appendix 17, Figures 19 to 22*), where the cloud of cost-outcome differences is distributed widely on either side of the x-axis (crossing all quadrants of the plane).

#### Outliers

We examined the influence of cost outliers on health and social care costs and cost-effectiveness (see *Appendix 16, Tables 80 to 82*). The exclusion of outliers had a large impact on costs so that, while the size of the differences associated with all outcome measures was little different from the base-case results, these differences were significantly different from zero. The point ICER associated with the BGSi attainment rating was similar to that of the base case; the point ICER associated with the GSES was approximately £3000 greater. The ICER associated with the QALY (DEMQOL-U) was approximately half the size of that in the base case; the ICER associated with the QALY (EQ5D3L) was a third the size of that in the base case.

The CEACs (see *Appendix 17, Figures 23 to 25*) and cost-effectiveness plane plots (see *Appendix 17, Figures 26 to 29*) were similar to those produced by base-case results for BGSi

and GSES. On the person with dementia and carer QALY measures, the probability of cost-effectiveness over the £0 to £50,000 range was low such that the probability of cost effectiveness on the person with dementia QALY (DEMQOL-U) was close to zero (CEAC for this outcome is not presented for this reason) and the probability of cost-effectiveness on the carer QALY (EQ5D3L) was low, not exceeding 5% over this range. Nonetheless, the inferences to be drawn from these results remain the same as those drawn from the base case.

### Multiple imputations

The results drawing on the 25 completed datasets produced by the multiple imputation process (see *Appendix 16, Tables 83 to 85*) produced a larger sample (231 CR, 231 TAU). The magnitude of the difference between groups on BGSi was very similar to the main analysis (1.35 vs 1.37 respectively). As in the base case, the groups did not differ in GSES scores; however, the coefficient for the between-group difference was smaller than in the base case. On the person with dementia QALY (DEMQOL-U), the coefficient was considerably lower than in the base case result (0.0003 vs 0.001); on the carer QALY (EQ5D3L), the coefficient was slightly larger (0.001 vs 0.003). The (non-significant) difference between groups in health and social care costs was similar to that of the complete cases analyses of GSES and QALY (DEMQOL and EQ5D3L). The result of the imputed data analyses was in contrast to the complete case BGSi attainment rating analyses results, where the between-group difference in health and social care costs was significant. Societal costs did not differ between groups, as in the base case. From the health and social care perspective, the point ICER for the BGSi was somewhat lower than in the complete case analyses (812 vs 1296); the point ICER for the GSES was slightly higher (5224 vs.4470). The cost per QALY for participants with dementia was more than three times higher than in the base case, the cost per QALY for carers was twice as high as in the base case. CEACs and cost-effectiveness plane plots were similar to the base case; however the probability of cost-effectiveness across the £0 to £50 000 range was lower across all measures (see *Appendix 17, Figures 30 to 37*). Thus while most results were similar to the complete case analyses, the results for the BGSi attainment rating suggest that the intervention was more effective and no more costly.

## **Conclusions**

There was no evidence of QALY gain for participants or carers, nor of cost-effectiveness by reference to QALY gains over a range of willingness-to-pay values. As assessed on the BGSII attainment rating, the CR intervention was cost-effective at willingness-to-pay values of £2500 and above from health and social care and societal perspectives. On the GSES, there was relatively little additional evidence of cost-effectiveness over a range of willingness-to-pay values. The average cost of the CR intervention for participants over nine months was £1736 (SE £25).

## ***Strengths and weaknesses***

The data on care and support received by participants who finished the trial were well completed, with few items missing in most cases. The evaluation was able to collect detailed information on both the number and duration of CR visits made to participants and thereby to estimate the per-participant costs of the CR intervention. Cost-effectiveness analytic methods have taken account of the correlation between the cost and outcome error terms and presented information on the cost of achieving improvements in outcomes in light of sampling uncertainty.

The analyses encountered some issues. Cost data in the complete-cases sample were skewed and there were a number of extreme outliers in the case of health and social care costs. The analyses therefore combined a parametric approach (SUR models, which assume normality) with non-parametric bootstrap sampling, which makes no distributional assumptions. A large number of replications were necessary to produce more efficient bias-corrected standard errors for the cost difference in the complete-case analyses. Other analytic models that permit a mixture of distributions for costs and effects could be investigated: for instance gamma-normal or gamma-beta bivariate models, estimated using Bayesian techniques.<sup>162</sup> The three-month costs in the interval between three and six months post-baseline were assumed to be the same as costs between six and nine months post-baseline and could over-estimate total costs if these were in fact more similar to costs over the initial three months post-baseline or were rising over this interval.

Concerns with the validity of the EQ-5D<sup>85,163,164</sup> to reflect HRQoL of people with dementia led us to choose the DEMQOL, a condition-specific measure as an outcome for the economic

evaluation. The authors of the instrument recommended using EQ-5D alongside DEMQOL<sup>85</sup> as they considered that the instrument required further testing to better understand its psychometric properties. However, we did not include EQ-5D in the battery of questionnaires and so are unable to assess whether using that instrument would have changed our assessment of the cost-effectiveness of the CR intervention. Emerging evidence suggests that EQ-5D and DEMQOL capture different aspects of changes in HRQOL over time.<sup>165</sup> In our study it is possible that the DEMQOL domains (social relationships, loneliness, negative emotion, positive emotion) were better suited to the types of goals identified by participants (engaging in conversation; knowing what is happening; keeping track of information).

We did not examine the budget impact of introducing the intervention at a national level as part of the economic evaluation. An implementation study following on from the trial will combine the data from the original GREAT trial with observational data from at least 15 participating sites to model the impact of scaling up the intervention at local and national levels.

The BGSi is a relatively new instrument: no societal willingness-to-pay threshold has been established for attaining an improvement on the BGSi attainment rating, such as that associated with a QALY gain to the NHS in the deliberations of NICE.<sup>166</sup>

### ***Implications***

The results indicate that, in terms of achieving an improvement in goal attainment as rated by the participant, the intervention is cost-effective from the health and social care and societal perspectives at willingness-to-pay values of £2500 and above. This achievement does not appear to have effected parallel improvements in participants' sense of self-efficacy, or participants' or carers' quality-adjusted life years (assessed by health-related quality of life and by quality of life in dementia, respectively); nor to have reduced costs from the health and social care or societal perspectives. Considering the QALY results, there are a few possible reasons for the apparent lack of effect. The intervention was not expected to affect survival so there was no reason to expect a difference between groups in the quantity of months lived. Also, the goals that were chosen by each individual participant would vary according to that individual's circumstances and interests. The goals that were set thus might be unrelated to the domains covered by the DEMQOL; also goals that were set by the participant would not necessarily impinge upon domains covered by the EQ5D that was

chosen to measure carer quality of life (for instance the carer's own self-care and usual activities).

Commissioners and planners contemplating funding a CR programme should not only consider cost-effectiveness in terms of cost per QALY gained by participant or carer (by which measures the intervention was not cost-effective). They will need to consider the value of goal attainment – the primary focus of this trial – in the context of other information provided in this report (see the evidence on clinical effectiveness in *Chapter 3*). The costs of implementing CR in the trial included the costs of substantial supervision for the therapists. In routine clinical practice, these levels of supervision and support would be lower, thus reducing the costs of CR. In turn, the different level of supervision and support could affect the outcomes achieved, although we cannot examine that possibility with the data from the present trial. A follow-on implementation study of CR delivered at scale in routine practice will provide an opportunity to examine these possibilities.

## Chapter 6. Discussion

The GREAT trial has provided definitive evidence about whether individualised, goal-oriented cognitive rehabilitation (CR) is a clinically-effective and cost-effective intervention for people with early-stage Alzheimer's disease, vascular or mixed dementia and their carers. Based on both participant-reported and carer-reported outcome measures, the CR intervention was effective in improving functioning in the areas targeted in the therapy at three-month follow-up, and this improvement was maintained at the nine-month follow-up. Improvements met criteria for clinical significance. Furthermore, participants in the CR group were more satisfied with their ability to carry out the everyday activities targeted in the intervention. There were no significant effects on secondary outcome measures for either participants with dementia or carers. However, participants and carers interviewed in depth about their experience of the intervention described improved psychological adjustment to living with dementia and a more positive perspective, reflected in greater confidence, less anxiety, better coping, a sense of empowerment, and better wellbeing and quality of life. CR was relatively inexpensive given that it was individual, home-delivered, provided by skilled therapists and comprised up to 14 sessions, and costs would be lower without trial-specific centralised supervision of therapists. CR was cost-effective from both the health and social care and societal perspectives at willingness-to-pay values of £2500 and above, in terms of achieving an improvement in participant-rated goal attainment.

We first consider these findings in relation to our objectives and hypotheses regarding clinical and cost-effectiveness, and in relation to other relevant literature.

### **Evidence on clinical effectiveness**

Our main objective was to compare the clinical effectiveness of goal-oriented cognitive rehabilitation with that of treatment as usual. Our first hypothesis was that this personalised intervention would improve functioning in areas directly targeted in the therapy, and that this would be reflected in self- and informant ratings. This hypothesis was supported by the quantitative data, with large effect sizes. The perceived improvements were also reflected in the interview responses. These clinically-significant improvements indicate that the therapy was perceived as having enabled participants to manage their daily lives better, participate in meaningful activities and address personally-relevant needs and goals.

Our second hypothesis was that the intervention might work through improving self-efficacy. This was not borne out by quantitative data, as there were no differences in self-efficacy scores for the CR and TAU groups. However, qualitative interview data obtained from consecutive series of people completing the trial indicated that following intervention participants and carers experienced greater confidence and felt that they coped better with the challenges of life with dementia. These descriptions reflect the essence of the self-efficacy construct. This suggests the hypothesis, although not borne out by our quantitative data, remains worthy of further exploration.

Our third hypothesis was that carers of participants receiving the intervention, having learned new ways of supporting and enabling their relatives, might report feeling less stressed following the intervention. This again was not borne out by quantitative data, as there were no differences in carer scores for stress between the CR and TAU groups. However, as noted above, in the qualitative interviews carers reported positive outcomes of the intervention, and commented that it had helped them be more understanding and patient in their interactions with the participant. CR does require some effort from carers, firstly to engage when they may feel they have already tried various strategies without success, and secondly to support the implementation of strategies through the therapy, but most carers found the effort worthwhile. Therefore, although the specific hypothesis was not supported, it appears that carers did experience some benefits which were not captured by questionnaire measures.

Examination of clinical effectiveness covered several additional secondary outcomes which showed changes in the pilot trial.<sup>63</sup> The finding of no differences in cognitive test scores was unsurprising as the intervention does not directly seek to improve cognitive function. The finding of no differences in scores for depression or anxiety is understandable since only a small proportion of participants reported clinical levels of depression or anxiety at baseline and therefore there was little scope for the intervention to demonstrate improvements in these domains. At the same time, it provides confidence that the intervention did no harm. There were also no differences between the groups in quality of life scores for either participants with dementia or carers.

### *Relating the findings on clinical effectiveness to other literature*

We updated the Cochrane review covering cognitive rehabilitation during the course of the trial.<sup>15</sup> At this time there were no further RCTs of cognitive rehabilitation, correctly-defined, that could be included, and our 2010 pilot trial remained the only available trial. At present we are preparing to update the review again, and to this end a new systematic literature search using the search terms and methods outlined in the published review was conducted by the Cochrane Dementia and Cognitive Improvement Group co-ordinating centre on 09/05/2017. We used the results of this search to check that the three potentially-relevant trials published since 2013 of which we were already aware appeared in the output, and to identify any additional potentially-relevant trials, of which we found one, published in 2017. Of these four trials, one described what appeared to be a CR intervention, although it is also described as ‘training’,<sup>167,168</sup> one described a mixed CR and cognitive training (CT) intervention,<sup>169</sup> and two described structured training of activities of daily living; one of these variously described the intervention as ‘cognitive rehabilitation’ or ‘cognitive training’,<sup>170</sup> while the other described the intervention as ‘structured relearning’ or ‘training’.<sup>171</sup>

The most important of these trials for present purposes is the ETNA-3 trial,<sup>167,168</sup> a large (n=653) trial conducted in France which compared individual CR with group CT, group reminiscence and usual treatment for people with mild to moderate Alzheimer’s disease (MMSE 16 – 26). Participants in the CR condition received individual 90 minute sessions weekly for three months and then six-weekly for the next 21 months, and their carers received telephone support weekly for three months and six-weekly for the next 21 months. This equates to approximately 28 90-minute sessions of CR for participants and 28 sessions of telephone support for carers. The CT and reminiscence conditions received group sessions weekly for three months and six-weekly for 21 months, while their carers participated in parallel group psychoeducation sessions.

The CR intervention in ETNA-3, which was delivered by psychologists, is not well-described. Furthermore, an unspecified proportion of participants in this condition did not receive CR but instead followed an individualised reminiscence programme; the reason for this is unclear. For those who did receive CR, goals involved either improving an activity of daily living or maintaining a leisure activity, and had to be personally-meaningful, although it is not clear how this was defined or in what way participants and carers were involved in choosing goals. The goals to be addressed were defined in the first two sessions, and could be changed by the treating psychologist at any time. The approach used to address goals is described as ‘training’ of

particular ‘activities’, without any further explanation, so it is possible that the intervention was closer to the structured training approaches described below than to the approach used in GREAT.

The design of the CR intervention in ETNA-3 appears to have drawn on some of our early feasibility studies, which are cited, but the authors do not acknowledge our pilot trial, even though they cite the updated Cochrane review<sup>15</sup> in which the pilot trial is discussed. In their 2013 paper<sup>167</sup> they incorrectly state that there are no published RCTs of CR, and in their 2015 paper they modify this to state that there is ‘no large RCT’. Some of our early feasibility studies focused on the possible benefits of errorless learning techniques, building on work on this topic in the brain injury field, and these techniques were used in ETNA-3<sup>168</sup> where ‘*the psychologist could rely on “errorless learning procedure” to train a particular activity*’ (p. 709). However, by 2008 we had accumulated evidence ourselves, and synthesised other available evidence, showing firstly that people with early-stage Alzheimer’s disease appear to learn equally well with errorless and trial-and-error methods, and secondly that even for groups where it does convey benefits, errorless learning is more suited to some types of task than others.<sup>59,60</sup> Interestingly, the most recent of the four trials identified<sup>171</sup> also failed to take note of this evidence; the REDALI-DEM trial assigned participants to structured relearning of activities of daily living using either errorless or trial-and-error instructional methods, and found no differences between the two groups, indicating as we would expect that both types of learning strategy were equally effective.

The primary outcome in ETNA-3 was survival without moderately severe to severe dementia at two years. This appears to suggest that the three psychological therapies were being evaluated as disease-modifying treatments expected to alter the trajectory of decline. This is an unusual and probably unrealistic expectation for interventions of this kind. Not surprisingly, in ETNA-3 none of the three treatments was effective in relation to this outcome. In relation to the kinds of outcomes more typically evaluated in trials of these kinds of interventions, evidence was already available in 2003 to show that CT is not effective in short- to medium-term outcomes for people with dementia,<sup>14</sup> and a recent definitive trial of group reminiscence failed to show any benefits in primary or secondary outcomes compared to usual treatment.<sup>172</sup> These findings were supported by ETNA-3, since neither CT nor reminiscence yielded any benefits over usual care. With regard to CR, there was no direct assessment of functional outcomes for the CR group, and no information is provided about whether goals were addressed successfully or whether any

changes in behaviour or perceptions of behaviour were seen as a result of the intervention. However, in secondary outcomes, CR was the only one of the three interventions to show any benefits relative to usual care. Participants in the CR group had lower functional decline at 24 months measured on the Disability Assessment for Dementia,<sup>173</sup> a six-month delay in institutionalisation compared to the usual treatment group, and lower rates of institutionalisation than all other conditions. There were no other significant differences in secondary outcomes, but the authors noted trends in neuropsychiatric symptoms, caregiver burden, and service utilisation. The authors concluded that cognition-focused group interventions are not effective and that individualised cognitive rehabilitation interventions should be used to delay institutionalisation for people with mild to moderate Alzheimer's disease.

Another trial combined CR with CT exercises and cognitive strategy training. Kim<sup>169</sup> reported a small (n=43) trial conducted in South Korea, in which participants with early-stage Alzheimer's disease (MMSE 18 and above) were randomised to receive eight weekly sessions of either CR (n=22) or an active control condition (n=21) consisting of group meetings with structured conversation and health-related videos. The CR sessions consisted of 30 minutes' group CT exercises and cognitive strategy training and 30 minutes' individual CR focused on addressing a personally-meaningful goal. The primary outcome was goal performance and satisfaction rated on the Canadian Occupational Performance Measure.<sup>38</sup> The CR group improved significantly in goal performance and satisfaction and quality of life scores also improved, while participants in the control group did not show any changes. However, this was a small trial yielding evidence of limited quality; analyses were restricted to separate pre-post comparisons for each group using t-tests, so the results should be interpreted with caution.

The other two trials identified, Voigt-Radloff et al.<sup>171</sup> and Thivierge et al.,<sup>170</sup> both describe trials in which the intervention involves structured training of activities of daily living.

Voigt-Radloff et al.<sup>171</sup> report an adequately-powered trial (n=161) conducted in Germany in which participants were randomly assigned to receive nine one-hour sessions in which everyday tasks were trained through either errorless (n=81) or trial-and-error (n=80) instructional methods. Up to three sessions were devoted to choosing the tasks to work on, which were selected from a list of 43 covering household tasks, leisure activities and cognitively-challenging tasks. Task performance was assessed with ratings based on observation. Performance improved in both groups with no differences between the two instructional methods. There were no changes in secondary outcomes for either group. As noted above, this trial failed to take note of available

evidence indicating that both types of learning strategy would be expected to be equally effective.<sup>60</sup>

Thivierge et al.<sup>170</sup> report a small (n=20) trial conducted in Canada using a block-randomisation wait-list control design. This tested an intervention that is variously described as ‘cognitive rehabilitation’ and ‘cognitive training’ but appears to involve structured training of instrumental activities of daily living (IADLs). In this study, following assessment to identify problematic IADLs, participants and carers selected one to be the focus of training. The chosen activity was trained twice a week for four weeks using errorless learning and expanding rehearsal methods, and was practised between sessions. Observational assessment indicated that task performance in the trained group improved and these gains were maintained at three months, but the groups did not differ on any other outcome measures on completion of the training or three months later.

These four trials taken together all focus on functional ability. However, they reflect two distinct approaches: one is goal-oriented CR addressing functioning in real-life contexts and the other is a form of cognitive training involving structured training in and practice of everyday tasks. The appearance of a form of cognitive training applied to everyday functional activities suggests that the concept of cognitive training, which describes practice on abstract cognitive tasks completed with pencil-and-paper or via computer, is being adapted for people with dementia to address the kinds of functional activities undertaken in everyday life. However, structured training does not address issues of transfer and generalisation of learning to the real-life setting,<sup>170,171</sup> and the learning may never be integrated into or used in daily life. The focus on relevant everyday tasks in these studies is very positive, but the potential difficulty with generalisation and integration into daily life precisely illustrates the reason why we took a different approach in GREAT and focused on improving functioning in the real-life setting with the activities participants were actually undertaking.

In terms of effectiveness, results from these trials confirm that the interventions produce improvements in the specific areas targeted, and clearly demonstrate that it is possible to improve functional ability for people with mild to moderate dementia. However, with the exception of the functional disability measure in ETNA-3, the interventions have no effects on scores on secondary outcome measures such as quality of life or carer burden. This is consistent with our findings in GREAT. One possibility is that changes in everyday functioning or ability to carry out specific activities, while very important in their own right and potentially very

beneficial, simply are not associated with appraisals of quality of life or carer stress. Quality of life of people with dementia, for example, is associated to a small degree with many different factors, and changes in one area may have little impact overall.<sup>174</sup> Another possibility is that changes in functional ability do have effects in other areas of life, but we do not have outcome measures that are sensitive to these changes. This is suggested by the responses identified from in-depth interviews with GREAT participants and carers. These interviews were undertaken by, and analysed by, researchers otherwise independent of the trial, to reduce risk of positive response bias, and it seems unlikely that participants and carers would make strong statements about feeling more confident and better able to cope if they did not genuinely feel some benefit in these areas alongside their observations of improved functional ability.

### **Evidence on cost-effectiveness**

Our second objective was to evaluate the cost-utility and cost-effectiveness of goal-oriented cognitive rehabilitation compared to treatment as usual.

There was no evidence for cost-utility in terms of QALY gains (using DEMQOL-U for people with dementia or EQ-5D-3L for carers), from either the health and social care system or the societal cost perspective. By reference to improvement of functioning in areas directly targeted in the therapy, which was the primary clinical outcome for the trial, CR could be cost-effective from the health and social care and societal perspectives, depending on decision-makers' willingness to pay for these gains in participant-rated goal attainment. These improvements associated with CR were perceived by participants as enabling them to achieve a number of goals that were personally relevant to them. These included better management of their daily lives and participation in activities that were meaningful to them. Assessed against this effectiveness measure, CR intervention is cost-effective at willingness-to-pay values of £2500 and above for a standardised mean difference of 1.32 on the BGS scale.

The economic evaluation had some strengths and weaknesses, over and above those discussed for the overall trial below. Data completion was good in relation to care and support, and there was detailed information on number and duration of CR visits per participant, in contrast to some other studies (e.g. Amieva et al.).<sup>168</sup> The cost-effectiveness analyses took account of correlation between cost and outcome error terms, and sampling

uncertainty. The cost data were highly skewed, which is very common in dementia studies, and statistical methods were used to address the issue, although there were a number of extreme outliers in health and social care costs, requiring a large number of replications in the non-parametric bootstrap analyses. Because the BGSi is a new instrument there are no established willingness-to-pay thresholds to guide the economic evaluation.

No previous studies of cognitive rehabilitation for people with dementia have looked at cost-effectiveness. There are some studies of cognitive remediation for other groups such as people with schizophrenia<sup>175</sup> that have included cost-effectiveness evaluations, but whilst they might offer some methodological pointers, their findings are not especially relevant to the interpretation of findings from the GREAT trial.

From an economics standpoint, the most relevant previous study of cognitive rehabilitation for people with dementia is the ETNA-3 trial.<sup>168</sup> Despite a number of design differences from GREAT, there are some similarities in outcome findings between the two studies. The ETNA-3 study found that CR was associated with a significant delay in institutionalisation over a 24-month follow-up period. We did not follow participants for the same duration of time in GREAT, and whilst health and social care systems differ between France (where ETNA trial was conducted) and the UK, this finding of delayed institutionalisation could suggest some similar longer-term economic gains might be achieved with CR in the UK even though no differences between CR and TAU groups were observed in healthcare, social care or other costs over the nine-month study period in the GREAT trial.

It is important to consider what outcome domains are important for different decision-makers. For people with dementia, and indeed also their carers, improvements in personally defined goal attainment is fundamentally important, and it is therefore clearly relevant that CR is found to be cost-effective by reference to that outcome. For commissioning purposes, however, we did not find that CR is cost-effective when gauged against QALY gains for either participants with dementia or carers. It would appear that the attainment of personally set goals did not bring about changes in those domains that are measured in the dementia-specific health-related quality of life measure (DEMQOL), nor did it improve carer health-related quality of life measure (measured by EQ5D).

The average cost per participant for the CR intervention was £1736. In routine clinical practice, levels of supervision and support would be lower than in the trial, which would

reduce the cost of CR below that observed in an experimental context. It might, however, also alter the outcomes achieved from CR. Next steps will be to examine the effectiveness and cost of CR implementation in routine practice.

### **Implications for future implementation**

Our final objective in GREAT was to examine how the goal-oriented cognitive rehabilitation approach could most effectively be integrated into routine NHS provision, to develop a pragmatic approach that could be directly applied within standard NHS services, and to develop materials to support the implementation of this approach within the NHS following trial completion.

The feasibility pilot work undertaken in the later stages of GREAT demonstrated the potential for CR to be integrated into NHS provision and showed that improvements in goal attainment comparable to those seen in the main trial can be achieved, even using a pragmatic approach involving fewer sessions delivered by less-qualified staff under local supervision. The experience gained, together with the results of supplementary and process evaluation analyses, highlight a number of issues relevant for future implementation efforts.

### ***Goal-setting***

Goals identified by participants and addressed in therapy reflected the multiple ways in which cognitive impairment impacts on everyday life for people with mild to moderate dementia. Some participants used goal-setting as a means to promote engagement in activities. Other aspects of the need for engagement were reflected in goals focusing on keeping in contact with family and friends and engaging in conversation. Some participants focused on managing everyday tasks and being able to use household appliances or devices such as mobile phones to help conduct their daily lives and to occupy and entertain themselves. A small number of goals focused on basic aspects of self-care such as washing and dressing. Many goals reflected the challenges of living with memory difficulties; participants wanted to be well-oriented, organised, and better able to retain or keep track of information and events, locate belongings, and recognise, identify and name people and objects. Managing emotions was an issue for a handful of participants.

Further, more detailed analysis of the goals participants chose will help in further developing the therapy, especially where goals can be cross-referenced with therapy logs to illustrate the

different ways in which cognitive impairment affected functional ability, the problems that therapists identified, and the strategies therapists used to overcome or offer solutions for these problems and help participants achieve their goals. This will provide valuable information to support wider implementation.

It is important to note that some participants who initially expressed interest in GREAT and were assessed at baseline did not proceed to randomisation because they felt content with their current situation and were unable to identify any areas of need in which they could formulate goals. CR does require active engagement and hence will not be appropriate for everyone. However, it is possible that carers in these cases had a different perspective and may have benefitted from support in solving problems and developing strategies. In clinical practice there may be opportunities to work directly with carers under these circumstances even if the person with dementia does not wish to engage.

### ***Perceptions of participants and carers***

The low attrition rates and good adherence rates, together with the positive evaluations recorded in the qualitative interview data, suggest that the therapy was very acceptable to those participants and carers who opted to take part. In addition to the specific focus on improving everyday functioning and the opportunity to develop new or more effective strategies, they valued the person-centred approach, the relationship they developed with the therapist, and the support this provided. The strong emphasis on the therapeutic relationship as the vehicle for change is instructive in terms of future implementation. Some people with dementia and carers may be able to make use of information about the approach and strategies they could use to engage in self-management but most are likely to require input from a therapist who can build trust and provide support in finding solutions to everyday challenges.

The qualitative data revealed some areas where participant and carer perceptions might have been managed better. Firstly, a few people were disappointed that while the intervention improved functioning it did not improve memory. CR was not presented as an intervention to improve memory or cognition *per se*, and indeed this is something that would have been made explicit from the start. Possibly this was not sufficiently explained in some cases, or perhaps it may have needed to be emphasised more throughout the therapy. Secondly, a few carers wondered if it was worthwhile to intervene given that dementia would progress anyway. This is a completely understandable reaction from carers who are facing, and perhaps grieving over, the

gradual decline they observe in their relative, but also suggests that the aims of rehabilitation and what it can realistically achieve may have needed more explanation in some cases in order to convince carers of the value of optimising functioning and reducing excess disability at any stage of dementia. It will be important to ensure that these messages are conveyed effectively in any future implementation, so that people with dementia and carers have realistic expectations about what CR can help them achieve.

### ***Challenges in delivering the intervention***

Therapists were able to deliver the intervention in line with the protocol. They could successfully engage participants and carers, explain the rationale for the CR approach, and conduct individually-tailored interventions addressing goals that participants and carers identified as relevant and meaningful. Therapists in GREAT faced the challenge of working with goals that had been set prior to their first meeting with the participant and carer as part of the baseline assessment. In clinical practice, and hence also in any future implementation, goals would typically be negotiated during the initial sessions with the therapist. Therapists noted the importance of being able to explain the therapy approach and the kinds of strategies used in a way that was accessible to participants and carers.

Therapists were expected to, and did, draw on their wider clinical skills and experience by developing good therapeutic relationships, managing relationship conflict between participants and carers when this emerged during sessions, providing information, and where necessary making onward referrals, for example to social services. These non-specific elements of the therapy need consideration in preparing therapists to work in this way in any future implementation, especially where CR is delivered by less-qualified staff, and need to be taken into account in training and in providing appropriate supervision arrangements.

### ***Identifying who is most likely to benefit***

Rehabilitation focuses on ‘doing with’ rather than ‘doing for’ or ‘doing to’.<sup>21</sup> For people in the early stages of dementia, CR requires some degree of active engagement. This implies that participants need to be able to identify something that they would like to change, improve or manage better. It is not necessary for them to acknowledge a specific dementia diagnosis or even the full range of difficulties they may be experiencing, but there needs to be something that they want to work on. This is not the case for everyone. We have conducted detailed investigations of awareness of difficulties among people with dementia; these show that a small proportion of

people with dementia are unwilling or unable to acknowledge any difficulties<sup>176</sup> and a larger proportion underestimate the impact of memory problems,<sup>47</sup> although there is some evidence that people with early-stage dementia are more accurate in estimating their own functional ability than are their carers.<sup>48</sup> Even where difficulties are acknowledged, people may have reached an acceptance of these or may not wish to make the effort required to bring about changes. Approximately 5% of the people with dementia assessed at baseline said they were content with their situation and could not identify any areas in which they felt changes were needed, and hence did not proceed to randomisation. Participants joining GREAT were able to identify areas for improvement and to evidence some motivation for change. Nevertheless, goal-setting could be challenging for some individuals, who required more time and support to identify suitable goals. As noted above, while in the trial goals were set as part of the initial assessment by the researcher, in usual practice goals would be negotiated by the therapist and could evolve over a number of therapy sessions, making this process more accessible.

Exploratory statistical analyses revealed few predictors to indicate which participants were likely to show greatest gains in goal attainment. Ratings of readiness to change at baseline, and number of sessions completed, were associated with greater gains. At three months, participants from professional occupational backgrounds had better outcomes than those from other occupational groups according to both participant and carer ratings. At nine months, MMSE score was predictive, and participants with MMSE scores of 24 or above had better outcomes according to both participant and carer ratings than those with MMSE scores of 23 or below, while participants aged under 75 did better than those aged 75 and over according to participant ratings only. Centre, gender, diagnosis, medication use and presence of co-morbid conditions were not linked to outcomes.

Data from the therapy logs analysis comparing the supplements these findings and suggests that participants with the best outcomes tended to have relatively good cognitive and functional ability, to be socially and physically active, and to be highly motivated. These participants were likely to acknowledge their difficulties and express anxiety about the impact of these, and to focus on challenging goals relating to IADLs or increasing engagement in social or leisure activities, and progress was evident early in the course of therapy. Participants who made the least progress were likely to have more extensive cognitive and functional difficulties and lower motivation, and were less likely to acknowledge difficulties or express anxiety about them. For

these participants, goals were more likely to relate to basic activities of daily living, and progress followed a slower trajectory.

In the GREAT trial, participants had to have a carer who was willing to contribute, in order that we could obtain collateral information such as carer ratings of goal attainment. However, in naturalistic settings, people with dementia may not have a carer, or may have a carer who is not able to support the intervention. This would not preclude them engaging in CR, but it would be an important factor for the therapist to consider when planning the intervention.

### *Differing levels and types of need*

In discussing their work in the focus group, the therapists seemed to distinguish different groups of participants based on levels of cognitive and functional ability and on time since diagnosis. These different groups were perceived to have different needs and to respond differently to the intervention. Participants who had received a dementia diagnosis in the previous few months, and their carers, were in the process of adjusting to dementia and were actively seeking strategies and solutions to help manage their everyday lives. Those who had been living with dementia for longer tended to have adapted to living with the condition and to be less motivated to make changes, and in some cases carers felt they had already tried various strategies without much success. Although participants in this latter group also benefitted, working with these participants presented more of a challenge for the therapists.

This provides valuable guidance on how to target the CR intervention in future implementation. Participants in GREAT had mild to moderate dementia, but this broad grouping encompasses a wide range of cognitive and functional ability. In terms of UK National Health Service (NHS) care pathways, it spans both the Cluster 18 Cognitive Impairment (Low Need) and Cluster 19 Cognitive Impairment (Moderate Need) care clusters. The principles of CR can be applied in different ways to optimise functioning, depending on need, and somewhat different approaches are likely to be required for different groups. The protocol used in GREAT, although applied effectively with both groups, appears to have been seen by therapists as more suitable for ‘Cluster 18’ participants.

CR may be a particularly valuable approach for people in the months following a dementia diagnosis, and could represent an important component of post-diagnostic support within the first year of being diagnosed. For this group, the aim would be to support people in remaining active

and engaged, maintaining confidence, and developing a range of strategies to support practical and emotional coping. An additional element for some, although not attempted in GREAT, might be vocational rehabilitation to support continuation in employment or transition to less-demanding employment or voluntary roles.

For people who have been living with dementia for longer, the aims may be more about maintaining basic skills of daily living, limiting the effects of excess disability, encouraging people to remain socially engaged, and ensuring opportunities to participate in pleasurable activities. As these individuals may find it harder to identify goals, carers are likely to be more involved in the goal selection process. An additional element for some might be the use of CR to support people with dementia who are returning home after a period of hospitalisation due to illness or injury or who have additional physical or mental health conditions.

This highlights the need for flexibility in applying the principles of CR to support optimal functioning for people with dementia. While GREAT followed a structured protocol, CR itself is not a fixed intervention, and can be adapted to different contexts to meet a variety of needs<sup>3</sup>. While the number of sessions was fixed for the trial, in practice the duration of the intervention could vary and could be tailored to participants' needs. Some individuals may need only one or a few sessions to address specific issues, while others may need longer periods of support to develop and implement strategies, or perhaps to regain function after a period of illness or hospitalisation. Some may benefit from several short episodes of CR as their needs change over time. In the pilot work on implementation that we conducted in NHS sites, we trialled shorter 6 and 8 session protocols as a starting point. However, experience with GREAT suggests that the group of people defined as having early-stage Alzheimer's, vascular or mixed dementia could be further sub-divided into two broad groups reflecting differing degrees of dementia progression. In future implementation, it will be important to prepare CR intervention protocols that meet the needs of each of these groups, to identify optimal timing and duration, and to explore outcomes accordingly.

## **Limitations**

Some limitations relating to trial design, outcome measures and participant inclusion criteria must be acknowledged.

(a) Trial design

This was a pragmatic trial comparing CR to treatment as usual (TAU). This design did not provide a means of controlling for the time and attention provided by the therapist, raising questions about whether treatment gains are specific to the therapy or non-specific. In this instance, however, the gains observed related specifically to the effects of CR and were demonstrated in improvements in goal attainment for goals directly targeted in the therapy. It is unlikely that these could be attributed to non-specific effects of the intervention. Furthermore, in the pilot trial CR demonstrated effectiveness when compared to an active control condition, relaxation therapy, with an equivalent number of therapist visits as well as when compared with TAU.

In trials of behavioural interventions which involve active participation and engagement it is not possible for participants to remain blind to their group allocation, especially where as in this case the intervention is compared to TAU, and this creates the potential for bias in responding on self-reported outcomes. The inclusion of parallel carer ratings may go some way towards mitigating this concern. Furthermore, if bias were present, we would expect to see it on all self-reported measures, and not just the ratings of goal attainment.

All possible precautions were taken to ensure that researchers collecting follow-up data remained blind to participants' group allocation. However, effective blinding is extremely difficult to achieve in trials of psychosocial interventions that do not include an active control condition. Despite all precautions taken, researchers conducting assessments are likely to surmise whether or not the participant received the intervention, as was the case in GREAT. It could possibly be argued that the statistically significant association of blinding inefficiency with greater improvement in BGSi ratings at follow-up could reflect researcher bias. However, it is more plausible to consider that the ability of the researchers to correctly identify which participants had received the intervention reflects the close relationship between the CR therapy and the outcome measure. The BGSi provides a proximal measure of treatment outcome that directly assesses whether the intervention addressed its intended targets. Participants who received CR would be expected to be more engaged with the personal goals identified and to remember them better. These participants would also have made ratings of progress with these goals in sessions with the therapist. Therefore it is likely that, if a participant had engaged well with the CR intervention and derived benefit from working on the identified goals, this would have been evident when making the BGSi ratings

in the follow-up assessment and consequently the researcher would have been able to correctly identify the participant's group allocation. Conversely, if it was not evident to the researcher that a participant who received CR was allocated in this way, it is likely that the participant was less engaged with the goals identified in the BGSI and that the treatment was less effective.

(b) Outcome measures

Primary and secondary outcomes in GREAT were evaluated mainly through participant-reported outcome measures, with collateral information from carers. This was a positive choice aiming to foreground the perspective of people with dementia and carers. It was also a practical choice because participant numbers and the focus on behavioural change in real-life situations precluded observational assessment as a means of evaluating therapy outcomes, and because, since CR was not expected to be a disease-modifying treatment, there was no particular justification for the use of physiological markers. The pilot trial<sup>63</sup> included a neuroimaging component which examined whether participation in therapy was associated with changes in particular brain areas seen on functional MRI; the findings were difficult to interpret, especially as only 28% of participants were able or willing to undergo MRI scanning, but some differences in activation patterns between CR and control participants were found following intervention, suggesting that the intervention produced a degree of restoration of function in frontal brain areas.<sup>66</sup> Physiological markers, therefore, may have some relevance, but the crucial question is a behavioural one: whether we can improve functioning in everyday life to enable people with dementia and carers to manage everyday life more effectively and with greater satisfaction. For the present trial, therefore, the focus was on behavioural change and on the perceptions of participants and carers.

The primary outcome measure, the BGSI, proved sensitive to changes resulting from the intervention. This used a valid and reliable rating method and participant responses were corroborated by the independent carer ratings. Ratings were collected by a blinded researcher not involved in the therapy, and given that scores on secondary outcome measures showed no changes, it is unlikely that changes in BGSI ratings in the CR group reflected a positive response bias. As discussed above, it is possible that secondary outcome measures were not sensitive to other changes resulting from the therapy. One limitation in outcome measurement is the lack of inclusion of a measure of functional ability. We did not have scope to include a long-term follow up to assess whether the intervention had any impact on rates of institutionalisation. In future

trials this is more likely to be feasible through the use of routine data and data linkage, but this option was not available to us when designing GREAT.

### (c) Participant selection

Because of the need for collateral information, we excluded any potential participants who did not have a carer available to contribute. This will have encompassed those who had a carer who was unwilling to contribute and those who had no carer involved and were perhaps living alone. People with dementia in either of these groups may be most in need of psychosocial support and in clinical practice it would be important to be able to offer CR in these circumstances. Consideration would need to be given to the best way of providing CR where there is no carer involved; this could include options such as working with volunteers or incorporating between-session contact with the therapist as a means of supporting practice with targeted activities. Participation was restricted to people with Alzheimer's, vascular or mixed dementia. While this accounts for the majority of dementia diagnoses,<sup>73</sup> people with other forms of dementia also have needs that could be addressed through CR. While the GREAT trial was in progress, we undertook a pilot trial with people who have either Parkinson's disease dementia or dementia with Lewy bodies.<sup>177,178</sup> This pilot trial replicated the methods used in our pilot trial of CR<sup>63</sup> and yielded similar results. This indicates that CR, in a similar form to that used in GREAT, is feasible and potentially effective for people with dementias associated with Parkinson's disease, and provides justification for a larger trial.<sup>179</sup> There is scope in future to explore the adaptation of CR for people with other rare dementias.

### ***Strengths***

Alongside these limitations, it is important to bear in mind the strengths of the trial. It included a diverse group of 474 people living with early-stage dementia and their carers, and attrition was low. The trial was conducted in eight regions of England and Wales, encompassing both urban and rural contexts, with consistent results across the eight centres. The intervention targeted real-life situations and aimed to improve participants' functioning in areas that were meaningful to them and that would make a difference in their daily lives, avoiding any problems relating to lack of transfer or generalisation of effects. The primary outcome measure was a proximal measure of outcome, directly evaluating perceptions of change in the areas targeted in the intervention, and demonstrated that the intervention led to improvements in ratings of goal attainment, with large effect sizes.

## **Next steps**

Building on the findings from GREAT, we will explore further the potential for implementation in health and social care services offering support to people living with dementia in the early stages, with similar profiles to those involved in the trial. We have secured implementation grant funding which will enable us to begin this process, starting in 2018. To support the implementation, we will develop materials, resources and training programmes. We will work with a number of partner organisations including NHS Trusts, local authority and non-profit social care providers to identify implementation plans, facilitate adoption of the approach into routine practice, and evaluate clinical and economic outcomes. We also aim to explore further the effectiveness of CR for people with dementias associated with Parkinson's disease, and the possible adaptation of this approach for people with other rare forms of dementia.

## **Conclusions**

The GREAT trial has demonstrated that individual, goal-oriented CR is clinically effective in enabling people with early-stage Alzheimer's, vascular or mixed dementia to improve their everyday functioning in relation to individual goals targeted in the therapy. This approach can facilitate the process of adjustment to living with dementia and increase confidence in managing the challenges dementia brings. The trial adds further evidence to support the view that individualised interventions that can be tailored to the particular current needs of people with dementia and carers and address these in a real-life context offer important benefits. CR represents an important contribution to improving the choice of interventions available to support people living with early-stage dementia and addressing the 'psychosocial intervention gap'.<sup>1,2</sup>

## Acknowledgements

We thank all the participants with dementia and their family supporters who generously contributed their time to be part of this study. We also thank Alzheimer's Society for supporting the study, and in particular we are grateful to Dr James Pickett and Malayka Rahman-Amin for helpful advice.

We would like to acknowledge the key roles in the research played by the following people.

- Trial therapists: Jenny Aindow, Eleanor Besso, Sue Evans, Jane Green, Myles Howard, Jane Hughes, Ruth Johns, Gayl Keddie, Pippa Page, and Alexis Tranah
- Trial researchers: Stephanie Barningham, Jasmine Blane, Claire Carter, Helen Cunnane, Dr Clare Freestone, Sophia Gerbase, India Hart, Dr Catherine Lawrence, James Middleton, Dr Jadwiga Nazimek, Emily Shah, Zoe Simkin, Nadezda Starkova, Olana Tansley-Hancock, and Joanna Waring
- Local team leaders: Andrew Hamilton, Amy Hammond, and Angela Parker
- NWOORTH Clinical Trials Unit team members: Statisticians Yvonne Sylvestre and Dr Lou Zhou, IT specialists Dr David Hunnisett and Lexi Bastable, Quality Assurance and Compliance Officer Debbie Skelhorn, and Trials Unit Managers Dr Huw Roberts and Jean Ryan
- Qualitative interviewers: Ho Yin Chan, Matthew Lewis and Julie Nixon
- Qualitative data analysts: Dr Gill Toms and Dr Krystal Warmoth
- Support for data analysis and reporting: Dr Rachel Collins

We are grateful for support for trial development and governance from the following people.

- Trial Steering Committee members: Professor Ian Robertson (Chair), Professor Ian Anderson, Hefin Francis (sponsor's representative, Bangor University), Dave Hanbury (expert by experience), Professor Narinder Kapur, Sue Lawrence (expert by experience), Victoria Morgan (expert by experience), and Gail Seymour (sponsor's representative, University of Exeter)
- Data Monitoring and Ethics Committee members: Professor Stephen Walters (Chair), Dr Thomas Chadwick, Dr Lesley Collier
- NIHR HTA research managers: Simon Bevan and Zoe Hurworth

We acknowledge the support of the participating Universities: University of Exeter (co-ordinating centre from 01/03/2015), Bangor University (co-ordinating centre to 28/02/2015), University of Bradford, Cardiff University, Kings College London, London School of Economics and Political Science, and University of Manchester. We also acknowledge the support of partner organisation Dementia Pal Ltd, Southampton, UK.

We acknowledge the support of the NHS organisations that hosted the trial and funded the work of the therapists by contributing NHS treatment costs: Betsi Cadwaladr University Health Board, Cardiff and Vale University Health Board, and the National Institute for Social Care and Health Research Wales (now Health and Care Research Wales); Birmingham and Solihull Mental Health Foundation Trust; Kent and Medway NHS and Social Care Partnership Trust; Manchester Mental Health and Social Care Trust; Northumberland, Tyne and Wear NHS Foundation Trust; RICE - Research Institute for the Care of Older People and NHS Bath and North East Somerset CCG; South London and the Maudsley NHS Foundation Trust.

We thank the following NHS organisations that supported recruitment by serving as participant identification centres (PICs) for the trial: Black Country Partnership NHS Foundation Trust; Dudley and Walsall Mental Health Partnership NHS Trust; Guy's and St Thomas's NHS Foundation Trust; Heart of England NHS Foundation Trust; Kings College Hospital NHS Foundation Trust; Oxleas NHS Foundation Trust; Pennine Care NHS Foundation Trust; Royal United Hospitals Bath NHS Foundation Trust and general practices in Wiltshire; St George's Healthcare NHS Trust.

We are grateful for support with participant recruitment from clinical research networks in England and Wales: NIHR Clinical Research Network and National Institute for Social Care and Health Research Wales (now Health and Care Research Wales).

### **Author contributions**

Professor Linda Clare, Professor of Clinical Psychology of Ageing and Dementia, University of Exeter, UK. Chief Investigator. Professor Clare developed the intervention, provided overall leadership for the trial, contributed to researcher supervision, and drafted the report  
Dr Aleksandra Kudlicka, Trial Manager, University of Exeter, UK provided operational management of the trial

Professor Jan Oyebode, Professor of Dementia Care, Bradford University, UK, PI for the West Midlands site, provided project leadership at the site, supervised the day-to-day work of the researchers and therapists, and contributed to researcher supervision and trial management

Professor Roy W. Jones, Consultant Geriatrician and Director of RICE - Research Institute for the Care of Older People, Bath, UK, PI for the South-West site, provided project leadership at the site, supervised the day-to-day work of the researchers and therapist, and contributed to trial management

Professor Antony Bayer, Professor of Geriatric Medicine, Cardiff University, UK, Principal Investigator (PI) for the South Wales site, provided project leadership at the site, supervised the day-to-day work of the researchers and therapist, and contributed to trial management

Dr Iracema Leroi, Clinical Senior Lecturer and Honorary Consultant Psychiatrist, University of Manchester, UK, PI for the North West site, provided project leadership at the site, supervised the day-to-day work of the researcher and therapists, and contributed to trial management

Professor Michael Kopelman, Professor of Neuropsychiatry, Kings College London, UK, PI for the London site, provided project leadership at the site, supervised the day-to-day work of the researchers and therapist, and contributed to trial management

Dr Ian A. James, Consultant Clinical Psychologist and Head of Newcastle Psychology and Challenging Behaviour Teams, Northumberland Tyne and Wear NHS Foundation Trust, PI for the North East site, provided project leadership at the site, supervised the day-to-day work of the researcher and therapist, and contributed to trial management

Dr Alison Culverwell, Consultant Clinical Psychologist and Research Lead for Older Peoples Service Line Research Lead, Kent and Medway NHS and Social Care Partnership Trust), PI for the South East site, provided project leadership at the site, supervised the day-to-day work of the researchers and therapist, and contributed to trial management

Jackie Pool, Occupational Therapist and Director of Dementia-Pal Ltd. Southampton, UK, provided expertise in applying cognitive rehabilitation in dementia care, led on therapist training, supervised the trial therapists and contributed to researcher supervision and trial management

Dr Andrew Brand, Trial Statistician, NWOORTH, Bangor University, UK, conducted the analysis of quantitative data

Catherine Henderson, Assistant Professorial Research Fellow, London School of Economics and Political Science, UK, conducted the health economic analyses

Dr Zoe Hoare, Principal Trial Statistician, NWOORTH, Bangor University, UK, oversaw the analysis of quantitative data

Professor Martin Knapp, Professor of Social Policy and Director of LSE Health and Social Care, London School of Economics, UK, led on health economic evaluation and contributed to trial management

Dr Sarah Morgan-Trimmer, Research Fellow, University of Exeter, UK, contributed to process evaluation analyses and oversaw analysis of qualitative data

Professor Alistair Burns, Professor of Old Age Psychiatry and Honorary Consultant Old Age Psychiatrist, University of Manchester, UK, contributed expertise in dementia research

Dr Anne Corbett, Senior Lecturer in Dementia Research, University of Exeter, UK, contributed expertise on patient and public involvement (PPI)

Rhiannon Whitaker, Statistical and Methodological Consultant, Whitaker Research Ltd, Bangor, UK, contributed to study design and set-up while acting as Associate Scientific Director, NWOORTH Clinical Trials Unit (to 30/09/2014)

Professor Bob Woods, Professor of the Clinical Psychology of Ageing and Director of the Dementia Services Development Centre (DSDC), Bangor University, UK, PI for the Bangor site, provided project leadership at the site, supervised the day-to-day work of the researcher and therapist, and contributed to researcher supervision and trial management

### **Data sharing**

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

### **Funding source**

This study was funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme; PI Professor L Clare; HTA reference 11/15/04. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

## References

1. British Psychological Society. Psychological dimensions of care: putting the person at the centre of care. Leicester, UK: British Psychological Society; 2016.
2. British Psychological Society. Clinical psychology in the early-stage dementia pathway. Leicester, UK: British Psychological Society; 2014.
3. Clare L. Rehabilitation for people living with dementia: a practical framework of positive support. *PLoS Med.* 2017;14(3):e1002245.
4. Squire LR, Knowlton BJ. Memory, hippocampus, and brain systems. In: Gazzaniga M, editor. *The cognitive neurosciences*. Boston: MIT Press; 1995. p. 825-37.
5. Fernández-Ballesteros R, Zamarrón MD, Tàrraga L, Moya R, Iniguez J. Cognitive plasticity in healthy, mild cognitive impairment (MCI) subjects and Alzheimer's disease patients: a research project in Spain. *Eur Psychol.* 2003;8(3):148-59.
6. Little AG, Volans PJ, Hemsley DR, Levy R. The retention of new information in senile dementia. *Br J Clin Psychol.* 1986;25(1):71-2.
7. Backman L. Memory training and memory improvement in Alzheimer's disease: rules and exceptions. *Acta Neurol Scand.* 1992;85:84-9.
8. World Health Organisation. *International Classification of Impairments, Disabilities, and Handicaps*. Geneva, Switzerland: World Health Organisation; 1980.
9. World Health Organisation. *International Classification of Impairments, Disabilities and Handicaps*. Geneva, Switzerland: World Health Organisation; 1998.
10. World Health Organisation. *International Classification of Functioning, Disability and Health*. Geneva, Switzerland: World Health Organisation; 2017.
11. Reifler BV, Larson E. Excess disability in dementia of the Alzheimer's type. In: Light E, Lebowitz BD, editors. *Alzheimer's disease treatment and family stress*. New York, NY: Hemisphere; 1990. p. 363-82.
12. Kitwood T. *Dementia reconsidered: the person comes first*. Buckingham, UK: Open University Press; 1997.

