Does befriending by trained lay workers improve psychological well-being and quality of life for carers of people with dementia, and at what cost? A randomised controlled trial

G Charlesworth, L Shepstone, E Wilson, M Thalanany, M Mugford and F Poland

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Does befriending by trained lay workers improve psychological well-being and quality of life for carers of people with dementia, and at what cost? A randomised controlled trial

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The research reported in this issue of the journal was commissioned by the HTA Programme as project number 99/34/07. The contractual start date was in January 2002. The draft report began editorial review in October 2006 and was accepted for publication in August 2007. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.
Objectives: To determine whether a social support intervention (access to an employed befriending facilitator in addition to usual care) is effective compared with usual care alone. Also to document direct and indirect costs, and establish incremental cost-effectiveness.

Design: The Befriending and Costs of Caring (BECCA) trial was a cost-effectiveness randomised controlled trial. Data on well-being and resource use were collected through interviews with participants at baseline and at 6, 15 and 24 months.

Setting: This research was carried out in the English counties of Norfolk and Suffolk, and the London Borough of Havering. It was a community-based study.

Participants: Participants were family carers who were cohabiting with, or providing at least 20 hours’ care per week for, a community-dwelling relative with a primary progressive dementia.

Interventions: The intervention was ‘access to a befriender facilitator’ (BF). BFs, based with charitable/voluntary-sector organisations, were responsible for local befriending schemes, including recruitment, screening, training and ongoing support of befriending volunteers, and for matching carers with befrienders. The role of befrienders was to provide emotional support for carers. The target duration for befriending relationships was 6 months or more.

Main outcome measures: Depression was measured by the Hospital Anxiety and Depression Scale (HADS) at 15 months postrandomisation. The health-related quality of life scale EQ-5D (EuroQol 5 Dimensions) was used to derive utilities for the calculation of quality-adjusted life-years (QALYs).

Results: A total of 236 carers were randomised into the trial (116 intervention; 120 control). At final follow-up, 190 carers (93 intervention; 97 control) were still involved in the trial (19% attrition). There was no evidence of effectiveness or cost-effectiveness from the primary analyses on the intention-to-treat population. The mean incremental cost per incremental QALY gained was in excess of £100,000, with only a 42.2% probability of being below £30,000 per QALY gained. Where care-recipient QALYs were included, mean incremental cost per incremental QALY gained was £26,848, with a 51.4% probability of being below £30,000 per QALY gained. Only 60 carers (52%) took up the offer of being matched with a trained lay befriender, and of these only 37 (32%) were befriended for 6 months or more. A subgroup analysis of controls versus those befriended for 6 months or more found a reduction in HADS-depression scores that approached statistical significance (95% CI –0.09 to 2.84).

Conclusions: ‘Access to a befriender facilitator’ is neither an effective nor a cost-effective intervention in the support of carers of people with dementia, although there is a suggestion of cost-effectiveness for the care dyad (carer and care recipient). In common with many services for carers of people with dementia, uptake of befriending services was not high. However, the small number of carers who engaged with befrienders for 6 months or more reported a reduction in HADS-depression scores that approached statistical significance compared with controls (95% CI –0.09 to 2.84). While providing only weak evidence of any beneficial effect, further research into befriending interventions for carers is warranted.
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Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout this review.

Glossary

**Befriender facilitator**  In the context of this study, a voluntary sector employee with the responsibility of recruiting, screening, training, matching and supporting volunteer befrienders.

**Befriending**  In the context of this study, befriending refers to one-to-one emotional support by a trained lay volunteer.

**Bootstrapping**  Statistical method for examining uncertainty. It is a non-parametric simulation method used in economic evaluation and is particularly useful when underlying data have a skewed distribution.

**Carers**  Carers are defined in this report as family members providing care for a person with a primary progressive dementia.

**Direct costs**  The costs of providing the intervention, primary and secondary care resource use, out-of-pocket expenses and travel costs incurred by patients or carers, and family care costs.

**Discounting**  A method by which future costs and benefits are converted to present values.

**Indirect costs**  In the context of this study, the value of time spent in the caring role.

**Opportunity cost**  The benefit that could have been obtained from the next best use of resources. The opportunity cost of an action is the value of the forgone alternative action. Opportunity costs arise because the resources available to meet wants are finite, so that all wants cannot be satisfied.