13. Small GW, Rabins PV, Barry PP, Buckholtz NS, DeKosky ST, Ferris SH, et al. Diagnosis and treatment of Alzheimer disease and related disorders: consensus statement of the American Association for Geriatric Psychiatry. *JAMA*. 1997;278:1363-71.
14. Clare L, Woods RT, Moniz-Cook ED, Orrell M, Spector A. Cognitive rehabilitation and cognitive training for early-stage Alzheimer's disease and vascular dementia (Cochrane Review). *Cochrane Database Syst Rev*. 2003;Issue 4, Art. No.: CD003260.
15. Bahar-Fuchs A, Clare L, Woods RT. Cognitive training and cognitive rehabilitation for mild to moderate Alzheimer's disease and vascular dementia. *Cochrane Database Syst Rev*. 2013;Issue 6, Art. No.: CD003260.
16. Global Council on Brain Health. Engage your brain: GCBH recommendations on cognitively stimulating activities. Available at: [www.globalcouncilonbrainhealth.org](http://www.globalcouncilonbrainhealth.org)2017.
17. Sitzer DI, Twamley EW, Jeste DV. Cognitive training in Alzheimer's disease: a meta-analysis of the literature. *Acta Neurol Scand*. 2006;114(2):75-90.
18. McLellan DL. Functional recovery and the principles of disability medicine. London, UK: Churchill Livingstone; 1991.
19. Wilson BA. Towards a comprehensive model of cognitive rehabilitation. *Neuropsychol Rehabil*. 2002;12(2):97-110.
20. Clare L. Neuropsychological rehabilitation and people with dementia. Hove, UK: Psychology Press; 2008.
21. Aspinall F, Glasby J, Rostgaard T, Tuntland H, Westendorp RG. New horizons: reablement - supporting older people towards independence. *Age Ageing*. 2016;45(5):574-8.
22. United Nations. Convention on the Rights of Persons with Disabilities. 2006; Accessed: 2 Feb 2017. URL: <http://www.un.org/disabilities/documents/convention/convoptprot-e.pdf>.
23. Cohen D., C. E. The loss of self: a family resource for the care of Alzheimer's disease and related disorders. New York, NY: W W Norton & Company; 1986.
24. Marshall M. Perspectives on rehabilitation and dementia. London, UK: Jessica Kingsley; 2005.

25. Allen J, Koziak A, Buddingh S, Liang J, Buckingham J, Beaupre LA. Rehabilitation in patients with dementia following hip fracture: a systematic review. *Physiother Can.* 2012;64(2):190-201.
26. Malec JF. Goal attainment scaling in rehabilitation. *Neuropsychol Rehabil.* 1999;9(3-4):253-75.
27. Locke EA, Latham GP. Building a practically useful theory of goal setting and task motivation: a 35-year odyssey. *Am Psychol.* 2002;57(9):705-17.
28. Rockwood K, Joyce B, Stolee P. Use of Goal Attainment Scaling in measuring clinically important change in cognitive rehabilitation patients. *J Clin Epidemiol.* 1997;50(5):581-8.
29. Trombly CA, Radomski MV, Trexel C, Burnett-Smith SE. Occupational therapy and achievement of self-identified goals by adults with acquired brain injury: phase II. *Am J Occup Ther.* 2002;56:489-98.
30. Cup EHC, Scholte op Reimer WJM, Thijssen MCE, van Kuyk-Minis MAH. Reliability and validity of the Canadian Occupational Performance Measure in stroke patients. *Clin Rehabil.* 2003;17:402-9.
31. Khan F, Pallant JF, Turner-Stokes L. Use of Goal Attainment Scaling in inpatient rehabilitation for persons with multiple sclerosis. *Arch Phys Med Rehabil.* 2008;89(4):652-9.
32. Dewar BK, Kapur N, Kopelman M. Do memory aids help everyday memory? A controlled trial of a Memory Aids Service. *Neuropsychol Rehabil.* 2016 Jun:1-19.
33. Rushton PW, Miller WC. Goal Attainment Scaling in the rehabilitation of patients with lower-extremity amputations: a pilot study. *Arch Phys Med Rehabil.* 2002;83:771-5.
34. Fisher K, Hardie RJ. Goal attainment scaling in evaluating a multidisciplinary pain management programme. *Clin Rehabil.* 2002;16(8):871-7.
35. Fisher K. Assessing clinically meaningful change following a programme for managing chronic pain. *Clin Rehabil.* 2008;22(3):252-9.
36. Rockwood K, Howlett S, Stadnyk K, Carver D, Powell C, Stolee P. Responsiveness of goal attainment scaling in a randomized controlled trial of comprehensive geriatric assessment. *J Clin Epidemiol.* 2003;56(8):736-43.

37. Kiresuk TJ, Sherman RE. Goal Attainment Scaling: a general method for evaluating comprehensive community mental health programs. *Community Ment Health J.* 1968;4(6):443-53.
38. Law M, Baptiste S, Carswell A, McColl MA, Polatajko H, Pollock N. *Canadian Occupational Performance Measure* 4th ed. Ottawa, ON: Canadian Association of Occupational Therapists Publications; 2005.
39. Carswell A, McColl MA, Baptiste S, Law M, Polatajko H, Pollock N. The Canadian Occupational Performance Measure: a research and clinical literature review. *Can J Occup Ther.* 2004;71(4):210-22.
40. Donnelly C, Carswell A. Individualized outcome measures: a review of the literature. *The Canadian Journal of Occupational Therapy.* 2002;69(2):84-94.
41. Eyssen ICJM, Beelen A, Dedding C, Cardol M, Dekker J. The reproducibility of the Canadian Occupational Performance Measure. *Clin Rehabil.* 2005;19(8):888-94.
42. Jenkinson N, Ownsworth T, Shum D. Utility of the Canadian Occupational Performance Measure in community-based brain injury rehabilitation. *Brain Inj.* 2007;21(12):1283-94.
43. Steeman E, de Casterle BD, Godderis J, Grypdonck M. Living with early-stage dementia: a review of qualitative studies. *J Adv Nurs.* 2006;54(6):722-38.
44. Clare L. The construction of awareness in early-stage Alzheimer's disease: a review of concepts and models. *Br J Clin Psychol.* 2004;43(2):155-75.
45. Clare L, Wilson BA, Carter G, Roth I, Hodges JR. Awareness in early-stage Alzheimer's disease: relationship to outcome of cognitive rehabilitation. *J Clin Exp Neuropsychol.* 2004;26(2):215-26.
46. Clare L, Markova IS, Roth I, Morris RG. Awareness in Alzheimer's disease and associated dementias: theoretical framework and clinical implications. *Aging Ment Health.* 2011;15(8):936-44.
47. Clare L, Whitaker CJ, Roberts J, Nelis S, Martyr A, Markova IS, et al. Memory awareness profiles differentiate mild cognitive impairment from early-stage dementia: evidence from assessments of performance monitoring and evaluative judgement. *Dement Geriatr Cogn Disord.* 2013;35(5-6):266-79.

48. Martyr A, Clare L. Awareness of functional ability in people with early-stage dementia. *Int J Geriatr Psychiatry*. 2017;Advance online publication.
49. Kurlychek RT. Use of a digital alarm chronograph as a memory aid in early dementia. *Clin Gerontol*. 1983;1:93-4.
50. Bourgeois MS. Enhancing conversation skills in patients with Alzheimer's disease using a prosthetic memory aid. *J Appl Behav Anal*. 1990;23(1):29-42.
51. Josephsson S, Backman L, Borell L, Bernspang B, Nygard L, Ronnberg L. Supporting everyday activities in dementia: an intervention study. *Int J Geriatr Psychiatry*. 1993;8(5):395-400.
52. Camp CJ. Facilitation of new learning in Alzheimer's disease. New York, NY: Springer; 1989.
53. Clare L, Wilson BA, Breen K, Hodges JR. Errorless learning of face-name associations in early Alzheimer's disease. *Neurocase*. 1999;5(1):37-46.
54. Clare L, Wilson BA, Carter G, Breen K, Gosses A, Hodges JR. Intervening with everyday memory problems in dementia of Alzheimer type: an errorless learning approach. *J Clin Exp Neuropsychol*. 2000;22(1):132-46.
55. Clare L, Wilson BA, Carter G, Hodges JR. Cognitive rehabilitation as a component of early intervention in dementia: a single case study. *Aging Ment Health*. 2003;7(1):15-21.
56. Clare L, Wilson BA. Memory rehabilitation for people with early-stage dementia: a single case comparison of four errorless learning methods. *Z Gerontol Psychol Psychiat*. 2004;17:109-17.
57. Clare L, Wilson BA, Carter G, Roth I, Hodges JR. Relearning of face-name associations in early-stage Alzheimer's disease. *Neuropsychology*. 2002;16(4):538-47.
58. Clare L, Wilson BA, Carter G, Hodges JR, Adams M. Long-term maintenance of treatment gains following a cognitive rehabilitation intervention in early dementia. *Neuropsychol Rehabil*. 2001;11(3-4):477-94.
59. Dunn J, Clare L. Learning face-name associations in early-stage dementia: comparing the effects of errorless learning and effortful processing. *Neuropsychol Rehabil*. 2007;17(6):735-54.

60. Clare L, Jones RSP. Errorless learning in the rehabilitation of memory impairment: a critical review. *Neuropsychol Rev*. 2008;18(1):1-23.
61. Bird M. Behavioural difficulties and cued recall of adaptive behaviour in dementia: experimental and clinical evidence. *Neuropsychol Rehabil*. 2001;11(3-4):357-75.
62. Lekeu F, Wojtasik V, Van der Linden M, Salmon E. Training early Alzheimer patients to use a mobile phone. *Acta Neurol Belg*. 2002;102(3):114-21.
63. Clare L, Linden DE, Woods RT, Whitaker R, Evans SJ, Parkinson CH, et al. Goal-oriented cognitive rehabilitation for people with early-stage Alzheimer's disease: a single-blind randomized controlled trial of clinical efficacy. *Am J Geriatr Psychiatry*. 2010;18(10):928-39.
64. Clare L, Evans S, Parkinson C, Woods RT, Linden D. Goal-setting in cognitive rehabilitation for people with early-stage Alzheimer's disease. *Clin Gerontol*. 2011;34(3):220-36.
65. van Paasschen J, Clare L, Woods RT, Linden DEJ. Can we change brain functioning with cognition-focused interventions in Alzheimer's disease? The role of functional neuroimaging. *Restor Neurol Neurosci*. 2009;27(5):473-91.
66. van Paasschen J, Clare L, Yuen K, Woods RT, Evans S, Parkinson C, et al. Cognitive rehabilitation changes memory-related brain activity in people with Alzheimer's disease. *Neurorehabil Neural Repair*. 2013;27(5):448-59.
67. Clare L, Woods RT. Cognitive rehabilitation and cognitive training in early-stage Alzheimer's disease and vascular dementia (Updated version). *Cochrane Database Syst Rev*. 2007;Issue 4, Art. No.:CD003260.
68. Wressle E, Marcusson J, Henriksson C. Clinical utility of the Canadian Occupational Performance Measure - Swedish version. *The Canadian Journal of Occupational Therapy*. 2002;69(1):40-8.
69. Cusick A, McIntyre S, Novak I, Lannin N, Lowe K. A comparison of goal attainment scaling and the Canadian Occupational Performance Measure for pediatric rehabilitation research. *Pediatr Rehabil*. 2006;9(2):149-57.

70. Clare L, Nelis SM, Jones IR, Hindle JV, Thom JM, Nixon JA, et al. The Agewell trial: a pilot randomised controlled trial of a behaviour change intervention to promote healthy ageing and reduce risk of dementia in later life. *BMC Psychiatry*. 2015;15:25.
71. Lautenschlager NT, Goh A, Etherton-Beer C, Liew D, Ames D, LoGiudice D, et al. The INDIGO Study: a randomized controlled trial of physical activity with individual goal-setting and volunteer mentors to overcome sedentary lifestyle in older adults at risk of cognitive decline. *Alzheimers Dement*. 2014;10(4 Suppl):124.
72. Clare L, Bayer A, Burns A, Corbett A, Jones R, Knapp M, et al. Goal-oriented cognitive rehabilitation in early-stage dementia: study protocol for a multi-centre single-blind randomised controlled trial (GREAT). *Trials*. 2013;14(152).
73. Prince M, Knapp M, Guerchet M, McCrone P, Prina M, Comas-Herrera A, et al. *Dementia UK*. 2nd ed. London, UK: Alzheimer's Society; 2014.
74. 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(3):189-98.
75. Russell D, Hoare ZSJ, Whitaker R, Whitaker CJ, Russell IT. Generalized method for adaptive randomization in clinical trials. *Stat Med*. 2011;30(9):922-34.
76. Pool J. *The Pool Activity Level (PAL) instrument for occupational profiling: a practical resource for carers of people with cognitive impairment*. 4th ed. ed. London: Jessica Kingsley; 2012.
77. Wenborn J, Challis D, Pool J, Burgess J, Elliott N, Orrell M. Assessing the validity and reliability of the Pool Activity Level (PAL). Checklist for use with older people with dementia. *Aging Ment Health*. 2008;12(2):202-11.
78. The National Institute for Health and Care Excellence (Great Britain). *Dementia: supporting people with dementia and their carers in health and social care*. London, UK: National Institute for Health and Clinical Excellence; 2006.
79. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clin Psychol Rev*. 1991;11(3):247-66.
80. Hawe P, Shiell A, Riley T. Complex interventions: how "out of control" can a randomised controlled trial be? *BMJ*. 2004;328(7455):1561.

81. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis Manag.* 1987;40(5):373-83.
82. Cusick A, Lannin NA, Lowe K. Adapting the Canadian Occupational Performance Measure for use in a paediatric clinical trial. *Disabil Rehabil.* 2007;29(10):761-6.
83. Wallen MA, Ziviani JM. Canadian Occupational Performance Measure: impact of blinded parent-proxy ratings on outcome. *Can J Occup Ther.* 2012;79(1):7-14.
84. Smith SC, Lampling DL, Banerjee S, Harwood RH, Foley B, Smith P, et al. Development of a new measure of health-related quality of life for people with dementia: DEMQOL. *Psychol Med.* 2007;37(5):737-46.
85. Mulhern B, Rowen D, Brazier J, Smith S, Romeo R, Tait R, et al. Development of DEMQOL-U and DEMQOL-PROXY-U: generation of preference-based indices from DEMQOL and DEMQOL-PROXY for use in economic evaluation. *Health Technol Assess.* 2013;17(5):1-140.
86. Schwarzer R, Jerusalem M. Generalized Self-Efficacy Scale. In: Weinman J, Wright S, Johnston M, editors. *Measures in health psychology: a user's portfolio.* Windsor, UK: NFER-Nelson; 1995. p. 35-7.
87. Luszczynska A, Gutierrez-Dona B, Schwarzer R. General self-efficacy in various domains of human functioning: evidence from five countries. *Int J Psychol.* 2005;40(2):80-9.
88. Snaith RP, Zigmond AS. *The Hospital Anxiety and Depression Scale.* Windsor, UK: NFER-Nelson; 1994.
89. Ablitt A, Jones G, Muers J. Awareness of carer distress in people with dementia. *Int J Geriatr Psychiatry.* 2010;25(12):1246-52.
90. Cooper C, Katona C, Orrell M, Livingston G. Coping strategies and anxiety in caregivers of people with Alzheimer's disease: the LASER-AD study. *J Affect Disord.* 2006;90(1):15-20.
91. Wilson BA, Baddeley AD, Cockburn J. *Rivermead Behavioural Memory Test II.* Bury St Edmunds, UK: Thames Valley Test Company; 2003.

92. Robertson IH, Ward T, Ridgeway V, Nimmo-Smith I. *The Test of Everyday Attention*. Bury St Edmunds, UK: Thames Valley Test Company; 1994.
93. Delis DC, Kaplan E., Kramer JH. *Delis-Kaplan Executive Function System (D-KEFS)*. London, UK: Pearson; 2001.
94. Jurado MB, Rosselli M. The elusive nature of executive functions: a review of our current understanding. *Neuropsychol Rev.* 2007;17:213-33.
95. Henry JD, Crawford JR, Phillips LH. Verbal fluency performance in dementia of the Alzheimer's type: a meta-analysis. *Neuropsychologia.* 2004;42(9):1212-22.
96. Beecham J., M. K. Costing psychiatric interventions. In: Thornicroft G, Brewin C, Wing J, editors. *Measuring mental health needs*. London, UK: Gaskell; 1992. p. 179-90.
97. Greene JG, Smith R, Gardiner M, Timbury GC. Measuring behavioural disturbance of elderly demented patients in the community and its effects on relatives: a factor analytic study. *Age Ageing.* 1982;11(2):121-6.
98. Skevington SM, Lotfy M, O'Connell KA. The World Health Organization's WHOQOL-BREF quality of life assessment: psychometric properties and results of the international field trial. A report from the WHOQOL Group. *Qual Life Res.* 2004;13(2):299-310.
99. Brooks R, Group E. EuroQol: the current state of play. *Health Policy.* 1996;37(1):53-72.
100. Rabin R, Charro FD. EQ-SD: a measure of health status from the EuroQol Group. *Ann Med.* 2001;33(5):337-43.
101. InferMed MACRO Version 4 [online data management solution]  
<https://www.elsevier.com/solutions/macro>.
102. Prikryl M. WinSCP Version 5.9.4. <https://sourceforge.net/projects/winscp/2000>.
103. Oracle Corporation. *Oracle Secure Global Desktop*. Redwood Shores, California:  
<https://www.oracle.com/virtualization/secure-global-desktop/index.html>; 1995.
104. Alfresco Software Inc. *Alfresco*. San Mateo, California, USA:  
<https://www.alfresco.com/platform>; 2005.

105. R Core Team. R: A language and environment for statistical computing. Version 3.3.1. Vienna, Austria: R Foundation for Statistical Computing; 2016.
106. IBM Corp. IBM SPSS Statistics for Windows. Version 22.0. Armonk, NY: IBM Corp; 2013.
107. McGrath RE, Meyer GJ. When effect sizes disagree: the case of  $r$  and  $d$ . *Psychol Methods*. 2006;11(4):386-401.
108. van Buuren S, Groothuis-Oudshoorn K. mice: Multivariate Imputation by Chained Equations in R. *J Stat Softw*. 2011;45(3):1-67.
109. Grund S, Lüdtke O, Robitzsch A. Pooling ANOVA results from multiply imputed datasets. *Methodology*. 2016;12(3):75-88.
110. Evans S, Pool, J., Besso, E., Cunnane, H., Freestone, C., Gerbase, S., Hart, I., Clare, L., Lawrence, C., Simkin, Z., Kudlicka, A. What do people with early-stage dementia identify as meaningful therapy goals? *Br J Occup Ther*. 2015;78:8(Suppl):78-9.
111. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101.
112. QSR International. NVivo Version 11. Doncaster, Victoria, Australia: <http://www.qsrinternational.com/what-is-nvivo>; 2015.
113. Ritchie J, Spencer L, O'Connor W. Carrying out qualitative analysis. In: Ritchie J, Lewis J, editors. *Qualitative research practice: a guide for social science students and researchers*. London, UK: SAGE Publications; 2003. p. 219-62.
114. Smith JA, Osborn, M., & Jarman, J. . Doing Interpretative Phenomenological Analysis. In: Chamberlain MMJ, editor. *Qualitative health psychology: theories and methods* London: Sage; 1999. p. 218-40.
115. Samsa G, Edelman D, Rothman ML, Williams GR, Lipscomb J, Matchar D. Determining clinically important differences in health status measures: a general approach with illustration to the Health Utilities Index Mark II. *Pharmacoeconomics*. 1999;15(2):141-55.

116. Rowen D, Mulhern B, Banerjee S, van Hout B, Young TA, Knapp M, et al. Estimating preference-based single index measures for dementia using DEMQOL and DEMQOL-Proxy. *Value Health*. 2012;15(2):346-56.
117. Dolan P, Gudex C, Kind P, Williams A. A social tariff for EuroQol: results from a UK general population survey (discussion paper 138). York: University of York; 1995.
118. Beecham JK, Knapp MRJ. Costing psychiatric interventions. In: Thornicroft G., Brewin C., Wing JK, editors. *Measuring Mental Health Needs*. 2nd ed. London: Gaskell; 2001. p. 220-4.
119. Department of Health. National schedule of reference costs 2012-13. London: Department of Health; 2013 Published 21 November 2013
120. Curtis L, editor. *Unit Costs of Health and Social Care 2014*. Canterbury: Personal Social Services Research Unit; 2014.
121. Curtis L, editor. *Unit Costs of Health and Social Care 2013*. Canterbury: Personal Social Services Research Unit; 2013.
122. Koopmanschap MA, van Exel JN, van den Berg B, Brouwer WB. An overview of methods and applications to value informal care in economic evaluations of healthcare. *Pharmacoeconomics*. 2008;26(4):269-80.
123. Pritchard C, Sculpher MJ. *Productivity costs*. London: Office of Health Economics; 2000.
124. Department of Health. *National Schedule of Reference Costs 2013-14*. London: Department of Health; 2014.
125. Greenleaf Cleaning. Our prices: Regular domestic cleaning [Web page]. Accessed: Nov 15, 2016. URL: <http://www.greenleaf-cleaning.co.uk/our-prices/>.
126. Hassle.com. Pricing [Web page]. Accessed: Nov 15, 2016. URL: <http://www.greenleaf-cleaning.co.uk/our-prices/>.
127. Homeclean. Home page [Web page]. Accessed: Nov 15, 2016. URL: <http://www.homeclean.co.uk/>.
128. Wandsworth Council. Laundry service 2008. URL: <http://www.wandsworth.gov.uk/moderngov/mgConvert2PDF.aspx?ID=6962>.

129. Banks L, Barnes, M. Evaluation of the East Sussex Carers' Breaks Demonstrator Site East Sussex: University of Brighton, Centre SSPaR; 2011.
130. Optical Confederation. Optics at a Glance 2014. London: Optical Confederation; 2014.
131. Department of Health. General Ophthalmic Services: increases to NHS sight test fee, pre-registration supervisors allowance and continuing education and training allowance and arrangements for universal credit. London: Department of Health; 2014.
132. Romeo R, Knapp M, Banerjee S, Morris J, Baldwin R, TARRIER N, et al. Treatment and prevention of depression after surgery for hip fracture in older people: Cost-effectiveness analysis. *J Affect Disord.* 2011;128(3):211-9.
133. NHS West Norfolk CCG. Freedom of Information request: WN-2015-00077(IR)–Structured Diabetes 2015.
134. D'Amico F, Rehill A, Knapp M, Aguirre E, Donovan H, Hoare Z, et al. Maintenance Cognitive Stimulation Therapy: An Economic Evaluation Within a Randomized Controlled Trial. *Journal of the American Medical Directors Association.* 2015;16(1):63-70.
135. Orgeta V, Leung P, Yates L, Kang S, Hoare Z, Henderson C, et al. Individual cognitive stimulation therapy for dementia: a clinical effectiveness and cost-effectiveness pragmatic, multicentre, randomised controlled trial. *Health Technol Assess.* 2015;19(42):1-108.
136. Quinn C, Toms G, Jones C, Brand A, Edwards RT, Sanders F, et al. A pilot randomized controlled trial of a self-management group intervention for people with early-stage dementia (The SMART study). *Int Psychogeriatr.* 2016;28(5):787-800.
137. Dementia Partnerships. Peer support projects 2014; Accessed: April 14, 2014. URL: <http://www.dementiapartnerships.org.uk>.
138. Alzheimer's Society (Hull & East Riding). Singing For The Brain: Alzheimer's Society; Accessed: May 31, 2017. URL: <http://www.dementiaeastriding.org.uk/singing-for-the-brain/>.
139. Alzheimer's Society (Surrey). News release: New "Singing for the Brain"® group for people with dementia in Oxted: Alzheimer's Society; 2016; Accessed: May 31, 2017. URL:

<http://www.woldingham.com/wp-content/uploads/2016/10/Singing-for-the-brain-PressRelease.pdf>.

140. Alzheimer's Society (Surrey). Singing with us: Alzheimer's Society; 2017; Accessed: May 31, 2017. URL: <http://www.surreymusiclub.com/assets/documents/singing-for-the-brain>.

141. Alzheimer's Society - Singing for the Brain. Alzheimer's Society - Singing for the Brain: Sheffield Directory; 2017; Accessed: May 31, 2017. URL: <http://www.sheffielddirectory.org.uk/kb5/sheffield/directory/service.page?id=QwDrnUSLP3s>

142. Witham MD, Fulton RL, Greig CA, Johnston DW, Lang CC, van der Pol M, et al. Efficacy and cost of an exercise program for functionally impaired older patients with heart failure: a randomized controlled trial. *Circ Heart Fail*. 2012;5(2):209-16.

143. Curtis L, editor. Unit Costs of Health and Social Care 2010. Canterbury: Personal Social Services Research Unit; 2010.

144. Department of Health Care Services Efficiency Delivery Programme Transforming Community Equipment Services national catalogue and tariff for Simple Aids to Daily Living 2010; Accessed: 19/2/2011.

145. Department of Health. Building Telecare in England 2005. p. 1-21.

146. Health and Social Care Information Centre. Prescription Cost Analysis, England 2013. Health and Social Care Information Centre; 2014.

147. GOV.UK. National Minimum Wage and National Living Wage rates 2017; Accessed: February 1, 2017. URL: <https://www.gov.uk/national-minimum-wage-rates>.

148. Automobile Association. Motoring costs 2013. Automobile Association; 2013.

149. NHS Employers. Pay Circular (AforC) 3/2013: Changes to the NHS Terms and Conditions of Service Handbook (amendment number 29 ): reimbursement of employee NHS business travel costs 2013; Accessed: 24 November 2014. URL: <http://www.nhsemployers.org/~media/Employers/Publications/Pay%20circulares/pay-circular-afc-3-2013.pdf>.

150. Curtis L, Burns A, editors. Unit costs of health and social care 2016. Canterbury: Personal Social Services Research Unit; 2016.

151. StataCorp. Stata multiple-imputation reference manual: release 14. College Station, Texas: StataCorp LP; 2015.
152. Faria R, Gomes M, Epstein D, White IR. A guide to handling missing data in cost-effectiveness analysis conducted within randomised controlled trials. *Pharmacoeconomics*. 2014;32(12):1157-70.
153. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med*. 2011;30(4):377-99.
154. StataCorp. Stata Statistical Software: Release 14. College Station, Texas, USA: <http://www.stata.com/company/>; 2015.
155. Vanderviere E, Huber M. An adjusted boxplot for skewed distributions. In: Antoch J, editor. *COMPSTAT2004 Symposium: Proceedings in Computational Statistics*. Heidelberg: Physica-Verlag; 2004. p. 1933-40.
156. Gelade W, Verardi V, Vermandele C. MEDCOUPLE: Stata module to compute medcouple measure of asymmetry and heaviness of the tails. *Statistical Software Components*: Boston College Department of Economics; 2013.
157. Drummond MF, Sculpher MJ, Torrance GW, O'Brien B, Stoddart GL. *Methods for the economic evaluation of health care programmes* 3rd ed. Oxford: Oxford University Press; 2005.
158. Willan AR, Briggs AH, Hoch JS. Regression methods for covariate adjustment and subgroup analysis for non-censored cost-effectiveness data. *Health Econ*. 2004;13(5):461-75.
159. Gould W, Pitblado J. How large should the bootstrapped samples be relative to the total number of cases in the dataset? [website]. StataCorp; 2017; Accessed: 16 March 2017. URL: <http://www.stata.com/support/faqs/statistics/bootstrapped-samples-guidelines/>.
160. Glick H. *Economic evaluation in clinical trials*. Oxford; New York: Oxford University Press; 2007.
161. Fenwick E, Marshall DA, Levy AR, Nichol G. Using and interpreting cost-effectiveness acceptability curves: an example using data from a trial of management strategies for atrial fibrillation. *BMC Health Serv Res*. 2006;6(52):1-8.

162. Mantopoulos T, Mitchell PM, Welton NJ, McManus R, Andronis L. Choice of statistical model for cost-effectiveness analysis and covariate adjustment: empirical application of prominent models and assessment of their results. *Eur J Health Econ.* 2016;17(8):927-38.
163. Hounsome N, Orrell M, Edwards RT. EQ-5D as a quality of life measure in people with dementia and their carers: evidence and key issues. *Value Health.* 2011;14(2):390-9.
164. Aguirre E, Kang S, Hoare Z, Edwards RT, Orrell M. How does the EQ-5D perform when measuring quality of life in dementia against two other dementia-specific outcome measures? *Qual Life Res.* 2016;25(1):45-9.
165. Ratcliffe J, Flint T, Easton T, Killington M, Cameron I, Davies O, et al. An empirical comparison of the EQ-5D-5L, DEMQOL-U and DEMQOL-Proxy-U in a post-hospitalisation population of frail older people living in residential aged care. *Appl Health Econ Health Policy.* 2017;15(3):399-412.
166. National Institute for Health and Care Excellence. Guide to the methods of technology appraisal. London: National Institute for Health and Clinical Excellence; 2013 June 2008.
167. Amieva H, Dartigues JF. ETNA3, a clinical randomized study assessing three cognitive-oriented therapies in dementia: rationale and general design. *Rev Neurol.* 2013;169(10):752-6.
168. Amieva H, Robert PH, Grandoulier AS, Meillon C, De Rotrou J, Andrieu S, et al. Group and individual cognitive therapies in Alzheimer's disease: the ETNA3 randomized trial. *Int Psychogeriatr.* 2016;28(5):707-17.
169. Kim S. Cognitive rehabilitation for elderly people with early-stage Alzheimer's disease. *J Phys Ther Sci.* 2015;27(2):543-6.
170. Thivierge S, Jean L, Simard M. A randomized cross-over controlled study on cognitive rehabilitation of instrumental activities of daily living in Alzheimer disease. *Am J Geriatr Psychiatry.* 2014;22(11):1188-99.
171. Voigt-Radloff S, de Werd MM, Leonhart R, Boelen DH, Rikkert MGO, Fliessbach K, et al. Structured relearning of activities of daily living in dementia: the randomized controlled REDALI-DEM trial on errorless learning. *Alzheimers Res Ther.* 2017;9(22):1-11.

172. Woods RT, Orrell M, Bruce E, Edwards RT, Hoare Z, Hounsome B, et al. REMCARE: pragmatic multi-centre randomised trial of reminiscence groups for people with dementia and their family carers: effectiveness and economic analysis. *PLoS One*. 2016;11(4):e0152843.
173. Gélinas I, Gauthier L, McIntyre M, Gauthier S. Development of a functional measure for persons with Alzheimer's disease: the disability assessment for dementia. *Am J Occup Ther*. 1999;53:471-81.
174. Clare L, Wu YT, Teale JC, MacLeod C, Matthews F, Brayne C, et al. Potentially modifiable lifestyle factors, cognitive reserve, and cognitive function in later life: a cross-sectional study. *PLoS Med*. 2017;14(3):e1002259.
175. Patel A, Knapp M, Romeo R, Reeder C, Matthiasson P, Everitt B, et al. Cognitive remediation therapy in schizophrenia: cost-effectiveness analysis. *Schizophr Res*. 2010;120(1-3):217-24.
176. Clare L, Quinn C, Jones IR, Woods RT. "I don't think of it as an illness": illness representations in mild to moderate dementia. *J Alzheimers Dis*. 2016;51(1):139-50.
177. Hindle JV, Watermeyer T, Roberts J, Martyr A, Lloyd-Williams H, Brand A, et al. Cognitive rehabilitation for Parkinson's disease dementia: study protocol for a randomised controlled trial (CORD-PD). *Trials*. 2016;17:152.
178. Watermeyer T, Hindle JV, Roberts J, Lawrence C, Martyr A, Lloyd-Williams. H., et al. Goal-setting for cognitive rehabilitation in mild to moderate Parkinson's disease dementia and dementia with Lewy bodies. *Parkinsons Dis*. 2016;Article ID 8285041:1-8.
179. Watermeyer T, Hindle JV, Clare L, editors. Cognitive rehabilitation for people with Parkinson's disease dementia and dementia with Lewy bodies: the CORD-PD pilot trial. *Alzheimer's Association International Conference; 2017; London*.

## APPENDICES

## **Appendix 1. Topics recorded by therapists in the therapy logs**

<b><u>Therapy log topic</u></b>	<b><u>Therapist ratings or comments recorded under relevant sessions</u></b>
Compliance	Whether given session was completed
Relationships	The relationship the therapist developed with the participant and carer, and the relationship between the participant and carer
Goals	Participant and carer responsiveness to the solution-focused problem-solving approach Goal 1: agreed strategies, between-session practice, and progress Goal 2: agreed strategies, between-session practice, and progress Goal 3: agreed strategies, between-session practice, and progress Any adjustments or modifications to goal statements provided at baseline In-session goal attainment ratings by participant, carer and therapist (sessions 10 and 14) and comments on these Selection of goal attainment scaling indicators for each goal (sessions 10 and 14) and comments on these
Activity levels	Review of activity levels, plan for behavioural activation to increase activity engagement, and comments on progress
Compensatory strategy use	Review of current use of compensatory strategies and environmental adaptations, plan to develop strategy use, and comments on progress
Restorative strategy use	Response to information about restorative strategies, plan for developing restorative strategy use, and comments on progress
Attention and concentration	Strategies introduced to help maintain attention and concentration, and progress with applying these strategies
Anxiety management	Current use of anxiety management strategies, carer's perspective on the participant's use of these strategies, introduction or refinement of anxiety management technique(s), and progress with use of anxiety management strategies
Carer well-being	Review with carer, and plan for enhancing carer well-being
Carer involvement	The extent to which the carer was engaged in supporting the process of therapy
Ending therapy	Plans for maintaining progress after the end of the intervention, and review of other sources of help and support
Experience of therapy	Review with the participant and with the carer, and therapist reflection on the process of therapy; therapist confidence in addressing participants' goals (following the nine month follow-up)

## **Appendix 2. Interview schedule for exploring participant and carer experience of the GREAT intervention**

### *Interview schedule for the person with dementia*

The interview will take form of a conversation and the interviewer will encourage the participant to talk freely about the experience of the cognitive rehabilitation intervention.

The researcher will begin by re-establishing consent for the interview and for audio-recording.

The researcher may begin with some general conversation to build rapport as appropriate.

The researcher will introduce the main part of the interview by saying:

*You've been taking part in the GREAT study and having visits from the therapist, and I'd like to know your views on what it was like. I'm interested in what it was like to take part in the study and how you found the visits from the therapist.*

#### **1. Experiences**

The researcher will explore the participant's experiences and feelings starting with general questions:

*How did you find the therapist's visits over the past few weeks?*

*What was it like to work with the therapist on your goals?*

More specific information will then be elicited using prompts such as the following:

*What were the more enjoyable things about your work with the therapist?*

*What were the less enjoyable things about your work with the therapist?*

*What aspects of your work with the therapist were more/less helpful?*

*Did you find it hard work to take part in the therapy?*

*What aspects of your work with the therapist were most challenging?*

The interviewer will encourage the person to give specific examples, where possible.

#### **2. Outcomes**

The researcher will explore the impact of taking part in cognitive rehabilitation on the person's everyday life and self-perceptions.

*What difference (if any) has your work with the therapist made to your daily life?*

*Has the experience changed anything in the way you think about your dementia/about yourself/about the future?*

*Has the experience changed anything in the way you relate to your carer/family?*

The researcher will draw on positive comments from the participant to end the conversation on a positive note.

### ***Interview schedule for the carer***

The interview will take form of a conversation and the interviewer will encourage the carer to talk freely about the experience of the cognitive rehabilitation intervention.

The researcher will begin by re-establishing consent for the interview and for audio-recording.

The researcher may begin with some general conversation to build rapport as appropriate.

The researcher will introduce the main part of the interview by saying:

*[Your relative] has been taking part in the GREAT study and having visits from the therapist, and I'd like to know your views on what it was like. I'm interested in what it was like to take part in the study and how you found the visits from the therapist.*

#### **2. Experiences**

The researcher will explore the carer's experiences and feelings starting with general questions:

*How did you find the therapist's visits over the past few weeks?*

*How do you think [your relative] felt about working with the therapist on his/her goals?*

More specific information will then be elicited using prompts such as the following:

*What were the more enjoyable things about working with the therapist on [your relative's] goals?*

*What were the less enjoyable things about working with the therapist [your relative's] goals?*

*What aspects of working with the therapist were more/less helpful?*

*Do you think [your relative] found it hard work to take part in the therapy?*

*What aspects of working with the therapist were most challenging?*

The interviewer will encourage the person to give specific examples, where possible.

#### **2. Outcomes**

The researcher will explore the impact of taking part in cognitive rehabilitation on the person's everyday life, and perception of the person with memory difficulties.

*What difference (if any) has the therapy made to your daily life?*

*What difference (if any) has the therapy made to [your relative's] daily life?*

*Has the experience changed anything in the way you think about [your relative's] memory difficulties/about [him/her]/about the future?*

*Has the experience changed anything in the way you relate to [your relative]?*

The researcher will draw on positive comments from the carer to end the conversation on a positive note.

### Appendix 3. Participant recruitment

Here we present cumulative recruitment figures in relation to targets, month-by-month recruitment figures, and a breakdown of recruitment by site.

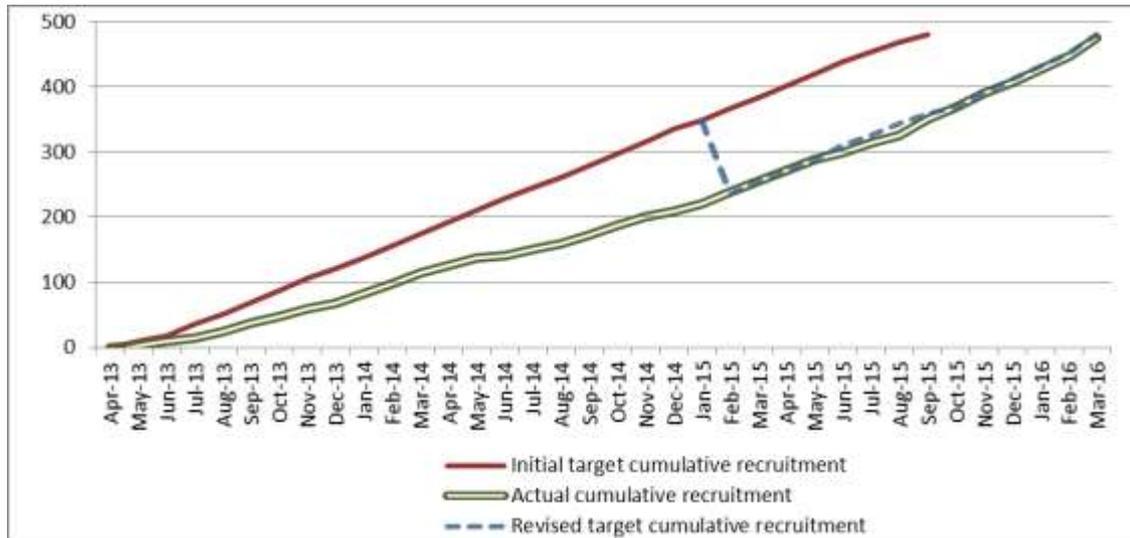


Figure 13. Cumulative recruitment figures in relation to targets

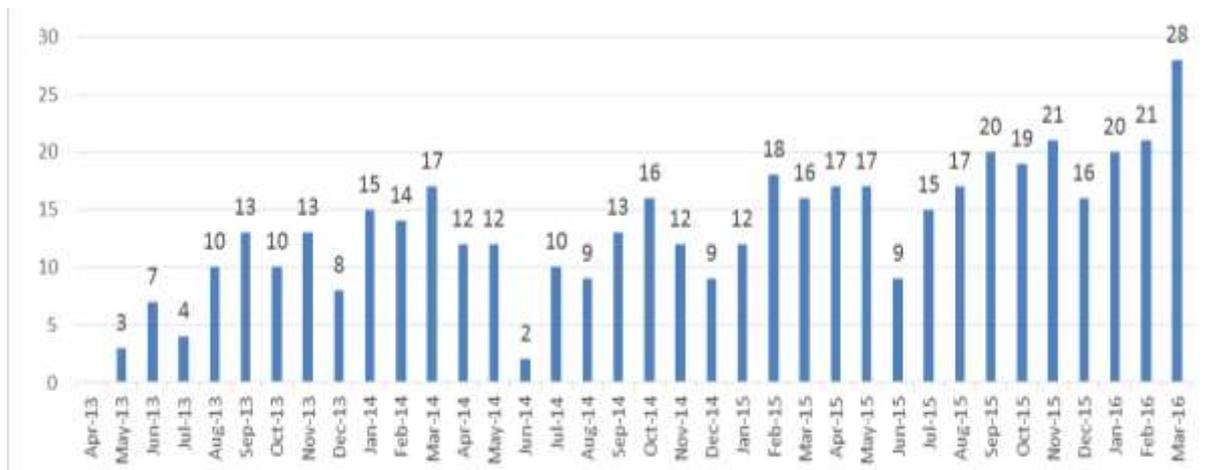


Figure 14. Recruitment figures by month

*Number of recruiting sites. Months 1 – 3: three sites; months 4 – 25: six sites; months 26 – 30: eight sites; months 31 – 36: 7 sites*

Table 25. Trial recruitment by site

<b>Site</b>	<b>Recruitment started</b>	<b>First randomisation</b>	<b>Recruitment ended</b>	<b>Months of recruitment</b>	<b>Original (and adjusted)*</b>	<b>Actual randomisations</b>
Bangor	24/04/2013	04/06/2013	31/03/2016	36	80 (90)	90 (19%)
Bath	24/04/2013	30/05/2013	31/03/2016	36	80 (90)	85 (17.9%)
Birmingham	24/04/2013	09/07/2013	30/09/2015	30	80	52 (11%)
Cardiff	28/06/2013	09/01/2014	31/03/2016	34	80	82 (17.3%)
Kent	16/05/2015	21/08/2015	31/03/2016	11	25	25 (5.3%)
London	28/06/2013	25/09/2013	31/03/2016	34	80	51 (10.8%)
Manchester	28/06/2013	20/08/2013	31/03/2016	34	80	62 (13.1%)
Newcastle	16/05/2015	17/07/2015	31/03/2016	11	25	27 (5.7%)

*\*These targets were adjusted during the course of the trial*

**Appendix 4. Demographic and clinical characteristics of the sample: additional details**

Table 26. Full demographic characteristics of the sample

(a) Participants with dementia

<b>Measure</b>	<b>Whole sample n= 474</b>	<b>CR n= 238</b>	<b>TAU n= 236</b>
Age	78.56 (7.07) 53 to 95	78.25 (7.13) 53 to 95	78.87(7.01) 55 to 95
Sex:			
Male	248 (52.3)	124 (52.1)	124 (52.5)
Female	226 (47.7%)	114 (47.9%)	112 (47.5%)
Ethnicity:			
White	457 (96.4)	226 (95.0)	231 (97.9)
Mixed / Multiple ethnic group	2 (0.42)	2 (0.84)	0 (0)
Asian / Asian British	6 (1.27)	3 (1.26)	3 (1.27)
Black / African / Caribbean / Black British	7 (1.48)	5 (2.10)	2 (0.85)
Other ethnic group	2 (0.42)	2 (0.84)	0 (0)
First language:			
English	445 (93.9)	222 (93.3)	223 (94.5)
Welsh	10 (2.1%)	5 (2.1%)	5 (2.1%)
Other	19 (4%)	11 (4.6%)	8 (3.4%)
Marital status:			
Single	5 (1.1%)	1 (0.4%)	4 (1.7%)
Married/Remarried	330 (69.6)	167 (70.2)	163 (69.1)
Civil partnership	2 (0.4%)	1 (0.4%)	1 (0.4%)
Separated/divorced	25 (5.3%)	14 (5.9%)	11 (4.7%)
Widowed	101 (21.3%)	48 (20.2%)	53 (22.5%)
Other	10 (2.1%)	7 (2.9%)	3 (1.3%)
Missing	1 (0.2%)	0 (0%)	1 (0.4%)
Length of marriage (years):	n=437 39.86 (19.22)	n=217	n=220 39.5 (18.67)

	0 to 70	40.24 (19.79) 0 to 70	0 to 69
Age at start of education:	n=473 4.86 (0.92) 2 to 15	n=237 4.86 (0.79) 2 to 8	n=236 4.85 (1.04) 3 to 15
Age when left education:	16.03 (2.32) 11 to 29	15.98 (2.24) 11 to 27	16.09 (2.41) 11 to 29
Years of education:	n = 471 12.57 (3.37) 5 to 33	n=236 12.57 (3.33) 6 to 24	N=235 12.58 (3.42) 5 to 33
Further Study:			
Yes	243 (51.3%)	124 (52.1%)	119 (50.4%)
No	231 (48.7%)	114 (47.9%)	117 (49.6%)
Years in further study:	n=472 1.38 (1.94) 0 to 10	n=237 1.43 (1.89) 0 to 9.5	n=235 1.34 (1.98) 0 to 10
Education Type:			
Left school at age 14-16, and did not go back to education	200 (42.2%)	103 (43.3%)	97 (41.1%)
Left school at age 17-18, and did not go back to education	21 (4.4%)	7 (2.9%)	14 (5.9%)
Further education (e.g. vocational qualifications: GNVQ/NVQ/HND)	161 (34%)	82 (34.5%)	79 (33.5%)
Higher education (BSc/BA or equivalent)	52 (11%)	25 (10.5%)	27 (11.4%)
Postgraduate education (MSc/MA/PhD or equivalent)	38 (8%)	20 (8.4%)	18 (7.6%)
Missing	2 (0.4%)	1 (0.4%)	1 (0.4%)
Occupational status:			
I Professional	52 (11)	23 (9.7)	29 (12.3)
II Managerial/technical	157 (33.1)	81 (34)	76 (32.2)
III N Skilled, non-manual	103 (21.7)	54 (22.7)	49 (20.8)