**Perspective**  A viewpoint for conducting a cost-effectiveness analysis. Four perspectives are used in this analysis. The **societal perspective** incorporates all costs and all health effects regardless of who incurs the costs and who obtains the effects. Thus, a societal perspective in healthcare means considering costs that fall upon health services, other public sector budgets such as provision of social support, cost of lost productivity as well as the costs that fall upon patients and caregivers. The **statutory sector perspective** incorporates costs incurred by the health service and other public sector budgets (e.g. social services) alone. The **voluntary sector perspective** incorporates costs incurred by the voluntary sector alone. The **household sector perspective** incorporates costs incurred by private households and individuals alone.

**Quality adjusted life-years (QALYs)**  A metric that combines both the quality and quantity of life gained from an intervention. One QALY is defined as 1 year of perfect health, or 2 years at ‘50% of perfect health’, etc.

**Resources**  In economics, ‘resources’ refer to all the factors of production (usually simplified to labour and capital) that are used to produce goods and services. In health programmes, resources include medical and nursing staff time, hospitals, medical equipment and drugs, and patients’ time.

**Sensitivity analysis**  A technique used in economic analysis to test whether uncertainty in the values of the main variables is sufficient to affect the results of the analysis.
### List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACH</td>
<td>Age Concern Havering</td>
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<td>ACS</td>
<td>Age Concern Suffolk</td>
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<td>BECCA</td>
<td>Befriending and Costs of Caring</td>
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<td>BF</td>
<td>befriender facilitator</td>
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<tr>
<td>BL</td>
<td>baseline</td>
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<tr>
<td>CADI</td>
<td>Carers Assessment of Difficulties Index</td>
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<td>CAS</td>
<td>Caregiver Activity Schedule</td>
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<tr>
<td>CBT</td>
<td>cognitive behavioural therapy</td>
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<tr>
<td>CEAC</td>
<td>cost-effectiveness acceptability curve</td>
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<tr>
<td>CI</td>
<td>confidence interval</td>
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<tr>
<td>CMHT</td>
<td>community mental health team</td>
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<tr>
<td>COPE</td>
<td>Coping Orientation for Problem Experience</td>
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<tr>
<td>CPN</td>
<td>community psychiatric nurse</td>
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<tr>
<td>CRB</td>
<td>Criminal Records Bureau</td>
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<tr>
<td>CSRI</td>
<td>Client Service Receipt Inventory</td>
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<tr>
<td>CUA</td>
<td>cost-utility analysis</td>
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<tr>
<td>EQ-5D</td>
<td>EuroQol 5 Dimensions</td>
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<td>FU</td>
<td>follow-up</td>
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<td>GLM</td>
<td>generalised linear model</td>
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<tr>
<td>HADS</td>
<td>Hospital Anxiety and Depression Scale</td>
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<tr>
<td>ICER</td>
<td>incremental cost-effectiveness ratio</td>
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<tr>
<td>ITT</td>
<td>intention-to-treat</td>
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<tr>
<td>MCBS</td>
<td>Mutual Communal Behaviours Scale</td>
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<tr>
<td>MREC</td>
<td>multisite research ethics committee</td>
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<tr>
<td>MSPSS</td>
<td>Multidimensional Scale of Perceived Social Support</td>
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<tr>
<td>$n$</td>
<td>number who selected a certain response</td>
</tr>
<tr>
<td>$N$</td>
<td>total number who answered a given question</td>
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<tr>
<td>NVS</td>
<td>Norwich and Norfolk Voluntary Services</td>
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<tr>
<td>ONS</td>
<td>Office for National Statistics</td>
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<tr>
<td>PANAS</td>
<td>Positive and Negative Affect Schedule</td>
</tr>
<tr>
<td>PANT</td>
<td>Practitioner Assessment of Network Type</td>
</tr>
<tr>
<td>PSSRU</td>
<td>Personal Social Services Research Unit</td>
</tr>
<tr>
<td>PwD</td>
<td>person (people) with dementia</td>
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<tr>
<td>QALY</td>
<td>quality-adjusted life-year</td>
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<tr>
<td>RCT</td>
<td>randomised controlled trial</td>
</tr>
<tr>
<td>RUD</td>
<td>Resource Utilization in Dementia</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
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<tr>
<td>VAS</td>
<td>visual analogue scale</td>
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All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g., NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.
Objectives