III M Skilled, manual	80 (16.9)	41 (17.2)	39 (16.5)
IV Partly skilled	50 (10.5)	24 (10.1)	26 (11)
V Unskilled	32 (6.8)	15 (6.3)	17 (7.2)

Data are n (%) or mean (SD) and range

(b) Carers

<b>Measure</b>	<b>Whole sample n= 474</b>	<b>CR n= 238</b>	<b>TAU n= 236</b>
Relationship to person with dementia:			
Spouse	296 (62.4%)	149 (62.6%)	147 (62.3%)
Partner	35 (7.4%)	18 (7.6%)	17 (7.2%)
Son/daughter	108 (22.8%)	52 (21.8%)	56 (23.7%)
Step-child	0 (0%)	0 (0%)	0 (0%)
Son/daughter-in-law	10 (2.1%)	6 (2.5%)	4 (1.7%)
Grandchild	2 (0.4%)	2 (0.8%)	0 (0%)
Brother/sister	6 (1.3%)	3 (1.3%)	3 (1.3%)
Nephew/niece	1 (0.2%)	0 (0%)	1 (0.4%)
Friend	7 (1.5%)	5 (2.1%)	2 (0.8%)
Neighbour	3 (0.6%)	0 (0%)	3 (1.3%)
Other	6 (1.3%)	3 (1.3%)	3 (1.3%)
Age:	68.74 (13.01); 17 to 92	68.45 (13.76); 17 to 92	69.04 (12.24);23 to 92
Sex:			
Male	142 (30%)	75 (31.5%)	67 (28.4%)
Female	332 (70%)	16 (68.5%)	169 (71.6%)
Ethnicity :			
White	449 (94.7)	224 (94.1)	225 (95.3)
Mixed / Multiple ethnic group	5 (1.1)	4 (1.7)	1 (0.42)
Asian / Asian British	10 (2.1)	4 (1.7)	6 (2.5)
Black / African / Caribbean / Black British	8 (1.7)	6 (2.5)	2 (0.85)
Other ethnic group	2 (0.42)	0 (0)	2 (0.85)
First language:			
English	443 (93.5%)	222 (93.3)	221 (93.6%)

Welsh	12 (2.5%)	6 (2.5%)	6 (2.5%)
Other	19 (4%)	10 (4.2%)	9 (3.8%)
Marital status:			
Single	31 (6.5%)	23 (9.7%)	8 (3.4%)
Married/Remarried	393 (82.9%)	187 (78.6%)	206 (87.3%)
Civil partnership	5 (1.1%)	3 (1.3%)	2 (0.8%)
Separated/divorced	20 (4.2%)	10 (4.2%)	10 (4.2%)
Widowed	12 (2.5%)	8 (3.4%)	4 (1.7%)
Other	13 (2.7%)	7 (2.9%)	6 (2.5%)
Marital Status Length (Years):	n=410 41.21 (17.7) 0 to 69	n=196 41.9 (17.96) 1 to 68	n=214 40.57(17.4) 0 to 69
Age at start of education:	4.66 (0.74) 2.5 to 8	4.64 (0.69) 2.5 to 7	4.69 (0.78) 3 to 8
Age when left education:	n=473 16.57 (2.35) 7.5 to 27	n=237 16.7 (2.29) 11 to 25	n=236 16.44 (2.41) 7.5 to 27
Years in education	n= 472 13.49 (3.52) 4 to 26	n=237 13.67 (3.45) 5 to 25	n=235 13.32 (3.58) 4 to 26
Carer further study:			
Yes	266 (56.1%)	135 (56.7%)	131 (55.5%)
No	207 (43.7%)	102 (42.9%)	105 (44.5%)
Not answered	1 (0.2%)	1 (0.4%)	0 (0%)
Years in further study:	n=472 1.59 (2.12) 0 to 15	n=237 1.61 (2.09) 0 to 12	n=235 1.56 (2.15) 0 to 15
Education type:			
Left school at age 14-16, and did not go back to education	156 (32.9%)	77 (32.4%)	79 (33.5%)
Left school at age 17-18, and did not go back to education	31 (6.5%)	16 (6.7%)	15 (6.4%)

Further education (e.g. vocational qualifications: GNVQ/NVQ/HND)	163 (34.4%)	79 (33.2%)	84 (35.6%)
Higher education (BSc/BA or equivalent)	72 (15.2%)	35 (14.7%)	37 (15.7%)
Postgraduate education (MSc/MA/PhD or equivalent)	48 (10.1%)	29 (12.2%)	19 (8.1%)
Missing	4 (0.8%)	2 (0.8%)	2 (0.8%)
Occupational status:			
I Professional	49 (10.3%)	30 (12.6%)	19 (8.1%)
II Managerial/technical	158 (33.3%)	74 (31.1%)	84 (35.6%)
III N Skilled, non-manual	137 (28.9%)	64 (26.9%)	73 (30.9%)
III M Skilled, manual	47 (9.9%)	24 (10.1%)	23 (9.7%)
IV Partly skilled	55 (11.6%)	27 (11.3%)	28 (11.9%)
V Unskilled	20 (4.2%)	14 (5.9%)	6 (2.5%)
Missing	8 (1.7%)	5 (2.1%)	3 (1.3%)
Carer Health:			
Excellent	68 (14.3%)	30 (12.6%)	38 (16.1%)
Very good	113 (23.8%)	59 (24.8%)	54 (22.9%)
Good	179 (37.8%)	89 (37.4%)	90 (38.1%)
Fair	83 (17.5%)	42 (17.6%)	41 (17.4%)
Poor	31 (6.5%)	18 (7.6%)	13 (5.5%)

Data are n (%) or mean (SD) and range

Table 27. Comorbid conditions

(a) Numbers of participants with comorbid conditions

Condition	Yes		No		Unknown	
	N	%	N	%	N	%
Connective tissue disease	163	34.4	307	64.8	4	0.8
Peripheral vascular disease	76	16.0	389	82.1	9	1.9
Diabetes	71	15.0	402	84.8	1	0.2
Any tumour	52	11.0	421	88.8	1	0.2
Chronic pulmonary disease	49	10.3	423	89.2	2	0.4
Myocardial infarct	40	8.4	430	90.7	4	0.8

Congestive heart failure	39	8.2	428	90.3	7	1.5
Ulcer disease	15	3.2	456	96.2	3	0.6
Moderate or severe renal disease	8	1.7	464	97.9	2	0.4
Diabetes with end organ damage	3	0.6	471	99.4	0	0
Lymphoma	3	0.6	470	99.2	1	0.2
Metastatic solid tumour	3	0.6	470	99.2	1	0.2
Mild liver disease	2	0.4	468	98.7	4	0.8
Moderate or severe liver disease	2	0.4	469	98.9	3	0.6
Leukaemia	1	0.2	472	99.6	1	0.2
Hemiplegia	0	0	474	100.0	0	0
AIDS	0	0	474	100.0	0	0

(b) Frequency of comorbid health conditions

<b>Total number of comorbid conditions</b>	<b>Whole sample (n=474)</b>	<b>%</b>	<b>CR (n=238)</b>	<b>%</b>	<b>TAU (n=236)</b>	<b>%</b>
0	162	34.2	83	34.9	79	33.5
1	177	37.3	86	36.1	91	38.6
2	78	16.5	38	16.0	40	16.9
3	38	8.0	21	8.8	17	7.2
4	16	3.4	9	3.8	7	3.0
5	2	0.4	1	0.4	1	0.4
6	1	0.2	0	0.0	1	0.4

(c) Frequency of comorbid health conditions using the Charlson Comorbidity Weighted Index

<b>Charlson Comorbidity Weighted Index</b>	<b>Whole sample (n=474)</b>	<b>%</b>	<b>CR (n=238)</b>	<b>%</b>	<b>TAU (n=236)</b>	<b>%</b>
1	125	26.4	63	26.5	62	26.3
2	151	31.9	78	32.8	73	30.9
3	103	21.7	53	22.3	50	21.2
4	51	10.8	22	9.2	29	12.3

5	27	5.7	14	5.9	13	5.5
6	10	2.1	6	2.5	4	1.7
7	3	0.6	0	0.0	3	1.3
8	1	0.2	0	0.0	1	0.4
10	2	0.4	1	0.4	1	0.4
11	1	0.2	1	0.4	62	26.3

(d) Number of participants scoring above and below the cut-off value of 5 on the Charlson Comorbidity Index

<b>Charlson Comorbidity Weighted Index</b>	<b>Whole sample (n=474)</b>	<b>%</b>	<b>CR (n=238)</b>	<b>%</b>	<b>TAU (n=236)</b>	<b>%</b>
0-4	430	90.72	216	90.76	214	90.68
5-11	44	9.28	22	9.24	22	9.32

(e) Number of participants scoring at each level on the Age-Adjusted Charlson Comorbidity Index

<b>Age-Adjusted Charlson Comorbidity Index</b>	<b>Whole sample (n=474)</b>	<b>%</b>	<b>CR (n=238)</b>	<b>%</b>	<b>TAU (n=236)</b>	<b>%</b>
3	4	0.8	4	1.7	0.0	0.0
4	24	5.1	9	3.8	15	6.4
5	70	14.8	40	16.8	30	12.7
6	117	24.7	60	25.2	57	24.2
7	113	23.8	51	21.4	62	26.3
8	77	16.2	39	16.4	38	16.1
9	40	8.4	19	8.0	21	8.9
10	20	4.2	13	5.5	7	3.0
11	3	0.6	1	0.4	2	0.8
12	3	0.6	0	0.0	3	1.3
14	1	0.2	1	0.4	0	0.0
15	2	0.4	1	0.4	1	0.4

Table 28. HADS scores for depression and anxiety at baseline and follow-up assessments

(a) HADS depression scores

HADS Score	Baseline			3 Months			9 Months		
	Total n=472	CR n=238	TAU n=234	Total n=444	CR n=218	TAU n=226	Total n=404	CR n=194	TAU n=210
11+	8 (1.7)	6 (2.5)	2 (0.9)	12 (2.7)	8 (0.9)	4 (1.8)	10 (2.5)	7 (3.6)	3 (1.4)
8 - 10	47 (10.0)	22 (9.2)	25 (10.7)	35 (7.9)	17 (10.7)	18 (8.0)	38 (9.4)	22 (11.3)	16 (7.6)
0 - 7	417 (88.3)	210 (88.2)	207 (88.5)	397 (89.4)	193 (88.5)	204 (90.3)	356 (88.1)	165 (85.1)	191 (91.0)

Data are n (%)

(b) HADS anxiety scores

HADS Score	Baseline			3 Months			9 Months		
	Total n=472	CR n=238	TAU n=234	Total n=442	CR n=216	TAU n=193	Total n=403	CR n=226	TAU n=210
11+	41 (8.7)	23 (9.7)	18 (7.7)	35 (7.9)	18 (8.3)	21 (10.9)	37 (9.2)	17 (7.5)	16 (7.6)
8 - 10	66 (14.0)	33 (13.9)	33 (14.1)	61 (13.8)	31 (14.4)	38 (19.7)	66 (16.4)	30 (13.3)	28 (13.3)
0 - 7	365 (77.3)	182 (76.5)	183 (78.2)	346 (78.3)	167 (77.3)	134 (69.4)	300 (74.4)	179 (79.2)	166 (79.0)

Data are n (%)

### Appendix 5. Comparison of participants who did and did not complete the trial

Table 29. Comparison of demographic characteristics of completers and non-completers who withdrew before the three-month follow-up

(a) Participants with dementia – continuous data

Measure	Completers N, Mean (SD)	Non- completers N, Mean (SD)	Effect Size (Completers - Non- completers)	95% CI for mean difference	Test Statistic	Unadjusted p value
Age	n=474 78.56 (7.07)	n=29 78.69 (6.90)	-0.13	-2.83 to 2.56	t(31.7) = -0.1	0.92
Years of education	n=471 12.57 (3.37)	n=29 12.05 (3.09)	0.52	-0.69 to 1.73	t(32.23) = 0.88	0.39
Length of marriage (years):	n=437 39.86 (19.22)	n=29 35.21 (19.09)	4.66	-2.80 to 12.12	t(31.88) = 1.27	0.21
Charlson Co- morbidity Index age adjusted score	n=474 6.84 (1.71)	n=29 7.17 (2.14)	-0.34	-1.16 to 0.49	t(30.23) = -0.83	0.41

(b) Participants with dementia – categorical data

	Completers N (%)	Non-completers N (%)	Fisher's Exact Count Test - p value
Group			0.06
CR	238 (50%)	20 (69%)	
TAU	236 (50%)	9 (31%)	
Sex			1
Male	248 (52%)	15 (52%)	
Female	226 (48%)	14 (48%)	
Ethnicity			0.62
White	457 (97%)	28 (97%)	

Mixed / Multiple ethnic group	2 (0%)	0 (0%)	
Asian / Asian British	6 (1%)	1 (0%)	
Black / African / Caribbean / Black British	7 (1%)	0 (0%)	
Other ethnic group	2 (0%)	0 (0%)	
First language			1
English	445 (94%)	28 (97%)	
Welsh	10 (2%)	0 (0%)	
Other	19 (4%)	1 (3%)	
Occupational status			0.55
I Professional	52 (11%)	4 (14%)	
II Managerial/technical	157 (33%)	7 (24%)	
III N Skilled, non-manual	103 (22%)	4 (14%)	
III M Skilled, manual	80 (17%)	7 (24%)	
IV Partly skilled	50 (11%)	4 (14%)	
V Unskilled	32 (7%)	3 (10%)	
Health			0.19
Excellent	39 (8%)	2 (7%)	
Very good	125 (26%)	7 (24%)	
Good	159 (34%)	11 (38%)	
Fair	121 (26%)	4 (14%)	
Poor	30 (6%)	5 (17%)	
Marital Status			0.81
Single	5 (1%)	0 (0%)	
Married/re-married	330 (70%)	19 (66%)	
Civil partnership	2 (0%)	0 (0%)	
Separated/divorced	25 (5%)	1 (3%)	
Widowed	101 (21%)	9 (31%)	
Other	10 (2%)	0 (0%)	
Centre			

Bangor	90 (19%)	6 (21%)	0.63
Cardiff	82 (17%)	5 (17%)	
Manchester	62 (13%)	6 (21%)	
Bath	85 (18%)	3 (10%)	
Birmingham	52 (11%)	1 (3%)	
London	51 (11%)	4 (14%)	
Kent	25 (5%)	1 (3%)	
Newcastle	27 (6%)	3 (10%)	

(c) Carers – continuous data

Measure	Completers N, Mean (SD)	Non- completers N, Mean (SD)	Effect Size (Completers - Dropouts)	Lower CI limit	Test Statistic	Unadjusted p value
Carer Age	n=474 68.84 (13.17)	n=11 59.45 (18.6)	9.38	-3.15 to 21.91	t(10.23) = 1.66	0.13
Years of education	n=472 13.49 (3.52)	n=11 13.09 (3.22)	0.4	-1.78 to 2.58	t(10.56) = 0.41	0.69
Carer Marital Status Length	n=410 41.21 (17.7)	n=9 32.56 (21.35)	8.65	-7.8 to 25.11	t(8.24) = 1.21	0.26

(d) Carers – categorical data

	Completers N (%)	Non-completers N (%)	Fisher's Exact Count Test - p value
Carer Relationship			0.69
Spouse /partner	331 (69%)	18 (62%)	
Adult child (including in-law)	64 (14%)	5 (17%)	
Other	79 (16%)	6 (21%)	
Sex			0.74
Male	142 (30%)	4 (36%)	

Female	332 (70%)	7 (64%)	
<b>Ethnicity</b>			
White	449 (94%)	10 (91%)	0.24
Mixed / Multiple ethnic group	5 (1%)	0 (0%)	
Asian / Asian British	10 (2%)	0 (0%)	
Black / African / Caribbean / Black British	8 (2%)	1 (9%)	
Other ethnic group	2 (0%)	0 (0%)	
<b>First language</b>			0.04
English	443 (93%)	8 (73%)	
Welsh	12 (3%)	1 (9%)	
Other	19 (4%)	2 (18%)	
<b>Marital Status</b>			0.5
Single	31 (7%)	1 (9%)	
Married/re-married	393 (83%)	9 (82%)	
Civil partnership	5 (1%)	0 (0%)	
Separated/divorced	20 (4%)	0 (0%)	
Widowed	12 (3%)	1 (9%)	
Other	13 (3%)	0 (0%)	
<b>Occupational status</b>			0.16
I Professional	49 (11%)	1 (9%)	
II Managerial/technical	158 (34%)	2 (18%)	
III N Skilled, non-manual	137 (29%)	2 (18%)	
III M Skilled, manual	47 (10%)	1 (9%)	
IV Partly skilled	55 (12%)	4 (36%)	
V Unskilled	20 (4%)	1 (9%)	

Table 30. Comparison of primary and secondary outcomes for completers and non-completers who withdrew before the three month follow up

<b>Measure</b>	<b>Completers N, Mean (SD)</b>	<b>Non- completers N, Mean (SD)</b>	<b>Effect Size (Completers - Non- completers)</b>	<b>95% CI for mean difference</b>	<b>Test Statistic</b>	<b>Unadjusted p value</b>
<b>Primary outcome measure</b>						
Participant rating of goal attainment	n=474 3.54 (1.67)	n=29 3.20 (1.56)	0.33	-0.28 to 0.94	t(32.06) = 1.12	0.27
Participant rating of satisfaction	n=474 3.81 (1.63)	n=29 4.25 (1.55)	-0.44	-1.05 to 0.16	t(31.89) = -1.49	0.15
Carer rating of goal attainment	n=474 2.74 (1.38)	n=29 2.36 (1.35)	0.39	-0.14 to 0.92	t(31.66) = 1.49	0.15
<b>Secondary outcome measures - Participants with dementia</b>						
DEMQL	n=472 92.30 (12.33)	n=29 94.62 (11.28)	-2.32	-6.73 to 2.10	t(32.25) = -1.07	0.29
GSES	n=469 30.94 (5.09)	n=28 31.86 (4.36)	-0.92	-2.67 to 0.83	t(31.55) = -1.07	0.29
HADS	n=472 8.91 (5.54)	n=29 8.62 (5.21)	0.29	-1.75 to 2.33	t(32.02) = 0.29	0.77
HADS Anxiety	n=472 5.14 (3.64)	n=29 4.48 (3.29)	0.65	-0.64 to 1.95	t(32.36) = 1.03	0.30
HADS Depression	n=472 3.77 (2.79)	n=29 4.14 (3.31)	-0.37	-1.65 to 0.92	t(30.49) = -0.58	0.56
RBMT immediate recall	n=473 2.66 (2.11)	n=29 2.52 (2.43)	0.14	-0.80 to 1.08	t(30.63) = 0.31	0.76
RBMT delayed recall	n=473 0.38 (1.96)	n=29 0.12 (1.54)	0.26	-0.35 to 0.87	t(33.79) = 0.86	0.40
TEA elevator counting	n=463 6.39 (1.16)	n=28 6.25 (1.40)	0.14	-0.42 to 0.69	t(29.29) = 0.5	0.62
TEA elevator counting with distraction	n=448 4.55 (2.72)	n=27 4.07 (2.91)	0.48	-0.70 to 1.65	t(28.8) = 0.83	0.41

DKEFS verbal fluency	n=470 26.27 (11.82)	n=29 21.76 (11.6)	4.52	-0.01 to 9.04	t(31.69) = 2.03	0.05
Secondary outcome measures - Carers						
RSS	n=471 18.96 (9.44)	n=29 21.14 (8.77)	-2.17	-5.61 to 1.26	t(32.12) = -1.29	0.21
WHOQOL physical	n=470 15.34 (2.95)	n=28 15.86 (3.04)	-0.52	-1.73 to 0.68	t(30.1) = -0.88	0.38
WHOQOL psychological	n=470 15.14 (2.15)	n=28 14.57 (2.70)	0.57	-0.49 to 1.63	t(29.07) = 1.09	0.28
WHOQOL social	n=468 15.13 (2.66)	n=28 15.18 (2.88)	-0.05	-1.19 to 1.09	t(29.83) = -0.09	0.93
WHOQOL environmental	n=470 16.43 (2.15)	n=28 16.39 (2.20)	0.04	-0.83 to 0.91	t(30.15) = 0.09	0.93
EQ5D3L index	n=468 0.78 (0.25)	n=29 0.80 (0.24)	-0.03	-0.12 to 0.07	t(31.71) = -0.6	0.55
EQ5D3L Visual Analogue Scale	n=467 74.48 (19.95)	n=28 74.79 (23.64)	-0.31	-9.64 to 9.02	t(29.35) = -0.07	0.95

## Appendix 6. Summary of missing data for secondary outcomes

Table 31. Missing data for the secondary outcome measures

### (a) Baseline assessment

Measure	Whole sample			CR			TAU		
	Missing	%	Total N	Missing	%	Total N	Missing	%	Total N
Participants with dementia									
DEMQOL	2	0.42%	472	1	0%	237	1	0.42%	235
GSES	5	1.05%	469	1	0%	237	4	1.69%	232
HADS Depression	2	0.42%	472	0	0%	238	2	0.85%	234
HADS Anxiety	2	0.42%	472	0	0%	238	2	0.85%	234
RBMT immediate recall	1	0.21%	473	1	0%	237	0	0.00%	236
RBMT delayed recall	1	0.21%	473	1	0%	237	0	0.00%	236
TEA elevator counting	11	2.32%	463	6	3%	232	5	2.12%	231
TEA elevator counting with distraction	26	5.47%	448	15	6%	223	11	4.66%	225
DKEFS verbal fluency	4	0.84%	470	3	1%	235	1	0.42%	235
Carers									
RSS	3	0.63%	471	2	1%	236	1	0.42%	235
WHOQOL physical	4	0.84%	470	1	0%	237	3	1.27%	233
WHOQOL psychological	4	0.84%	470	1	0%	237	3	1.27%	233
WHOQOL social	6	1.26%	468	3	1%	235	3	1.27%	233
WHOQOL environmental	4	0.84%	470	1	0%	237	3	1.27%	233
EQ5D3L index	6	1.26%	468	3	1%	235	3	1.27%	233
EQ5D Visual Analogue Scale	7	1.47%	467	4	2%	234	3	1.27%	233

## (b) Three-month follow-up

Measure	Whole sample			CR			TAU		
	Missing	%	Total N	Missing	%	Total N	Missing	%	Total N
<b>Participants with dementia</b>									
DEMQOL	0	0.00%	445	0	0.00%	218	0	0.00%	227
GSES	6	1.35%	439	3	1.38%	215	3	1.32%	224
HADS Depression	1	0.22%	444	0	0.00%	218	1	0.44%	226
HADS Anxiety	3	0.67%	442	2	0.92%	216	1	0.44%	226
RBMT immediate recall	1	0.22%	444	0	0.00%	218	1	0.44%	226
RBMT delayed recall	3	0.67%	442	1	0.46%	217	2	0.88%	225
TEA elevator counting	16	3.60%	429	8	3.67%	210	8	3.52%	219
TEA elevator counting with distraction	39	8.76%	406	20	9.17%	198	19	8.37%	208
DKEFS verbal fluency	1	0.22%	444	1	0.46%	217	0	0.00%	227
<b>Carers</b>									
RSS	12	2.70%	433	6	2.75%	212	6	2.64%	221
WHOQOL physical	13	2.92%	432	6	2.75%	212	7	3.08%	220
WHOQOL psychological	13	2.92%	432	6	2.75%	212	7	3.08%	220
WHOQOL social	15	3.37%	430	7	3.21%	211	8	3.52%	219
WHOQOL environmental	13	2.92%	432	6	2.75%	212	7	3.08%	220
EQ5D3L index	19	4.27%	426	9	4.13%	209	10	4.41%	217
EQ5D Visual Analogue Scale	20	4.49%	425	10	4.59%	208	10	4.41%	217

## (c) Nine-month follow-up

Measure	Whole sample			CR			TAU		
	Missing	%	Total N	Missing	%	Total N	Missing	%	Total N
Participants with dementia									
DEMQOL	9	2.11%	417	4	1.92%	204	5	2.29%	213
GSES	25	5.87%	401	14	6.73%	194	11	5.05%	207
HADS Depression	22	5.16%	404	14	6.73%	194	8	3.67%	210
HADS Anxiety	23	5.40%	403	15	7.21%	193	8	3.67%	210
RBMT immediate recall	15	3.52%	411	8	3.85%	200	7	3.21%	211
RBMT delayed recall	16	3.76%	410	8	3.85%	200	8	3.67%	210
TEA elevator counting	29	6.81%	397	17	8.17%	191	12	5.50%	206
TEA elevator counting with distraction	56	13.15%	370	31	14.90%	177	25	11.47%	193
DKEFS verbal fluency	17	3.99%	409	10	4.81%	198	7	3.21%	211
Carers									
RSS	15	3.52%	411	8	3.85%	200	7	3.21%	211
WHOQOL physical	17	3.99%	409	9	4.33%	199	8	3.67%	210
WHOQOL psychological	17	3.99%	409	9	4.33%	199	8	3.67%	210
WHOQOL social	19	4.46%	407	11	5.29%	197	8	3.67%	210
WHOQOL environmental	17	3.99%	409	9	4.33%	199	8	3.67%	210
EQ5D3L index	19	4.46%	407	12	5.77%	196	7	3.21%	211
EQ5D Visual Analogue Scale	17	3.99%	409	10	4.81%	198	7	3.21%	211

Table 32. Missing data in the primary and secondary outcome measures in descending order of per cent missing, with participants who withdrew counted as missing data

<b>Measure</b>	<b>N missing</b>	<b>% missing</b>	<b>Total N</b>
TEA Distractor Task at 9 months	104	21.90%	370
TEA No Distractor Task at 9 months	77	16.20%	397
GSES at 9 months	73	15.40%	401
HADS at 9 months	71	15.00%	403
TEA ECD at 3 months	68	14.30%	406
WHOQOL Social Scale at 9 months	67	14.10%	407
EQ5D3L Index at 9 months	67	14.10%	407
WHOQOL Environmental Scale at 9 months	65	13.70%	409
WHOQOL Psychological Scale at 9 months	65	13.70%	409
WHOQOL Physical Scale at 9 months	65	13.70%	409
EQ5D3L VAS at 9 months	65	13.70%	409
DKEFS FAS Test at 9 months	65	13.70%	409
RBMT Delayed Recall Score at 9 months	64	13.50%	410
RSS at 9 months	63	13.30%	411
RBMT Immediate Recall Score at 9 months	63	13.30%	411
BGSI Participant Satisfaction Rating at 9 months	62	13.10%	412
BGSI Carer Goal Attainment Rating at 9 months	59	12.40%	415
BGSI Participant Goal Attainment Rating at 9 months	58	12.20%	416
DEMQOL at 9 months	57	12.00%	417
EQ5D3L VAS at 3 months	49	10.30%	425
EQ5D3L Index at 3 months	48	10.10%	426
TEA Elevator Counting at 3 months	45	9.50%	429
WHOQOL Social Scale at 3 months	44	9.30%	430
WHOQOL Environmental Scale at 3 months	42	8.90%	432
WHOQOL Psychological Scale at 3 months	42	8.90%	432
WHOQOL Physical Scale at 3 months	42	8.90%	432
RSS at 3 months	41	8.60%	433
GSES at 3 months	35	7.40%	439
BGSI Carer Goal Attainment Rating at 3 months	35	7.40%	439

RBMT Delayed Recall Score at 3 months	32	6.80%	442
HADS at 3 months	32	6.80%	442
DKEFS FAS Test at 3 months	30	6.30%	444
RBMT Immediate Recall Score at 3 months	30	6.30%	444
DEMQOL at 3 months	29	6.10%	445
BGSI Participant Satisfaction Rating at 3 months	29	6.10%	445
BGSI Participant Goal Attainment Rating at 3 months	29	6.10%	445
TEA ECD at Baseline	26	5.50%	448
TEA Elevator Counting at Baseline	11	2.30%	463
EQ5D3L VAS at Baseline	7	1.50%	467
WHOQOL Social Scale at Baseline	6	1.30%	468
EQ5D3L Index at Baseline	6	1.30%	468
GSES at Baseline	5	1.10%	469
WHOQOL Environmental Scale at Baseline	4	0.80%	470
WHOQOL Psychological Scale at Baseline	4	0.80%	470
WHOQOL Physical Scale at Baseline	4	0.80%	470
DKEFS Verbal Fluency at Baseline	4	0.80%	470
RSS at Baseline	3	0.60%	471
HADS at Baseline	2	0.40%	472
DEMQOL at Baseline	2	0.40%	472
RBMT Delayed Recall Score at Baseline	1	0.20%	473
RBMT Immediate Recall Score at Baseline	1	0.20%	473
BGSI Carer Goal Attainment Score at Baseline	0	0.00%	474
BGSI Participant Satisfaction Score at Baseline	0	0.00%	474
BGSI Participant Goal Attainment Score at Baseline	0	0.00%	474

## Appendix 7. Exploratory analyses for the primary outcome measure

### Participants' goal attainment ratings

#### *Participant characteristics as predictors of differences in participants' own BGSi goal attainment ratings*

Table 33. Linear mixed effects model fitted to identify potential participant characteristics as predictors of differences between the BGSi attainment ratings at baseline and three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	15.52	1	0.000
Gender	0.21	1	0.646
Age (Stratified)	1.91	1	0.167
MMSE Score	0.51	1	0.476
Diagnosis	2.05	2	0.358
Medication	0.18	1	0.674
Education	0.71	4	0.950
Comorbidity	0.02	1	0.897
Social status	16.66	5	0.005
Blinding inefficient	16.95	1	0.000
Centre	1.58	1	0.209

$Chisq(18) = 41.74, R^2 = 0.19, p = 0.001$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline

	B (Estimate)	Std. Error	df	t value	p value	95% CI
(Intercept)	3.49	0.89	212.87	3.94	0.000	1.73 to 5.25
Age 75 or Above vs Under 75	-0.44	0.32	216.78	-1.38	0.168	-1.06 to 0.19

Blinding inefficient vs maintained	1.24	0.30	216.87	4.12	0.000	0.54 to 1.76
Gender - Male vs Female	-0.14	0.31	213.81	-0.46	0.647	-0.77 to 0.48
MMSE - 24 or Above vs below 24	0.20	0.28	216.70	0.71	0.476	-0.35 to 0.75
Comorbidity	0.01	0.09	216.93	0.13	0.897	-0.18 to 0.20
Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.49	0.53	214.37	-0.92	0.359	-1.55 to 0.57
Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.26	0.35	216.99	0.74	0.462	-0.44 to 0.96
Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	-0.56	0.80	216.26	-0.70	0.484	-2.15 to 1.02
Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	-0.15	0.33	216.77	-0.46	0.648	-0.79 to 0.49
PwD_Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	-0.22	0.52	212.44	-0.42	0.673	-1.25 to 0.81
Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left	-0.28	0.61	210.50	-0.47	0.640	-1.48 to 0.91

school at age 14-16, and did not go back to education						
Medication – Yes vs No	-0.18	0.44	216.02	-0.42	0.674	-1.04 to 0.68
Social status - II Managerial/technical vs I Professional	-0.86	0.56	211.15	-1.53	0.127	-2.48 to 0.08
Social status - III N Skilled, non-manual vs I Professional	-1.66	0.65	214.71	-2.55	0.012	-3.39 to -0.56
Social status - III M Skilled, manual vs I Professional	-2.11	0.65	216.57	-3.28	0.001	-4.17 to -1.05
Social status - IV Partly skilled vs I Professional	-1.93	0.75	216.88	-2.58	0.011	-3.83 to -0.67
Social status - V Unskilled vs I Professional	-0.84	0.81	216.41	-1.03	0.302	-2.73 to 0.56

Table 34. Linear mixed effects model fitted to identify potential participant characteristics as predictors of differences between the BGSi attainment ratings at baseline and nine-month follow up

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	2.38	1	0.123
Blinding inefficient	17.75	1	0.000
Age	4.35	1	0.037
Gender	0.14	1	0.712
Education	1.82	4	0.769
Social status	8.96	5	0.111
Ethnicity	8.68	9	0.468
Living situation	0.00	1	0.976

Diagnosis	5.10	2	0.078
MMSE Score	9.38	1	0.002
Medication	1.96	1	0.161
Comorbidity	0.03	1	0.855

Chisq(28) = 68.61, R2 = 0.32, p < 0.001

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSII attainment scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	3.71	2.40	202.66	1.54	0.124	-1.03 to 8.45
Blinding inefficient vs maintained	1.35	0.32	199.86	4.21	0.000	0.71 to 1.99
Age 75 or Above vs Under 75	-0.05	0.02	200.60	-2.08	0.038	-0.09 to- 0.00
Gender – Female vs Male	0.13	0.35	198.44	0.37	0.713	-0.56 to 0.82
MMSE - 24 or Above vs below 24	0.16	0.05	199.31	3.06	0.002	0.06 to 0.26
Comorbidity	-0.02	0.11	199.72	-0.18	0.855	-0.24 to 0.20
Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-1.25	0.58	201.57	-2.14	0.034	-2.40 to - 0.10
Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.58	0.39	200.38	-1.47	0.144	-1.35 to 0.20
Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and	0.32	0.90	200.09	0.36	0.719	-1.47 to 2.11

did not go back to education						
Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	-0.40	0.37	200.34	-1.08	0.283	-1.13 to 0.33
Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	-0.46	0.56	197.23	-0.82	0.415	-1.56 to 0.64
Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-0.43	0.65	196.81	-0.65	0.514	-1.72 to 0.86
Ethnicity - Any other Asian background vs Welsh/English/Scottish/Northern Irish/British	0.85	1.55	201.37	0.55	0.583	-2.22 to 3.92
Ethnicity - African vs Welsh/English/Scottish/Northern Irish/British	-0.11	2.12	199.11	-0.05	0.959	-4.30 to 4.07
Ethnicity - Caribbean vs Welsh/English/Scottish/Northern Irish/British	-0.79	1.48	198.49	-0.53	0.594	-3.72 to 2.13
Ethnicity - Any other ethnic group vs	0.35	1.49	198.44	0.24	0.813	-2.58 to 3.29

Welsh/English/Scottish/Northern Irish/British						
Ethnicity - Irish vs Welsh/English/Scottish/Northern Irish/British	-1.40	0.98	200.21	-1.43	0.156	-3.34 to 0.54
Ethnicity - Any other White background vs Welsh/English/Scottish/Northern Irish/British	1.19	1.07	198.49	1.11	0.268	-0.92 to 3.30
Ethnicity - White and Black Caribbean vs Welsh/English/Scottish/Northern Irish/British	0.91	2.10	198.39	0.43	0.665	-3.23 to 5.05
Ethnicity - Any other Mixed/Multiple ethnic background vs Welsh/English/Scottish/Northern Irish/British	-2.26	2.12	200.30	-1.07	0.287	-6.46 to 1.93
Ethnicity - Indian vs Welsh/English/Scottish/Northern Irish/British	4.45	2.36	201.54	1.88	0.061	-0.24 to 9.12
Living situation - Not alone vs alone	0.01	0.41	197.96	0.03	0.977	-0.79 to 0.82
Medication - Yes vs No	-0.68	0.48	198.58	-1.40	0.163	-1.63 to 0.27
Social status - II Managerial/technical vs I Professional	-1.02	0.61	196.38	-1.67	0.096	-2.21 to 0.18
Social status - III N Skilled, non-manual vs I Professional	-1.42	0.71	198.56	-2.01	0.045	-2.82 to -0.03

Social status - III M Skilled, manual vs I Professional	-1.77	0.69	200.80	-2.55	0.011	-3.13 to -0.40
Social status - IV Partly skilled vs I Professional	-2.02	0.82	199.67	-2.47	0.014	-3.63 to -0.41
Social status - V Unskilled vs I Professional	-0.98	0.90	201.09	-1.09	0.276	-2.76 to 0.79

***Carer characteristics as predictors of differences in participant's own rating BGSII goal attainment***

Table 35. Linear mixed effects model to identify potential carer factors as predictors of differences between the participants' BGSII attainment ratings at baseline and three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in participants' BGSII attainment scores between three months and baseline

	<b>Sum of Squares</b>	<b>Df</b>	<b>F value</b>	<b>p value</b>
(Intercept)	0.02	1	0.00	0.946
Carer Age	0.18	1	0.04	0.845
Carer Gender	3.95	1	0.85	0.358
Carer Education	36.00	4	1.93	0.107
PwD & Carer Relationship	27.38	7	0.84	0.556
Carer Hours	29.16	8	0.78	0.619
Residuals	866.40	186	NA	NA

$F(21,186) = 0.88, R^2 = 0.09, p = 0.614$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-0.13	1.97	186	-0.07	0.946	-4.02 to 3.76
Carer Age	0.00	0.02	186	0.20	0.845	-0.03 to 0.04
Carer Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	1.51	0.66	186	2.28	0.024	0.21 to 2.82
Carer Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	0.36	0.39	186	0.93	0.355	-0.41 to 1.14
Carer Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	0.41	0.51	186	0.81	0.420	-0.59 to 1.41
Carer Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	1.06	0.52	186	2.05	0.042	0.04 to 2.08
Carer Gender – Male vs Female	-0.32	0.35	186	-0.92	0.358	-1.00 to 0.36

Carer Hours - Less than 1 hour vs Provides no help in a typical day	0.51	0.72	186	0.71	0.476	-0.91 to 1.93
Carer Hours - More than 1 hour and up to 2 hours vs Provides no help in a typical day	-0.02	0.76	186	-0.03	0.975	-1.52 to 1.47
Carer Hours - More than 2 hours and up to 3 hours vs Provides no help in a typical day	0.52	0.79	186	0.65	0.515	-1.04 to 2.07
Carer Hours - More than 3 hours and up to 5 hours vs Provides no help in a typical day	1.12	0.82	186	1.38	0.171	-0.49 to 2.73
Carer Hours - More than 5 hours and up to 10 hours vs Provides no help in a typical day	1.01	0.80	186	1.26	0.209	-0.57 to 2.60
Carer Hours - More than 10 hours, but not overnight vs Provides no help in a typical day	0.85	0.95	186	0.89	0.373	-1.02 to 2.72
Carer Hours - More than 10 hours and/including overnight vs Provides no help in a typical day	0.57	0.74	186	0.77	0.445	-0.89 to 2.02
Carer Hours - Other, describe vs Provides no help in a typical day	2.08	1.67	186	1.24	0.215	-1.22 to 5.38
PwD & Carer Relationship – Friend vs Brother/Sister	0.35	1.79	186	0.20	0.845	-3.18 to 3.88

PwD & Carer Relationship - Grandchild vs Brother/Sister	1.48	2.65	186	0.56	0.577	-3.74 to 6.70
PwD & Carer Relationship - Other vs Brother/Sister	2.77	1.79	186	1.55	0.124	-0.76 to 6.30
PwD & Carer Relationship - Partner vs Brother/Sister	1.00	1.39	186	0.72	0.470	-1.73 to 3.74
PwD & Carer Relationship - Son/daughter vs Brother/Sister	1.48	1.37	186	1.08	0.283	-1.23 to 4.19
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	0.62	1.72	186	0.36	0.720	-2.78 to 4.01
PwD & Carer Relationship - Spouse vs Brother/Sister	1.72	1.28	186	1.34	0.182	-0.81 to 4.26

Table 36. Linear mixed effects model to identify potential carer factors as predictors of differences between the participants' BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline

	<b>Sum of Squares</b>	<b>df</b>	<b>F value</b>	<b>p value</b>
(Intercept)	0.07	1	0.01	0.913
Carer Age	2.31	1	0.39	0.532
Carer Gender	1.39	1	0.24	0.627
Carer Education	24.30	4	1.03	0.391
PwD & Carer Relationship	34.18	7	0.83	0.563
Carer Hours	84.75	8	1.80	0.080
Residuals	1017.09	173	NA	NA

$F(21,173) = 1.02, R^2 = 0.11, p = 0.442$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participants' BGSi attainment scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	0.25	2.25	173	0.11	0.913	-4.19 to 4.68
Carer Age	-0.01	0.02	173	-0.63	0.532	-0.06 to 0.03
Carer Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	0.80	0.75	173	1.07	0.287	-0.68 to 2.28
Carer Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	0.75	0.46	173	1.62	0.107	-0.16 to 1.65
Carer Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	0.38	0.59	173	0.64	0.523	-0.78 to 1.54
Carer Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	1.01	0.60	173	1.67	0.097	-0.18 to 2.20
Carer Gender – Male vs Female	-0.20	0.41	173	-0.49	0.627	-1.00 to 0.61

Carer Hours - Less than 1 hour vs Provides no help in a typical day	2.42	0.83	173	2.93	0.004	0.79 to 4.05
Carer Hours - More than 1 hour and up to 2 hours vs Provides no help in a typical day	1.55	0.85	173	1.81	0.072	-0.14 to 3.24
Carer Hours - More than 2 hours and up to 3 hours vs Provides no help in a typical day	2.34	0.89	173	2.63	0.009	0.58 to 4.09
Carer Hours - More than 3 hours and up to 5 hours vs Provides no help in a typical day	2.82	0.95	173	2.97	0.003	0.94 to 4.69
Carer Hours - More than 5 hours and up to 10 hours vs Provides no help in a typical day	2.06	0.91	173	2.27	0.024	0.27 to 3.85
Carer Hours - More than 10 hours, but not overnight vs Provides no help in a typical day	2.23	1.10	173	2.03	0.044	0.06 to 4.40
Carer Hours - More than 10 hours and/including overnight vs Provides no help in a typical day	1.64	0.84	173	1.97	0.051	-0.01 to 3.29
Carer Hours - Other, describe vs Provides no help in a typical day	4.07	1.88	173	2.16	0.032	0.35 to 7.78
PwD & Carer Relationship – Friend vs Brother/Sister	-1.81	2.25	173	-0.81	0.421	-6.25 to 2.62

PwD & Carer Relationship - Grandchild vs Brother/Sister	-1.33	2.98	173	-0.44	0.657	-7.22 to 4.56
PwD & Carer Relationship - Other vs Brother/Sister	-0.71	2.27	173	-0.32	0.753	-5.19 to 3.76
PwD & Carer Relationship - Partner vs Brother/Sister	0.71	1.57	173	0.45	0.653	-2.39 to 3.80
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.25	1.55	173	0.16	0.873	-2.81 to 3.31
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	-0.32	1.94	173	-0.17	0.867	-4.15 to 3.50
PwD & Carer Relationship - Spouse vs Brother/Sister	1.16	1.45	173	0.80	0.423	-1.69 to 4.01

### Carers' ratings of participant goal attainment

#### *Carer characteristics as predictors of differences in carer's rating of BGSII goal attainment*

Table 37. Linear mixed effects model fitted to identify potential carer factors as predictors of differences between the carers' BGSII attainment ratings at baseline and three-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in carers' BGSII attainment ratings between three months and baseline

	<b>Sum of Squares</b>	<b>df</b>	<b>F Value</b>	<b>P-Value</b>
(Intercept)	0.31	1	0.07	0.793
Carer's Age	0.26	1	0.06	0.809
Carer's Gender	7.92	1	1.76	0.186
Carer's Education	38.27	4	2.13	0.078

PwD & Carer Relationship	32.22	7	1.03	0.415
Residuals	897.85	200	NA	NA

$F(13,200) = 1.28, R^2 = 0.08, p = 0.226$

(b) Regression analysis examining the influence of carer characteristics in predicting differences in carers' BGSII attainment ratings between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
Carer's Age	0.88	1.83	202	0.48	0.631	-2.73 to 4.49
Carer Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	-0.00	0.02	202	-0.12	0.908	-0.04 to 0.03
Carer Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	1.38	0.66	202	2.09	0.038	0.08 to 2.68
Carer Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	0.19	0.37	202	0.51	0.607	-0.54 to 0.93
Carer Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	0.20	0.49	202	0.41	0.685	-0.76 to 1.15

Carer Gender – Male vs Female	0.73	0.49	202	1.49	0.138	-0.24 to 1.70
PwD & Carer Relationship – Friend vs Brother/Sister	-0.22	0.33	202	-0.67	0.507	-0.88 to 0.43
PwD & Carer Relationship - Grandchild vs Brother/Sister	1.22	1.58	202	0.77	0.444	-1.91 to 4.34
PwD & Carer Relationship - Other vs Brother/Sister	1.32	2.62	202	0.51	0.614	-3.85 to 6.49
PwD & Carer Relationship - Partner vs Brother/Sister	2.90	1.78	202	1.63	0.106	-0.62 to 6.41
PwD & Carer Relationship - Son/daughter vs Brother/Sister	1.18	1.36	202	0.87	0.388	-1.51 to 3.86
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	1.43	1.36	202	1.05	0.294	-1.25 to 4.11
PwD & Carer Relationship - Spouse vs Brother/Sister	0.57	1.71	202	0.33	0.740	-2.80 to 3.94

Table 38. Linear mixed effects model to identify carer characteristics predicting differences between carers' BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline

	<b>Sum of Squares</b>	<b>df</b>	<b>F value</b>	<b>p value</b>
(Intercept)	6.55	1	1.05	0.306
Carer's Age	4.15	1	0.67	0.415
Carer's Gender	4.56	1	0.73	0.393
Carer's Education	19.24	4	0.77	0.544

PwD & Carer Relationship	65.52	7	1.51	0.168
Residuals	1169.09	188	NA	NA

$F(13,188) = 1.08, R^2 = 0.07, p = 0.377$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
Carer's Age	2.67	2.15	189	1.24	0.217	-1.58 to 6.91
Carer Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	-0.02	0.02	189	-0.78	0.439	-0.06 to 0.03
Carer Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	0.62	0.77	189	0.80	0.422	-0.90 to 2.13
Carer Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education vs Left school at age 14-16, and did not go back to education	0.41	0.45	189	0.91	0.364	-0.48 to 1.29
Carer Education - Postgraduate education	0.19	0.58	189	0.32	0.749	-0.96 to 1.33

(MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education						
Carer Gender – Male vs Female	0.61	0.59	189	1.04	0.301	-0.55 to 1.76
PwD & Carer Relationship - Friend vs Brother/Sister	-0.01	0.40	189	-0.02	0.982	-0.79 to 0.77
PwD & Carer Relationship - Grandchild vs Brother/Sister	0.29	1.92	189	0.15	0.878	-3.50 to 4.08
PwD & Carer Relationship - Other vs Brother/Sister	-0.89	3.04	189	-0.29	0.771	-6.89 to 5.11
PwD & Carer Relationship - Partner vs Brother/Sister	-0.16	2.30	189	-0.07	0.943	-4.70 to 4.37
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.58	1.58	189	0.37	0.713	-2.54 to 3.70
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	0.35	1.58	189	0.22	0.824	-2.76 to 3.46
PwD & Carer Relationship - Spouse vs Brother/Sister	-0.62	1.98	189	-0.31	0.755	-4.52 to 3.28

***Participant characteristics as predictors of differences in carers' BGSi goal attainment ratings***

Table 39. Linear mixed effects model to identify participant characteristics predicting the difference between carer BGSi goal attainment ratings at baseline and at three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between three months and baseline

	$\chi^2$	df	p value
(Intercept)	16.18	1	0.000
Gender	0.07	1	0.797
Age	0.28	1	0.597
MMSE	2.41	1	0.121
Diagnosis	0.17	2	0.920
Medication	0.43	1	0.511
Education	3.74	4	0.442
Comorbidity	0.09	1	0.762
Social status	14.54	5	0.013
Centre	0.10	1	0.752

$Chisq(17) = 27.24, R^2 = 0.12, p = 0.055$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between three months and baseline

	B (Estimate)	Std. Error	df	t value	p value	95% CI
(Intercept)	3.52	0.88	209.17	4.02	0.000	1.82 to 5.26
Age - 75 or Above vs Under 75	-0.17	0.32	213.40	-0.53	0.598	-0.81 to 0.47
Gender – Female vs Male	-0.08	0.33	212.67	-0.26	0.797	-0.73 to 0.56
MMSE - 24 or Above vs Below 24	0.45	0.29	214.41	1.55	0.122	-0.11 to 1.02
Comorbidity	-0.03	0.10	212.65	-0.30	0.762	-0.22 to 0.16

Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.18	0.55	182.80	0.33	0.741	-0.90 to 1.27
Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.12	0.36	213.42	0.33	0.743	-0.60 to 0.83
Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	-1.24	0.82	214.98	-1.51	0.133	-2.86 to 0.37
Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	0.09	0.34	214.77	0.26	0.798	-0.58 to 0.75
Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	0.38	0.54	211.43	0.70	0.482	-0.68 to 1.42
Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-0.29	0.62	207.88	-0.47	0.636	-1.53 to 0.92
Medication – Yes vs No	0.30	0.46	214.45	0.66	0.512	-0.60 to 1.19
Social status - II Managerial/technical vs I Professional	-0.85	0.58	209.24	-1.46	0.146	-2.00 to 0.29
PwD Social status - III N Skilled, non-manual vs I Professional	-1.83	0.68	214.14	-2.70	0.007	-3.15 to -0.50

Social status - III M Skilled, manual vs I Professional	-1.63	0.67	214.99	-2.46	0.015	-2.94 to -0.33
Social status - IV Partly skilled vs I Professional	-1.30	0.77	214.36	-1.70	0.091	-2.81 to 0.21
Social status - V Unskilled vs I Professional	-0.21	0.84	214.47	-0.25	0.803	-1.85 to 1.44

Table 40. Linear mixed effects model to identify participant characteristics predicting the difference between the carer BGSi attainment ratings at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	11.81	1	0.001
Gender	0.03	1	0.873
Age	1.46	1	0.227
MMSE	7.91	1	0.005
Diagnosis	1.28	2	0.528
Medication	0.56	1	0.454
Education	2.03	4	0.731
Comorbidity	0.27	1	0.603
Social status	9.97	5	0.076
Centre	2.48	1	0.115

Chisq(17) = 31.1823, R2 = 0.1529, p = 0.019

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in carers' BGSi attainment ratings between nine months and baseline

	<b>B</b> (Estimate)	Std. Error	df	t value	p value	95% CI
(Intercept)	3.59	1.04	199.06	3.44	0.001	1.52 to 5.65
Age - 75 or Above vs Under 75	-0.46	0.38	203.22	-1.21	0.228	-1.22 to 0.29
Gender – Female vs Male	0.06	0.39	200.54	0.16	0.873	-0.71 to 0.83

MMSE - 24 or Above vs Below 24	0.96	0.34	202.98	2.81	0.005	0.29 to 1.63
Comorbidity	0.06	0.11	203.31	0.52	0.604	-0.17 to 0.28
Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.75	0.66	203.73	-1.13	0.260	-2.06 to 0.56
Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.16	0.43	203.66	-0.37	0.712	-1.00 to 0.68
Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	-1.04	1.01	203.00	-1.03	0.305	-3.07 to 0.98
Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	-0.19	0.40	201.80	-0.47	0.640	-0.97 to 0.50
Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	-0.69	0.62	199.50	-1.12	0.263	-1.92 to 0.53
Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-0.20	0.72	197.40	-0.27	0.784	-1.62 to 1.22

Medication – Yes vs No	-0.42	0.55	200.68	-0.75	0.454	-1.51 to 0.68
Social status - II Managerial/technical vs I Professional	-0.50	0.68	197.44	-0.74	0.463	-0.94 to 0.42
Social status - III N Skilled, non-manual vs I Professional	-1.51	0.79	201.73	-1.92	0.056	-2.09 to -0.48
Social status - III M Skilled, manual vs 1 I Professional	-1.06	0.78	203.06	-1.36	0.175	-1.73 to -0.09
Social status - IV Partly skilled vs I Professional	-1.87	0.90	203.39	-2.08	0.039	-2.71 to -0.78
Social status - V Unskilled vs I Professional	-0.13	1.00	203.32	-0.14	0.893	-0.54 to 1.30

## Participants' ratings of satisfaction with goal attainment

### *Participant characteristics as predictors of differences in participants BGSi satisfaction ratings*

Table 41. Linear mixed effects model to identify participant characteristics predicting the difference between BGSi satisfaction ratings at baseline and at three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' ratings of BGSi satisfaction scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	6.02	1	0.014
Blinding inefficient	10.30	1	0.001
Age (Stratified)	3.08	1	0.079
Gender	0.50	1	0.478
Education	6.06	4	0.194
Social status	16.82	5	0.005
Ethnicity	4.41	9	0.882
Living situation	1.46	1	0.227
Diagnosis	2.36	2	0.307
MMSE Score (Stratified)	2.61	1	0.106
Medication	0.31	1	0.576
Comorbidity	0.00	1	0.973

$\text{Chisq}(28) = 49.89, R^2 = 0.21, p = 0.007$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi satisfaction ratings between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	5.26	2.15	217	2.45	0.015	1.04 to 9.49
Blinding inefficient vs maintained	0.96	0.30	217	3.21	0.002	0.37 to 1.54
Age 75 or Above vs Under 75	-0.03	0.02	217	-1.75	0.081	-0.07 to 0.00

Gender – Female vs Male	-0.23	0.32	217	-0.71	0.479	-0.86 to 0.41
MMSE Score - 24 or Above vs Below 24	0.07	0.05	217	1.62	0.107	-0.02 to 0.17
Comorbidity	0.00	0.10	217	0.03	0.973	-0.19 to 0.20
Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.57	0.52	217	-1.10	0.274	-1.58 to 0.45
Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.23	0.35	217	0.66	0.512	-0.46 to 0.92
Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	0.12	0.79	217	0.15	0.878	-1.44 to 1.69
Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	-0.63	0.33	217	-1.91	0.058	-1.29 to 0.02
Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	0.06	0.52	217	0.11	0.915	-0.97 to 1.09
Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-0.98	0.61	217	-1.60	0.112	-2.18 to 0.23
Ethnicity - Any other Asian background vs Welsh/English/Scottish/Northern Irish/British	-0.85	1.42	217	-0.60	0.550	-3.64 to 1.94

Ethnicity - African vs Welsh/English/Scottish/Northern Irish/British	-0.82	1.98	217	-0.42	0.678	-4.71 to 3.07
Ethnicity - Caribbean vs Welsh/English/Scottish/Northern Irish/British	-0.72	1.02	217	-0.71	0.481	-2.73 to 1.29
Ethnicity - Any other ethnic group vs Welsh/English/Scottish/Northern Irish/British	0.47	1.40	217	0.33	0.739	-2.28 to 3.21
Ethnicity - Irish vs Welsh/English/Scottish/Northern Irish/British	-1.06	0.91	217	-1.16	0.248	-2.85 to 0.74
Ethnicity - Any other White background vs Welsh/English/Scottish/Northern Irish/British	0.67	1.00	217	0.67	0.504	-1.30 to 2.65
Ethnicity - White and Black Caribbean vs Welsh/English/Scottish/Northern Irish/British	-2.09	1.97	217	-1.06	0.290	-5.97 - 1.79
Ethnicity - Any other Mixed/Multiple ethnic background vs Welsh/English/Scottish/Northern Irish/British	-0.41	1.97	217	-0.21	0.837	-4.30 - 3.48
Ethnicity - Indian vs Welsh/English/Scottish/Northern Irish/British	1.93	2.15	217	0.90	0.369	-2.29 to 6.15
Living situation - Not alone vs alone	-0.45	0.37	217	-1.21	0.229	-1.18 to 0.28
Medication – Yes vs No	-0.24	0.43	217	-0.56	0.577	-1.09 to 0.61

Social status - II Managerial/technical vs I Professional	-0.82	0.56	217	-1.46	0.145	-1.92 to 0.28
Social status - III N Skilled, non- manual vs I Professional	-1.73	0.65	217	-2.67	0.008	-3.01 to -0.46
Social status - III M Skilled, manual vs I Professional	-2.10	0.63	217	-3.34	0.001	-3.33 to -0.86
Social status - IV Partly skilled	-1.92	0.75	217	-2.57	0.011	-3.39 to -0.45
Social status - V Unskilled vs I Professional	-1.33	0.81	217	-1.64	0.102	-2.93 to 0.26

Table 42. Linear mixed effects model fitted to predict the difference between the participants' BGSi satisfaction ratings at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participants' BGSi satisfaction ratings between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	0.36	1	0.549
Blinding inefficient	14.35	1	0.000
Age	0.99	1	0.320
Gender	0.04	1	0.846
Education	5.16	4	0.271
Social status	7.45	5	0.189
Ethnicity	6.55	8	0.586
Living situation	0.30	1	0.582
Diagnosis	4.07	2	0.131
MMSE Score	15.79	1	0.000
Medication	0.71	1	0.399
Comorbidity	0.04	1	0.848

$\chi^2(27) = 54.26, R^2 = 0.25, p = 0.001$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participants' BGSi satisfaction ratings between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	1.46	2.44	200.31	0.60	0.550	-3.35 to 6.27
Blinding inefficient vs maintained	1.23	0.33	200.33	3.79	0.000	0.58 to 1.88
Age 75 or Above vs Under 75	-0.02	0.02	201.19	-0.99	0.321	-0.00 to 0.01
Gender – Female vs Male	0.07	0.36	197.40	0.19	0.846	0.10 to 0.52
MMSE Score - 24 or Above vs Below 24	0.20	0.05	199.45	3.97	0.000	0.22 to 0.27
Comorbidity	-0.02	0.11	200.71	-0.19	0.848	-0.05 to 0.10
Diagnosis - Vascular dementia (VaD) Alzheimer's Disease (AD)	-1.18	0.59	201.99	-2.01	0.046	-2.34 to -0.02
Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.21	0.40	201.19	-0.54	0.592	-1.00 to 0.57
Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	0.61	0.91	200.35	0.67	0.501	0.04 to 1.42
Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	-0.73	0.38	200.91	-1.96	0.052	-0.53 to -0.21
Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	-0.17	0.57	196.08	-0.29	0.771	-0.25 to 0.48

Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-0.62	0.67	194.91	-0.93	0.355	-0.66 to 0.17
Ethnicity - Any other Asian background vs Welsh/English/Scottish/Northern Irish/British	0.27	1.56	201.79	0.17	0.864	-0.49 to 1.74
Ethnicity - Caribbean vs Welsh/English/Scottish/Northern Irish/British	-2.70	1.50	198.31	-1.80	0.073	-3.29 to -1.19
Ethnicity - Any other ethnic group vs Welsh/English/Scottish/Northern Irish/British	0.29	1.51	198.61	0.19	0.848	0.27 to 2.10
Ethnicity - Irish vs Welsh/English/Scottish/Northern Irish/British	-0.37	0.99	200.81	-0.37	0.711	-0.85 to 0.57
Ethnicity - Any other White background vs Welsh/English/Scottish/Northern Irish/British	1.34	1.09	198.63	1.24	0.218	1.14 to 2.55
Ethnicity - White and Black Caribbean vs Welsh/English/Scottish/Northern Irish/British	-0.74	2.13	198.56	-0.35	0.729	-0.44 to 1.96
Ethnicity - Any other Mixed/Multiple ethnic background vs Welsh/English/Scottish/Northern Irish/British	-1.80	2.14	200.71	-0.84	0.399	-6.07 to 0.15

Ethnicity - Indian vs Welsh/English/Scottish/Northern Irish/British	2.47	2.38	201.86	1.04	0.300	-2.27 to 7.20
Living situation - Not alone vs Alone	-0.23	0.41	197.11	-0.55	0.582	-1.05 to 0.59
Medication – Yes vs No	-0.41	0.49	198.71	-0.84	0.400	-0.46 to 0.16
Social status - II Managerial/technical vs I Professional	-1.14	0.62	194.38	-1.85	0.066	-1.20 to -0.41
Social status - III N Skilled, non-manual vs I Professional	-1.60	0.72	198.09	-2.23	0.027	-1.79 to -0.83
Social status - III M Skilled, manual vs I Professional	-1.61	0.70	201.23	-2.30	0.022	-1.85 to -0.90
Social status - IV Partly skilled vs I Professional	-2.05	0.83	199.62	-2.48	0.014	-2.31 to -1.18
Social status - V Unskilled vs I Professional	-1.38	0.91	200.01	-1.51	0.132	-1.21 to -0.20

## Appendix 8. Exploratory analyses for the secondary outcomes

### *Participant outcomes*

Table 43. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant DEMQOL scores at baseline and three-month follow-up

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	0.22	1	0.635
Gender	0.13	1	0.720
Age	0.01	1	0.943
MMSE	0.08	1	0.774
Diagnosis	0.34	2	0.844
Social status	3.03	5	0.695
Centre	0.21	1	0.646

$\text{Chisq}(11) = 3.538, R^2 = 0.0204, p = 0.982$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	1.16	2.44	191.98	0.47	0.636	-3.67 to 5.97
Age 75 or Above vs under 75	0.10	1.43	215.87	0.07	0.943	-2.64 to 2.94
Gender – Female vs Male	-0.52	1.45	214.82	-0.36	0.720	-3.36 to 2.33
MMSE - 24 or Above vs below 24	-0.36	1.26	216.76	-0.29	0.775	-2.76 to 2.15
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.63	1.75	199.73	-0.36	0.719	-4.13 to 2.67
PwD Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.52	1.55	214.58	0.34	0.737	-2.61 to 3.42

Social status - II Managerial/technical vs I Professional	0.07	2.32	214.08	0.03	0.975	-4.52 to 4.55
Social status - III N Skilled, non-manual vs I Professional	0.48	2.60	216.95	0.18	0.855	-4.66 to 5.47
Social status - III M Skilled, manual vs I Professional	-1.01	2.53	214.51	-0.40	0.691	-6.03 to 3.84
Social status - IV Partly skilled vs I Professional	1.76	2.91	209.83	0.60	0.547	-4.00 to 7.34
Social status - V Unskilled vs I Professional	3.71	3.31	216.86	1.12	0.263	-2.74 to 10.16

Table 44. Linear mixed effects model fitted to identify participant characteristics as predicting differences between participant DEMQOL scores at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	0.31	1	0.577
Gender	0.53	1	0.466
Age	0.00	1	1.000
MMSE	1.94	1	0.164
Diagnosis	1.13	2	0.567
Social status	1.78	5	0.879
Centre	0.00	1	1.000

$Chisq(11) = 5.439, R^2 = 0.0266, p = 0.908$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant DEMQOL scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	1.45	2.60	203.00	0.56	0.577	-3.67 to 6.58
Age 75 or Above vs under 75	0.00	1.55	203.00	0.00	1.000	-3.05 to 3.05
Gender – Female vs Male	-1.13	1.55	203.00	-0.73	0.467	-4.18 to 1.92
MMSE - 24 or Above vs below 24	-1.87	1.34	203.00	-1.39	0.165	-4.52 to 0.78
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	1.68	1.85	203.00	0.91	0.365	-1.96 to 5.32
PwD Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	1.33	1.66	203.00	0.80	0.424	-1.94 to 4.61
Social status - II Managerial/technical vs I Professional	-0.60	2.53	203.00	-0.24	0.813	-5.59 to 4.39
Social status - III N Skilled, non-manual vs I Professional	0.66	2.83	203.00	0.24	0.814	-4.90 to 6.23
Social status - III M Skilled, manual vs I Professional	0.29	2.76	203.00	0.11	0.916	-5.15 to 5.73
Social status - IV Partly skilled vs I Professional	2.16	3.11	203.00	0.69	0.488	-3.96 to 8.29
Social status - V Unskilled vs I Professional	1.78	3.62	203.00	0.49	0.624	-5.35 to 8.91

Table 45. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS anxiety scores at baseline and three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS anxiety scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	0.25	1	0.619
Gender	0.09	1	0.761
Age CAT	0.15	1	0.696
MMSE CAT	1.70	1	0.192
PwD Diagnosis	3.16	2	0.206
PwD Social status	1.52	5	0.911
Centre	0.11	1	0.735

$Chisq(11) = 6.235, R^2 = 0.0314, p = 0.857$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS anxiety scores between three months and baseline

	B (Estimate)	Std. Error	df	t value	p value	95% CI
(Intercept)	-0.38	0.77	188.86	-0.50	0.619	-1.88 to 1.14
Age 75 or Above vs under 75	-0.18	0.45	212.99	-0.39	0.696	-1.07 to 0.71
Gender – Female vs Male	-0.14	0.46	214.31	-0.30	0.761	-1.04 to 0.76
MMSE - 24 or Above vs below 24	-0.52	0.40	214.79	-1.30	0.193	-1.30 to 0.26
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.94	0.55	189.06	1.69	0.092	-0.15 to 2.02
PwD Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.02	0.49	212.76	-0.04	0.970	-0.98 to 0.94
Social status - II Managerial/technical vs I Professional	0.30	0.73	212.86	0.41	0.680	-1.14 to 1.75

Social status - III N Skilled, non-manual vs I Professional	0.60	0.82	215.85	0.74	0.462	-1.01 to 2.21
Social status - III M Skilled, manual vs I Professional	-0.00	0.80	212.50	-0.00	0.999	-1.58 to 1.56
Social status - IV Partly skilled vs I Professional	0.80	0.93	205.55	0.86	0.391	-1.03 to 2.61
Social status - V Unskilled vs I Professional	0.16	1.04	215.78	0.16	0.875	-1.90 to 2.23

Table 46. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS anxiety scores at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS anxiety scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	0.01	1	0.932
Gender	0.11	1	0.740
Age	1.94	1	0.163
MMSE	0.14	1	0.707
Diagnosis	0.94	2	0.625
Social status	2.09	5	0.836
Centre	0.00	1	1.000

$Chisq(11) = 5.13, R^2 = 0.026, p = 0.925$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS Anxiety scores between nine months and baseline

	B (Estimate)	Std. Error	df	t value	p value	95% CI
(Intercept)	0.08	0.88	193.00	0.09	0.932	-1.66 to 1.81
Age 75 or Above vs under 75	-0.72	0.52	193.00	-1.39	0.165	-1.75 to 0.30
Gender – Female vs Male	0.18	0.53	193.00	0.33	0.741	-0.87 to 1.22
MMSE - 24 or Above vs below	-0.17	0.46	193.00	-0.38	0.707	-1.07 to 0.73

PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.12	0.63	193.00	-0.19	0.848	-1.37 to 1.12
PwD Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.55	0.57	193.00	-0.96	0.337	-1.66 to 0.57
Social status - II Managerial/technical vs I Professional	0.99	0.87	193.00	1.14	0.258	-0.73 to 2.70
Social status - III N Skilled, non-manual vs I Professional	0.52	0.97	193.00	0.53	0.593	-1.40 to 2.44
Social status - III M Skilled, manual vs I Professional	1.03	0.94	193.00	1.10	0.273	-0.82 to 2.89
Social status - IV Partly skilled vs I Professional	0.78	1.05	193.00	0.74	0.458	-1.28 to 2.84
Social status - V Unskilled vs I Professional	0.35	1.22	193.00	0.29	0.772	-2.0 to 2.75

Table 47. Linear mixed effects model fitted to identify participant characteristics predicting differences between participant HADS depression scores at baseline, and three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS depression scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	0.08	1	0.779
Gender	0.05	1	0.822
Age	0.17	1	0.681
MMSE	1.81	1	0.179
Diagnosis	0.71	2	0.702
Social status	3.07	5	0.689
Centre	0.00	1	1.000

$Chisq(11) = 5.5314, R^2 = 0.0252, p = 0.903$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS depression scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	0.19	0.69	218.00	0.28	0.779	-1.16 to 1.54
Age 75 or Above vs under 75	-0.17	0.40	218.00	-0.41	0.681	-0.96 to 0.63
Gender – Female vs Male	0.09	0.41	218.00	0.22	0.823	-0.71 to 0.89
MMSE - 24 or Above vs below 24	-0.48	0.35	218.00	-1.34	0.180	-1.17 to 0.22
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.23	0.49	218.00	0.47	0.636	-0.73 to 1.20
PwD Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.23	0.44	218.00	-0.53	0.594	-1.09 to 0.62
Social status - II Managerial/technical vs I Professional	0.16	0.65	218.00	0.24	0.807	-1.13 to 1.45
Social status - III N Skilled, non-manual vs I Professional	-0.15	0.73	218.00	-0.21	0.836	-1.59 to 1.29
Social status - III M Skilled, manual vs I Professional	0.75	0.71	218.00	1.05	0.294	-0.65 to 2.16
Social status - IV Partly skilled vs I Professional	-0.00	0.82	218.00	-0.00	0.998	-1.61 to 1.61
Social status - V Unskilled vs I Professional	0.64	0.93	218.00	0.68	0.494	-1.20 to 2.47

Table 48. Linear mixed effects model fitted to identify participant characteristics predicting for differences between participant HADS depression scores at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of participant characteristics as predictors of differences in participant HADS depression scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	0.07	1	0.794
Gender	0.69	1	0.407
Age	0.90	1	0.343
MMSE	0.00	1	0.979
Diagnosis	0.20	2	0.907
Social status	2.00	5	0.849
Centre	-0.00	1	1.000

$Chisq(11) = 3.27, R^2 = 0.017, p = 0.987$

(b) Regression analysis examining the influence of participant characteristics as predictors of differences in participant HADS Depression scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	0.19	0.74	194.00	0.26	0.795	-1.27 to 1.65
Age 75 or Above vs under 75	0.41	0.43	194.00	0.95	0.344	-0.44 to 1.27
Gender – Female vs Male	0.37	0.44	194.00	0.83	0.408	-0.51 to 1.24
MMSE - 24 or Above vs below 24	-0.01	0.38	194.00	-0.03	0.979	-0.77 to 0.75
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.13	0.53	194.00	0.24	0.810	-0.92 to 1.17
PwD Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.13	0.48	194.00	-0.28	0.779	-1.07 to 0.80
Social status - II Managerial/technical vs I Professional	-0.01	0.73	194.00	-0.02	0.987	-1.45 to 1.42

Social status - III N Skilled, non-manual vs I Professional	-0.65	0.82	194.00	-0.80	0.425	-2.26 to 0.96
Social status - III M Skilled, manual vs I Professional	-0.09	0.79	194.00	-0.12	0.905	-1.65 to 1.46
Social status - IV Partly skilled vs I Professional	-0.60	0.88	194.00	-0.69	0.493	-2.34 to 1.13
Social status - V Unskilled vs I Professional	-0.11	1.02	194.00	-0.11	0.914	-2.13 to 1.91

Table 49. Linear mixed effects model fitted to identify carer characteristics predicting differences between participant total GSES scores at baseline and three-month follow-up for participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in participant GSES scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	0.04	1	0.847
Gender	4.04	1	0.044
Age	0.17	1	0.681
MMSE	0.14	1	0.710
Diagnosis	5.20	2	0.074
Social status	4.92	5	0.425
Centre	0.00	1	1.000

$Chisq(11) = 12.2207, R^2 = 0.0558, p = 0.347$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participant GSES scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	0.22	1.12	214.00	0.19	0.847
Age - 75 or Above vs below 75	-0.27	0.66	214.00	-0.41	0.682
Gender – Female vs Male	1.35	0.67	214.00	2.01	0.046
MMSE - 24 or Above vs Under 24	-0.22	0.58	214.00	-0.37	0.711
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.95	0.81	214.00	1.17	0.241
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-1.10	0.71	214.00	-1.54	0.125
Social status - II Managerial/technical vs I Professional	0.01	1.06	214.00	0.01	0.995
Social status - III N Skilled, non-manual vs I Professional	-0.92	1.20	214.00	-0.77	0.444
Social status - III M Skilled, manual vs I Professional	0.34	1.16	214.00	0.29	0.770
Social status - IV Partly skilled vs I Professional	-1.20	1.33	214.00	-0.90	0.368
Social status - V Unskilled vs I Professional	1.31	1.52	214.00	0.86	0.390

Table 50. Linear mixed effects model fitted to identify carer characteristics predicting differences between participant GSES scores at baseline and nine-month follow-up for participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in participant GSES scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	0.80	1	0.371
Gender	1.09	1	0.296
Age	0.70	1	0.402
MMSE	1.22	1	0.269
Diagnosis	7.71	2	0.021
Social status	2.07	5	0.839
Centre	0.00	1	1.000

$\text{Chisq}(11) = 14.3, R^2 = 0.072, p = 0.216$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in participant GSES scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-1.19	1.33	193.00	-0.90	0.372 to -3.81
Age - 75 or Above vs below 75	-0.66	0.79	193.00	-0.84	0.403 to -2.21
Gender – Female vs Male	0.83	0.80	193.00	1.04	0.297 to -0.74
MMSE - 24 or Above vs Under 24	0.76	0.69	193.00	1.11	0.270 to -0.60
PwD Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	2.67	0.96	193.00	2.77	0.006 to 0.77
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.82	0.86	193.00	0.96	0.337 to -0.86
Social status - II Managerial/technical vs I Professional	0.42	1.30	193.00	0.32	0.748 to -2.15

Social status - III N Skilled, non-manual vs I Professional	0.35	1.46	193.00	0.24	0.809 to -2.53
Social status - III M Skilled, manual vs I Professional	0.24	1.42	193.00	0.17	0.868 to -2.55
Social status - IV Partly skilled vs I Professional	-0.64	1.60	193.00	-0.40	0.688 to -3.79
Social status - V Unskilled vs I Professional	1.77	1.83	193.00	0.97	0.335 to -1.84

### *Carer outcomes*

Table 51. Linear mixed effects model fitted to identify carer characteristics predicting differences between carer RSS scores at baseline and three-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in carer RSS scores between three months and baseline

	<b>Sum of Squares</b>	<b>df</b>	<b>F value</b>	<b>p value</b>
(Intercept)	21.38	1	0.62	0.433
Carer Age	9.20	1	0.27	0.607
Carer Gender	121.97	1	3.52	0.062
Carer Education	192.63	4	1.39	0.240
Carer Social status	243.56	5	1.41	0.225
Carer Ethnicity	282.88	6	1.36	0.234
PwD & Carer Relationship	327.08	7	1.35	0.231
Carer Health	54.27	4	0.39	0.815
Carer Hours	194.42	8	0.70	0.690
Residuals	5581.21	161	NA	NA

$F(36,161) = 0.92, R^2 = 0.17, p = 0.601$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in carer RSS scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-5.32	6.77	-0.79	0.433	-18.69 to 8.05
Carer Age	0.03	0.06	0.52	0.607	-0.09 to 0.15
Carer Education - Left school at age 17-18, and did not go back to education vs Left school at age 14-16, and did not go back to education	0.73	2.01	0.36	0.716	-3.24 to 4.70
Carer Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	0.63	1.20	0.53	0.597	-1.73 to 2.99
Carer Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	0.06	1.74	0.03	0.975	-3.38 to 3.49
Carer Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-3.25	1.88	-1.72	0.086	-6.96 to 0.47
Carer Ethnicity - Any other Asian background vs Welsh/English/Scottish/Northern Irish/British	-5.50	4.56	-1.21	0.229	-14.50 to 3.50
Carer Ethnicity - Caribbean vs Welsh/English/Scottish/Northern Irish/British	0.64	2.72	0.23	0.815	-4.73 to 6.01

Carer Ethnicity - Irish vs Welsh/English/Scottish/Northern Irish/British	6.74	3.36	2.00	0.047	0.10 to 13.39
Carer Ethnicity - Any other White background vs Welsh/English/Scottish/Northern Irish/British	0.57	4.65	0.12	0.902	-8.62 to 9.76
Carer Ethnicity - Any other Mixed/Multiple ethnic background	6.16	3.75	1.64	0.102	-1.24 to 13.56
Carer Ethnicity - Indian vs Welsh/English/Scottish/Northern Irish/British	-2.21	6.30	-0.35	0.727	-14.66 to 10.24
Carer Gender – Male vs Female	-2.11	1.13	-1.88	0.062	-4.34 to 0.11
Carer Health – Fair vs Excellent	-0.27	1.70	-0.16	0.874	-3.63 to 3.09
Carer Health - Good vs Excellent	-0.71	1.51	-0.47	0.641	-3.69 to 2.28
Carer Health - Poor vs Excellent	-1.96	2.14	-0.91	0.362	-6.18 to 2.27
Carer Health - Very good vs Excellent	-1.37	1.54	-0.89	0.374	-4.42 to 1.67
Carer Hours - Less than 1 hour vs Provides no help in a typical day	-0.57	2.13	-0.27	0.789	-4.79 to 3.64
Carer Hours - 3 More than 1 hour and up to 2 hours vs 1 Provides no help in a typical day	-0.12	2.22	-0.05	0.958	-4.50 to 4.26
Carer Hours - More than hour and up to 3 hours vs 1 Provides no help in a typical day	-0.77	2.37	-0.33	0.744	-5.45 to 3.90
Carer Hours - More than 3 hour and up to 5 hours vs Provides no help in a typical day	-0.74	2.41	-0.31	0.758	-5.50 to 4.01

Carer Hours - More than 5 hour and up to 10 hours vs Provides no help in a typical day	1.12	2.44	0.46	0.648	-3.71 to 5.94
Carer Hours - More than 10 hours, but not overnight vs Provides no help in a typical day	-2.75	2.76	-1.00	0.321	-8.21 to 2.71
Carer Hours - More than 10 hours and/including overnight vs Provides no help in a typical day	1.34	2.19	0.61	0.540	-2.98 to 5.66
Carer Hours – Other vs Provides no help in a typical day	1.06	4.64	0.23	0.820	-8.11 to 10.23
Carer Social status - II Managerial/technical vs I Professional	-1.42	1.66	-0.86	0.392	-4.70 to 1.85
Carer Social status - III N Skilled, non-manual vs I Professional	-2.63	1.95	-1.35	0.180	-6.49 to 1.22
Carer Social status - III M Skilled, manual vs I Professional	1.50	2.29	0.65	0.514	-3.03 to 6.02
Carer Social status - IV Partly skilled vs I Professional	-0.73	2.24	-0.33	0.745	-5.16 to 3.70
Carer Social status - V Unskilled vs I Professional	-3.85	2.77	-1.39	0.168	-9.33 to 1.63
PwD & Carer Relationship – Friend vs Brother/Sister	1.33	5.79	0.23	0.819	-10.10 to 12.76
PwD & Carer Relationship - Grandchild vs Brother/Sister	12.90	7.73	1.67	0.097	-2.37 to 28.16
PwD & Carer Relationship - Other vs Brother/Sister	0.95	5.33	0.18	0.858	-9.57 to 11.48
PwD & Carer Relationship - Partner vs Brother/Sister	7.21	4.16	1.73	0.085	-1.00 to 15.42
PwD & Carer Relationship - Son/daughter vs Brother/Sister	6.52	4.12	1.58	0.115	-1.61 to 14.65
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	10.45	5.34	1.96	0.052	-0.10 to 20.99

PwD & Carer Relationship - Spouse vs Brother/Sister	7.24	3.91	1.85	0.066	-0.47 to 14.95
---	------	------	------	-------	----------------

Table 52. Linear mixed effects model fitted to identify carer characteristics predicting differences between carer RSS scores at baseline and nine-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of carer characteristics as predictors of differences in carer RSS scores between nine months and baseline

	Sum of Squares	Df	F-value	Value
(Intercept)	27.77	1	0.76	0.385
Carer Age	24.16	1	0.66	0.417
Carer Gender	124.16	1	3.40	0.067
Carer Education	44.90	4	0.31	0.873
Carer Social status	83.90	5	0.46	0.806
Carer Ethnicity	313.05	6	1.43	0.207
PwD & Carer Relationship	229.18	7	0.90	0.511
Carer Health	148.86	4	1.02	0.400
Carer Hours	150.49	8	0.51	0.844
Residuals	5516.54	151	NA	NA

$F(36,151) = 0.89, R^2 = 0.17, p = 0.652$

(b) Regression analysis examining the influence of carer characteristics as predictors of differences in carer RSS scores between nine months and baseline

	B (Estimate)	Std. Error	t value	p value	95% CI
(Intercept)	-6.23	7.14	-0.87	0.385	-20.35 to 7.89
Carer Age	0.05	0.06	0.81	0.417	-0.07 to 0.18
Carer Education - Left school at age 17-18, and did not go back to	-2.21	2.09	-1.06	0.292	-6.35 to 1.92

education vs Left school at age 14-16, and did not go back to education					
Carer Education - Further education (e.g. vocational qualifications: GNVQ/NVQ/HND) vs Left school at age 14-16, and did not go back to education	-0.16	1.25	-0.13	0.896	-2.64 to 2.31
Carer Education - Higher education (BSc/BA or equivalent) vs Left school at age 14-16, and did not go back to education	-0.70	1.87	-0.38	0.708	-4.39 to 2.99
Carer Education - Postgraduate education (MSc/MA/PhD or equivalent) vs Left school at age 14-16, and did not go back to education	-0.82	1.98	-0.41	0.680	-4.73 to 3.09
Carer Ethnicity - Any other Asian background vs Welsh/English/Scottish/Northern Irish/British	-8.93	4.72	-1.89	0.060	-18.26 to 0.40
Carer Ethnicity - Caribbean vs Welsh/English/Scottish/Northern Irish/British	4.18	3.58	1.17	0.246	-2.90 to 11.25
Carer Ethnicity - Irish vs Welsh/English/Scottish/Northern Irish/British	5.80	3.47	1.67	0.097	-1.06 to 12.65
Carer Ethnicity - Any other White background vs Welsh/English/Scottish/Northern Irish/British	1.35	6.51	0.21	0.836	-11.51 to 14.21
Carer Ethnicity - Any other Mixed/Multiple ethnic background	2.59	3.87	0.67	0.504	-5.06 to 10.25

Carer Ethnicity - Indian vs Welsh/English/Scottish/Northern Irish/British	-4.24	6.52	-0.65	0.516	-17.14 to 8.65
Carer Gender – Male vs Female	-2.32	1.26	-1.84	0.067	-4.82 to 0.17
Carer Health – Fair vs Excellent	2.18	1.86	1.17	0.243	-1.50 to 5.86
Carer Health - Good vs Excellent	-0.49	1.61	-0.30	0.761	-3.66 to 2.68
Carer Health - Poor vs Excellent	-0.44	2.27	-0.19	0.846	-4.92 to 4.04
Carer Health - Very good vs Excellent	-0.52	1.66	-0.31	0.754	-3.79 to 2.75
Carer Hours - Less than 1 hour vs Provides no help in a typical day	-0.36	2.22	-0.16	0.870	-4.74 to 4.02
Carer Hours - More than 1 hour and up to 2 hours vs Provides no help in a typical day	0.69	2.31	0.30	0.764	-3.87 to 5.26
Carer Hours - More than 2 hour and up to 3 hours vs Provides no help in a typical day	1.38	2.42	0.57	0.570	-3.40 to 6.15
Carer Hours - More than 3 hour and up to 5 hours vs Provides no help in a typical day	1.63	2.62	0.62	0.535	-3.54 to 6.80
Carer Hours - More than 5 hour and up to 10 hours vs Provides no help in a typical day	2.68	2.47	1.09	0.280	-2.20 to 7.57
Carer Hours - More than 10 hours, but not overnight vs Provides no help in a typical day	1.03	2.91	0.35	0.724	-4.72 to 6.78
Carer Hours - More than 10 hours and/including overnight vs Provides no help in a typical day	1.72	2.26	0.76	0.447	-2.73 to 6.18

Carer Hours - Other, describe vs Provides no help in a typical day	-0.98	4.76	-0.21	0.837	-10.39 to 8.43
Carer Social status - II Managerial/technical vs I Professional	0.30	1.77	0.17	0.864	-3.20 to 3.81
Carer Social status - III N Skilled, non-manual vs I Professional	1.07	2.09	0.51	0.608	-3.05 to 5.20
Carer Social status - III M Skilled, manual vs I Professional	1.92	2.51	0.76	0.445	-3.04 to 6.88
Carer Social status - IV Partly skilled vs I Professional	-0.41	2.38	-0.17	0.863	-5.11 to 4.29
Carer Social status - V Unskilled vs I Professional	-1.53	3.12	-0.49	0.625	-7.70 to 4.64
PwD & Carer Relationship – Friend vs Brother/Sister	-0.20	6.13	-0.03	0.974	-12.31 to 11.91
PwD & Carer Relationship - Grandchild vs Brother/Sister	11.23	8.09	1.39	0.167	-4.76 to 27.22
PwD & Carer Relationship - Other vs Brother/Sister	0.66	5.54	0.12	0.906	-10.29 to 11.60
PwD & Carer Relationship - Partner vs Brother/Sister	4.53	4.38	1.03	0.303	-4.13 to 13.18
PwD & Carer Relationship - Son/daughter vs Brother/Sister	5.29	4.37	1.21	0.228	-3.34 to 13.91
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	8.51	5.28	1.61	0.109	-1.93 to 18.96
PwD & Carer Relationship - Spouse vs Brother/Sister	5.16	4.12	1.25	0.213	-2.99 to 13.30

Table 53. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF physical scores at baseline and three-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	1.17	1	0.280
PwD & Carer Relationship	2.37	7	0.937
Carer Gender	1.02	1	0.311
PwD Diagnosis	0.71	2	0.702
PwD MMSE	0.22	1	0.641
Centre	4.48	1	0.034

$Chisq(12) = 8.12, R^2 = 0.07, p = 0.775$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-1.12	1.04	211.30	-1.08	0.281	-3.16 to 0.92
Carer's Gender – Male vs Female	-0.27	0.27	205.29	-1.01	0.313	-0.79 to 0.25
MMSE - 24 or Above vs below 24	-0.12	0.25	210.15	-0.47	0.641	-0.62 to 0.38
PwD & Carer Relationship – Friend vs Brother/Sister	1.49	1.29	207.44	1.15	0.250	-1.05 to 4.04
PwD & Carer Relationship - Grandchild vs Brother/Sister	0.54	1.61	206.90	0.33	0.739	-2.64 to 3.73
PwD & Carer Relationship - Other vs Brother/Sister	1.28	1.44	207.82	0.89	0.375	-1.56 to 4.12
PwD & Carer Relationship - Partner vs Brother/Sister	1.22	1.10	206.57	1.10	0.271	-0.96 to 3.39
PwD & Carer Relationship - Son/daughter vs Brother/Sister	1.00	1.05	206.69	0.95	0.344	-1.08 to 3.08

PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	0.51	1.44	208.43	0.36	0.722	-2.33 to 3.36
PwD & Carer Relationship - Spouse vs Brother/Sister	1.17	1.04	209.03	1.13	0.260	-0.88 to 3.22
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.20	0.35	211.87	0.57	0.566	-0.49 to 0.89
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.14	0.31	211.86	-0.44	0.661	-0.74 to 0.47

Table 54. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF physical scores at baseline and nine-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	1.59	1	0.207
PwD & Carer Relationship	4.25	7	0.751
Carer Gender	0.15	1	0.698
PwD Diagnosis	0.79	2	0.672
PwD MMSE	0.33	1	0.563
Centre	1.88	1	0.171

$Chisq(12) = 7.56, R^2 = 0.053, p = 0.819$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF physical scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-1.25	0.99	198.87	-1.26	0.209	-3.20 to 0.70
Carer's Gender – Male vs Female	0.10	0.26	193.28	0.39	0.699	-0.42 to 0.62
MMSE - 24 or Above vs below 24	-0.15	0.25	198.65	-0.58	0.564	-0.64 to 0.35
PwD & Carer Relationship – Friend vs Brother/Sister	2.07	1.30	197.15	1.59	0.114	-0.50 to 4.65
PwD & Carer Relationship - Grandchild vs Brother/Sister	-0.13	1.55	195.57	-0.08	0.934	-3.19 to 2.94
PwD & Carer Relationship - Other vs Brother/Sister	1.25	1.39	196.15	0.90	0.369	-1.48 to .98
PwD & Carer Relationship - Partner vs Brother/Sister	1.14	1.07	194.98	1.06	0.290	-0.97 to 3.25
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.81	1.02	195.49	0.80	0.423	-1.19 to 2.82
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	0.99	1.39	197.33	0.71	0.476	-1.74 to 3.73
PwD & Carer Relationship - Spouse vs Brother/Sister	1.05	1.00	197.92	1.05	0.296	-0.93 to 3.02
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.25	0.34	197.18	-0.73	0.469	-0.93 to 0.43
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.09	0.30	198.68	0.30	0.765	-0.50 to 0.68

Table 55. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF psychological scores at baseline and three-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	5.37	1	0.020
PwD & Carer Relationship	8.62	7	0.281
Carer Gender	0.01	1	0.907
PwD Diagnosis	0.50	2	0.781
PwD MMSE	0.79	1	0.375
Centre	1.04	1	0.307

$Chisq(12) = 10.5, R^2 = 0.061, p = 0.57$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-2.04	0.88	211.89	-2.32	0.021	-3.78 to - 0.31
Carer's Gender – Male vs Female	0.03	0.23	206.53	0.12	0.907	-0.42 to 0.48
MMSE - 24 or Above vs below 24	0.19	0.22	211.67	0.89	0.376	-0.24 to 0.62
PwD & Carer Relationship – Friend vs Brother/Sister	3.06	1.11	209.23	2.76	0.006	0.88 to 5.25
PwD & Carer Relationship - Grandchild vs Brother/Sister	1.75	1.39	208.87	1.26	0.209	-0.99 to 4.49
PwD & Carer Relationship - Other vs Brother/Sister	2.00	1.24	209.05	1.62	0.108	-0.44 to 4.44
PwD & Carer Relationship - Partner vs Brother/Sister	1.82	0.95	208.40	1.92	0.056	-0.05 to 3.69
PwD & Carer Relationship - Son/daughter vs Brother/Sister	1.58	0.90	208.48	1.75	0.081	-0.20 to 3.37

PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	1.94	1.24	210.50	1.57	0.118	-0.50 to 4.38
PwD & Carer Relationship - Spouse vs Brother/Sister	1.60	0.89	211.08	1.80	0.074	-0.16 to 3.35
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.07	0.29	207.32	0.24	0.810	-0.52 to 0.66
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.18	0.26	211.10	0.70	0.484	-0.33 to 0.70

Table 56. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF psychological scores at baseline and nine-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	1.23	1	0.268
PwD & Carer Relationship	1.74	7	0.973
Carer Gender	0.37	1	0.545
PwD Diagnosis	2.13	2	0.344
PwD MMSE	0.01	1	0.917
Centre	0.92	1	0.338

$Chisq(12) = 5.00, R^2 = 0.040, p = 0.959$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF psychological scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-1.01	0.91	198.86	-1.11	0.269	-2.81 to 0.79
Carer's Gender – Male vs Female	0.15	0.24	190.77	0.61	0.546	-0.30 to 0.60
MMSE - 24 or Above vs below 24	0.02	0.23	198.76	0.10	0.917	-0.38 to 0.47
PwD & Carer Relationship – Friend vs Brother/Sister	0.43	1.20	196.79	0.35	0.724	-1.67 to 2.82
PwD & Carer Relationship - Grandchild vs Brother/Sister	-0.06	1.43	194.44	-0.04	0.967	-2.62 to 2.66
PwD & Carer Relationship - Other vs Brother/Sister	0.25	1.28	195.05	0.20	0.843	-2.03 to 2.68
PwD & Carer Relationship - Partner vs Brother/Sister	0.86	0.99	193.47	0.87	0.385	-0.96 to 2.68
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.59	0.94	194.27	0.63	0.528	-1.08 to 2.37
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	0.30	1.28	197.04	0.23	0.815	-2.04 to 2.66
PwD & Carer Relationship - Spouse vs Brother/Sister	0.44	0.92	197.90	0.48	0.630	-1.17 to 2.21
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.30	0.31	194.16	-0.95	0.346	-0.91 to 0.24
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.22	0.27	197.85	0.82	0.414	-0.27 to 0.73

Table 57. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF social scores at baseline and three-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	0.79	1	0.374
PwD & Carer Relationship	2.90	7	0.894
Carer Gender	0.06	1	0.811
PwD Diagnosis	2.40	2	0.301
PwD MMSE	0.21	1	0.647
Centre	0.00	1	1.000

$Chisq(12) = 6.23, R^2 = 0.029, p = 0.904$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between three months and baseline

	B (Estimate)	Std. Error	df	t value	p value	95% CI
(Intercept)	-1.07	1.20	211.00	-0.89	0.375	-3.44 to 1.30
Carer's Gender – Male vs Female	0.07	0.31	211.00	0.24	0.811	-0.54 to 0.69
MMSE - 24 or Above vs below 24	0.14	0.30	211.00	0.46	0.648	-0.45 to 0.72
PwD & Carer Relationship – Friend vs Brother/Sister	1.03	1.52	211.00	0.68	0.498	-1.96 to 4.02
PwD & Carer Relationship - Grandchild vs Brother/Sister	-0.07	1.90	211.00	-0.03	0.972	-3.81 to 3.68
PwD & Carer Relationship - Other vs Brother/Sister	1.01	1.70	211.00	0.60	0.551	-2.33 to 4.36
PwD & Carer Relationship - Partner vs Brother/Sister	0.26	1.30	211.00	0.20	0.839	-2.29 to 2.82
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.92	1.24	211.00	0.74	0.459	-1.52 to 3.36

PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	-0.36	1.69	211.00	-0.21	0.830	-3.70 to 2.97
PwD & Carer Relationship - Spouse vs Brother/Sister	0.61	1.22	211.00	0.50	0.616	-1.78 to 3.00
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.62	0.40	211.00	1.55	0.123	-0.17 to 1.40
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.17	0.36	211.00	0.46	0.643	-0.54 to 0.87

Table 58. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF social scores at baseline and nine-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	3.10	1	0.078
PwD & Carer Relationship	7.08	7	0.420
Carer Gender	3.34	1	0.068
PwD Diagnosis	0.63	2	0.730
PwD MMSE	0.12	1	0.728
Centre	0.00	1	1.000

Chisq(12) = 10.81, R2 = 0.054, p = 0.545

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF social scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-2.25	1.28	196.00	-1.76	0.080	-4.76 to 0.27
Carer's Gender – Male vs Female	0.63	0.34	196.00	1.83	0.069	-0.05 to 1.31
MMSE - 24 or Above vs below 24	0.11	0.33	196.00	0.35	0.728	-0.53 to 0.76
PwD & Carer Relationship – Friend vs Brother/Sister	3.31	1.69	196.00	1.96	0.052	-0.02 to 6.64
PwD & Carer Relationship - Grandchild vs Brother/Sister	1.63	2.02	196.00	0.81	0.419	-2.34 to 5.61
PwD & Carer Relationship - Other vs Brother/Sister	2.81	1.80	196.00	1.56	0.120	-0.74 to 6.36
PwD & Carer Relationship - Partner vs Brother/Sister	1.82	1.39	196.00	1.30	0.194	-0.93 to 4.56
PwD & Carer Relationship - Son/daughter vs Brother/Sister	1.69	1.32	196.00	1.28	0.201	-0.91 to 4.29
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	-0.23	1.80	196.00	-0.13	0.900	-3.77 to 3.32
PwD & Carer Relationship - Spouse vs Brother/Sister	1.78	1.29	196.00	1.38	0.170	-0.76 to 4.33
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	0.11	0.44	196.00	0.24	0.808	-0.76 to 0.98
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.31	0.39	196.00	0.79	0.429	-0.46 to 1.07

Table 59. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF environmental scores at baseline and three-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between three months and baseline

	$\chi^2$	df	p value
(Intercept)	0.61	1	0.434
PwD & Carer Relationship	6.59	7	0.473
Carer Gender	1.54	1	0.215
PwD Diagnosis	1.84	2	0.399
PwD MMSE	0.23	1	0.629
Centre	0.00	1	1.000

$Chisq(12) = 9.3171, R^2 = 0.0432, p = 0.676$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between three months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-0.61	0.78	212.00	-0.78	0.435	-2.16 to 0.93
Carer's Gender – Male vs Female	-0.25	0.20	212.00	-1.24	0.216	-0.66 to 0.15
MMSE - 24 or Above vs below 24	0.09	0.19	212.00	0.48	0.629	-0.29 to 0.47
PwD & Carer Relationship – Friend vs Brother/Sister	0.03	0.99	212.00	0.03	0.976	-1.92 to 1.98
PwD & Carer Relationship - Grandchild vs Brother/Sister	0.02	1.24	212.00	0.02	0.987	-2.42 to 2.46
PwD & Carer Relationship - Other vs Brother/Sister	1.38	1.11	212.00	1.25	0.212	-0.79 to 3.56
PwD & Carer Relationship - Partner vs Brother/Sister	0.40	0.85	212.00	0.47	0.641	-1.27 to 2.06
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.83	0.81	212.00	1.02	0.307	-0.76 to 2.42

PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	-0.31	1.10	212.00	-0.28	0.777	-2.49 to 1.86
PwD & Carer Relationship - Spouse vs Brother/Sister	0.77	0.79	212.00	0.98	0.331	-0.79 to 2.33
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.05	0.26	212.00	-0.19	0.853	-0.56 to 0.46
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	-0.31	0.23	212.00	-1.35	0.180	-0.77 to 0.14

Table 60. Linear mixed effects model fitted to identify characteristics predicting differences between carer WHOQOL-BREF environmental scores at baseline and nine-month follow-up for carers of participants in the CR group

(a) ANOVA examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between nine months and baseline

	$\chi^2$	df	p value
(Intercept)	2.57	1	0.109
PwD & Carer Relationship	11.65	7	0.113
Carer Gender	0.01	1	0.944
PwD Diagnosis	0.21	2	0.901
PwD MMSE	0.19	1	0.662
Centre	-0.00	1	1.000

$Chisq(12) = 11.5908, R^2 = 0.0569, p = 0.479$

(b) Regression analysis examining the influence of characteristics as predictors of differences in carer WHOQOL-BREF environmental scores between nine months and baseline

	<b>B (Estimate)</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI</b>
(Intercept)	-1.37	0.85	199.00	-1.60	0.110	-3.05 to 0.31
Carer's Gender – Male vs Female	0.02	0.23	199.00	0.07	0.944	-0.44 to 0.47
MMSE - 24 or Above vs below 24	0.10	0.22	199.00	0.44	0.662	-0.33 to 0.52
PwD & Carer Relationship – Friend vs Brother/Sister	0.79	1.13	199.00	0.70	0.484	-1.43 to 3.02
PwD & Carer Relationship - Grandchild vs Brother/Sister	0.28	1.35	199.00	0.20	0.839	-2.38 to 2.93
PwD & Carer Relationship - Other vs Brother/Sister	3.34	1.21	199.00	2.77	0.006	0.97 to 5.72
PwD & Carer Relationship - Partner vs Brother/Sister	1.32	0.93	199.00	1.42	0.157	-0.51 to 3.16
PwD & Carer Relationship - Son/daughter vs Brother/Sister	0.94	0.88	199.00	1.06	0.289	-0.80 to 2.68
PwD & Carer Relationship - Son/daughter-in-law vs Brother/Sister	-0.02	1.20	199.00	-0.02	0.985	-2.39 to 2.35
PwD & Carer Relationship - Spouse vs Brother/Sister	1.02	0.86	199.00	1.18	0.239	-0.68 to 2.72
PwD_Diagnosis - Vascular dementia (VaD) vs Alzheimer's Disease (AD)	-0.06	0.29	199.00	-0.21	0.831	-0.64 to 0.51
PwD_Diagnosis - Mixed AD and vascular dementia vs Alzheimer's Disease (AD)	0.09	0.26	199.00	0.33	0.739	-0.42 to 0.59

## Appendix 9. Complete case analyses with no imputation

Table 61. ANCOVA Summary table for BGSi ratings without imputations

(a) Three-month follow-up

<b>Measure</b>	<b>p</b>	<b>Adjusted p</b>	<b>Mean difference</b>	<b>95% CI for mean difference</b>	<b>d</b>	<b>95% CI for d</b>
Participant rating of attainment	<0.001	<0.001	1.71	1.32 to 2.1	0.91	0.7 to 1.13
Participant rating of satisfaction	<0.001	<0.001	1.56	1.14 to 1.98	0.78	0.56 to 0.99
Carer rating of attainment	<0.001	<0.001	1.89	1.51 to 2.28	1.03	0.81 to 1.25

(b) Nine-month follow-up

<b>Measure</b>	<b>p</b>	<b>Adjusted p</b>	<b>Mean difference</b>	<b>95% CI for mean difference</b>	<b>d</b>	<b>95% CI for d</b>
Participant rating of attainment	<0.001	<0.001	1.81	1.34 to 2.28	0.86	0.63 to 1.09
Participant rating of satisfaction	<0.001	<0.001	1.69	1.21 to 2.17	0.78	0.55 to 1.01
Carer rating of attainment	<0.001	<0.001	1.85	1.38 to 2.31	0.88	0.65 to 1.11

Table 62. ANCOVA summary table for analysis of secondary outcomes without imputations

(a) Three-month follow-up

Measure	p	Adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
<b>Participants with dementia</b>						
DEMQOL	0.505	1	0.59	-1.14 to 2.31	0.07	-0.14 to 0.28
GSES	0.157	1	0.65	-0.25 to 1.56	0.15	-0.06 to 0.36
HADS	0.659	1	-0.2	-1.07 to 0.68	-0.05	-0.25 to 0.16
RBMT immediate recall	0.259	1	0.22	-0.16 to 0.6	0.12	-0.09 to 0.33
RBMT delayed recall	0.668	1	0.07	-0.27 to 0.41	0.05	-0.16 to 0.25
TEA elevator counting	0.391	1	0.1	-0.13 to 0.32	0.09	-0.12 to 0.3
TEA elevator counting with distraction	0.427	1	0.21	-0.31 to 0.73	0.08	-0.12 to 0.29
DKEFS verbal fluency	0.924	1	0.07	-1.35 to 1.49	0.01	-0.2 to 0.22
<b>Carers</b>						
RSS	0.362	1	-0.59	-1.87 to 0.68	-0.1	-0.3 to 0.11
WHOQOL physical	0.171	1	0.23	-0.1 to 0.55	0.15	-0.06 to 0.35
WHOQOL psychological	0.133	1	0.25	-0.08 to 0.57	0.16	-0.05 to 0.37
WHOQOL social	0.930	1	-0.02	-0.46 to 0.42	-0.01	-0.22 to 0.2

WHOQOL environmental	0.029	0.488	0.33	0.03 to 0.63	0.23	0.03 to 0.44
EQ5D3L index	0.189	1	0.02	-0.01 to 0.06	0.14	-0.07 to 0.35
EQ5D Visual Analogue Scale	0.153	1	2.72	-1.02 to 6.47	0.15	-0.06 to 0.36

(b) Nine-month follow-up

Measure	p	Adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
<b>Participants with dementia</b>						
DEMQOL	0.254	1	1.23	-0.89 to 3.36	0.13	-0.09 to 0.35
GSES	0.357	1	0.48	-0.54 to 1.5	0.1	-0.12 to 0.32
HADS	0.121	1	0.76	-0.2 to 1.72	0.18	-0.05 to 0.4
RBMT immediate recall	0.704	1	0.08	-0.32 to 0.47	0.04	-0.18 to 0.26
RBMT delayed recall	0.335	1	-0.18	-0.54 to 0.19	-0.11	-0.33 to 0.11
TEA elevator counting	0.764	1	-0.04	-0.33 to 0.24	-0.03	-0.25 to 0.19
TEA elevator counting with distraction	0.176	1	0.38	-0.17 to 0.93	0.15	-0.07 to 0.37
DKEFS verbal fluency	0.679	1	0.36	-1.34 to 2.05	0.05	-0.17 to 0.27
<b>Carers</b>						
RSS	0.529	1	0.44	-0.93 to 1.81	0.07	-0.15 to 0.29

WHOQOL physical	0.126	1	0.31	-0.09 to 0.72	0.17	-0.05 to 0.39
WHOQOL psychological	0.544	1	0.11	-0.25 to 0.46	0.07	-0.15 to 0.29
WHOQOL social	0.165	1	0.36	-0.15 to 0.87	0.16	-0.06 to 0.38
WHOQOL environmental	0.607	1	0.09	-0.24 to 0.41	0.06	-0.16 to 0.28
EQ5D3L index	0.858	1	0	-0.05 to 0.04	- 0.02	-0.24 to 0.2
EQ5D Visual Analogue Scale	0.009	0.147	4.72	1.21 to 8.24	0.3	0.08 to 0.52

## Appendix 10. Within-group analysis for the cognitive rehabilitation group

Table 63. ANCOVA Summary table for BGSi ratings without imputations

(a) Three-month follow-up

<b>Measure</b>	<b>p</b>	<b>Adjusted p</b>	<b>Mean difference</b>	<b>95% CI for mean difference</b>	<b>d</b>	<b>95% CI for d</b>
Participant rating of attainment	<0.001	<0.001	1.71	1.32 to 2.1	0.91	0.7 to 1.13
Participant rating of satisfaction	<0.001	<0.001	1.56	1.14 to 1.98	0.78	0.56 to 0.99
Carer rating of attainment	<0.001	<0.001	1.89	1.51 to 2.28	1.03	0.81 to 1.25

(b) Nine-month follow-up

<b>Measure</b>	<b>p</b>	<b>Adjusted p</b>	<b>Mean difference</b>	<b>95% CI for mean difference</b>	<b>d</b>	<b>95% CI for d</b>
Participant rating of attainment	<0.001	<0.001	1.81	1.34 to 2.28	0.86	0.63 to 1.09
Participant rating of satisfaction	<0.001	<0.001	1.69	1.21 to 2.17	0.78	0.55 to 1.01
Carer rating of attainment	<0.001	<0.001	1.85	1.38 to 2.31	0.88	0.65 to 1.11

Table 64. ANCOVA summary table for analysis of secondary outcomes without imputations

(a) Three-month follow-up

Measure	p	Adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
<b>Participants with dementia</b>						
DEMQOL	0.505	1	0.59	-1.14 to 2.31	0.07	-0.14 to 0.28
GSES	0.157	1	0.65	-0.25 to 1.56	0.15	-0.06 to 0.36
HADS	0.659	1	-0.2	-1.07 to 0.68	-0.05	-0.25 to 0.16
RBMT immediate recall	0.259	1	0.22	-0.16 to 0.6	0.12	-0.09 to 0.33
RBMT delayed recall	0.668	1	0.07	-0.27 to 0.41	0.05	-0.16 to 0.25
TEA elevator counting	0.391	1	0.1	-0.13 to 0.32	0.09	-0.12 to 0.3
TEA elevator counting with distraction	0.427	1	0.21	-0.31 to 0.73	0.08	-0.12 to 0.29
DKEFS verbal fluency	0.924	1	0.07	-1.35 to 1.49	0.01	-0.2 to 0.22
<b>Carers</b>						
RSS	0.362	1	-0.59	-1.87 to 0.68	-0.1	-0.3 to 0.11
WHOQOL physical	0.171	1	0.23	-0.1 to 0.55	0.15	-0.06 to 0.35
WHOQOL psychological	0.133	1	0.25	-0.08 to 0.57	0.16	-0.05 to 0.37
WHOQOL social	0.930	1	-0.02	-0.46 to 0.42	-0.01	-0.22 to 0.2

WHOQOL environmental	0.029	0.488	0.33	0.03 to 0.63	0.23	0.03 to 0.44
EQ5D3L index	0.189	1	0.02	-0.01 to 0.06	0.14	-0.07 to 0.35
EQ5D Visual Analogue Scale	0.153	1	2.72	-1.02 to 6.47	0.15	-0.06 to 0.36

(b) Nine-month follow-up

Measure	p	Adjusted p	Mean difference	95% CI for mean difference	d	95% CI for d
<b>Participants with dementia</b>						
DEMQOL	0.254	1	1.23	-0.89 to 3.36	0.13	-0.09 to 0.35
GSES	0.357	1	0.48	-0.54 to 1.5	0.1	-0.12 to 0.32
HADS	0.121	1	0.76	-0.2 to 1.72	0.18	-0.05 to 0.4
RBMT immediate recall	0.704	1	0.08	-0.32 to 0.47	0.04	-0.18 to 0.26
RBMT delayed recall	0.335	1	-0.18	-0.54 to 0.19	-0.11	-0.33 to 0.11
TEA elevator counting	0.764	1	-0.04	-0.33 to 0.24	-0.03	-0.25 to 0.19
TEA elevator counting with distraction	0.176	1	0.38	-0.17 to 0.93	0.15	-0.07 to 0.37
DKEFS verbal fluency	0.679	1	0.36	-1.34 to 2.05	0.05	-0.17 to 0.27
<b>Carers</b>						
RSS	0.529	1	0.44	-0.93 to 1.81	0.07	-0.15 to 0.29

WHOQOL physical	0.126	1	0.31	-0.09 to 0.72	0.17	-0.05 to 0.39
WHOQOL psychological	0.544	1	0.11	-0.25 to 0.46	0.07	-0.15 to 0.29
WHOQOL social	0.165	1	0.36	-0.15 to 0.87	0.16	-0.06 to 0.38
WHOQOL environmental	0.607	1	0.09	-0.24 to 0.41	0.06	-0.16 to 0.28
EQ5D3L index	0.858	1	0	-0.05 to 0.04	- 0.02	-0.24 to 0.2
EQ5D Visual Analogue Scale	0.009	0.147	4.72	1.21 to 8.24	0.3	0.08 to 0.52

### Appendix 11. Effectiveness of blinding

Table 65. Researchers' accuracy in estimating group allocation at follow-up assessments

(a) Three-month follow-up (n=444)

Researcher estimates	Whole sample		CR		TAU	
	n	%	n	%	n	%
Incorrect estimation	86	19.3	64	29.4	22	9.7
Correct estimation	358	80.4	154	70.6	204	89.9

(b) Nine-month follow-up (n=426)

Researcher estimates	Whole sample		CR		TAU	
	n	%	n	%	n	%
Incorrect estimation	93	21.8	66	31.7	27	12.4
Correct estimation	333	78.2	142	68.3	191	87.6

Table 66. Researchers' responses regarding their estimations of group allocation for each participant at three-month follow-up

Questions asked of researchers	Whole sample (n=444)	CR (n=218)	TAU (n=226)
Which condition the researcher thought the PwD had been allocated to:			
Indicated CR	176 (39.6)	154 (70.6)	22 (9.7)
Indicated TAU	268 (60.2)	64 (29.4)	204 (89.9)
How confident/certain was the researcher of their judgment about group allocation:			
Very uncertain (complete guess)	81 (18.2)	43 (19.7)	38 (16.7)
Uncertain	148 (33.3)	73 (33.5)	75 (33.0)
Quite certain	141 (31.7)	57 (26.1)	84 (37.0)
Very certain	74 (16.6)	45 (20.6)	29 (12.8)

Did the participant make the group allocation explicit to the researcher:			
Yes	66 (14.8)	44 (20.2)	22 (9.7)
No	378 (84.9)	174 (79.8)	204 (89.9)
Were there any indirect clues about group allocation? (e.g. new adaptations at home):			
Yes	37 (8.3)	33 (15.1)	4 (1.8)
No	407 (91.5)	185 (84.9)	222 (97.8)
Were the responses to these questions influenced by change/no change in the participant's goal performance rating:			
Yes	215 (48.3)	93 (42.7)	122 (53.7)
No	229 (51.5)	125 (57.3)	104 (45.8)

*Data are n (%)*

Table 67. Researchers' responses regarding their estimations of group allocation for each participant at nine-month follow-up

<b>Questions asked of researchers</b>	<b>Whole sample (n=426)</b>	<b>CR (n= 208)</b>	<b>TAU (n=218)</b>
Which condition the researcher thought the PwD had been allocated to:			
Indicated CR	169 (39.7)	142 (68.3)	27 (12.4)
Indicated TAU	257 (60.3)	66 (31.7)	191 (87.6)
How confident/certain was the researcher of their judgment about group allocation:			
Very uncertain (complete guess)	63 (14.8)	31 (14.9)	32 (14.7)
Uncertain	149 (35.0)	66 (31.7)	83 (38.1)
Quite certain	130 (30.5)	54 (26.0)	76 (34.9)
Very certain	84 (19.7)	57 (27.4)	27 (12.4)
Did the participant make the group allocation explicit to the researcher:			
Yes	71 (16.7)	54 (26.0)	17 (7.8)
No	355 (83.3)	154 (74.0)	201 (92.2)
Were there any indirect clues about group allocation? (e.g. new adaptations at home):			
Yes	38 (8.9)	32 (15.4)	6 (2.8)
No	388 (91.1)	176 (84.6)	212 (97.2)
Were the responses to these questions influenced by change/no change in the participant's goal performance rating:			
	n=425	n=207	
Yes	188 (44.2)	84 (40.6)	104 (47.7)
No	237 (55.8)	123 (59.4)	114 (52.3)

*Data are n (%)*

Table 68. Researchers' responses regarding blinding effectiveness at three months where blinding was either effective or ineffective

<b>Question</b>	<b>Blinding ineffective (n= 358)</b>	<b>Blinding effective (n=86)</b>
Which condition the researcher thought the PwD had been allocated to:		
Indicated CR	154 (43.0)	22 (25.6)
Indicated TAU	204 (57.0)	64 (74.4)
How confident/certain was the researcher of their judgment about group allocation:		
Very uncertain (complete guess)	52 (14.5)	29 (33.7)
Uncertain	112 (31.3)	36 (41.9)
Quite certain	121 (33.8)	20 (23.3)
Very certain	73 (20.4)	1 (1.2)
Did the participant make the group allocation explicit to the researcher:		
Yes	66 (18.4)	0 (0)
No	292 (81.6)	86 (100.0)
Were there any indirect clues about group allocation? (e.g. new adaptations at home):		
Yes	35 (9.8)	2 (2.3)
No	323 (90.2)	84 (97.7)
Were the responses to these questions influenced by change/no change in the participant's goal performance rating:		
Yes	183 (51.1)	32 (37.2)
No	175 (48.9)	54 (62.8)

Data are n (%)

Table 69. Researchers' responses regarding blinding effectiveness at nine months where blinding was either effective or ineffective

<b>Question</b>	<b>Blinding ineffective (n= 333)</b>	<b>Blinding effective (n=93)</b>
Which condition the researcher thought the PwD had been allocated to:		
Indicated CR	142 (42.6)	27 (29.0)
Indicated TAU	191 (57.4)	66 (71.0)
How confident/certain was the researcher of their judgment about group allocation:		
Very uncertain (complete guess)	44 (13.2)	19 (20.4)
Uncertain	105 (31.5)	44 (47.3)
Quite certain	107 (32.1)	23 (24.7)
Very certain	77 (23.1)	7 (7.5)
Have the participants made the group allocation explicit to the researcher:		
Yes	70 (21.0)	1 (1.1)
No	263 (79.0)	92 (98.9)
Were there any indirect clues about group allocation? (e.g. new adaptations at home):		
Yes	34 (10.2)	4 (4.3)
No	299 (89.8)	89 (95.7)
Were the responses to these questions influenced by change/no change in the participant's goal performance rating:		
Yes	154 (46.4)	34 (36.6)
No	178 (53.6)	59 (63.4)

Data are n (%)

## Appendix 12. Relationship of adherence to outcome

Table 70. Analyses examining whether adherence (number of sessions completed) was associated with outcome

(a) Three-month follow-up

	Estimate	Std. Error	df	t value	p value	95% CI Limits
<b>Primary outcomes</b>						
Participant rating of attainment	0.17	0.09	215	2.01	0.046	0 to 0.34
Participant rating of satisfaction	0.15	0.09	215	1.8	0.073	-0.01 to 0.32
Carer rating of attainment	0.21	0.08	213	2.46	0.015	0.04 to 0.37
<b>Secondary outcomes - Participants with dementia</b>						
DEMQOL	-0.3	0.37	214	-0.81	0.421	-1.02 to 0.43
GSES	-0.33	0.18	211	-1.8	0.073	-0.69 to 0.03
HADS depression	0.14	0.12	213	1.18	0.241	-0.09 to 0.37
HADS anxiety	0.02	0.1	215	0.23	0.816	-0.18 to 0.23
RBMT immediate recall	-0.03	0.07	214	-0.36	0.722	-0.16 to 0.11
RBMT delayed recall	0	0.06	213	-0.01	0.995	-0.12 to 0.12
TEA elevator counting	0.07	0.05	207	1.44	0.151	-0.03 to 0.17
TEA elevator counting with distraction	0	0.11	190	-0.04	0.971	-0.22 to 0.21
DKEFS verbal fluency	0.2	0.28	211	0.72	0.472	-0.35 to 0.74
<b>Secondary outcomes - Carers</b>						
RSS	-0.1	0.25	208	-0.39	0.698	-0.6 to 0.40
WHOQOL physical	0.03	0.08	209	0.35	0.729	-0.13 to 0.18
WHOQOL psychological	0.04	0.07	209	0.65	0.516	-0.09 to 0.18
WHOQOL social	0.1	0.09	208	1.09	0.278	-0.08 to 0.27
WHOQOL environmental	-0.04	0.06	209	-0.65	0.514	-0.16 to 0.08
EQ5D3L index	0	0.01	204	0.62	0.535	-0.01 to 0.02
EQ5D3L VAS	-0.73	0.79	205	-0.92	0.361	-2.29 to 0.84

## (b) Nine-month follow-up

	<b>Estimate</b>	<b>Std. Error</b>	<b>df</b>	<b>t value</b>	<b>p value</b>	<b>95% CI Limits</b>
<b>Primary outcomes</b>						
Participant rating of attainment	0.24	0.1	202	2.36	0.019	0.04 to 0.44
Participant rating of satisfaction	0.25	0.11	200	2.33	0.021	0.04 to 0.47
Carer rating of attainment	0.28	0.1	201	2.68	0.008	0.07 to 0.48
<b>Secondary outcomes - Participants with dementia</b>						
DEMQOL	-0.43	0.44	200	-0.98	0.329	-1.3 to 0.44
GSES	-0.38	0.25	190	-1.54	0.126	-0.86 to 0.11
HADS depression	-0.06	0.15	190	-0.43	0.671	-0.36 to 0.23
HADS anxiety	-0.04	0.12	191	-0.3	0.763	-0.28 to 0.21
RBMT immediate recall	-0.07	0.08	197	-0.89	0.376	-0.24 to 0.09
RBMT delayed recall	-0.01	0.06	197	-0.16	0.874	-0.14 to 0.12
TEA elevator counting	-0.1	0.07	186	-1.4	0.162	-0.23 to 0.04
TEA elevator counting with distraction	0.1	0.13	168	0.72	0.472	-0.17 to 0.36
DKEFS verbal fluency	0.25	0.36	193	0.71	0.481	-0.46 to 0.96
<b>Secondary outcomes - Carers</b>						
RSS	0.09	0.28	197	0.32	0.749	-0.47 to 0.65
WHOQOL physical	0	0.01	194	-0.44	0.657	-0.02 to 0.01
WHOQOL psychological	-1.55	0.78	193	-1.98	0.049	-3.09 to -0.01
WHOQOL social	-0.06	0.08	196	-0.79	0.432	-0.22 to 0.09
WHOQOL environmental	-0.06	0.07	196	-0.81	0.419	-0.2 to 0.08
EQ5D3L index	-0.14	0.1	194	-1.4	0.164	-0.34 to 0.06
EQ5D3L VAS	-0.12	0.07	196	-1.81	0.071	-0.25 to 0.01

### **Appendix 13. Four case studies from the GREAT trial**

Four illustrative case studies from the GREAT trial show the kinds of needs and concerns that prompted participants and carers to choose particular goals and demonstrate how the therapists worked with participants and carers to address their goals during the cognitive rehabilitation intervention. Names and identifying details have been changed.

#### **David: overcoming anxiety to maintain independence**

David, a retired factory worker aged 70, lived with his wife Julie on the outskirts of a small town. Both were involved in numerous community activities. David had been diagnosed with Alzheimer's disease a few months prior to joining the trial.

Although quite capable in everyday activities and household tasks, David was afraid to use appliances of any kind for fear of making a mistake and getting things wrong. He found this tremendously frustrating. It was severely compromising his independence, and his increasing reliance on Julie was causing friction between them. Julie felt frustrated when she tried unsuccessfully to explain how things worked, and she regretted that at times she could be very impatient with David. At the same time, she felt that David was capable of managing better, and that she should be pushing him to do more for himself. David and Julie wanted to work on this area of difficulty.

The therapist's assessment showed that David had the capacity to manage daily activities with only a small amount of guidance or support, but was functioning considerably below this level. David's anxiety needed to be understood in the context of his previous experience of episodes of anxiety and depression, and the therapist noted that he was currently taking anti-depressants to try to stabilise his mood. The results of his cognitive tests indicated that he would be able to direct his attention to a task or activity, but would need extra support with taking in information or remembering instructions, as it would be difficult for him to take in and retain information or instructions given verbally, especially if the surroundings were distracting. Although David was worried about his memory, the therapist found that he had some good strategies for managing memory difficulties; for example, when he needed to learn new songs for the choir he belonged to, he would break down the lyrics and learn a

couple of lines at a time, building up to the whole song. This suggested that David had good potential to develop new ways of coping and should be able to learn to overcome his anxiety and manage to use various appliances. Both David and Julie were keen to try out any strategies that might help. The therapist's work with David and Julie therefore focused mainly on enabling David to achieve his aim of being able to use various appliances without experiencing crippling levels of anxiety, with the wider aim of allowing him to function more independently.

We illustrate this here in relation to one of the goals, which was for David to be able to use his mobile phone whenever he wanted or needed to. Being able to use the mobile phone would give David confidence to be out and about on his own, either to do shopping or errands or to participate in his chosen activities, knowing that he could contact Julie if he needed to. At the start of therapy, David could 'wake up' the phone and display the contacts list on the screen, but could not get beyond this step as he developed feelings of panic at the thought that he might do the wrong thing and then the phone would not work at all. David, Julie and the therapist all independently rated his current use of the phone at 2 out of 10. Julie was sceptical that any progress could be made as she had already obtained a simple 'Doro' phone for David and tried to teach him to use it, without success, but the therapist convinced her that it was worth trying to apply more specific learning techniques.

The first priority was to find a way to reduce David's extreme anxiety. This was done by identifying a single key-press that would always take David back to the main menu if necessary. The phone had two smart keys. One of these was for cancelling choices and returning to the main menu; David and the therapist called this the 'No, go back' key. The other was for confirming choices on the display; David and the therapist labelled this the 'Yes, go ahead' key. The therapist initially taught David, using action based learning with spaced retrieval, the functions of two smart keys on the phone. The left-hand key was designated 'yes', and the right-hand key 'no, go back'. David was encouraged to use the 'No, go back' key to return to the main menu at any time, so that he did not need to fear that he would make a mistake.

Once the use of the 'No, go back' key was well-established, the therapist and David identified the different ways in which David needed to use the phone. Initially the focus was on receiving and making calls, and this was later extended to receiving and sending texts.

Each activity was taught in sequence, with an appropriate set of learning strategies applied. The therapist worked with David to list the steps involved in the activity, and develop step-by-step instructions that made sense to David. David had to engage in thinking about each step, and write down the instructions for himself, reflecting effortful processing of the information. He kept these instructions together in a folder that he could refer to at any time.

Using an action learning approach, each step was taught in turn, with the therapist demonstrating the actions needed and David repeating them, using an expanding rehearsal approach with practice spaced at gradually increasing intervals. David was encouraged to practise in a quiet environment without distractions, and allow plenty of time in order to help him stay focussed. Simple steps were taught first and more complex ones later, following the principle of graded activity. For example, David first learned to access the text screen and then when he was confident in doing this he learned to write a text. This was followed, in sequence, by learning to sending the text, then receiving a text and reading it. David then practised the full sequence of steps, including sending texts to the therapist between sessions and receiving texts from the therapist. As David became more confident Julie demonstrated how to add punctuation to his text messages, and taught him how to delete old messages. She did this using expanding rehearsal strategies, focusing on one instruction at a time.

Having learned how to carry out a task such as making a call, the next stage involved gaining confidence in using the phone through graded exposure to increasingly demanding situations. David began to practise using the phone in the house. First he used it in staged situations, such as making a test call to Julie or to the therapist, and then moved on to using it for real-life purposes, such as making a call about one of his activities or to a company representative. David then practised using the phone while out in the garden, with Julie on standby in the house in case he needed help. Finally, he practised using the phone while he was out and about, initially contacting the therapist and then using it for real-life purposes. . Julie helped by identifying situations where David could use the phone and encouraging him to do so. Julie gave verbal prompts to ensure that David took his phone with him and had switched it on before leaving the house; these prompts were gradually faded out as the routine became established.

At this stage one last issue emerged. Now that David had largely mastered the skills of using his phone, he needed to remember to always take it with him when he went out, so that he

could contact Julie if needed. A solution-focused problem solving approach was used to develop a strategy to help David remember to take the phone with him. The method David and the therapist selected involved creating a cue card as a reminder. When going out he usually remembered to take his bus pass and his wallet, both of which he kept in the same specific place, so the cue card was placed in the same location. The card contained the mnemonic BMW, standing for Bus pass, Mobile phone and Wallet and had “*I’m taking the BMW*” written on it. David first had to learn the mnemonic and this was achieved by Julie prompting him twice daily, with the prompts gradually faded out once David was reliably able to respond.

By the end of the intervention period, David, Julie and the therapist all found that David’s ability to use the mobile phone had improved considerably. David and Julie both rated his ability to use the phone as 7 out of 10, and the therapist as 8 out of 10. David’s ability and confidence continued to improve throughout the six-month maintenance period, as he regularly practised his new skills. He still experienced occasional anxiety, but was much better able to manage it. In session 14 David and Julie both gave attainment ratings of 8 out of 10 and the therapist rated his goal attainment as 9 out of 10. Using pre-defined goal attainment descriptors, the therapist rated the goal as 100% achieved in both session 10 and session 14, as David was able to use the phone routinely to make and receive calls and return to the home screen when any difficulties arose, and in addition he was using the phone to send and reply to texts.

During the therapy David and Julie also worked on David’s ability to use other appliances independently and similar improvements were seen in these other areas. Julie gained some valuable new skills to help with learning and re-learning, and during the course of the therapy she applied these to help David learn to use the cooker and washing machine, using compensatory strategies such as colour-coding controls.

At the end of therapy, David said that his ‘*fear has gone*’. The anxiety around using appliances had considerably abated and he was much less afraid of making mistakes. David felt more confident to try things out and gain new skills, knowing that he could determine how to learn at his own pace. Julie felt she had become more willing to allow him to complete activities at his own pace and much more patient with him, which meant there were fewer tensions between them.

## **Doris – staying safe and in control**

Doris, aged 63, lived independently in an inner-city area. She had a large extended family, many of whom would call in during the course of each day. Doris said she had been experiencing memory problems for about four years, and these had worsened considerably over the past two years. She been diagnosed with vascular dementia within the previous month. Her eldest daughter, Dawn, was the main carer, and was very protective of Doris, being justifiably concerned about her safety. Dawn frequently expressed anger about other family members who she felt were not doing enough to support her. Doris also frequently dealt with her feelings of stress by expressing anger at Dawn and other family members.

Doris valued her independence and it was important to her to feel in control. She was worried about her difficulties with memory and decision-making, found that her thoughts were muddled, and felt she had trouble making herself understood. She often experienced feelings of fear, even panic, as if something awful was about to happen, and was especially anxious in new situations or situations where something was expected of her. She used to be very sociable and outgoing, and enjoyed going into town or to the pub, but was now uncomfortable in crowds and had almost completely stopped going out alone. Even going along the road to the local post office could produce feelings of panic, which Doris could not account for.

The therapist's work with Doris focused largely on enabling her to safely remain in control and be as independent as possible, both in and out of the house. Doris readily adopted the problem-solving approach; she considered solving problems one of her particular strengths. One important consideration for the therapist was the discovery that Doris had struggled at school as a child and had never learned to read or write, other than her name.

Doris usually forgot to lock her door when she went out or went to bed, creating a security risk, and Doris and Dawn agreed this was an important goal to work on. They, and the therapist, all scored current attainment at 1 out of 10. The therapist worked with Doris to rehearse the procedure of locking the doors, followed by telephoning Dawn to confirm she had done it, using an action learning approach. To stimulate this behaviour, visual prompts were created consisting of a photograph of the door keys, and these were placed next to the front door, in the living room and at the top of the stairs where Doris transferred off the stair

lift. Family members were asked to prompt Doris to lock the door whenever they were leaving at the end of a visit, and to telephone Doris at night to remind her to lock the door before going to bed, although this did not happen consistently. In session 10 Doris and her daughter both rated attainment as 6 out of 10 and the therapist as 7. All these ratings increased to 8 out of 10 at session 14, and at this stage the therapist rated this goal as 75% achieved since Doris was mostly locking the door independently but still required some prompting on occasion.

Doris used a cash machine at the local post office to withdraw money, but found this anxiety-provoking and was unable to remember the PIN number she had to enter into the cash machine to retrieve her money, describing herself as 'stupid'. She had written the number on a piece of paper and placed it in her purse under a clear plastic window visible on opening the purse. This was very unsafe especially as she tended to misplace her purse. She was increasingly anxious about using her card and inclined to avoid going altogether. Instead, family members had started to withdraw money on her behalf. Current attainment was rated by Doris, Dawn and the therapist as 1 out of 10. Doris could recognise numbers and indeed was considered to be 'good with numbers', and the therapist judged that she was capable of learning the PIN number to enable her to use her bank card independently while removing the risk of financial exploitation. She herself was very motivated to work on this as she found it important to be in control of her finances and saw this as a marker of independence. This was a sensitive area, however, for the therapist to work with, and one that required extra safeguards. The approach to be taken was discussed in depth with Doris, with her family, and with the trial team. Doris was deemed to have capacity both to choose the goal and to give an opinion about the proposed strategy; had there been concerns about capacity for these specific decisions then a best interests decision would have been needed. It might have been possible to indirectly through the carer, but Doris's daughter preferred the therapist to work on this goal directly with Doris rather than providing her with strategies to assist Doris and guidance on implementing them. In weighing up all of these factors, everyone involved agreed that given the risks Doris was exposed to currently, sharing the PIN number with the therapist represented a safer option and in this instance the best way to proceed. Full details of the circumstances and the team's discussions were also recorded in Doris's clinical notes held by the NHS memory service.

To help Doris learn the PIN number, the number was first changed to something that would be relatively easy to remember. Chunking the information meant that initially the first two numbers were learned using expanding rehearsal, followed by the second two numbers, and finally all four digits. Visual mapping of the numbers on the key pad was attempted using action-based learning to set up a habitual pattern of movement. By session 10 Doris and Dawn rated attainment as 5 out of 10, with the therapist selecting 6 out of 10.

The therapist introduced controlled breathing techniques that Doris thought she could put into practice quickly and effectively. Doris understood the principles of controlled breathing and was able to demonstrate the technique when relaxed but found it hard to put the technique into practice when she was anxious. Dawn and Doris used solution-focused problem solving to identify ways of reducing anxiety about going to the post office and fear of experiencing a panic attack; this included identifying the days and times when the post office was quiet and planning to go at these specific times so Doris could use her card independently without feeling rushed. A plan for graded exposure was followed whereby Doris gradually increased the frequency of visits to the post office to practise using her card. By session 14, Doris could reliably remember her PIN number and Doris, Dawn and the therapist rated attainment as 10 out of 10, with the goal rated as 100% achieved. Doris continued to work on managing her anxiety about going to the post office.

Other work focused on ensuring Doris remembered to have her mobile phone with her at all times so that she could be in contact with her family while retaining her independence. Everyone was concerned that she might fall or otherwise need help and wanted to make sure she could summon help if needed. This was achieved by using visual prompts to remind Doris to take her phone with her when going out and return it to a designated place in the house when indoors. Doris made good use of these strategies and her family felt reassured about her safety.

The therapist spent time with Dawn to help her understand and deal with Doris' behaviour and to point her towards local resources for carers. As a consequence, Dawn established an extensive network to support Doris' needs, identified some sources of support for herself and started to allocate time for her own needs. Dawn was very engaged in the intervention and provided considerable support with grading activity and prompting the use of anxiety management strategies. Following the intervention she felt she had a better understanding of

Doris' abilities, and began to apply similar principles to other situations, such as helping Doris to create and use her own shopping lists using visual prompts such as collecting and storing product labels. Dawn was very positive about Doris' progress with goals, development of compensatory strategies and general increase in motivation, and felt that participation had been beneficial in terms of helping Doris to maximise goal attainment and maintain independence and well-being.

Doris and Dawn both felt they had always been 'problem solvers' but they found the framework for solution-focused problem-solving used in the intervention particularly useful in that it gave consideration to what had worked in the past. This enabled them to identify and develop strategies to maximise Doris' independence, self-efficacy and self-esteem and apply these to a range of situations, as well as bringing the family together to support Doris' goal attainment.

### **Shahid – re-engaging with people and activities**

Shahid, aged 77, had worked in marketing prior to retirement. He lived with his wife Sylvia near to their daughter and grandchildren. He had previously been actively involved in his local community and an accomplished public speaker. He was a keen photographer, but had not done any photography for over a year. Shahid had been diagnosed with Alzheimer's disease about two months before joining the trial.

Shahid had lost confidence and had become anxious about engaging with people and activities. One reason for this was his difficulty with word-finding, which made it hard to engage in conversation. He sometimes had trouble finding the correct words to use, which interrupted his flow of speech, and this led to him feeling embarrassed and getting quite frustrated and annoyed with himself. Often Sylvia would supply the word for him, but sometimes she was unsure of the word he was searching for, leading to more frustration. He wanted to be able to speak fluently again, and in particular he wanted to find the right word during a conversation to enable him to participate. Shahid also wanted to take up photography again, and meet up with other photographers. However, he was confused and unsure about how to manage the camera settings and lacked the confidence to try.

The therapist's assessment showed that Shahid was able to carry out most activities independently but he had difficulty motivating himself or initiating activity, and occasionally needed reminding about self-care. He was worried and anxious about his poor memory and lack of concentration, and had become quite withdrawn and reluctant to participate in social interactions.

The therapist's work with Shahid focused on helping him to feel more confident about engaging with people and activities. The first priority was to help Shahid feel better able to find his words during a conversation and hence less anxious about engaging with people. Initially Shahid and Sylvia rated his current attainment as 5 out of 10, while the therapist opted for 4 out of 10. This indicated that his ability in conversation was fair, but reflected his desire for improvement.

The therapist, Shahid and Sylvia developed a plan to tackle word-finding problems. This had several elements. The first involved effortful processing and errorless learning. Instead of supplying the missing word, Sylvia instead gave either a cue, such as the first letter, or a clue to help Shahid find the word, so that he was more likely to retrieve the correct word himself. The cues or clues were intended to be precise enough to prompt the desired word, increasing the probability that this would also be recalled in future; this provided a natural opportunity for errorless learning.

The second involved providing support for naming everyday items and objects. Items around the room were labelled to encourage Shahid to associate each object with its name, and he practised naming both labelled and unlabelled items when requested by Sylvia. The therapist prepared a set of picture cards and Shahid practised naming the items depicted, with Sylvia's help. As Shahid gained confidence with naming the objects, these activities were graded by gradually increasing the number of items shown in any one session and by presenting them at greater speed.

The third element was the use of word exercises. These were practised during the session and further examples were left for Shahid and Sylvia to practise between sessions. Several different types of exercises were used, including supplying missing words in a sentence, providing antonyms or synonyms, listing items under a given category (e.g. modes of

transport), identifying similarities and differences between pairs of words, and answering comprehension questions about short stories.

The fourth element involved devising specific strategies for particular words or types of words. Shahid developed mnemonics and used expanding rehearsal within an errorless learning framework to remember specific words that often eluded him.

Shahid seemed to enjoy focusing on word-finding and doing the various exercises, and made good progress. Sylvia became adept at providing cues or clues whenever he was unable to retrieve a word. By session 10, Shahid felt much better able to engage in conversation, and no longer saw word-finding or engaging in conversation as a problem. Shahid and Sylvia both rated his attainment as 8 out of 10. The therapist observed that his conversation was much more fluent and rated his attainment as 9 out of 10. Shahid kept up his progress and the ratings made in session 14 were identical. The therapist rated the goal as 100% achieved in both session 10 and session 14, noting that Shahid was more confident about his word-finding ability and was usually able to find the necessary word and able to continue a conversation.

During the therapy, Shahid also worked on re-engaging with his interest in photography. There were technical issues with managing camera settings and using digital cameras, and Shahid preferred to discuss these with his son rather than with the therapist. The therapist's role was to encourage Shahid to persist with solving the problems. The eventual solution was to provide Shahid with a phone that had a good quality camera and was easy to link to his computer and TV screen to download and show images. This did enable Shahid to take photographs, and the good results that ensued gave him confidence and motivated him to continue. Holidays and visits to family provided interesting photographic opportunities, and he was able to produce some good photographs. Ratings of attainment improved from 2 at the start of therapy to 8 in session 10 and 9 (Shahid and Sylvia) or 10 (therapist) in session 14. The therapist identified this goal as 75% achieved by session 10 and 100% achieved by session 14.

Shahid also developed his use of compensatory strategies such as using a calendar to remember appointments, and began to carry a small notebook in his pocket containing a daily 'to do' list. This increased self-determination was mirrored by Sylvia offering prompts rather

than doing things for him. He learned a strategy of intentional chanting for times when he might get distracted or interrupted, for example when going upstairs to fetch something, and practised various anxiety management strategies before settling on using music to calm himself. He managed to motivate himself to clear his computer room and make space for working on his photographs, and this increased motivation also extended to getting other tasks done around the house. Shahid and Sylvia both became more active, developing a routine of playing golf once a week and going for a walk together once a week.

### **Gareth - managing everyday challenges**

Gareth, a 71-year-old widower, had retired from a skilled technical job a few years previously. He lived independently and kept in contact with his daughters and grandchildren mainly by telephone, although they lived nearby. Gareth had been diagnosed with mixed Alzheimer's disease and vascular dementia three months before joining the trial. He also had some other health problems which meant he needed to eat regularly and keep to a healthy diet, and which limited his physical ability. His main source of support was his eldest daughter Ginny.

Gareth was troubled by difficulties with concentrating, planning and organising his activities, remembering appointments, remembering things he needed to do such as taking his medication, and finding key items such as keys, wallet or phone. His strategy of using a Dictaphone to record notes and messages was only partially successful. These difficulties were making it hard for him to complete everyday tasks independently and safely, manage his health problems, and participate in social events. Gareth was particularly frustrated by his difficulties with planning and the impact these were having on his everyday life. He and Ginny identified some basic everyday skills where improvements would help him to maintain independence and reduce the need to rely on Ginny. The therapist's assessment showed that while Gareth had the potential to manage many activities and tasks independently he needed some practical guidance and support to enable him to function optimally.

The therapist's work with Gareth focused on improving everyday skills to support his independence. The first priority was cooking. Gareth prepared his own meals but tended to lose track of what he was doing and forget that food was in the oven. This meant that food was often burnt and inedible. To make matters worse, Gareth had lost his sense of smell, so

that he could not detect the olfactory cues associated with food overcooking. Gareth often felt tired and would leave the kitchen to sit down comfortably while food was cooking, but he was hard of hearing, so that if he was not in the kitchen he did not hear the oven timer. In addition he often fell asleep while waiting for food to be ready and then woke up feeling confused about what he had been doing or what he needed to do. When Gareth was in the kitchen, his tendency to lose track meant that he often picked up trays or plates from the oven without realising they were hot and burnt himself, and there was a risk of the gas hob being turned on but unlit. Because of these difficulties, Gareth was limiting the extent to which he cooked for himself, either eating out, which was proving too expensive, or just having snacks. Gareth was keen to manage his cooking better and Ginny was very concerned about his safety, wanting to make sure he was able to eat a healthy diet without hurting himself or setting fire to the kitchen. Gareth, Ginny and the therapist rated Gareth's current ability in cooking his own meals at 4 out of 10.

The strategy that Gareth and the therapist devised involved two main components. Firstly, Gareth was encouraged to focus his attention on the process of planning the meal and work through a series of steps, reading the food packaging, writing down the cooking instructions, listing what preparation was needed, and then recording what time the food went into the oven and when it was due to be ready. For this Gareth used a whiteboard in the kitchen. Secondly, a portable timer was introduced to provide an auditory cue to check the oven at the appropriate time. Gareth learned to take the whiteboard and timer with him when leaving the kitchen, so that he would be able to hear it if he was in another room or if he fell asleep. Gareth opted to set the alarm to go off shortly before the food was due to be ready as this gave him time to get to the kitchen.

One additional practical change that the therapist recommended and Gareth and Ginny followed up was to purchase a halogen work-top cooker that turned off automatically, to remove safety concerns about leaving the gas on. This was intended to replace using the oven as it had a built in timer and so turns itself off and 'beeps' when done. Gareth had no difficulty adjusting to using this and was able to demonstrate to therapist how it worked. The therapist also involved Telecare for an assessment of gas safety and provision of additional sensors, over and above Gareth's two functioning smoke detectors.

Gareth could see an immediate improvement as a result of using the whiteboard and timer and readily adopted the use of these aids. By week 10 he was cooking meals safely without burning the food. He now cooked for himself at home most days. Having got used to the halogen cooker, Gareth gained confidence in using the hob to boil vegetables, and rediscovered how to use the microwave. At both session 10 and session 14, Gareth rated his current ability as 7 out of 10, Ginny as 6 out of 10, and the therapist as 8 out of 10. The therapist rated this goal as 100% achieved in week 10.

A second area of concern for which similar strategies were adopted was remembering to take essential medication. Gareth had to take medication both morning and evening and while he usually remembered his morning regime he often forgot his evening medication, especially when he had been out during the day, potentially putting his health at risk. Some tablets were in a blister pack but others were not, which made it harder to determine whether or not a dose had been missed. Usually one of his daughters would telephone to remind him, but this was not always possible and was proving stressful for the family. Gareth rated his current functioning as 5 out of 10, Ginny as 6 and the therapist as 3.

The strategy adopted had several components. Firstly, a specific 'workstation' was set up on a table in the living room as the special place where medication would be taken. This was clearly visible from Gareth's favourite chair as this was where he usually went to take his tablets. The medication was placed permanently on the table along with a bottle of water, so that Gareth would always be able to see his medication and would not be distracted by leaving the room to get a drink of water. An attempt to link evening medication with an established routine such as watching the 6pm news on television was trialled but this was not effective as Gareth often went out in the evening, especially in the summer. As an alternative, an alarm clock was set for 7.30am and 7.30pm as an auditory cue to remind Gareth to take his morning and evening doses. Gareth chose the timing of the alarm himself as the one that best fitted with his routine, and the therapist taught Gareth to respond to the alarm clock cue by taking medication at the appropriate time. To adapt the strategy for use on days out, Gareth's mobile phone was also set to give an alarm at 7.30pm, and if going out Gareth took his medication with him in a small container. Gareth found the strategy very useful and when the alarm went off he would only cancel it after he had taken his tablets, to ensure that he did not get distracted. The therapist rated this goal as 75% achieved in week 10 and 100% achieved in week 14. Gareth rated his current ability as 8 in week 10 and 9 in week 14;

Ginny's ratings were 7 and 6 respectively and the therapist rated his ability as 8 and 10 respectively.

During the intervention Gareth also worked on other areas with the therapist, including remembering names of family and friends, staying engaged in conversation, and improving attention. He became anxious when confronted with tasks, events or activities for which he was not prepared; to manage this better, the therapist introduced the idea of using a wall calendar to write down appointments and messages and a notebook for details. The therapist modelled the use of these aids and enabled Gareth to incorporate them in his daily routine. Gareth himself used the problem-solving approach to tackle other challenges, such as keeping his paperwork in order, organising telecare documents and managing his financial information. He used filing boxes and made lists, and reviewed things weekly with Ginny to make sure everything was as it should be.

Gareth tended to get bored on his own at home and this was another area that the therapist focused on. Gareth's usual strategy for dealing with boredom was to go out for a drive but he did not like to drive in the dark or when the weather was bad. The therapist worked with Gareth to identify activities he could do at home to occupy himself in the evenings or during bad weather. Gareth was also encouraged to practise using public transport, to prepare for a time when driving may no longer be feasible, and he began to try using the bus instead of driving. As Gareth often felt lonely the therapist introduced him to the local Alzheimer's Society branch and he started to attend their groups and activities, which he engaged with enthusiastically, feeling that his social life had been greatly improved.

Gareth embraced the CR intervention, was enthusiastic about adopting a range of compensatory strategies, and integrated these very effectively into his daily life. He enjoyed working with the therapist and thought he would miss the regular visits. Ginny and his other daughters were equally enthusiastic and willing to try new ideas. They all gained skills in problem-solving and developing new strategies, and felt able to manage daily challenges better.

## **Concluding comments**

These four typical case studies taken from the therapy logs compiled by GREAT trial therapists illustrate the types of goals participants chose and the way in which participants, carers and therapists worked together to apply a problem-solving approach and develop strategies to enable participants to improve their functioning and attain their goals. They are consistent with the findings from the qualitative analysis of interviews with participants and carers. These emphasised the key importance of the relationship with the therapist as the vehicle for change, and the time taken to understand needs and develop personalised strategies.

## **Appendix 14. Feasibility of implementation**

In the later stages of the trial the GREAT team undertook to explore the feasibility of implementing the CR approach within NHS services. This was an opportunity to examine the challenges that could arise when translating the intervention to a real-world setting, and consider how these might be overcome to facilitate successful implementation. The aims of this feasibility project were:

- To explore how best to approach the training of staff to enable them to offer CR
- To explore how goal-oriented CR can best be incorporated into practice.
- To evaluate the effectiveness of the intervention for people with dementia and carers under these circumstances.
- To understand the views of the therapists delivering the intervention.
- To identify lessons learned to inform future implementation work.

Three sites were involved, Bangor, Birmingham and Kent.

### ***Implementation methods***

At the Bangor site, the Occupational Therapy Service within the BCUHB Older People's Mental Health Directorate expressed interest and was identified as a suitable service to provide the intervention. Occupational Therapists (OTs) and Technical Instructors (TIs) from the service attended a one-day training event in May 2016, facilitated by the GREAT therapist and researcher. Following training ten OTs and their linked TIs from different memory clinics across BCUHB offered the intervention to a total of eight service users. Based on early feedback from the OTs, the intervention was adapted from the ten sessions used in the trial so that it could be delivered in either six or eight sessions. Typically the OT undertook initial assessment and goal-setting, supervised the TI in conducting the intervention, and evaluated the outcome. Specialist supervision and support was provided to all OTs and TIs involved by the GREAT trial therapist with the support of the GREAT trial local PI.

At the Kent site, staff from Kent and Medway NHS Partnership Trust were offered a one and a half day training course. Six staff members completed the course, one OT, one OT assistant, two CPNs and two support workers. Following training, four staff members each worked with one service user and one worked with two; one did not implement CR due to

workload pressures. The intervention was offered in the form of six weekly sessions followed by two fortnightly sessions, with two fortnightly follow up telephone calls. Small group supervision was provided and specialist advice was available from the GREAT trial therapist on request. It should be noted that this site, having joined the GREAT trial at a late stage, overcame particular time constraints to join the feasibility study.

At the Birmingham site, eight OTs from Birmingham and Solihull Mental Health NHS Foundation Trust participated in training workshops and were keen to try out the approach in practice. However, around the time the workshops were delivered, the Trust unexpectedly introduced a reorganisation of work roles and proposed to downgrade all OTs, leading to uncertainty and loss of morale. As a result, the trained OTs were not in a position to proceed with the implementation pilot.

### ***Format of the intervention***

The intervention delivered during the feasibility pilot in Bangor and in Kent followed the key principles of the GREAT trial intervention: individualised, evidence-based rehabilitation, addressing needs through identification of personally-meaningful goals that were SMART (specific, measurable, attainable, realistic and time-bound). The core element involved work on up to two personally-meaningful therapy goals, based on a problem-solving approach and using compensatory and restorative strategies as appropriate. Additional content was provided in modular form and could be selected or omitted according to the needs of the person with dementia. These additional modules covered behavioural activation to increase activity levels, emotion regulation and anxiety management, improving attention and concentration, work on a further personal goal, identification of local sources of support, and a focus on carer well-being. In general, work focused mainly on personal goals, augmented by other approaches where relevant.

The service users receiving CR ranged in age from 58 to 90 years and were diagnosed with either Alzheimer's, vascular or mixed dementia. While the trial required involvement of a carer who could provide collateral information on progress and outcomes, in this clinical implementation we included people with dementia who did not have support available from a carer or friend.

### ***Outcomes for participants***

The CR therapists used the Bangor Goal-Setting Interview as a means of enabling participants to identify goals and eliciting ratings of progress towards goal attainment. Ratings for each goal were made independently by participants, carers (where available) and therapists at the start and end of therapy. To support the therapists in evaluating the intervention, at the initial assessment, participants completed the ACE-III and DEMQOL, and carers completed the Relatives' Stress Scale (RSS). The DEMQOL and RSS were completed again on completion of the intervention.

### ***Results***

The results provided by the Bangor and Kent sites are presented below.

#### **Bangor**

Eight participants with dementia, 5 of whom were female, received the intervention. Five had a diagnosis of Alzheimer's disease, 1 had a diagnosis of vascular dementia, and 2 while known to have dementia were still awaiting a specific diagnosis from the memory service. Those with a diagnosis had received this within the previous 12 months. The mean ACE-III score was 71 (range 62 – 78). Six participants had a carer involved; the carers were five spouses and an adult child. Five participants received a six-session intervention and three an eight-session intervention.

Participants identified a total of 16 goals; two identified one goal, four identified two goals, and two identified three goals. The goals included learning to use new technology, remembering names and activities undertaken or planned, locating items around the house, orientation to the current day and date, planning activities, and engaging in social contact and community activities.

Participant and therapist pre- and post-intervention ratings of goal attainment and satisfaction with attainment were available for 13 goals. Carer ratings were available for 9 goals. Mean scores improved significantly post-intervention, as shown in *Table 71*. Scrutiny of individual goals indicated that a clinically meaningful improvement of at least 2 points was obtained for attainment of 12 out of 13 goals as rated by participants.

OTs and TIs also rated the extent of goal attainment post-intervention by matching current functioning to the goal statements and goal attainment descriptors identified at the initial assessment. Nine of 16 goals (56%) were rated as fully achieved, six as partially achieved, and only one as not achieved.

Table 71. BGSi goal performance and goal satisfaction ratings during implementation at the Bangor site

Rating	Pre-intervention		Post-intervention		Statistical comparison
	n	Mean (sd), range	n	Mean (sd), range	
Service user goal attainment	13	3.23 (1.83), 1 - 6	13	7.54 (1.98), 3 - 10	$t(12) = -7.018, p < .005$
Service user satisfaction	13	3.38 (1.98), 1 - 7	13	8.15 (1.51), 5 - 10	$t(12) = -7.315, p < .005$
Carer goal attainment	9	3.33 (1.73), 1 - 6	9	7.44 (1.74), 5 - 10	$t(8) = -5.094, p < .005$
Therapist goal attainment	13	2.38 (1.26), 1 - 4	13	7.85 (2.12), 4 - 10	$t(12) = -8.309, p < .005$

*Data are mean (SD) range*

Mean DEMQOL scores where available ( $n = 7$ ) increased from 90.29 (12.55) at initial assessment to 96.14 (6.47) at the end of the intervention, reflecting more positive ratings of quality of life, and mean RSS scores ( $n = 6$ ) decreased from 16.5 (3.51) at initial assessment to 13.5 at the end of the intervention, reflecting lower levels of stress. However, the small numbers precluded statistical analysis.

#### Kent

Outcome information was available for five of the six service users included. Between them, these 5 service users worked on eight goals. BGSi attainment ratings were made by service users for all eight goals, by carers for 7 goals and by therapists for four goals (two participants). Mean initial attainment ratings by service users were 3.13 (SD 1.46) and mean post-intervention ratings were 7.75 (SD 0.89), reflecting a significant improvement ( $t(7) = -6.56, p < .001$ ). Carers' mean initial attainment ratings were 3.43 (SD 1.27) and mean post-intervention ratings were 7.86 (SD 1.07), a significant improvement ( $t(6) = -7.75, p < .001$ ).

Therapists' mean initial ratings were 2.75 (SD 0.96), and post-intervention ratings were 8.25 (SD 0.96), again reflecting a significant improvement ( $t(3) = -8.52, p < .05$ ). Service user satisfaction ratings improved from a mean of 2.88 (SD .99) at initial assessment to 8.13 (SD .83) post-intervention, also reflecting a significant change ( $t(7) = -9.98, p < .001$ ). Carers' scores for stress decreased only minimally from 36.67 (SD 17.01) at initial assessment to 36.33 (SD 11.93) post-intervention, and this was non-significant.

### ***Service users' experience of the intervention***

At the Bangor site, at the end of therapy participants and carers were asked to complete a questionnaire about their experiences and return it to the GREAT therapist in a pre-paid envelope. Four responses were received. Comments were sought on both helpful and less helpful aspects of the intervention. No unhelpful aspects were identified. Responses suggested that the intervention had a positive impact on participants' lives in various ways:

- I'm using the strategies to help in my everyday life.
- Getting back to some of the things I had stopped doing. Restarted my painting.
- Knowing there is help if we need it.
- Strategies to help memory retrieval, and ways to remember new things.
- Getting my wife to put down the day and date each day as part of a reminder each day. Similar notes or reminders could be useful with our everyday tasks.
- Goals were something to work towards. Gave great satisfaction.

Feedback from the Kent site indicated that the most important benefit that service users mentioned was an increase in confidence.

### ***Staff members' experience of delivering the intervention***

At the Bangor site, views of the OTs and TIs were sought at two time-points. Following the training day, they were asked to give their views on the training and orientation to the intervention via an anonymous questionnaire. All found the training was informative, easy to follow, and pitched at the right level, with useful materials provided. All felt they would be able to apply what they had learned. Most felt adequate time was provided but one would have liked more time for discussion. They felt that completing the one-day training in a single session was quite intensive and preferred the idea of training being split over two half-days.

On completing their work with the feasibility pilot, the OTs and TIs were invited to complete anonymised questionnaires reporting on their experiences of learning about and delivering the intervention, and to share their experiences in a group discussion with the supervisor.

The therapists initially found it challenging at the start to get to grips with something new, and most had taken the therapy resource materials home to study in their own time. However, once they had begun to use the approach, they quickly became keen on working in this way and saw it as something they wanted to be involved in: *'It's what we joined the profession to do, actually do interventions with people'*. They thought the goal-setting process was useful, finding that it gave focus to the intervention, facilitated the process of change for participants and family members, and was a valuable source of feedback. The intervention could make participants feel valued in that someone was taking the time to help, and could create opportunities for carers to respond more positively to the person with dementia. Positive responses from participants and carers stimulated the therapists' enthusiasm: *'It's so rewarding, each time I went they were full of praise.'* They felt the intervention was of an appropriate length, although they could sometimes have continued working for longer as additional needs emerged. Some found the modular approach confusing. The therapists uniformly disliked paperwork and preferred not to use questionnaires to evaluate outcomes. All were convinced there was a service need for this kind of intervention to be more widely available: *'We're going out and seeing a lot more people that we could be doing it with, but with time restraints and waiting lists and other work commitments, there's just not the time to be able to do it with them all is there. It's such a shame.'* They indicated that time constraints and existing workloads would make it difficult to continue using the intervention, especially given current staff shortages, and that they were looking into ways of being able to sustain their work; for example one TI was introducing goal-setting into an existing group, one OT and TI pair were putting together a business case for more TI hours, and one TI was actively seeking to have CR included in her role.

At the Kent site, views of staff were obtained, firstly on the training and support provided and secondly on delivering the therapy. Staff found the training helpful and ratings at the end of training indicated that they felt reasonably confident to start delivering CR. However, they found the training very intensive and would have preferred it to be split over several days. They also felt that additional, or 'refresher', sessions would have been useful once they were providing CR. They valued the small group supervision and access to specialist advice.

Reflecting on the experience of delivering CR, staff found the process of developing goals that were genuinely important to the service user very helpful in focusing their work, and felt that this added to their skills and transferred to other areas of work. They noted how service users increased in confidence, and found it very motivating to see this positive change and receive positive feedback from service users and carers. Some commented that doing CR made them feel like a ‘*proper OT*’ or ‘*proper CPN*’ again. They were unsure about the value of adding follow up telephone contacts and felt this was helpful for some service users but less so for others who struggled to use the phone or were difficult to reach by phone. Some staff found the dual role of delivering therapy to service users for whom they acted as care co-ordinator challenging.

### ***Lessons for future implementation***

This feasibility pilot has demonstrated that delivery on the ground can achieve improvements in goal attainment comparable to those observed in the main trial, even with a considerably shortened intervention period. The approach clearly appeals to staff and offers them the opportunity to work in a way that they feel meets their professional aspirations, and the positive benefits they observe in service users enhance motivation and morale. The pilot has also provided valuable insights into what will be required to implement CR in routine clinical practice. These are discussed below.

*Training.* Sufficient time is needed for initial training to enable staff to assimilate new information and engage with the approach. Staff prefer training spread over several days in shorter sessions rather than intensive one- or two-day workshops. Staff also need some study time to review training materials and consolidate their learning. Training needs to be flexible to take account of different staff backgrounds and levels of experience, and some types of staff will need more input than others. It may be helpful to provide follow-up training sessions once staff are engaged in delivering CR. With regard to the content of training, it is important for staff to understand how CR is different to their current everyday practice. Some staff may feel they already set treatment goals and suggest strategies, and need to understand how this differs from the goal-setting and strategy application approaches used in CR, which is a more detailed and collaborative process based on careful assessment of intrinsic capacity, current ability and task demands, uses a problem-solving approach to identify goals and possible solutions, and expresses goals in clear behavioural terms. Providing staff with a

checklist to use following training, to remind them of what they should be considering in their work, may help to enhance and maintain adherence to the therapy model.

*Supervision.* Staff find supervision and access to advice extremely helpful and it is important that time is allocated for staff to participate in supervision, especially in the early stages of familiarisation with the approach.

*Intervention.* The adaptation to a six or eight session format worked well, and increasing the length of time between later sessions, for example by moving from weekly to fortnightly sessions, may be helpful. Telephone follow up was helpful in some cases but not others, and should be used flexibly. The modular protocol was intended to allow for individual tailoring but requires revision to enable staff to utilise the available guidance to tailor the intervention optimally for each person. It will clearly be important to limit ‘paperwork’ and recording requirements, and ensure that any evaluation is not burdensome.

*Service users.* As with participants in the main trial, service users differed in the extent to which they were able to identify goals and in their motivation to make changes. It is important to be able to identify those service users who are likely to benefit from CR and, equally, to be able to offer other, more appropriate kinds of support to those who are not likely to engage with the approach. It is also important that the intervention approach is sufficiently flexible to accommodate service users with different degrees of cognitive difficulty, and that therapists are trained and supported to apply CR in ways that meet the needs of a range of service users.

*Staff.* It may be preferable to avoid staff being in the dual roles of care co-ordinator and CR therapist.

*Service constraints.* Unsurprisingly, time constraints, heavy workloads and staff shortages presented challenges for the implementation. The unexpected reorganisation at the Birmingham site was a classic example of the way in which wider issues can hinder implementation efforts. Future implementation work should only be considered in services where reorganisation is not envisaged within the timeframe of the work. A fuller implementation programme will need to address this through a top-down approach by engaging service managers and key decision-makers. The consistent support of management

at all levels, both senior managers and local line managers, is essential to achieve effective implementation and sustainability.

### Appendix 15. Full unit costs

Table 72. Unit costs

Variable name	Unit cost (£2013/14)	Unit	Source	Notes/assumptions
<b>Respite and care home use</b>				
Private sector residential care for older people, cost of stay	79	per day	PSSRU UC 2014, table 1.2 <sup>120</sup>	Excludes personal living expenses
Private and other independent sector residential home for people with dementia, cost of stay	91	per day	PSSRU UC 2014, table 1.3 <sup>120</sup>	Excludes personal living expenses
LA residential care for older people, cost of stay	157	per day	PSSRU UC 2014, table 1.3 <sup>120</sup>	Excludes personal living expenses
Private sector nursing home for older people, cost of stay	104	per day	PSSRU UC 2014, table 1.1 <sup>120</sup>	Excludes personal living expenses
Social care schemes, cost of stay	84	per day	PSSRU UC 2014, table 1.2 <sup>120</sup>	Average across the 4 schemes
<b>Community health and social care services</b>				
GP time, Home visit	3.60	per minute	PSSRU UC 2013, table 10.8b <sup>121</sup>	No information about home visits in the 2014 volume. Assumed ratio of clinic to home cost per minute remained the same.

GP time, Home visit average visit cost (23.4 minutes)	85	per visit	PSSRU UC 2013, table 10.8b <sup>121</sup>	No information about home visits in the 2014 volume. Assumed ratio of clinic to home cost per minute remained the same. Assumed average duration of visit remained the same
GP time, Clinic visit	2.90	per minute	PSSRU UC 2014, table 10.8b <sup>120</sup>	No direct care staff and no qualification costs
GP time, Clinic visit	50	per visit	PSSRU UC 2014, table 10.8b <sup>120</sup>	No direct care staff and no qualification costs
Practice nurse, face-to-face time	0.73	per minute	PSSRU UC 2014, table 10.6 <sup>120</sup>	Excludes qualification costs
Practice nurse, face-to-face time	11.37	per consultation	PSSRU UC 2014, table 10.6 <sup>120</sup>	Excludes qualification costs
District nursing time, face-to-face contact	37	per contact	NHS reference costs 2013/14 <sup>124</sup>	
District nursing time, direct contact time	1.23	per minute	NHS reference costs 2013/14 <sup>124</sup>	Assumes 30 minute contact
District nursing time, home visit	1	per minute	PSSRU UC 2013, table 10.1 <sup>121</sup>	Excludes qualification cost
District nursing visit, per home visit	56	per visit	PSSRU UC 2013, table 10.1 <sup>121</sup>	Excludes qualification cost
Nurse (mental health), face-to-face contact	1.1	per minute	PSSRU UC 2014, table 10.2 <sup>120</sup>	Excludes qualification costs

Nurse (mental health), face-to-face contact	33	per contact	PSSRU UC 2014, table 10.2 <sup>120</sup>	Excludes qualification costs
Consultant: Psychiatrist, face-to-face	4.43	per minute	PSSRU UC 2014, table 15.7 <sup>120</sup>	Excludes qualification costs
Consultant: Psychiatrist, face-to-face session	221.45	per contact	PSSRU UC 2014, table 15.7 <sup>120</sup>	Excludes qualification costs
Clinical psychologist	2.23	per minute	PSSRU UC 2014, table 9.5 <sup>120</sup>	Excludes qualification costs (no information on them)
Social worker, face-to-face time	2.65	per minute	PSSRU UC 2014, table 11.2 <sup>120</sup>	Excludes qualification costs
Community physiotherapist, home visit	52	per contact	NHS reference costs 2013/14 <sup>124</sup>	home/clinic not specified
Community physiotherapist, home visit	0.5	per minute	PSSRU UC 2014, table 9.1 <sup>120</sup>	Excludes qualification costs
Community physiotherapist, per clinic visit	12.43	per contact	PSSRU UC 2014, table 13.1 <sup>120</sup>	home/clinic not specified. Excludes qualification costs
Community physiotherapist, clinic visit	0.53	per minute	PSSRU UC 2014, table 13.1 <sup>120</sup>	home/clinic not specified. Excludes qualification costs
NHS occupational therapist, cost per hour	0.53	per minute	PSSRU UC 2014, table 9.2 <sup>120</sup>	Excludes qualification costs
NHS clinical support worker, cost per hour	0.33	per minute	PSSRU UC 2014, table 10.5 <sup>120</sup>	Excludes qualification costs
Community pharmacist, patient-related activities	1.07	per minute	PSSRU UC 2014, table 10.5 <sup>120</sup>	Excludes qualification costs

Community occupational therapist (social services), cost per hour	0.68	per minute	PSSRU UC 2014, table 11.5 <sup>120</sup>	Excludes qualification costs
Dietician, cost per hour	0.55	per minute	PSSRU UC 2014, table 13.4 <sup>120</sup>	Excludes qualification costs
Dietician, cost per visit	80	per contact	NHS reference costs 2013/14 <sup>120</sup>	
Counselling services in primary care	0.83	per minute	PSSRU UC 2014, table 2.7 <sup>120</sup>	
Counselling services in primary care	45.83	per visit	PSSRU UC 2014, table 2.7 <sup>120</sup>	
NHS community mental health team (CMHT) worker for older people (OP) with mental health problems, per team member	0.68	per minute	PSSRU UC 2014, table 12.1 <sup>120</sup>	
NHS community mental health team (CMHT) worker for older people (OP) with mental health problems, per team member	41	per visit	PSSRU UC 2014, table 12.1 <sup>120</sup>	
Home care - Average of independent and social services (average cost per hour 19.64)	0.33	per minute	PSSRU UC 2014, table 11.6 <sup>120</sup>	Average cost of private and Social Services costs; weighted average of weekday and weekend costs
Cleaner	0.17	per minute	Greenleaf Cleaning, <sup>125</sup> Hassle.com, <sup>126</sup> Homeclean <sup>127</sup>	Internet search of 3 cleaning companies; average across prices. Deflated using HCHS index

Meals on wheels	5.8	per meal	PSSRU compendium 2014, table 8.1.1 <sup>120</sup>	Uprated using HCHS Pay&Prices Index
Laundry service, cost per week per service user	26.43	per service user per week	Wandsworth Council <sup>128</sup>	Uprated from 2008 to 2014 prices using HCHS Pay&Prices inflator
Sitting service i.e. Crossroads	0.29	per minute	Evaluation of the East Sussex Carers' Breaks Demonstrator Site <sup>129</sup>	Cost of short break for carers
Carer support worker	0.5	per minute	Evaluation of the East Sussex Carers' Breaks Demonstrator Site <sup>129</sup>	
Chiropodist	0.53	per minute	PSSRU UC 2014, table 9.4 <sup>120</sup>	
Chiropodist	39	per visit	NHS reference costs 2013/14 <sup>124</sup>	
Optician	21.1	per visit	Optics at a glance, Optical Confederation <sup>130</sup>	Cost of sight test
Optician	57.92	per visit	Department of Health <sup>131</sup>	Adds the fee payable for first patient seen at one domiciliary visit, NHS
Dentist, weighted average cost per hour of patient contact for a performer-only and providing-performer	1.71	per minute	PSSRU UC 2014 <sup>120</sup>	Tables 10.9 & 10.10
Dentist, community dental service	125	per visit	NHS reference costs 2013/14 <sup>124</sup>	
Dentist, general dental service	85	per visit	NHS reference costs 2013/14 <sup>124</sup>	

Audiologist	51.94	per contact	NHS reference costs 2013/14 <sup>124</sup>	
Health visitor, patient-related work	1.08	per minute	PSSRU UC 2014 Schema 10.3 <sup>120</sup>	
Health visitor, per contact	45.07	per contact	NHS reference costs 2013/14 <sup>124</sup>	CHS tab, N03F - Health Visitor, Other Clinical Intervention
Speech and language therapist	84	per contact	NHS reference costs 2013/14 <sup>124</sup>	A13A1 - Speech and Language Therapist, Adult, One to One
Speech and language therapist	0.53	per minute	PSSRU UC 2014, table 13.3 <sup>120</sup>	Excludes qualifications
Day care for older people, per session	56	per session	PSSRU UC 2014, table 1.6 <sup>120</sup>	
Day care in NHS facilities, per attendance	146	attendance	NHS reference costs 2013/14 <sup>124</sup>	CHS tab
Day care for people with mental health problems, per session	40	per session	PSSRU UC 2014, table 2.5 <sup>120</sup>	
Lunch club	7.71	per session	Romeo et al. <sup>132</sup>	Uprated using HCHS Pay&Prices inflator pay&prices index.
Patient education classes	Range: 59, 36, 11;9	Per session	NHS West Norfolk CCG, <sup>133</sup> D'Amico et al., <sup>134</sup> Orgeta et al., <sup>135</sup> Quinn et al., <sup>136</sup>	2015 price, downrated using the HCHS inflator; Uprated to 2013/14 prices using HCHS Pay&Prices inflator ;Uprated to 2013/4 using HCHS Pay&Prices inflator
Respiratory support group	5.50	per session	Romeo et al. <sup>132</sup>	Assumed social club; uprated using HCHS Pay&Prices inflator

Community memory café run by voluntary sector	3	per session	Dementia Partnerships <sup>137</sup>	
Befriending of older adults	7.33	per session	PSSRU UC 2014, Schema 2.11 <sup>120</sup>	
Choral singing, people with dementia	3.13	per session	Alzheimer's Society <sup>138-141</sup>	Charges across 4 choirs
Exercise classes	38.66	per person per class	Witham et al. <sup>142</sup>	Uprated to 2013/4 using HCHS Pay&Prices inflator
Paramedic visit, See and treat and refer	180	per attendance	NHS reference costs 2013/14 <sup>124</sup>	ASS01 See and treat or refer
Memory clinic	422	per attendance	PSSRU UC 2014, table 1.10 <sup>120</sup>	Assumes 1 hour contact
Minor injuries unit, weighted average of all attendances (admission and non-admission)	55.16	per attendance	PSSRU UC 2010, table 7.1 <sup>143</sup>	Uprated to 2013/4 pay&prices inflator
Consultant contact – community-based	1.68	per minute	PSSRU UC 2014, table 15.5 <sup>120</sup>	Assumed the same cost as a medical consultant in hospital
Non-emergency ambulance use, average cost of a non-emergency patient transfer	43.26	per transfer	PSSRU UC 2010, p.60 <sup>143</sup>	Uprated using HCHS Pay&Prices inflator. The 2013 compendium does not record
Equipment and adaptations				
Wheelchair (non-powered average of active user and self/attendant)	34.25	Per item	PSSRU UC 2014, table 7.2 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months

propelled), Mean annual equipment cost				
Wheelchair (powered), Mean annual equipment cost	106	Per item	PSSRU UC 2014, table 7.2 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months
Outdoor rail	0.85	Per item	PSSRU UC 2014, table 7.3.2 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months
Stair/grab rail	0.6	Per item	PSSRU UC 2014, table 7.3.2 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months
Over bath shower	36	Per item	PSSRU UC 2014, table 7.3.2 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months
Walk-in shower/ shower cubicle replacing bath	119.75	Per item	PSSRU UC 2014, table 7.3.1 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months
Outdoor ramp	3.5	Per item	PSSRU UC 2014, table 7.3.2 <sup>120</sup>	Annuitised over 10 years*; cost over 3 months
Perching stool	0.68	Per item	PSSRU UC 2013, table 7.3.1 <sup>121</sup>	Uprated using HCHS Pay&Prices inflator inflator- annuitised over 10 years*; cost over 3 months
Commode	1.73	Per item	PSSRU UC 2013, table 7.3.1 <sup>121</sup>	Uprated using HCHS Pay&Prices inflator inflator- annuitised over 10 years*; cost over 3 months

Kitchen trolley	1.04	Per item	PSSRU UC 2013, table 7.3.1 <sup>121</sup>	Uprated using HCHS Pay&Prices inflator inflator- annuitised over 10 years*; cost over 3 months
Toilet frame/raised toilet seat,	0.91	Per item	PSSRU UC 2013, table 7.3.1 <sup>143</sup>	Annuitised over 10 years*; cost over 3 months. Uprated to 2013/14 prices using HCHS Pay&Prices inflator
Walking stick	0.22	Per item	Transforming Community Equipment Services national catalogue and tariff for Simple Aids to Daily Living <sup>144</sup>	Annuitised over 10 years*; cost over 3 months. Uprated to 2013/14 prices using HCHS Pay&Prices inflator
All 4 wheeled and four footed walking frames	0.93	Per item	Transforming Community Equipment Services national catalogue and tariff for Simple Aids to Daily Living <sup>144</sup>	Annuitised over 10 years*; cost over 3 months. Uprated to 2013/14 prices using HCHS Pay&Prices inflator
Bath seat	0.51	Per item	Transforming Community Equipment Services national catalogue and tariff for Simple Aids to Daily Living <sup>144</sup>	Annuitised over 10 years*; cost over 3 months. Uprated to 2013/14 prices using HCHS Pay&Prices inflator
Bed lever/rail	0.91	Per item	Transforming Community Equipment Services national	Annuitised over 10 years*; cost over 3 months. Uprated to 2013/14 prices using HCHS Pay&Prices inflator

			catalogue and tariff for Simple Aids to Daily Living <sup>144</sup>	
Individual alarm system	98.53	Per item	Building Telecare in England, pp.1-21 <sup>145</sup>	Uprated using HCHS Pay&Prices inflator inflator- annuitised over 10 years*; cost over 3 months
Medications				
Various	Range: 0.029 - 8.45	Standard quantity units	Prescription cost analysis, England <sup>146</sup>	
Unpaid carer costs				
National minimum wage	6.31	per hour	National Minimum Wage and National Living Wage rates <sup>147</sup>	
Travel costs				
Cost per mile of travel for carer (car running costs), per mile	0.25	per mile	AA car running costs 2013 <sup>148</sup>	Price when new between £22 000 to £26 000
Professional travel for delivery of CR – NHS reimbursement rate	0.43	Per mile	NHS mileage rates 2013 <sup>149</sup>	
Hospital services				
A&E attendances, weighted average of admitted and non-admitted	124	Attendance	NHS reference costs 2013/14 <sup>124</sup>	
Minor injury unit	55	Attendance	PSSRU UC 2010, table 7.1 <sup>143</sup>	Uprated using HCHS Pay&Prices inflator
Inpatients				

Subchapter AA: Nervous System Procedures and Disorders	420	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter BZ: Eyes and Periorbita Procedures and Disorders	565	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab
Subchapter CA: Ear, Nose, Mouth, Throat and Neck Procedures	841	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab
Subchapter DZ: Thoracic Procedures and Disorders	370	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter EA: Cardiac Procedures	896	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter EB: Cardiac Disorders	412	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter FZ: Digestive System Procedures and Disorders	482	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter HA: Orthopaedic Trauma Procedures	1661	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter HB: Orthopaedic Non- Trauma Procedures	567	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter HC: Spinal Surgery and Disorders	651	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab
Subchapter HD: Musculoskeletal Disorders	374	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab

Subchapter LA: Renal Procedures and Disorders	522	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter LB: Urological and Male Reproductive System Procedures and Disorders	598	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab
Subchapter MB: Urological and Male Reproductive System Procedures and Disorders	452	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab
Subchapter VC: Rehabilitation	298	Day	NHS reference costs 2013/14 <sup>124</sup>	REHAB tab
Subchapter WA: Multiple Trauma	356	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter WD: Treatment of Mental Health Patients by Non-Mental Health Service Providers	474	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL and NEL_XS Tabs
Subchapter YR: Vascular Imaging Interventions	646	Day	NHS reference costs 2013/14 <sup>124</sup>	NEL tab
Day cases				
Subchapter CA: Ear, Nose, Mouth, Throat and Neck Procedures	938	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab
Subchapter EA: Cardiac Procedures	1333	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab

Subchapter BZ: Eyes and Periorbita Procedures and Disorders	784	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab
Subchapter FZ: Digestive System Procedures and Disorders	566	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab
Subchapter HD: Musculoskeletal Disorders	374	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab
Subchapter JD: Skin Disorders	513	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab
Day cases, weighted average across specialities	698	Day	NHS reference costs 2013/14 <sup>124</sup>	DC tab
Outpatients				
Service code 100: General Surgery	112	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 101: Urology	92	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 103: Breast Surgery	118	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 104: Colorectal Surgery	110	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 105: Hepatobiliary and Pancreatic Surgery	156	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab

Service code 107: Vascular Surgery	138	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 108: Spinal Surgery Service	133	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 110: Trauma and Orthopaedics	104	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 120: ENT	83	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 130: Ophthalmology	80	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 141: Restorative Dentistry	117	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 144: Maxillo-Facial Surgery	104	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 150: Neurosurgery	172	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 160: Plastic Surgery	85	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 170: Cardiothoracic Surgery	271	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab

Service code 191: Pain Management	121	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 301: Gastroenterology	118	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 302: Endocrinology	131	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 303: Clinical Haematology	156	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 304: Clinical Physiology	60	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 307: Diabetic Medicine	142	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 320: Cardiology	118	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 324: Anticoagulant Service	27	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 330: Dermatology	93	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 340: Respiratory Medicine	138	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab

Service code 341: Respiratory Physiology	128	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 350: Infectious Diseases	210	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 361: Nephrology	141	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 370: Medical Oncology	138	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 400: Neurology	156	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 410: Rheumatology	122	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 430: Geriatric Medicine	175	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 502: Gynaecology	120	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 650: Physiotherapy	44	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 652: Speech and Language Therapy	84	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab

Service code 653: Podiatry	42	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 654: Dietetics	61	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 656: Clinical Psychology	184	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 657: Prosthetics	53	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 658: Orthotics	111	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 662: Optometry	95	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 715: Old Age Psychiatry	107	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 812: Diagnostic Imaging	44	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Service code 840: Audiology	122	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab
Weighted average of follow-up attendances across service codes	102	Attendance	NHS reference costs 2013/14 <sup>124</sup>	Consultant and non-consultant-led follow-up face-to-face attendances, CL tab

Note: PSSRU UC=PSSRU Unit Costs of Health and Social Care; NHS Reference Costs 2013/14=NHS National Schedule of Reference Costs 2013/14

**Appendix 16. Participant resource use and replacement costs**

Table 73. Resources used by person with dementia over the prior 3 months, at baseline assessment. Sample: all available cases where CSRI was partially or wholly completed

Resources	Units	CR (N=238)		TAU (N=236)	
		Users N/ Valid n	Sample mean (SE)	Users N/ Valid n	Sample mean (SE)
<b>Hospital services</b>					
A&E	Attendances	28/236	0.19 (0.05)	15/233	0.07 (0.02)
Inpatient	Days	13/236	0.66 (0.28)	12/233	0.17 (0.06)
Outpatient	Attendances	123/236	1.10 (0.11)	107/233	0.98 (0.10)
Day hospital	Days	2/236	0.01 (0.01)	4/233	0.04 (0.02)
<b>Primary and community health</b>					
GP	Contacts <sup>a</sup>	161/236	1.60 (0.13)	172/233	1.69 (0.15)
Practice nurse	Contacts <sup>a</sup>	115/236	0.85 (0.09)	131/233	1.16 (0.12)
Community nurse	Contacts <sup>a</sup>	21/236	0.36 (0.14)	24/233	0.48 (0.23)
Physiotherapist	Contacts <sup>a</sup>	24/236	0.25 (0.07)	22/233	0.38 (0.10)
OT	Contacts <sup>a</sup>	15/236	0.18 (0.06)	11/233	0.15 (0.07)
Specialist nurse	Contacts <sup>a</sup>	40/236	0.25 (0.04)	36/233	0.38 (0.17)
Dietician	Contacts <sup>a</sup>	4/236	0.02 (0.01)	5/233	0.03 (0.01)
Counsellor	Contacts <sup>a</sup>	1/236	0.01 (0.01)	0/233	0

Optician	Contacts <sup>a</sup>	75/236	0.40 (0.04)	62/233	0.33 (0.04)
Chiropodist	Contacts <sup>a</sup>	71/236	0.39 (0.04)	83/233	0.54 (0.06)
Dentist	Contacts <sup>a</sup>	90/236	0.53 (0.06)	84/233	0.49 (0.05)
Mental health					
Mental health nurse	Contacts <sup>a</sup>	23/236	0.19 (0.05)	18/233	0.12 (0.04)
Psychiatrist	Contacts <sup>a</sup>	38/236	0.17 (0.03)	32/233	0.16 (0.03)
Psychologist	Contacts <sup>a</sup>	24/236	0.17 (0.06)	20/233	0.17 (0.05)
Mental health team worker	Contacts <sup>a</sup>	4/236	0.03 (0.01)	5/233	0.06 (0.04)
Community care					
Social worker/care manager	Contacts <sup>a</sup>	18/236	0.11 (0.03)	12/233	0.07 (0.02)
Home care/home help	Contacts	25/236	6.32 (1.65)	26/233	12.07 (3.18)
Home care/home help	Hours	25/236	73.43 (6.68)	26/233	105.01 (13.80)
Cleaner	Contacts	50/236	2.20 (0.41)	53/233	2.53 (0.36)
Meals on wheels	Contacts	1/236	0.05 (0.05)	3/233	0.48 (0.37)
Laundry service	Contacts	3/236	0.13 (0.08)	9/233	0.24 (0.10)
Sitting service	Contacts	1/236	0.05 (0.05)	7/233	0.22 (0.10)
Carer support worker	Contacts	9/236	0.09 (0.04)	9/233	0.07 (0.03)
Other health and social care services					
SALT <sup>b</sup>	Contacts	1/230	0.01 (0.01)	1/230	0
Health visitor <sup>b</sup>	Contacts	1/230	0.01 (0.01)	0/230	0
Medical consultant <sup>b</sup>	Contacts	1/230	0	0/230	0

Paramedic <sup>b</sup>	Contacts	0/230	0	0/230	0
Audiology <sup>b</sup>	Contacts	2/229	0.02 (0.01)	5/230	0.02 (0.01)
Community pharmacist <sup>b</sup>	Contacts	0/229	-	0/230	-
Healthcare support worker <sup>b</sup>	Contacts	6/233	0.09 (0.05)	4/231	0.03 (0.01)
Day care					
Day centre	Attendances	23/236	1.51 (0.44)	25/233	1.26 (0.31)
Lunch club	Attendances	23/236	0.83 (0.24)	12/233	0.47 (0.15)
Patient education course	Attendances	8/236	0.29 (0.12)	10/233	0.24 (0.09)
Other day services					
Memory café /dementia support <sup>c</sup>	Attendances	16/236	0.33 (0.11)	12/233	0.25 (0.09)
Befriender <sup>c</sup>	Attendances	2/236	0.06 (0.06)	2/233	0.11 (0.11)
Singing for the brain/dementia choirs <sup>c</sup>	Attendances	3/236	0.08 (0.06)	5/233	0.10 (0.05)
Exercise classes for older people <sup>c</sup>	Attendances	3/236	0.14 (0.08)	1/233	0.06 (0.06)
Respiratory support groups <sup>c</sup>	Attendances	1/236	0.04 (0.04)	0/233	0
Other					
Equipment adaptations (NHS/SSD)	Items	76/236	0.86 (0.11)	76/233	0.80 (0.10)
Equipment privately purchased	Items	130/236	1.27 (0.11)	140/233	1.45 (0.11)
Medications	Units	190/236	1.15 (0.06)	193/233	1.11 (0.05)
Hypnotics and anxiolytics	Units	3/236	0.02 (0.01)	2/233	0.01 (0.01)
Antipsychotics	Units	2/236	0.01 (0.01)	2/233	0.01 (0.01)

Antidepressants	Units	59/236	0.26 (0.03)	42/233	0.21 (0.03)
Antiepileptics	Units	1/236	0.00 (0.00)	1/233	0.00 (0.00)
Dementia medications	Units	170/236	0.82 (0.04)	182/233	0.83 (0.03)
Principal carer care	Hours	207/235	609.43 (52.25)	200/232	534.91 (47.67)
Other carer care	Hours	81/236	92.94 (19.80)	75/232	57.50 (10.87)

Notes: OT=Occupational Therapist; SALT=Speech and Language Therapist

a Combines home and office contacts

b New categories of service use derived from textual descriptions of other health and social care services

c New categories of day care service use derived from textual descriptions of other day care services

Table 74. Resources used by person with dementia over the prior three months, at three months. Sample: all available cases. Sample: all available cases where CSRI was partially or wholly completed

Resources	Units	CR (N=238)		TAU (N=236)	
		Users N/ valid n	Sample mean use (SE)	Users N/ valid n	Sample mean use (SE)
Hospital services					
A&E	Attendances	21/215	0.13 (0.03)	22/223	0.11 (0.02)
Inpatient	Days	8/215	0.35 (0.15)	15/223	0.52 (0.23)
Outpatient	Attendances	114/215	1.23 (0.21)	96/223	0.93 (0.19)
Day hospital	Days	3/215	0.05 (0.03)	0/223	0
Primary and community health					
GP	Contacts <sup>a</sup>	143/215	1.37 (0.10)	147/223	1.41 (0.11)
Practice nurse	Contacts <sup>a</sup>	104/215	0.89 (0.09)	113/223	1.07 (0.13)
Community nurse	Contacts <sup>a</sup>	12/215	0.38 (0.17)	14/223	0.74 (0.40)
Physiotherapist	Contacts <sup>a</sup>	19/215	0.42 (0.15)	15/223	0.27 (0.09)
OT	Contacts <sup>a</sup>	14/215	0.16 (0.06)	9/223	0.08 (0.03)
Specialist nurse	Contacts <sup>a</sup>	23/215	0.15 (0.04)	23/223	0.15 (0.03)
Dietician	Contacts <sup>a</sup>	5/215	0.03 (0.01)	6/223	0.03 (0.01)
Counsellor	Contacts <sup>a</sup>	1/215	0.02 (0.02)	0/223	0
Optician	Contacts <sup>a</sup>	56/215	0.30 (0.04)	62/223	0.35 (0.04)
Chiropodist	Contacts <sup>a</sup>	66/215	0.46 (0.06)	75/223	0.51 (0.06)

Dentist	Contacts <sup>a</sup>	78/215	0.55 (0.06)	79/223	0.52 (0.06)
Mental health					
Mental health nurse	Contacts <sup>a</sup>	10/215	0.05 (0.02)	8/223	0.09 (0.06)
Psychiatrist	Contacts <sup>a</sup>	24/215	0.11 (0.02)	20/223	0.09 (0.02)
Psychologist	Contacts <sup>a</sup>	7/215	0.07 (0.04)	6/223	0.04 (0.02)
Mental health team worker	Contacts <sup>a</sup>	5/215	0.09 (0.06)	8/223	0.11 (0.05)
Community care					
Social worker	Contacts	16/215	0.17 (0.05)	15/223	0.14 (0.05)
Home care/home help	Contacts	27/215	8.43 (2.22)	30/223	11.02 (2.72)
Home care/home help	Hours	27/215	95.98 (8.60)	30/223	67.61 (7.40)
Cleaner	Contacts	48/215	2.84 (0.59)	52/223	2.71 (0.38)
Meals on wheels	Contacts	1/215	0.01 (0.01)	3/223	0.33 (0.27)
Laundry service	Contacts	5/215	0.20 (0.09)	7/223	0.23 (0.12)
Sitting service	Contacts	2/215	0.05 (0.04)	4/223	0.11 (0.06)
Carer support worker	Contacts	9/215	0.11 (0.06)	8/223	0.05 (0.02)
Other health and social care services					
SALT <sup>b</sup>	Contacts	1/215	0	0/223	0
Health visitor <sup>b</sup>	Contacts	0/215	0	0/223	0
Medical consultant <sup>b</sup>	Contacts	1/215	0	0/223	0
Paramedic <sup>b</sup>	Contacts	3/212	0.01 (0.01)	1/218	0
Audiology <sup>b</sup>	Contacts	1/209	0	2/216	0.01 (0.01)

Community pharmacist <sup>b</sup>	Contacts	0/209	-	0/216	-
Healthcare support worker <sup>b</sup>	Contacts	2/211	0.03 (0.02)	3/217	0.06 (0.05)
Day care					
Day centre	Attendances	30/215	1.72 (0.40)	28/223	1.63 (0.38)
Lunch club	Attendances	17/215	0.64 (0.22)	21/223	0.91 (0.23)
Patient education course	Attendances	8/215	0.31 (0.12)	3/223	0.04 (0.04)
Other day services					
Memory café /dementia support <sup>c</sup>	Attendances	21/215	0.48 (0.13)	14/223	0.39 (0.13)
Befriender <sup>c</sup>	Attendances	2/215	0.07 (0.06)	5/223	0.04 (0.03)
Singing for the brain/dementia choirs <sup>c</sup>	Attendances	6/215	0.19 (0.11)	5/223	0.13 (0.07)
Exercise classes for older people <sup>c</sup>	Attendances	0/215	0	2/223	0.17 (0.13)
Respiratory support groups <sup>c</sup>	Attendances	1/215	0.06 (0.06)	0/223	0
Other					
Equipment adaptations (NHS/SSD)	Items	86/215	1.04 (0.12)	82/223	0.83 (0.10)
Equipment privately purchased	Items	130/215	1.36 (0.12)	131/223	1.43 (0.11)
Medications	Items	170/215	1.16 (0.06)	186/223	1.13 (0.06)
Hypnotics and anxiolytics	Units	1/215	0.00 (0.00)	2/223	0.01 (0.01)
Medications used in psychoses	Units	2/215	0.01 (0.01)	4/223	0.02 (0.01)
Antidepressants	Units	57/215	0.31 (0.04)	41/223	0.21 (0.03)
Anti-epileptics	Units	1/215	0.00 (0.00)	1/223	0.00 (0.00)

Dementia medications	Units	157/215	0.80 (0.04)	175/223	0.86 (0.04)
Principal carer care	Hours	189/213	578.13 (53.01)	191/221	613.98 (52.21)
Other carer care	Hours	76/214	95.75 (20.21)	73/222	50.14 ( 8.78)

Notes: OT=Occupational Therapist; SALT=Speech and Language Therapist

a Combines home and office contacts

b New categories of service use derived from textual descriptions of other health and social care services

c New categories of day care service use derived from textual descriptions of other day care services

Table 75. Resources used by person with dementia over the prior three months, at nine months. Sample: all available cases. Sample: all available cases where CSRI was partially or wholly completed

Resources	Units	CR (N=238)		TAU (N=236)	
		Users N/ valid n	Sample mean use (SE)	Users N/ valid n	Sample mean use (SE)
<b>Hospital services</b>					
A&E	Attendances	24/205	0.14 (0.03)	25/210	0.18 (0.05)
Inpatient	Days	12/205	0.72 (0.36)	7/210	0.35 (0.17)
Outpatient	Attendances	96/205	1.40 (0.24)	103/210	1.19 (0.21)
Day hospital	Days	3/205	0.04 (0.02)	2/210	0.02 (0.01)
<b>Primary and community health</b>					
GP	Contacts <sup>a</sup>	139/205	1.42 (0.12)	145/210	1.56 (0.11)
Practice nurse	Contacts <sup>a</sup>	108/205	1.17 (0.16)	104/210	0.91 (0.10)
Community nurse	Contacts <sup>a</sup>	12/205	0.39 (0.17)	12/210	0.60 (0.23)
Physiotherapist	Contacts <sup>a</sup>	21/205	0.22 (0.06)	28/210	0.60 (0.16)
OT	Contacts <sup>a</sup>	22/205	0.24 (0.08)	19/210	0.13 (0.03)
Specialist nurse	Contacts <sup>a</sup>	22/205	0.16 (0.04)	18/210	0.15 (0.05)
Dietician	Contacts <sup>a</sup>	4/205	0.02 (0.01)	1/210	0
Counsellor	Contacts <sup>a</sup>	1/205	0.05 (0.05)	0/210	0
Optician	Contacts <sup>a</sup>	48/205	0.27 (0.04)	52/210	0.28 (0.04)
Chiropodist	Contacts <sup>a</sup>	67/205	0.46 (0.05)	84/210	0.65 (0.07)

Dentist	Contacts <sup>a</sup>	75/205	0.48 (0.05)	83/210	0.57 (0.07)
Mental health					
Mental health nurse	Contacts <sup>a</sup>	8/205	0.05 (0.02)	12/210	0.08 (0.03)
Psychiatrist	Contacts <sup>a</sup>	18/205	0.12 (0.03)	29/210	0.16 (0.03)
Psychologist	Contacts <sup>a</sup>	8/205	0.10 (0.06)	12/210	0.06 (0.02)
Mental health team worker	Contacts <sup>a</sup>	3/205	0.02 (0.01)	3/210	0.03 (0.02)
Community care					
Social worker/care manager	Contacts	14/205	0.12 (0.04)	22/210	0.16 (0.04)
Home care/home help	Contacts	29/205	9.16 (2.16)	28/209	13.73 (3.49)
Home care/home help	Hours	29/205	77.51 (8.18)	28/210	141.89 (17.13)
Cleaner	Contacts	47/205	2.66 (0.52)	49/209	2.68 (0.42)
Meals on wheels	Contacts	3/205	0.48 (0.45)	6/209	0.31 (0.22)
Laundry service	Contacts	5/205	0.29 (0.16)	7/209	0.29 (0.12)
Sitting service	Contacts	3/205	0.26 (0.17)	5/209	0.11 (0.06)
Carer support worker	Contacts	8/205	0.06 (0.02)	13/209	0.22 (0.10)
Other health and social care services					
SALT <sup>b</sup>	Contacts	1/202	0.01 (0.01)	5/203	0.03 (0.02)
Health visitor <sup>b</sup>	Contacts	0/202	0	0/203	0
Medical consultant <sup>b</sup>	Contacts	0/202	0	1/203	0.01 (0.01)
Paramedic <sup>b</sup>	Contacts	1/202	0	3/204	0.02 (0.02)
Audiology <sup>b</sup>	Contacts	0/202	0	2/204	0.01 (0.01)

Community pharmacist <sup>b</sup>	Contacts	1/202	-	0/204	-
Healthcare support worker <sup>b</sup>	Contacts	2/202	0.07 (0.07)	2/203	0
Day care					
Day centre	Attendances	30/205	1.82 (0.39)	25/210	2.01 (0.48)
Lunch club	Attendances	19/205	0.92 (0.26)	16/210	0.48 (0.14)
Patient education course	Attendances	6/205	0.18 (0.12)	1/210	0.06 (0.06)
Other day services					
Memory café /dementia support <sup>c</sup>	Attendances	26/205	0.84 (0.24)	17/210	0.40 (0.13)
Befriender <sup>c</sup>	Attendances	3/205	0.08 (0.07)	6/210	0.32 (0.16)
Singing for the brain/dementia choirs <sup>c</sup>	Attendances	8/205	0.31 (0.12)	9/210	0.34 (0.13)
Exercise classes for older people <sup>c</sup>	Attendances	1/205	0.05 (0.05)	1/210	0.19 (0.19)
Respiratory support groups <sup>c</sup>	Attendances	1/205	0.06 (0.06)	1/210	0.06 (0.06)
Other					
Equipment (NHS/SSD)	Items	92/205	1.26 (0.15)	79/210	1.07 (0.14)
Equipment privately purchased	Items	129/205	1.47 (0.12)	141/210	1.67 (0.12)
Medications	Items	162/205	1.20 (0.07)	175/210	1.16 (0.06)
Hypnotics and anxiolytics	Units	4/205	0.02 (0.01)	2/210	0.01 (0.01)
Medications used in psychoses	Units	5/205	0.02 (0.01)	5/210	0.02 (0.01)
Antidepressants	Units	58/205	0.31 (0.04)	46/210	0.25 (0.03)
Antiepileptics	Units	1/205	0.00 (0.00)	2/210	0.01 (0.01)

Dementia medications	Units	150/205	0.80 (0.04)	163/210	0.81 (0.03)
Principal carer care	Hours	181/203	660.67 (58.16)	209/209	647.52 (54.78)
Other carer care	Hours	84/204	71.73 (14.28)	82/209	59.39 (12.40)

Notes: OT=Occupational Therapist; SALT=Speech and Language Therapist

a Combines home and office contacts

b New categories of service use derived from textual descriptions of other health and social care services

c New categories of day care service use derived from textual descriptions of other day care services

Table 76. Types of care and support tasks provided by the principal carer. Sample: complete cases<sup>a</sup>

Type of care or support	CR (n=236)		TAU (n=233)	
	N	%	N	%
<b>Baseline</b>				
Personal care	74	31	66	28
Helping with finances	179	76	175	75
Practical help	191	81	176	76
Taking the person to appointments	205	87	201	87
Medications	178	75	172	74
Keeping the person company	202	86	200	86
Making sure the person is safe (supervision)	146	62	148	64
Helping person to organise schedule <sup>b</sup>	6	3	3	2
Helping person's mental state – morale <sup>b</sup>	0	0	5	3
Driving or navigating for person <sup>b</sup>	4	2	3	2
<b>3 month follow-up</b>				
Personal care	64	30	80	36
Helping with finances	161	75	182	83
Practical help	171	80	179	81
Taking the person to appointments	185	86	199	90
Medications	163	76	168	76
Keeping the person company	183	86	195	88

Making sure the person is safe (supervision)	135	63	144	65
Helping person to organise schedule <sup>b</sup>	2	1	3	2
Helping person's mental state – morale <sup>b</sup>	1	1	2	1
Driving or navigating for person <sup>b</sup>	3	2	5	3
9 month follow-up				
Personal care	78	38	90	43
Helping with finances	162	80	171	82
Practical help	160	79	176	84
Taking the person to appointments	175	86	187	89
Medications	158	78	160	77
Keeping the person company	186	92	185	89
Making sure the person is safe (supervision)	135	67	146	70
Helping person to organise schedule <sup>b</sup>	4	3	3	2
Helping person's mental state – morale <sup>b</sup>	1	1	0	0
Driving or navigating for person <sup>b</sup>	4	3	7	5

a Dyads completing baseline assessments: 236 CR; 233 TAU; dyads completing 3 month assessments: 213 CR; 222 TAU; dyads completing 9 month assessments: 204 CR; 210 TAU

b Recoded from free-text responses describing “other” care tasks

Table 77. Sensitivity analysis: replacement cost. Person with dementia: outcome scores and costs at nine months from regression estimates.