The aims of this trial were two-fold. First, to determine whether a social support intervention (access to an employed befriending facilitator in addition to usual care) is effective compared with usual care alone, through randomly allocating carers of people with dementia to one of two groups (intervention versus usual care control) and follow-up for 2 years post-randomisation. Secondly, to document direct and indirect costs in both the intervention and control group, and establish incremental cost-effectiveness, calculating the costs from the perspectives of the statutory and voluntary sectors and from a societal perspective.

Methods

Design
The Befriending and Costs of Caring (BECCA) trial was a cost-effectiveness randomised controlled trial that compared outcomes and associated costs for family carers offered ‘access to befriending facilitator’ with those of control carers receiving standard services only. Data on well-being and resource use were collected through interviews with participants at baseline and at three follow-up interviews (6, 15 and 24 months). The main end-point was at 15 months post-randomisation, and for the economic analyses the perspective in the base case is society.

Setting
This research was carried out in the English counties of Norfolk and Suffolk, and the London Borough of Havering. It was a community-based study.

Participants
Participants were family carers who were cohabiting with, or providing at least 20 hours’ care per week for, a community-dwelling relative with a primary progressive dementia.

Intervention
The intervention was ‘access to a befriending facilitator’ (BF). BF’s, based with charitable/voluntary-sector organisations, were responsible for local befriending schemes, including recruitment, screening, training and ongoing support of befriending volunteers, and for matching carers with befrienders. The role of befrienders was to provide emotional support for carers. The target duration for befriending relationships was 6 months or more.

Main outcome measures
The main outcome was depression as measured by the Hospital Anxiety and Depression Scale (HADS) at 15 months post-randomisation. Secondary measures were anxiety, positive affect, loneliness and global health. The health-related quality of life scale EQ-5D (EuroQol 5 Dimensions) was used to derive utilities for the calculation of quality-adjusted life-years (QALYs). Resource use and other data related to costs were collected using a semi-structured interview based on the Resource Utilisation in Dementia questionnaire and Client Service Receipt Inventory. Measures of burden, social support and coping were also used.

Results
Of 316 people expressing interest in participating, 236 (75%) were randomised into the trial (116 intervention; 120 control). At final follow-up (24 months post-randomisation) 190 carers (93 intervention; 97 control) were still involved in the trial (19% attrition). There was no evidence of effectiveness or cost-effectiveness from the primary analyses on the intention-to-treat population. The mean incremental cost per incremental QALY gained was in excess of £100,000, with only a 42.2% probability of being below £30,000 per QALY gained. Analyses on secondary outcomes were similarly negative, and there was no evidence of cost-effectiveness in the alternative scenarios considered except where care-recipient QALYs were included. In this case mean incremental cost per incremental QALY gained was £26,848, with a 51.4% probability of being below £30,000 per QALY gained. Only 60 carers (52%) took up the offer of being matched with a trained lay befriender, and of these only 57 (32%) were befriended for 6 months or more. A subgroup
analysis of controls versus those befriended for 6 months or more found a reduction in HADS-depression scores that approached statistical significance (95% CI –0.09 to 2.84).

**Conclusions**

‘Access to a befriender facilitator’ is neither an effective nor a cost-effective intervention in the support of carers of people with dementia, although there is a suggestion of cost-effectiveness for the care dyad (carer and care recipient). In common with many services for carers of people with dementia, uptake of befriending services was not high. However, the small number of carers who engaged with befrienders for 6 months or more reported a reduction in scores on HADS depression that approached statistical significance compared with controls (95% CI –0.09 to 2.84). While providing only weak evidence of any beneficial effect, further research into befriending interventions for carers is warranted.

**Implications for healthcare**

Volunteers can be safely involved in the provision of emotional support for carers. When considering commissioning support services for carers of people with dementia, befriending schemes alone should not be commissioned, and short-term contracts should not be considered.