Sample: complete cases

	<b>CR<sup>a</sup></b> <b>(n=201)</b>	<b>95% CI<sup>b</sup></b>	<b>TAU<sup>a</sup></b> <b>(n=206)</b>	<b>95% CI<sup>b</sup></b>	<b>CR-TAU</b> <b>Mean Difference</b>	<b>95% CI<sup>b</sup></b>	<b>p</b> <b>value</b>
BGSI <sup>c</sup>	4.57	4.36 to 4.79	3.21	3.02 to 3.41	1.37	1.09 to 1.64	0.000
Societal <sup>d</sup>	49 394	44 237 to 54 811	52 588	47 256 to 58 260	-3 195	-9 329 to 2 760	0.350
	(n=190)		(n=199)				
GSES <sup>c</sup>	20.14	19.70 to 20.56	19.92	19.45 to 20.37	0.23	-0.32 to 0.78	0.435
Societal <sup>d</sup>	48 042	42 909 to 53 544	52 327	46 999 to 58 073	-4 285	-10 480 to 1 693	0.172
	(n=196)		(n=205)				
QALY <sup>e</sup> (DEMQOL-U)	0.45	0.44 to 0.46	0.45	0.44 to 0.46	0.00	-0.01 to 0.01	0.897
Societal <sup>d</sup>	49 561	44 276 to 55 039	53 276	47 988 to 58 970	-3 716	-9 795 to 2 230	0.278

a Estimated marginal means

b bias- replications corrected bootstrapped 95% confidence intervals (60000)

c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome

d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.

e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points

Table 78. Sensitivity analysis: replacement cost. Carer: outcome scores and costs at nine months from regression estimates. Sample: complete cases

	<b>CR<sup>a</sup></b> <b>(n=192)</b>	<b>95% CI<sup>b</sup></b>	<b>TAU<sup>a</sup></b> <b>(n=198)</b>	<b>95% CI<sup>b</sup></b>	<b>CR-TAU<sup>a</sup></b> <b>Mean</b> <b>Difference</b>	<b>95% CI<sup>b</sup></b>	<b>p value</b>
QALY <sup>a</sup> (EQ5-3L)	0.56	0.54 to 0.58	0.56	0.54 to 0.58	0.00	-0.02 to 0.02	0.926
Societal <sup>d</sup>	48709	43 702 to 54 009	52 989	47 560 to 58 777	-4280	-10 423 to 1 758	0.223

a Estimated marginal means

b bias-corrected bootstrapped 95% confidence intervals (60000 replications)

c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome

d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in 3 months pre-baseline.

e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points

Table 79. Sensitivity analysis: replacement cost. Person with dementia and carer: Point ICER<sup>a</sup> for CR over TAU, from health and social care and societal perspectives

	<b>BGSI<sup>a</sup></b> <b>(N=407)</b>	<b>GSES<sup>b</sup></b> <b>(N=389)</b>	<b>QALY (DEMQOL-U)<sup>c</sup></b> <b>(N=401)</b>	<b>QALY (EQ5D3L)<sup>c</sup></b> <b>(N=390)</b>
<b>Person with dementia, 9 months</b>				
Societal <sup>g</sup>	-3 195/1.37=-2 332	-4 285/0.23=-18 630	-3 716/0.0005=-7 432 000	NA
<b>Carer 9 months</b>				
Societal <sup>g</sup>	NA	NA	NA	-4 280/0.001=-4 280 000

a Cost of achieving a 1.32 points difference between groups at nine months

b Cost of achieving a 1.53 points difference between groups at nine months

c Cost of achieving a QALY gain over nine months; difference in QALY rounded to first non-zero decimal place

Table 80. Sensitivity analysis: Exclusion of high-cost outliers from health and social care costs. Person with dementia: outcome scores and costs at nine months from regression estimates. Sample: health and social care costs outlier excluded

	<b>CR<sup>a</sup></b> <b>(n=196)</b>	<b>95% CI<sup>b</sup></b>	<b>TAU<sup>a</sup></b> <b>(n=204)</b>	<b>95% CI<sup>b</sup></b>	<b>CR-TAU</b> <b>Mean Difference</b>	<b>95% CI<sup>a</sup></b>	<b>p</b> <b>value</b>
BGSI <sup>b</sup>	4.60	4.38 to 4.82	3.22	3.03 to 3.42	1.38	1.09 to 1.65	0.000
Health & social care <sup>c</sup>	4 595	4 253 to 5 026	3 295	2 807 to 3 826	1 300	696 to 1 953	0.000
	(n=186)		(n=197)				
GSES <sup>b</sup>	20.16	19.72 to 20.60	20.00	19.54 to 20.44	0.17	-0.395 to 0.732	0.564
Health & social care <sup>c</sup>	4 543	4 174 to 4 951	3 288	2833 to 3822	1 255	628 to 1 831	0.000
	(n=191)		(n=203)				
QALY <sup>b</sup> (DEMQOL-U)	0.45	0.44 to 0.46	0.45	0.44 to 0.46	0.00	-0.01 to 0.01	0.721
Health & social care <sup>c</sup>	4592	4226 4986	3432	2960 3981	1160	520 to 1742	0.000

a Estimated marginal means

b bias-corrected bootstrapped 95% confidence intervals (60000 replications)

c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome

d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.

e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points

Table 81. Sensitivity analysis: Exclusion of high-cost outliers from health and social care costs Carer: outcome scores and costs at nine months from regression estimates. Sample: health and social care costs outlier excluded

	<b>CR (n=189)</b>	<b>95% CI</b>	<b>TAU (n=195)</b>	<b>95% CI</b>	<b>CR-TAU<sup>a</sup> Mean Difference</b>	<b>95% CI</b>	<b>p value</b>
QALY <sup>a</sup> (EQ5-3L)	0.56	0.54 to 0.58	0.56	0.54 to 0.58	0.01	-0.01 to 0.02	0.553
Health & social care	4 647	4 294 to 5 090	3342	2 819 to 3 900	1 305	669 to 2 008	0.000

a Estimated marginal means

b bias-corrected bootstrapped 95% confidence intervals (3000 replications)

c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome

d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.

e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points

Table 82. Sensitivity analysis: Exclusion of high-cost outliers from health and social care costs Person with dementia and carer: Point ICER<sup>a</sup> for CR over TAU, from health and social care and societal perspectives Sample: outliers excluded

	<b>BGSI (n=400)</b>	<b>GSES (n=383)</b>	<b>QALY (DEMQOL-U)<sup>c</sup> (n=394)</b>	<b>QALY (EQ5D3L)<sup>c</sup> (n=384)</b>
<b>Person with dementia, 9 months</b>				
Health and social care <sup>f</sup>	1 300/1.38=942	1 255/0.17=7 382	1 160/0.002=580 000	
<b>Carer, 9 months</b>				
Health and social care <sup>f</sup>	NA	NA	NA	1 305/0.01=130 500

a Cost of achieving a 1.32 points difference between groups at nine months

b Cost of achieving a 1.53 points difference between groups at nine months

c Cost of achieving a QALY gain over nine months

Table 83. Sensitivity analysis: Imputed data. Person with dementia: outcome scores and costs at nine months from regression estimates

	<b>CR<sup>a</sup></b> <b>(n=231)</b>	<b>95% CI<sup>b</sup></b>	<b>TAU<sup>a</sup></b> <b>(n=231)</b>	<b>95% CI<sup>b</sup></b>	<b>CR-TAU</b> <b>Mean Difference</b>	<b>95% CI<sup>b</sup></b>	<b>p</b> <b>value</b>
BGSI <sup>b</sup>	4.56	4.37 to 4.76	3.209	3.03 to 3.39	1.35	1.10 to 1.62	0.000
GSES <sup>b</sup>	20.160	19.791 20.537	19.946	19.559 20.337	0.21	-0.27 to 0.71	0.388
QALY <sup>b</sup> (DEMQOL-U)	0.45	0.44 to 0.45	0.45	0.44 to 0.46	0.00	-0.01 to 0.01	0.938
Health & social care <sup>c</sup>	5426	4692 6452	4329	3357 5745	1 097	-326 to 2 258	0.102
Societal <sup>c</sup>	23359	21404 25659	23343	21407 25468	-15	-2 545 to 2 279	0.990

a Estimated marginal means

b bias-corrected bootstrapped 95% confidence intervals (3000 replications)

c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome

d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.

e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points

Table 84. Sensitivity analysis: Imputed data. Carer: outcome scores and costs at nine months from regression estimates

	<b>CR<sup>a</sup></b> <b>(n=231)</b>	<b>95% CI<sup>b</sup></b>	<b>TAU<sup>a</sup></b> <b>(n=231)</b>	<b>95% CI<sup>b</sup></b>	<b>CR-TAU<sup>a</sup></b> <b>Mean Difference</b>	<b>95% CI<sup>b</sup></b>	<b>p value</b>
QALY <sup>ce</sup> (EQ5-3L)	0.56	0.54 to 0.58	0.56	0.54 to 0.58	0.00	-0.01 to 0.01	0.715
Health & social care <sup>c</sup>	5 423	4 689 to 6 435	4 332	3 363 to 5 771	1091	-337 to 2 236	0.102
Societal <sup>c</sup>	23 298	21 351 to 25 446	23404	21 434 to 25 700	-106	-2 560 to 2 163	0.930

Note: Imputed data: 25 complete datasets were generated by the imputation model.

a Estimated marginal means

b bias-corrected bootstrapped 95% confidence intervals (3000 replications)

c Estimates from outcome equation: adjusted for centre, age and sex of person with dementia, stratified MMSE score, allocation to treatment, baseline outcome

d Estimates from costs equation: adjusted for centre, age and sex of person with dementia, MMSE score above or below 24, allocation to treatment, costs in three months pre-baseline.

e QALY calculated using the area-under-the-curve method with linear interpolation between assessment points

Table 85. Sensitivity analysis: Imputed data. Person with dementia and carer: Point ICER<sup>a</sup> for CR over TAU, from health and social care and societal perspectives Sample: Imputed data

	<b>BGSI<sup>a</sup></b> <b>(n=462)</b>	<b>GSES<sup>b</sup></b> <b>(n=462)</b>	<b>QALY (DEMQOL-U)<sup>c</sup></b> <b>(n=462)</b>	<b>QALY (EQ5D3L)<sup>c</sup></b> <b>(n=462)</b>
<b>Person with dementia, 9 months</b>				
Health and social care	1 097/1.35=813	1 097/0.21=5 224	1 097/0.0003=3 656 667	NA
Societal	-15/1.35=-11	-15/0.21=-71	-15/0.0003=-50 000	NA
<b>Carer, 9 months</b>				
Health and social care	NA	NA	NA	1091/0.003=363 667
Societal	NA	NA	NA	-106/0.003=-35 333

Note: Imputed data: 25 complete datasets were generated by the imputation model. Numbers of observations given represent the maximum number of observations: numbers of observations varied between datasets (range of 460 to 462) because survival of the person with dementia was imputed.

a Cost of achieving a 1.32 points difference between groups at nine months

b Cost of achieving a 1.53 points difference between groups at nine months

c Cost of achieving a QALY gain over nine months; difference in QALY rounded to first non-zero decimal place

## Appendix 17. Cost-effectiveness acceptability curves and cost-effectiveness planes

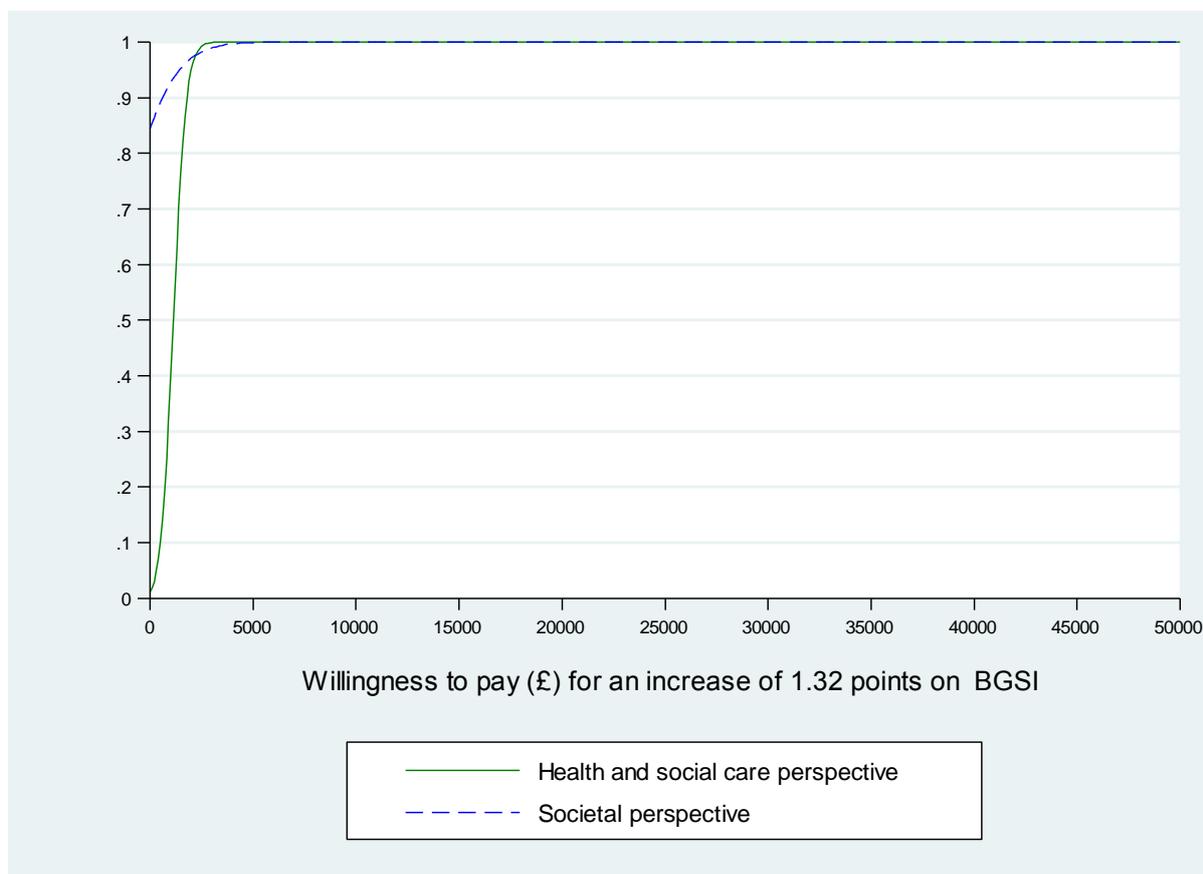


Figure 15. Cost-effectiveness acceptability curve: BGSi, person with dementia; replacement costs of unpaid care

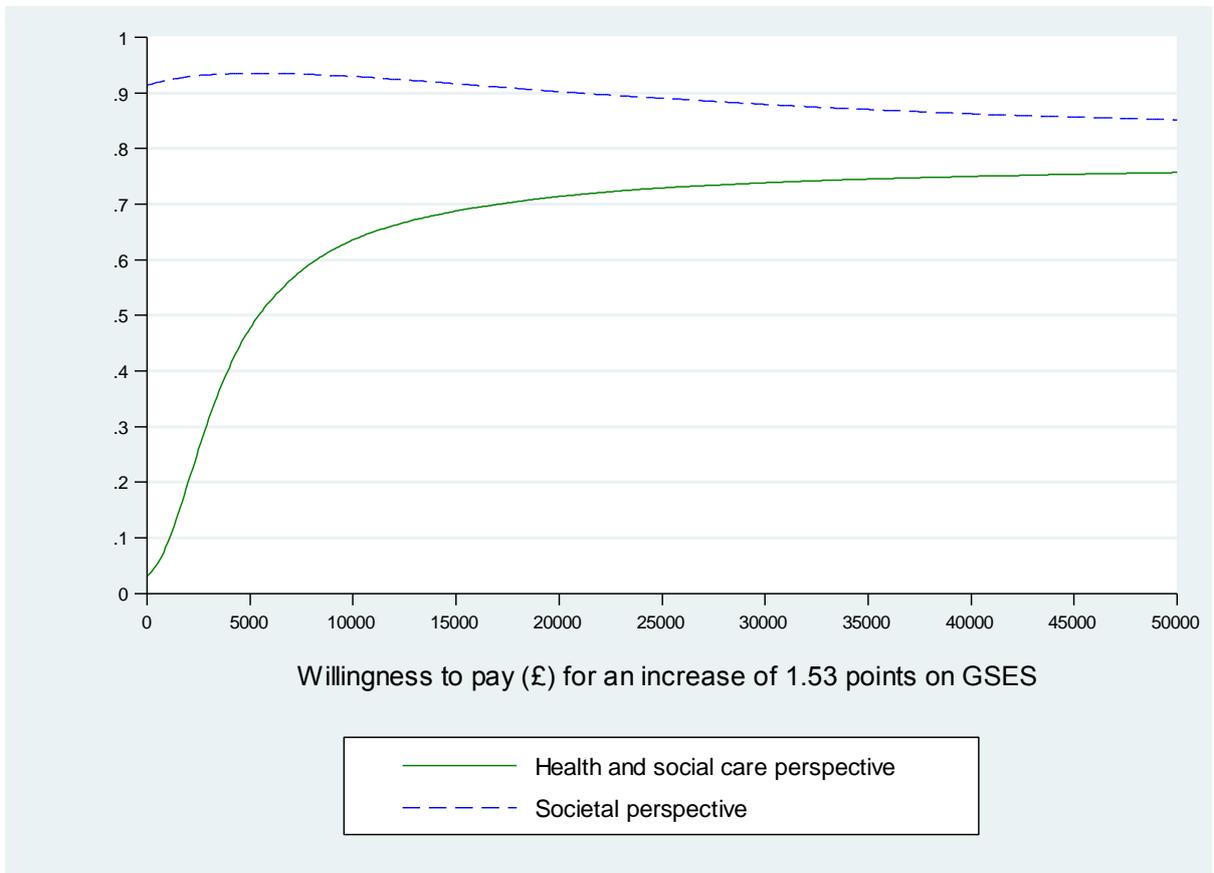


Figure 16. Cost-effectiveness acceptability curve: GSES, person with dementia; replacement costs of unpaid care

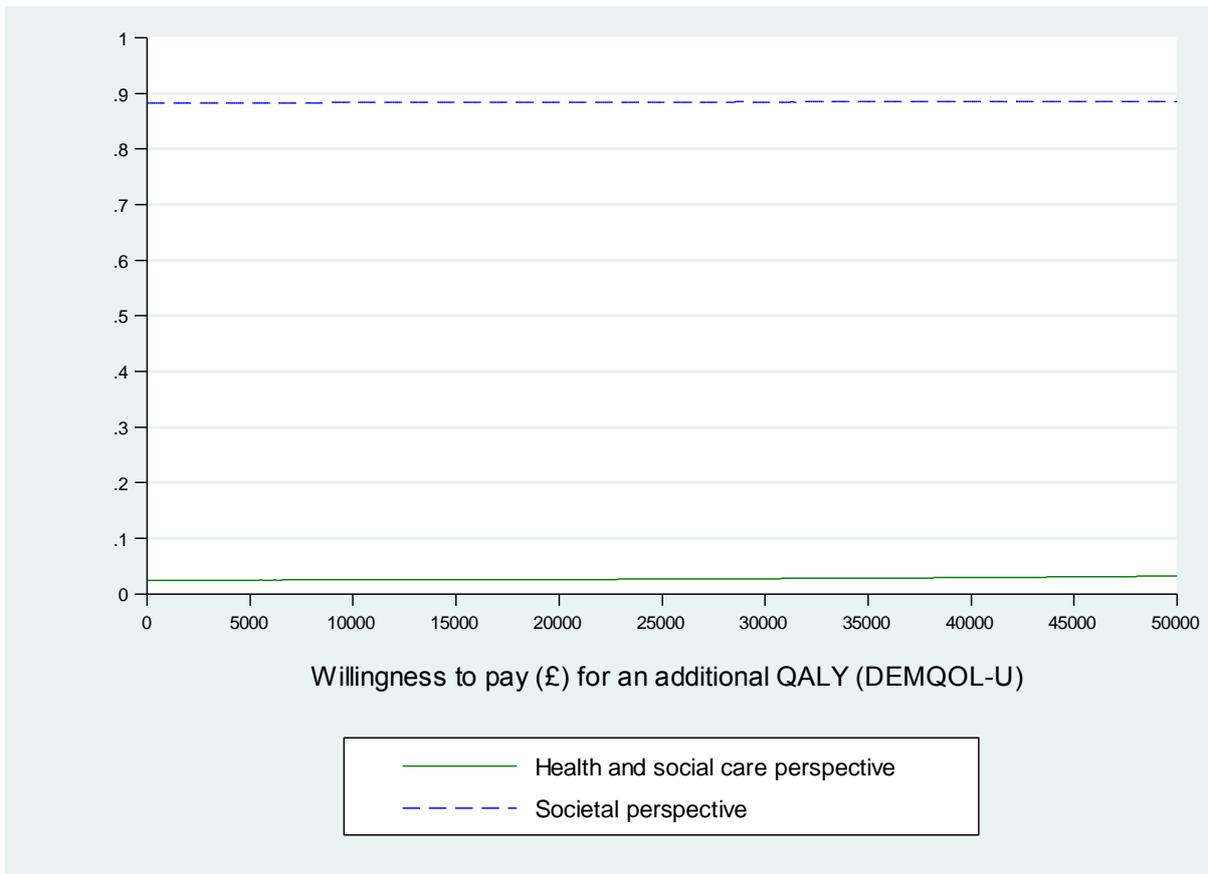


Figure 17. Cost-effectiveness acceptability curve: QALY (DEMQOL-U), person with dementia; replacement costs of unpaid care

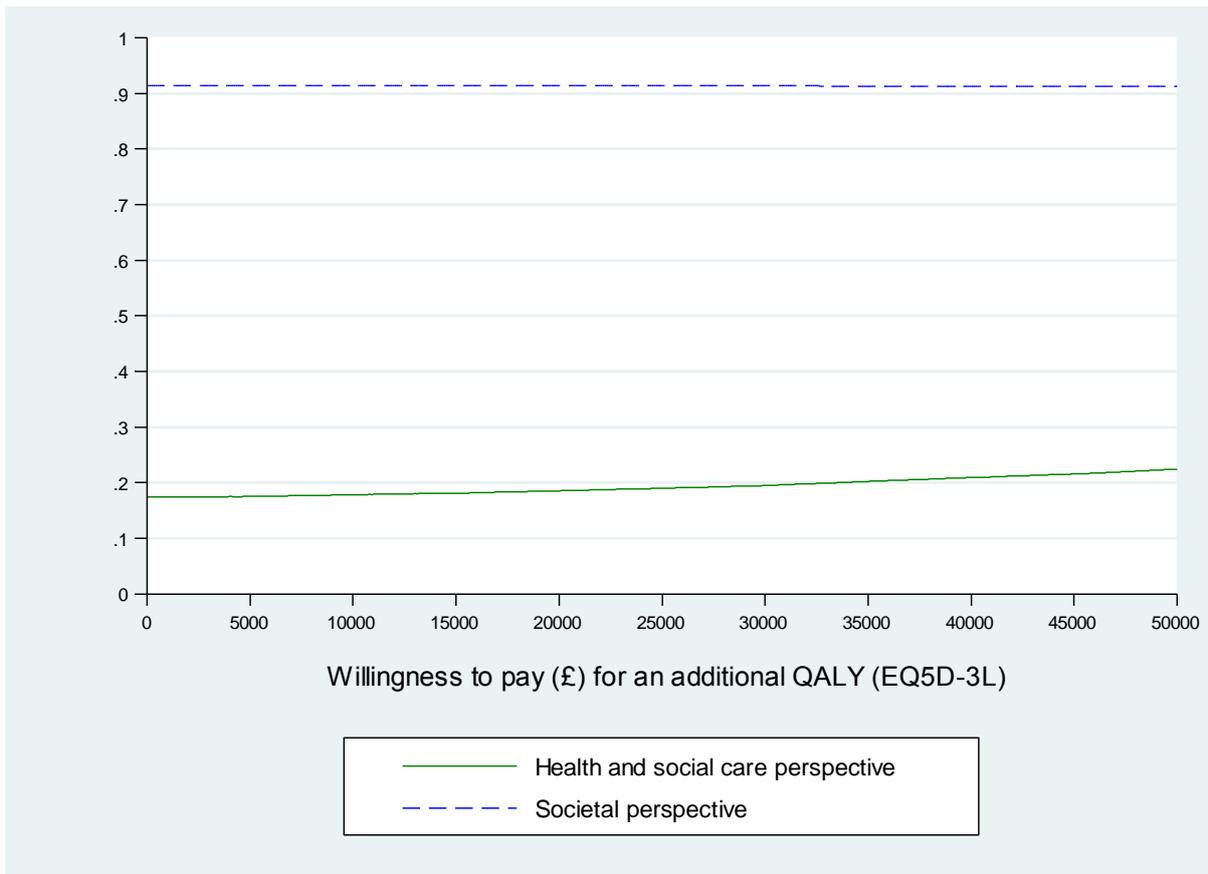


Figure 18. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer; replacement costs of unpaid care

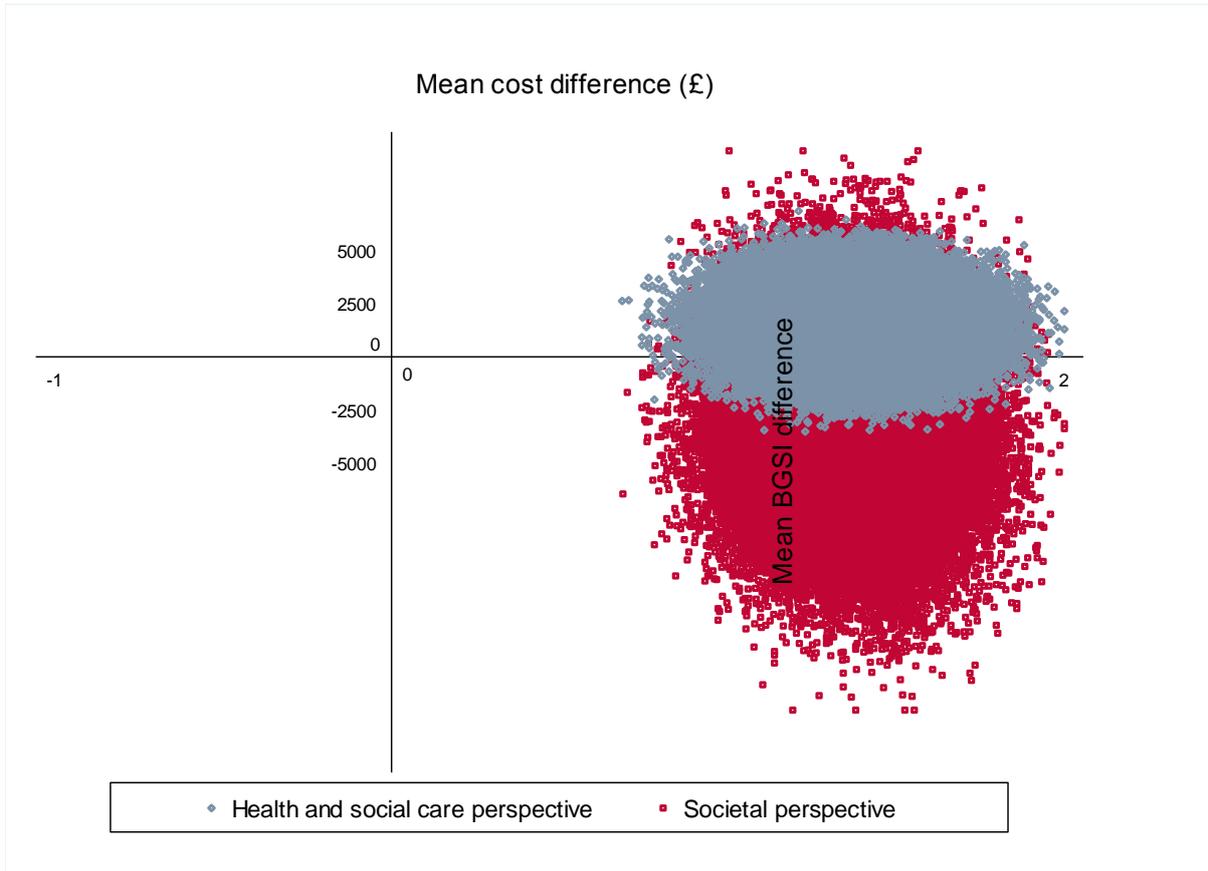


Figure 19. Cost-effectiveness plane: incremental costs and endpoint difference on BGSi at nine months, person with dementia; replacement costs of unpaid care

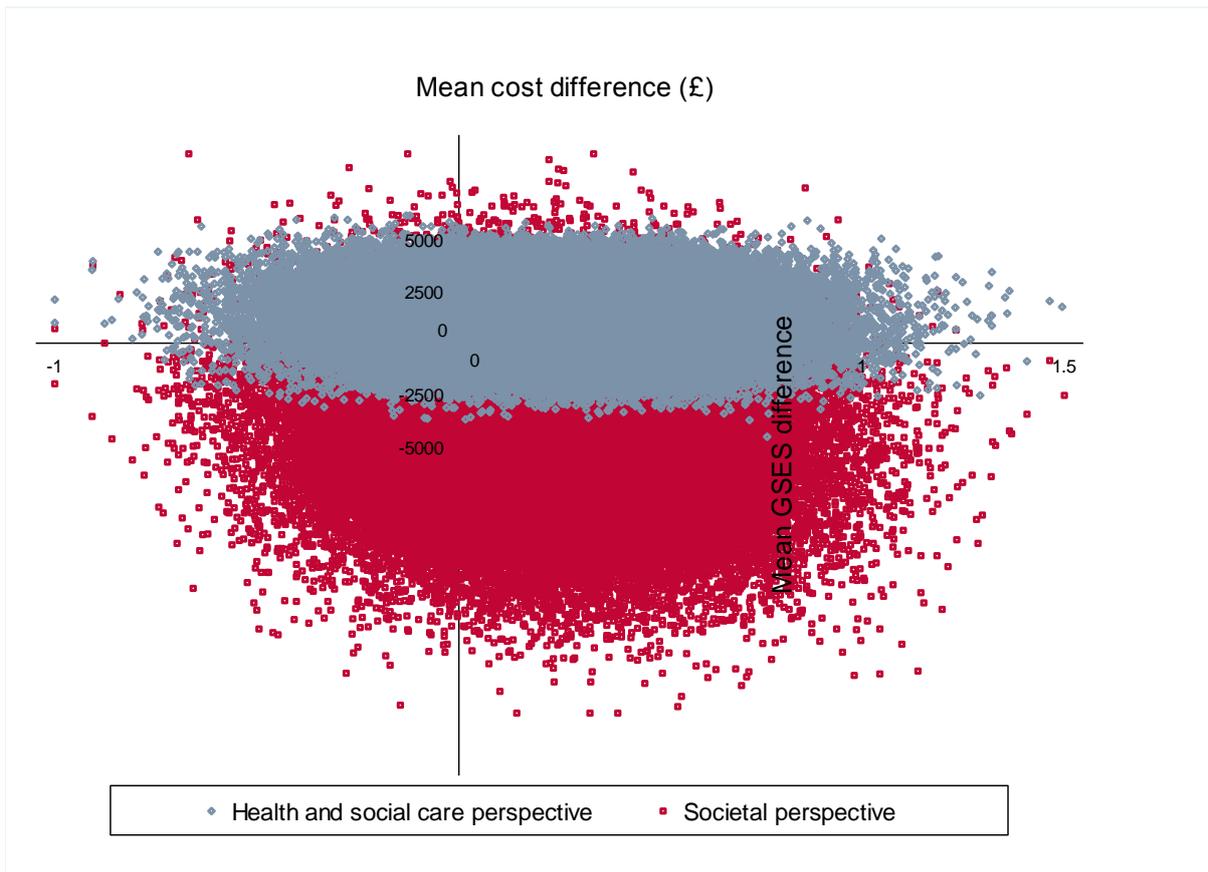


Figure 20. Cost-effectiveness plane: incremental costs and endpoint difference GSES at nine months, person with dementia; replacement costs of unpaid care

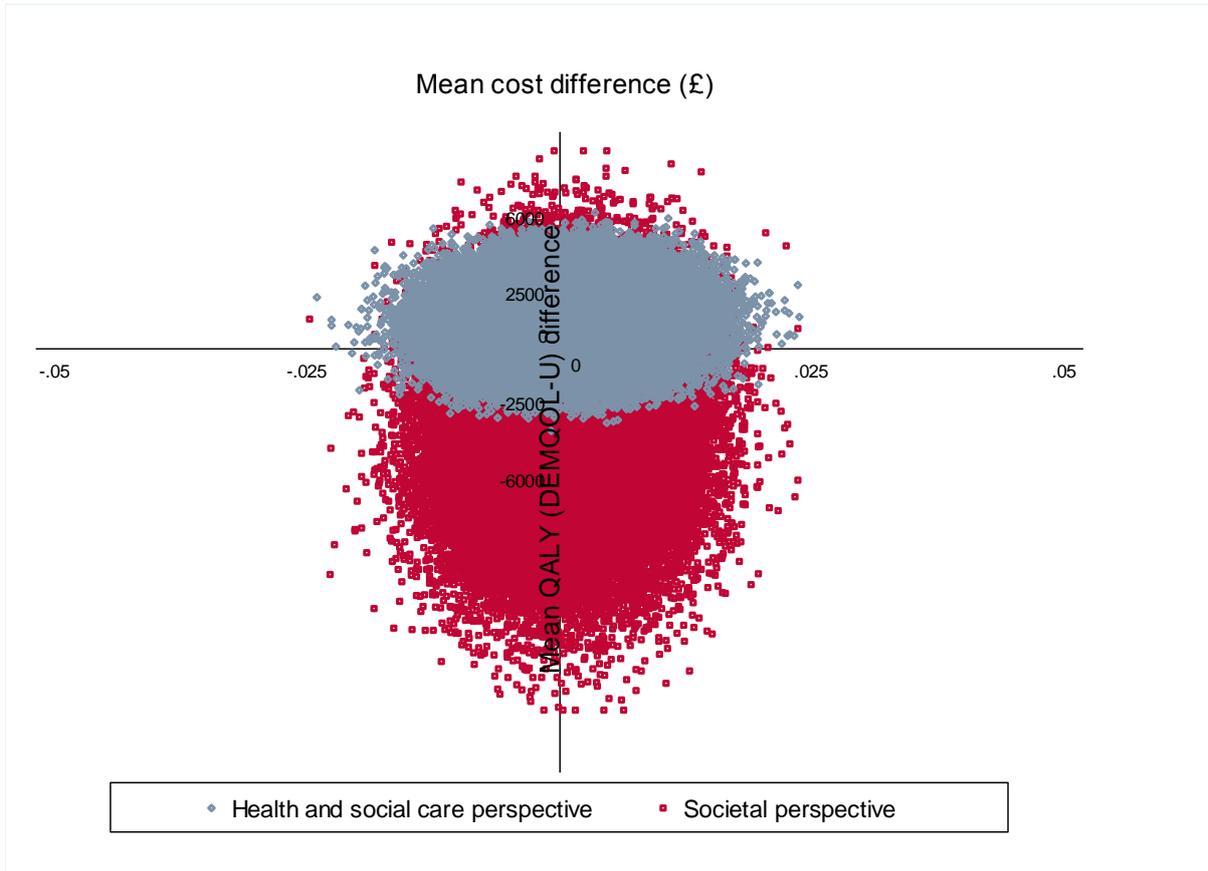


Figure 21. Cost-effectiveness plane: incremental costs and QALY (DEMQOL-U) at nine months, person with dementia; replacement costs of unpaid care

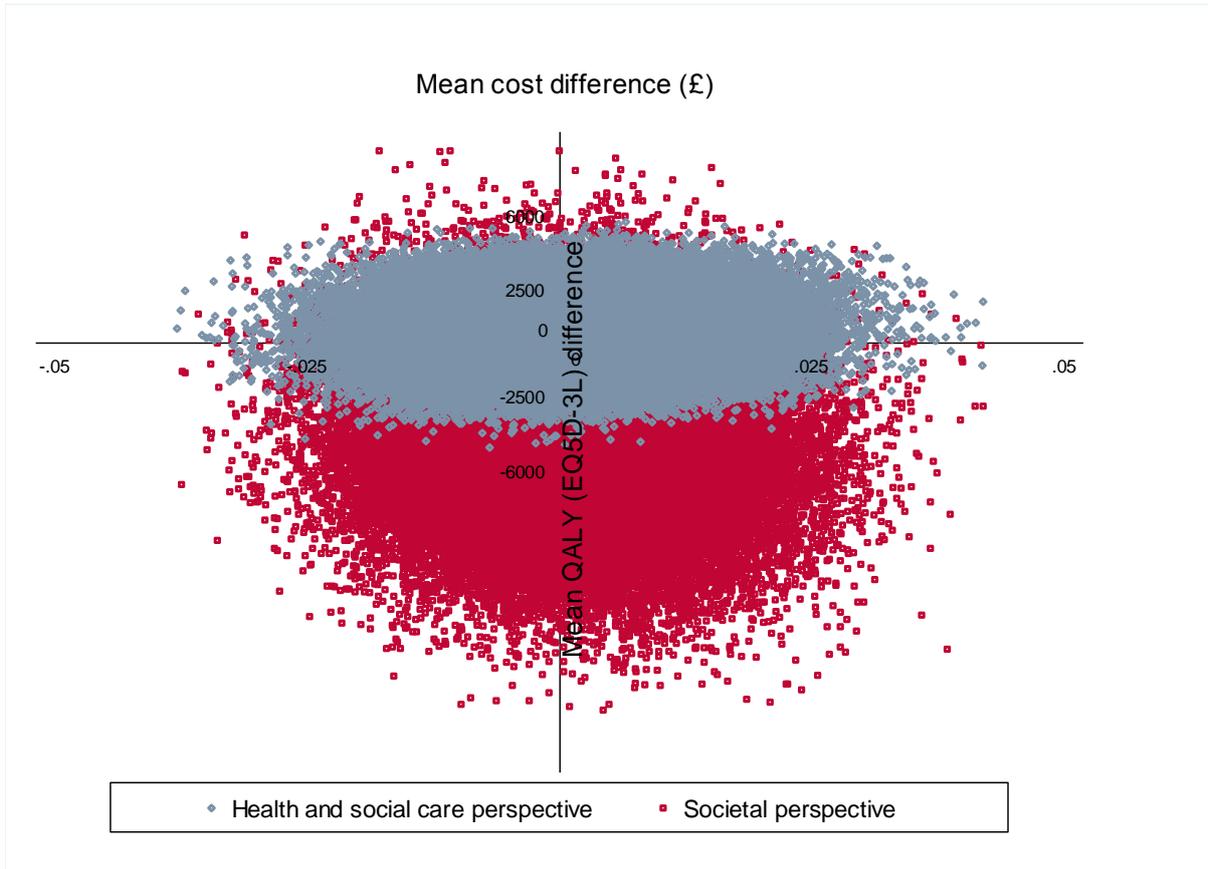


Figure 22. Cost-effectiveness plane: incremental costs and QALY (EQ5D3L) at nine months, carer; replacement costs of unpaid care

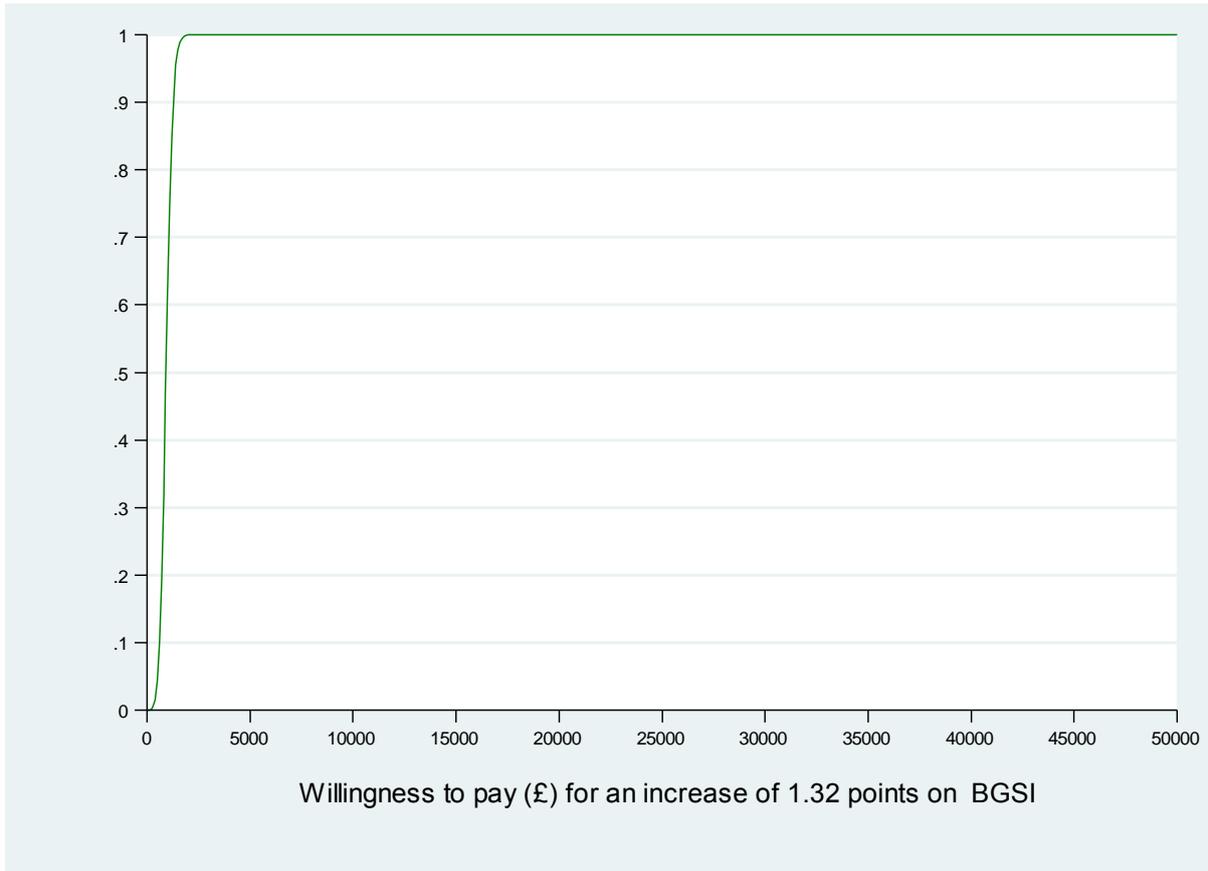


Figure 23. Cost-effectiveness acceptability curve: BGSi, person with dementia; excluding high-cost outliers

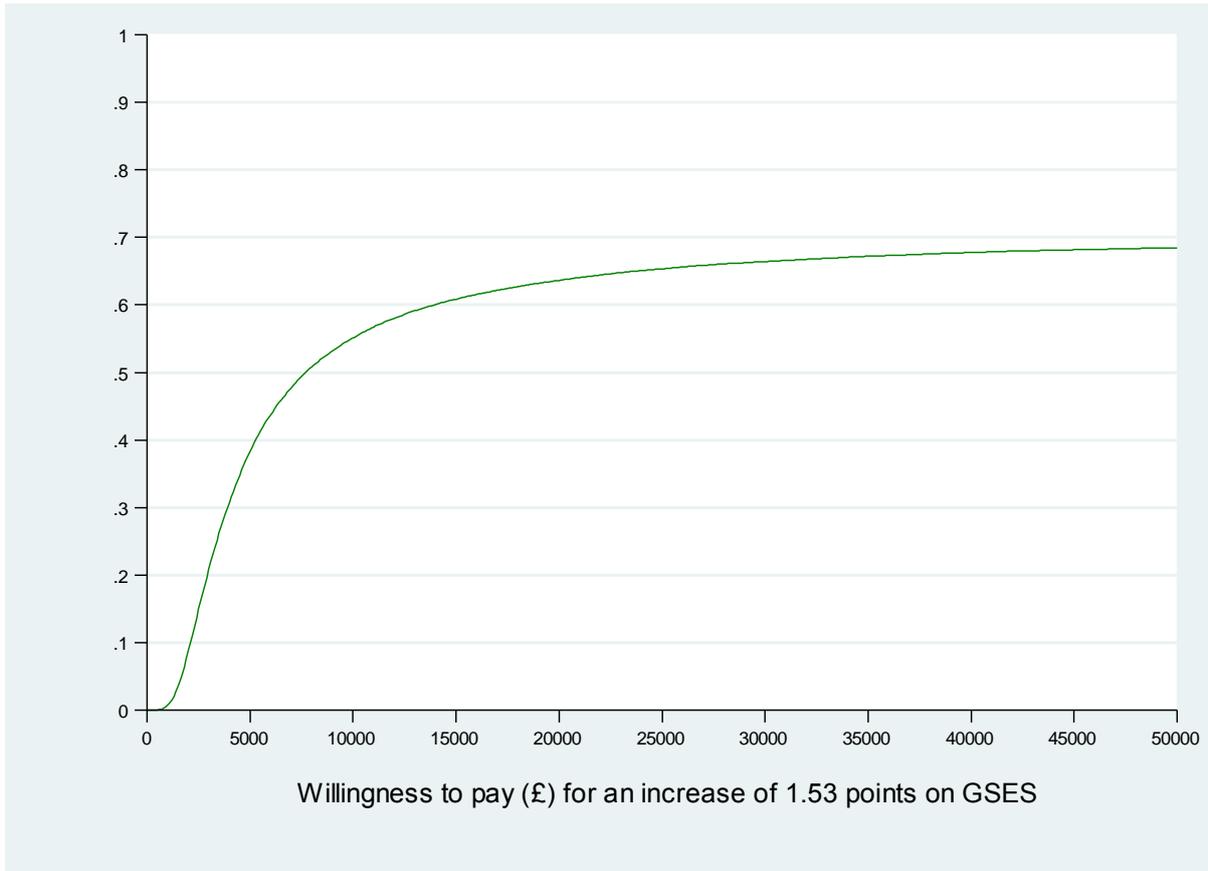


Figure 24. Cost-effectiveness acceptability curve: GSES, person with dementia; excluding high-cost outliers

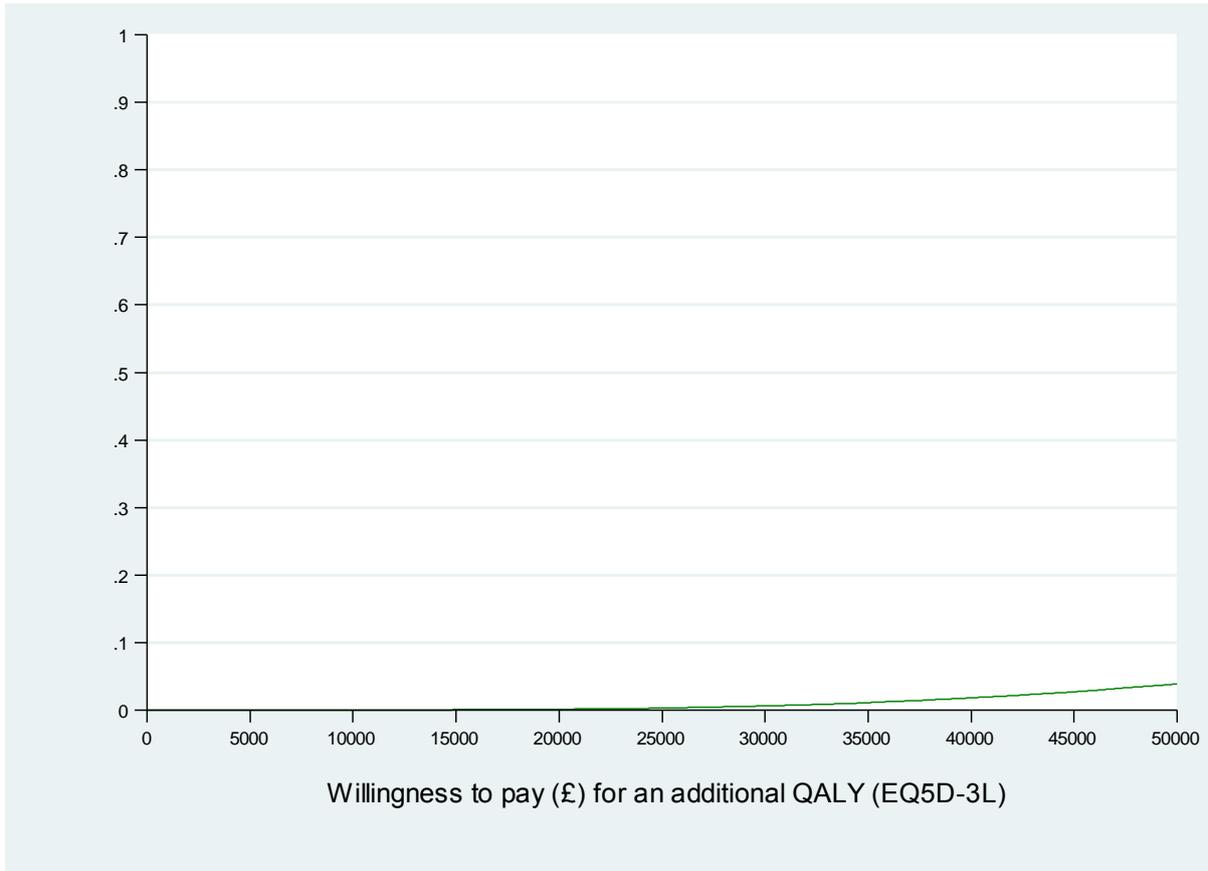


Figure 25. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer; excluding high-cost outliers

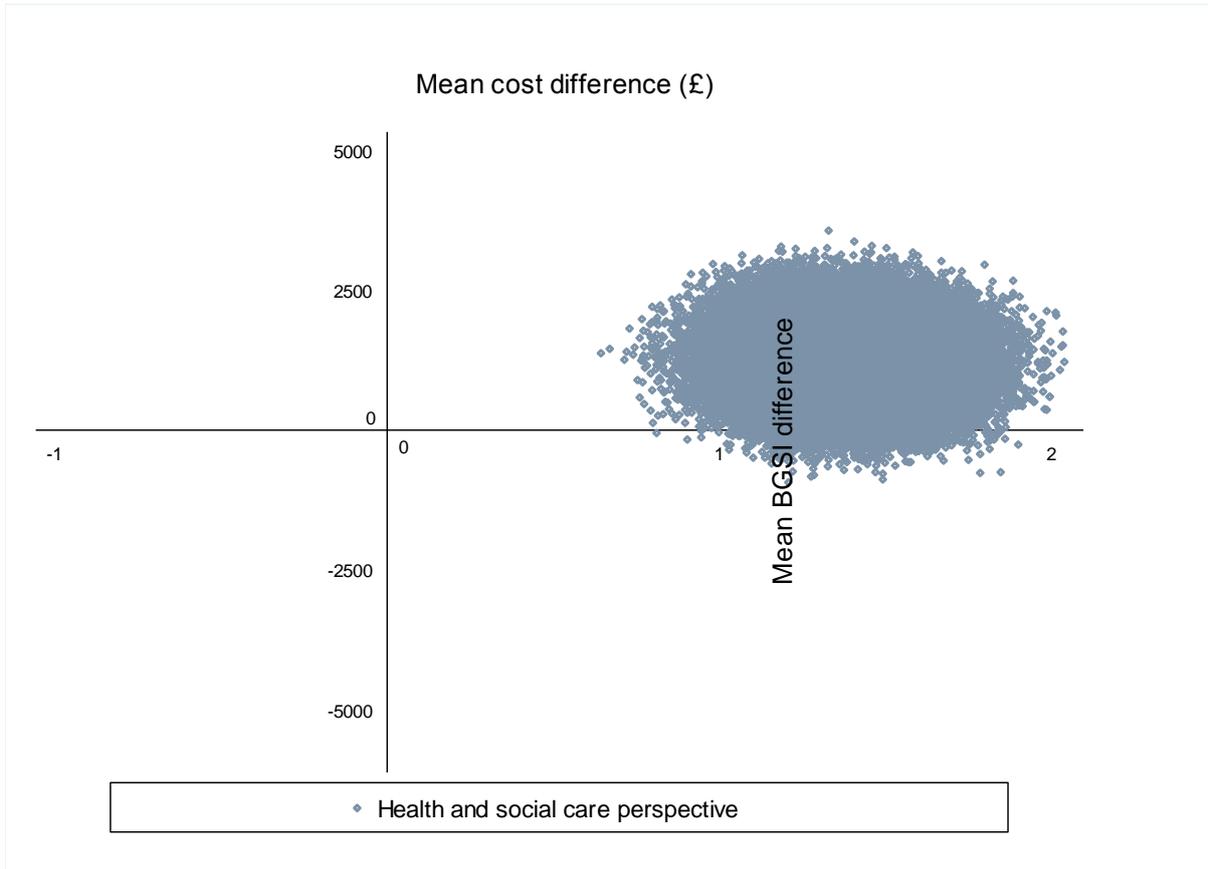


Figure 26. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and endpoint difference on BGSJ at nine months, person with dementia

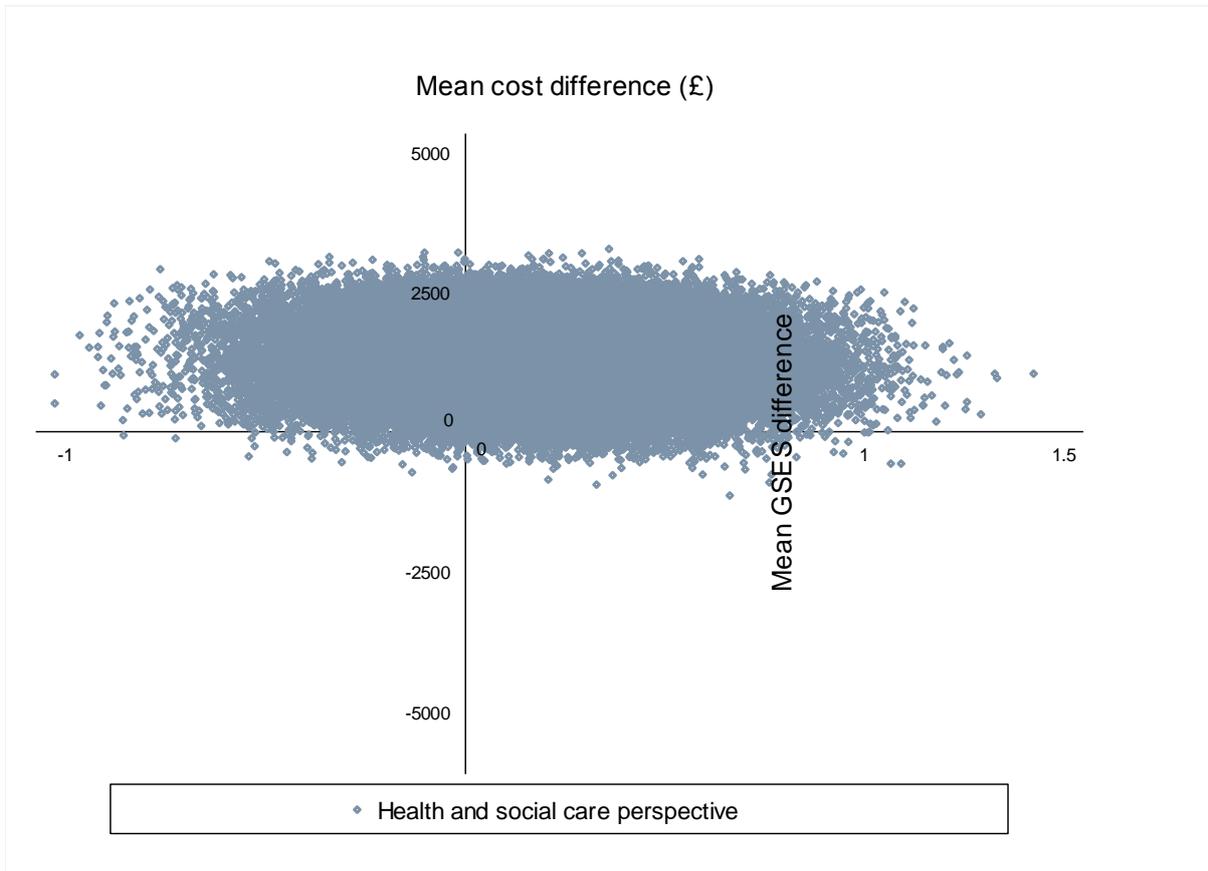


Figure 27. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and endpoint difference GSES at nine months, person with dementia

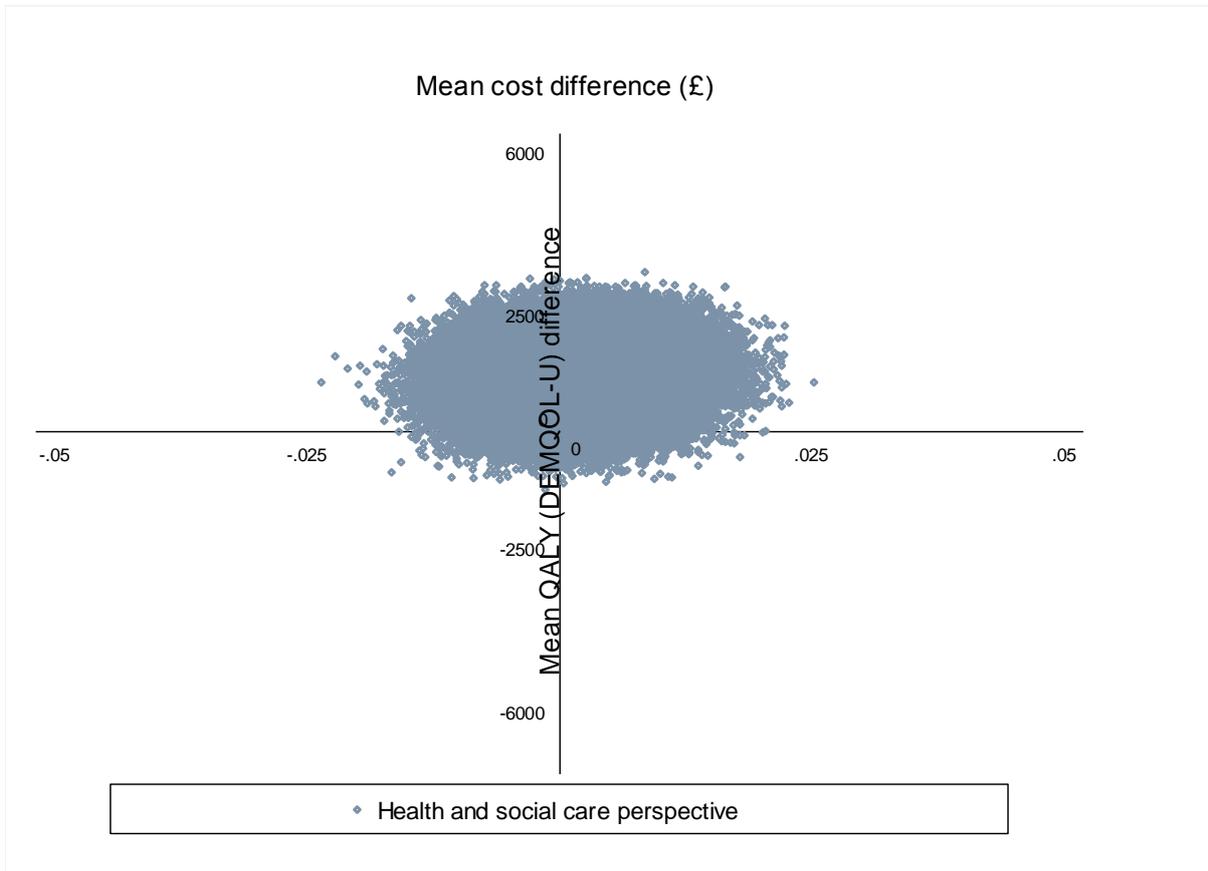


Figure 28. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and QALY (DEMQOL-U) at nine months, person with dementia

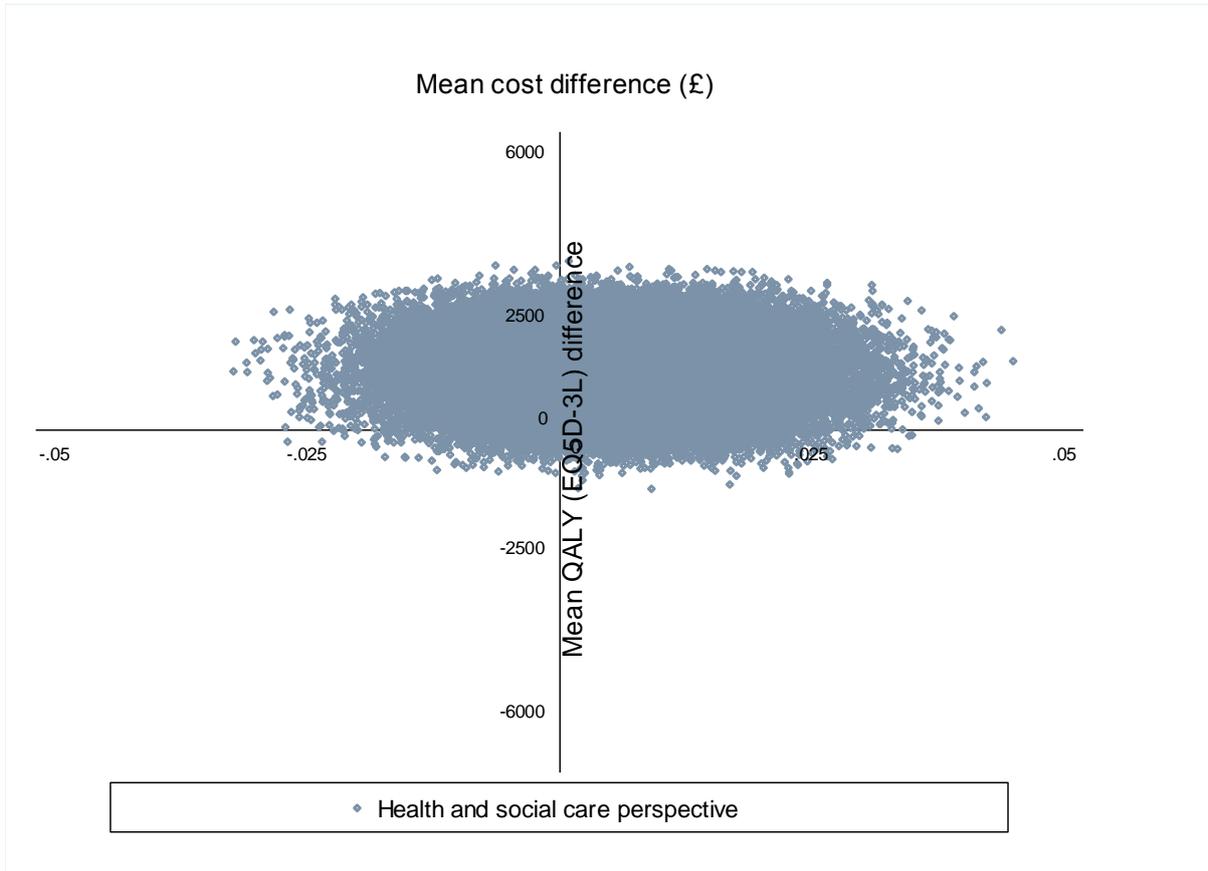


Figure 29. Cost-effectiveness plane: incremental costs (excluding high-cost outliers) and QALY (EQ5D3L) at nine months, carer

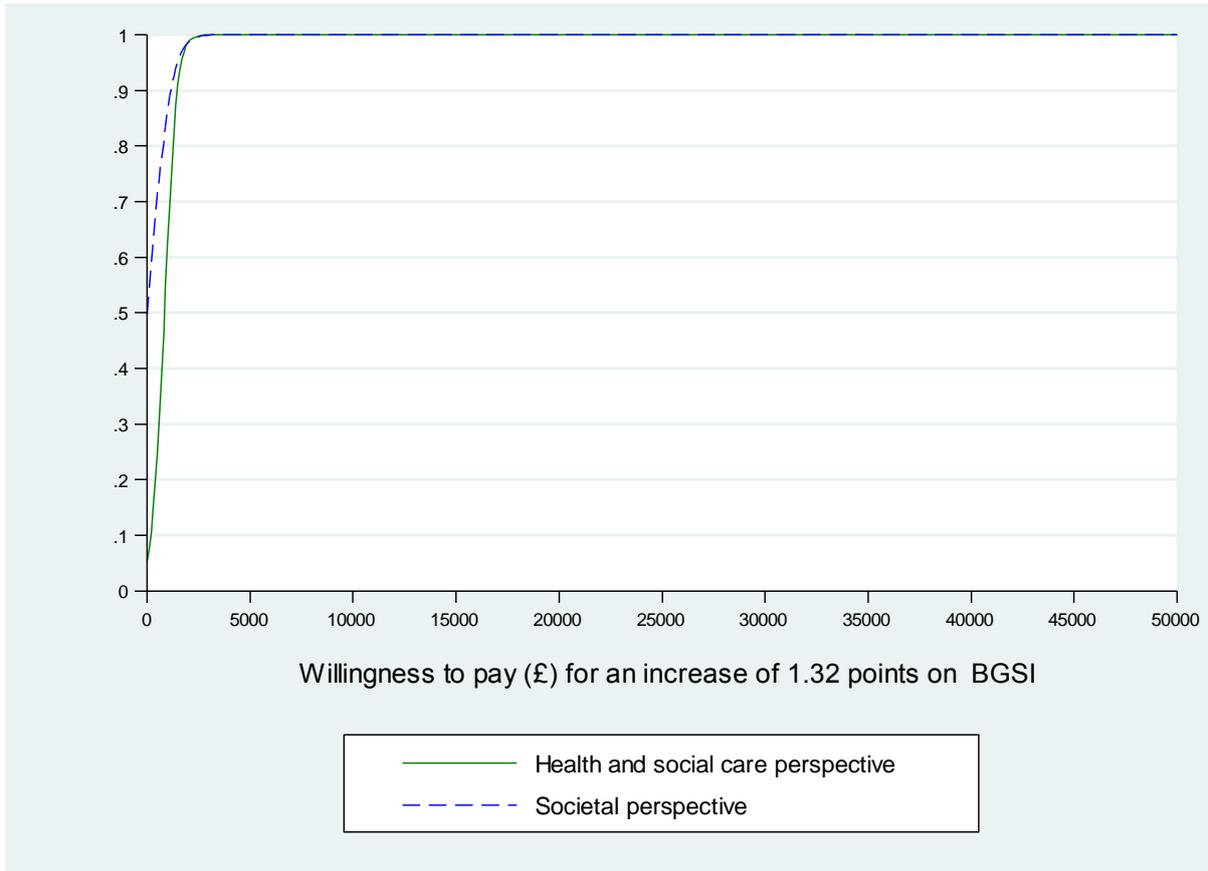


Figure 30. Cost-effectiveness acceptability curve: BGSi, person with dementia; imputed data

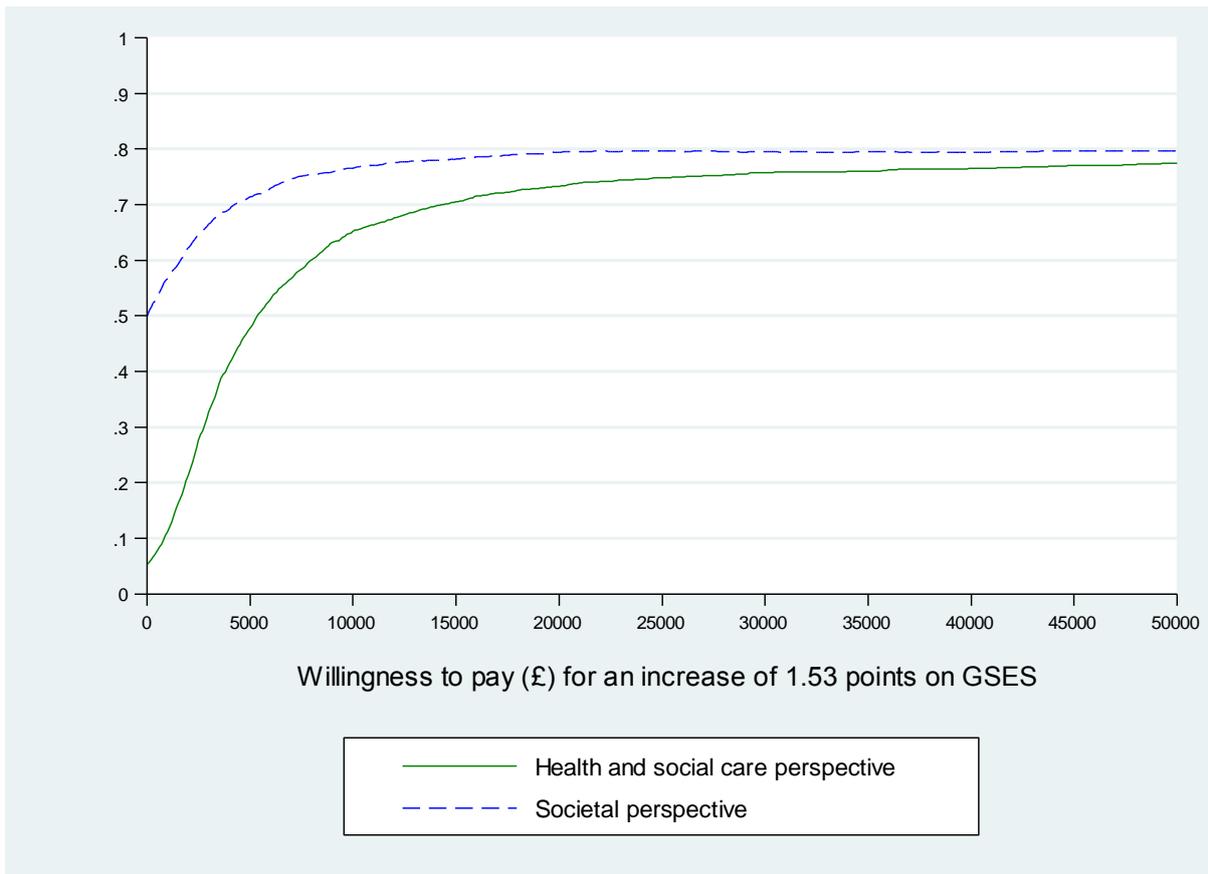


Figure 31. Cost-effectiveness acceptability curve: GSES, person with dementia; imputed data

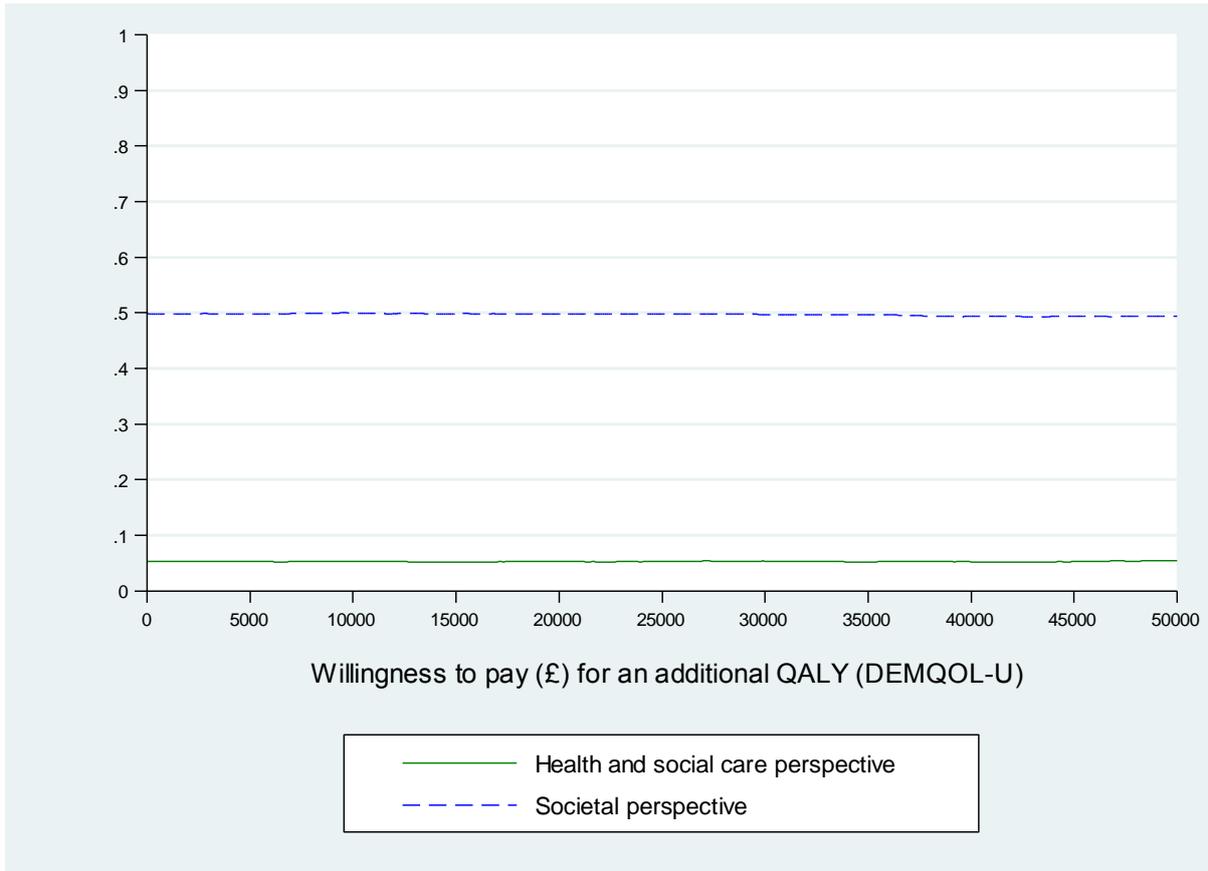


Figure 32. Cost-effectiveness acceptability curve: QALY (DEMQOL-U), person with dementia; imputed data

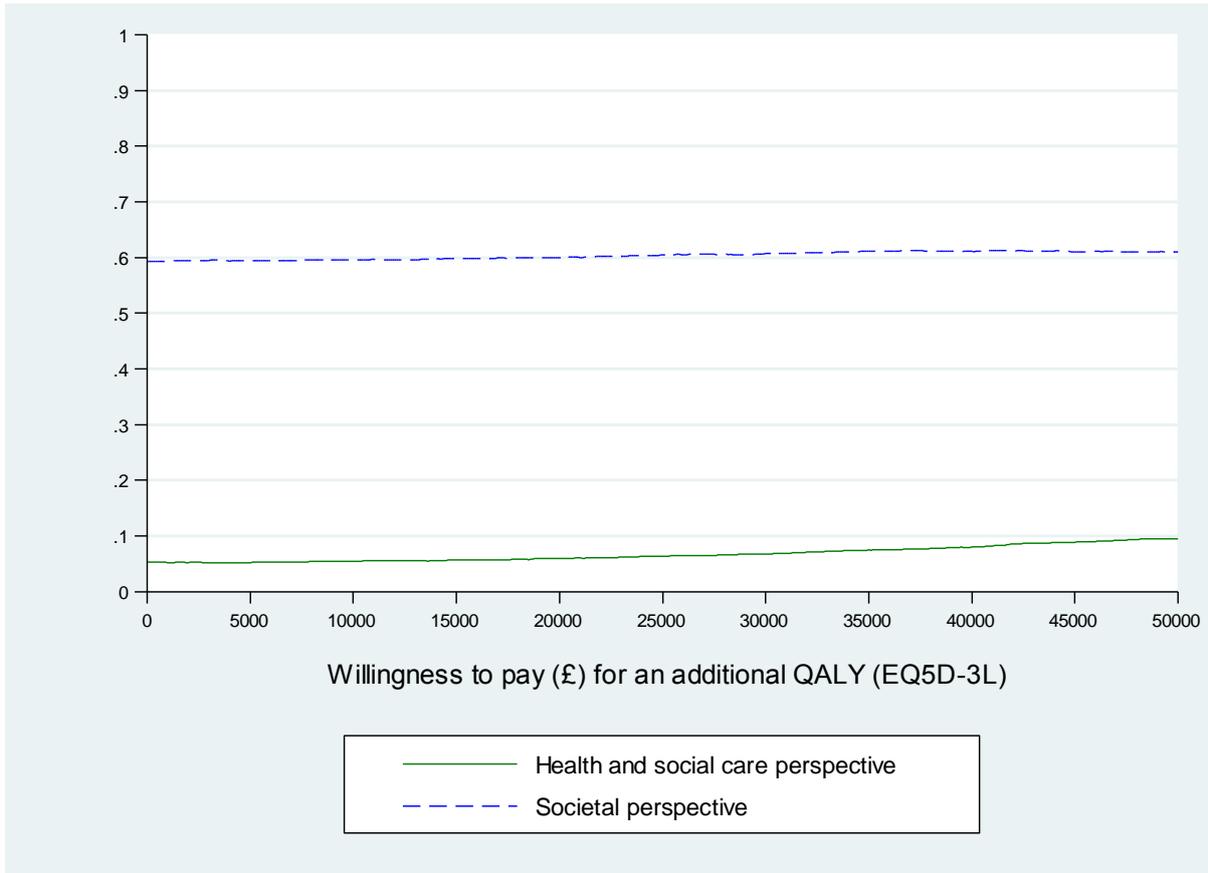


Figure 33. Cost-effectiveness acceptability curve: QALY (EQ5D3L), carer; imputed data

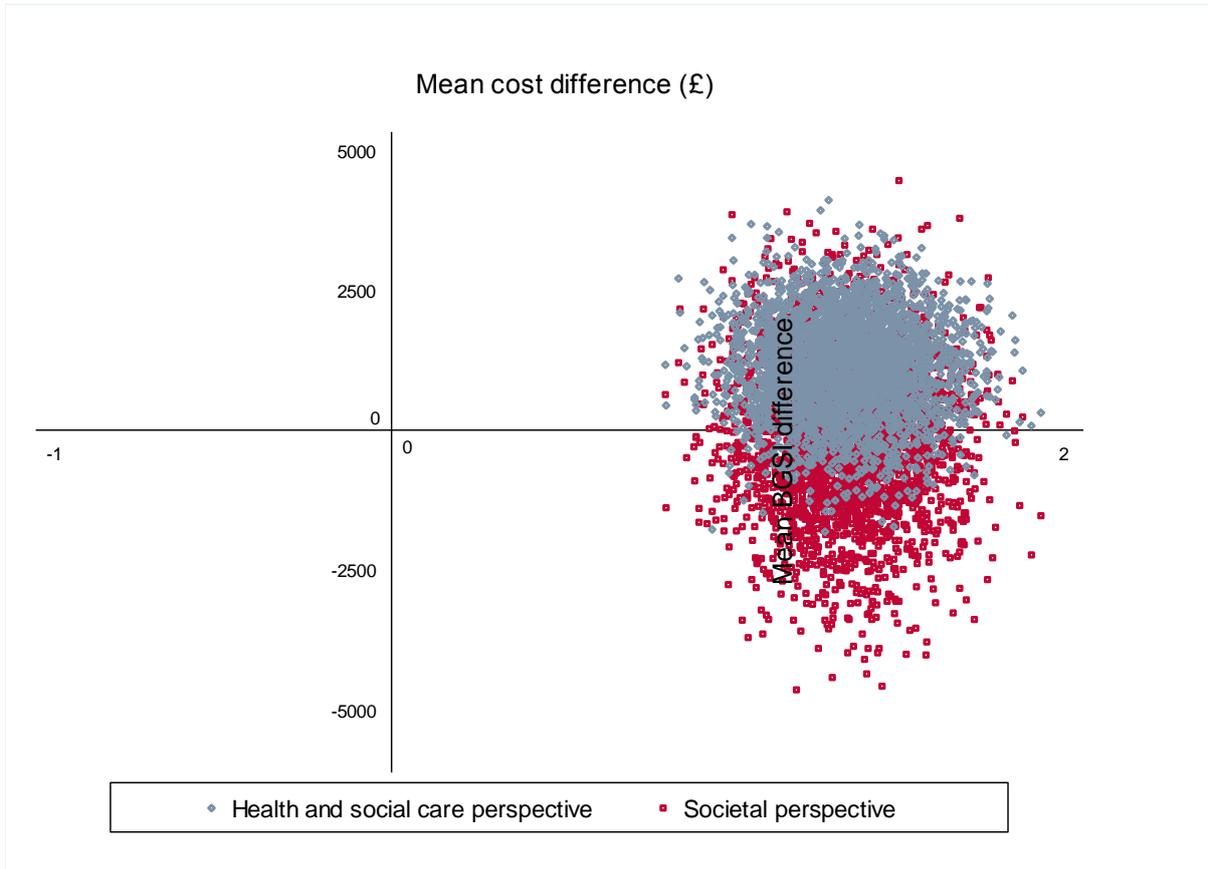


Figure 34. Cost-effectiveness plane: incremental costs and endpoint difference on BGSi at nine months, person with dementia; imputed data

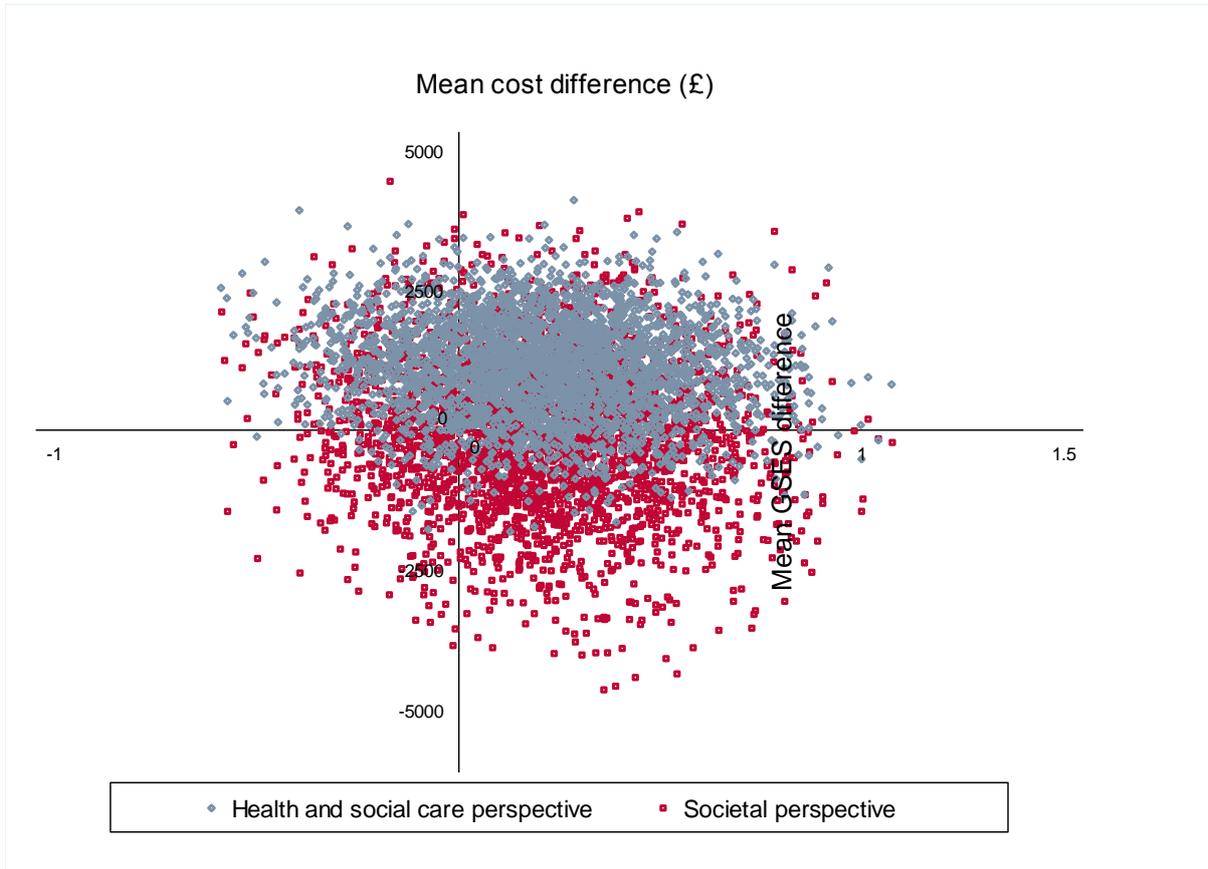


Figure 35. Cost-effectiveness plane: incremental costs and endpoint difference GSES at nine months, person with dementia; imputed data

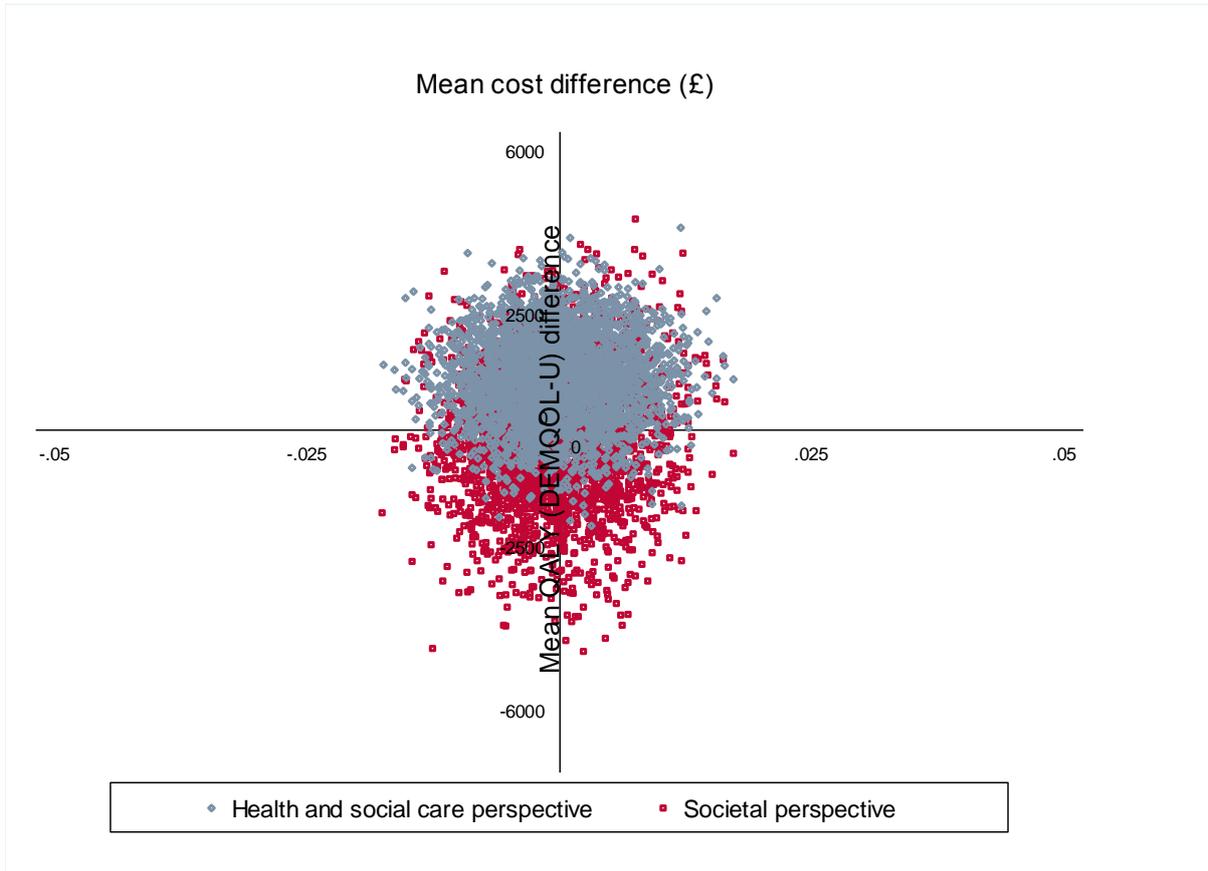


Figure 36. Cost-effectiveness plane: incremental costs and QALY (DEMQOL-U) at nine months, person with dementia; imputed data

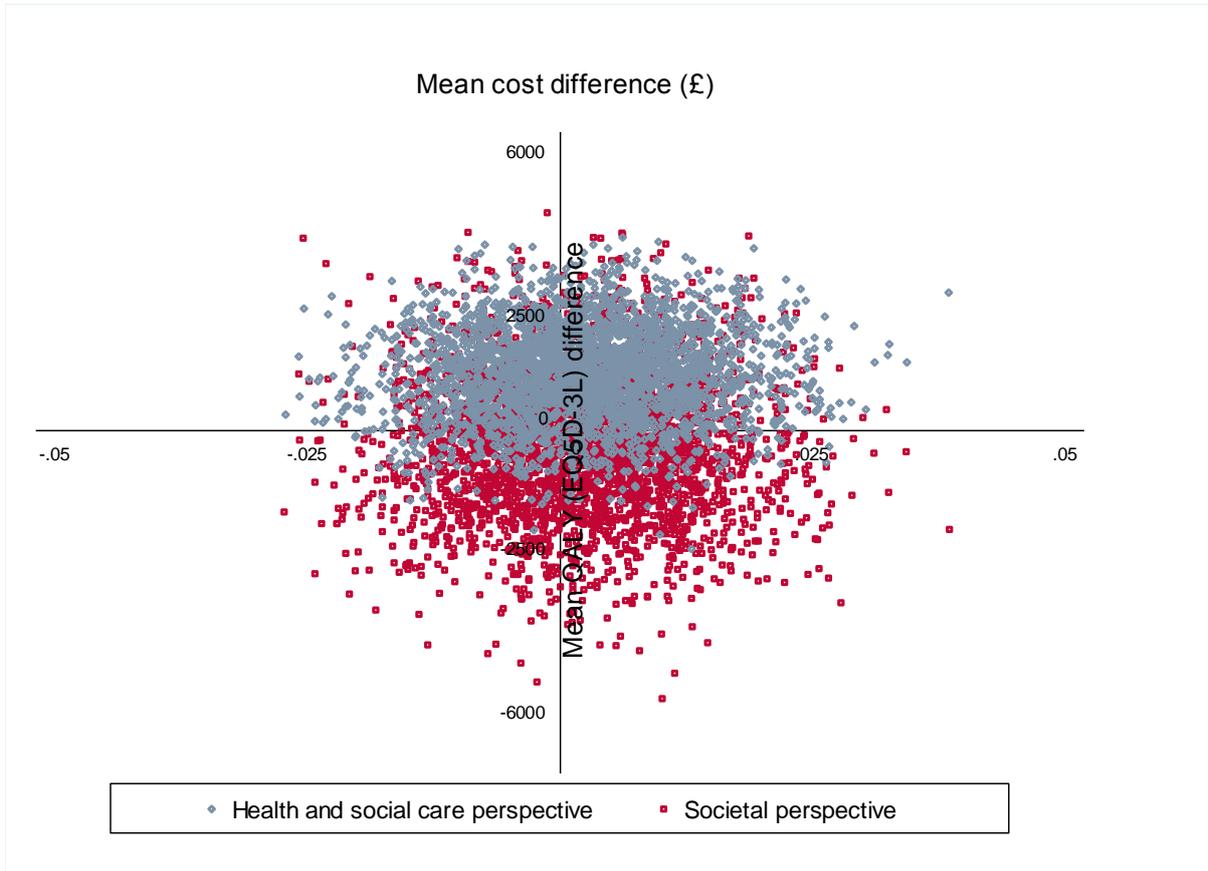


Figure 37. Cost-effectiveness plane: incremental costs and QALY (EQ5D3L) at nine months, carer; imputed data