**Recommendations for further research**

- Additional research is required to establish: the characteristics of carers most likely to take up befriending; befriender–carer characteristics of successful matches; interplay between statutory and voluntary support services and support from families; carer well-being in the context of receipt of befriending; and placement of the care recipient in long-term residential or nursing care.

- Future cost-effectiveness evaluations of carer support should include outcomes for both the carer and care recipient.

- Further work is required on economic methods for carer intervention research.
Chapter 1

Introduction

Background

This study was a response to a call for bids from the NHS Health Technology Assessment (HTA) Programme for research into ‘support for carers of people with dementia’. The call was made in the context of increased recognition of the needs of carers and the associated UK government legislation and initiatives such as the Carers (Recognition and Services) Act 1995 and the National Strategy for Carers, and in the National Service Frameworks for Mental Health and for Older People. The needs of carers of people with dementia were highlighted as a particular concern, with there being perceived deficiencies in the evidence base, especially in terms of evidence on cost-effectiveness.

It is estimated that there are around 6.8 million adult carers in the UK, with up to 1.5 million people involved in caring for a relative or friend with a mental illness or some form of dementia. Dementia is an umbrella term encompassing a broad range of cognitive losses, usually including multiple deficits in aspects of memory, expressive and/or receptive language, perception and executive function. Dementia is the consequence of a large number of progressive brain disorders, the most common being Alzheimer’s disease and vascular dementias. The prevalence of dementia depends greatly on the age structure of the population and for UK the prevalence rates are 2% in the 65–70 age group; 5% in the 70–80 age group and 20% in the over-80 age group (Alzheimer’s Society, UK). It is estimated that there are currently over 750,000 people in the UK with dementia, which may increase to 840,000 by 2026 and 1.2 million by 2050.

Dementias are long-term, pervasive illnesses, affecting all aspects of a person’s life. The person with dementia (PwD) becomes increasingly dependent on those around them, most usually their spouse or other family members. It is widely accepted that providing care for a person with dementia is stressful and demanding, and research has provided evidence on the poorer physical and mental health of carers compared with non-carers. In addition, there is some evidence that carers who experience caring as stressful are at higher risk of mortality than non-carers.

Social consequences of caring

The association between social support and well-being is well established for both physical and mental health, with low levels of support being associated with poorer health. Family carers can experience a reduction in their social network owing to a lack of opportunities to socialise and/or the stigma associated with illness. Carers report less social interaction and fewer friendships. The emotional and physical burden of caring can result in family role conflicts that may reduce the amount of emotional support available. A carer’s family and friends may distance themselves physically and/or psychologically from the carer and care recipient, contributing to a reduction in social support for the carer.

Given the commitment involved in caring for a relative with increasing levels of cognitive impairment and dependency, carers of people with dementia may be particularly at risk of social isolation. Carers who experience social isolation are more vulnerable to the negative impacts of caring.

Social isolation is a risk factor for loneliness, and loneliness has been associated with increased mortality and morbidity, including psychiatric morbidity. Protective factors are thought to include companionship and long-standing friendships, especially for women, and where the friendship is based on choice and not obligation.

Support provision

Support provision for family carers in the UK is part of a mixed economy of care in which statutory, private and voluntary sectors provide community services in addition to the support given by family and friends. Britain has a long tradition of voluntary action, and the emphasis on partnership in recent government policies has given voluntary, community and user organisations a more central role in the delivery of services.
At the same time, social service departments have been encouraged to develop local markets in care by providing fewer direct care services themselves and commissioning independent service providers. Local authority welfare provision in England is organised to prioritise instrumental needs within a system of case management in which needs are assessed, care packages are set up and cases are discharged. Such procedure-based care management systems prevent the formation of sustained relationships. As Community Mental Health Teams integrate the working practice of the NHS and Social Services and move towards an ‘assess and discharge’ model, it can be voluntary and charitable sector workers who provide long-term support. For carers of PwD, emotional support may have a greater influence on the course of stressors than instrumental support.

Psychosocial interventions

A range of psychosocial interventions has been developed to support carers, including, but not limited to, the provision of accessible and relevant information on available services, education and training programmes, access to support groups, short-term breaks, and interventions targeted at the whole family, such as family therapy and family counselling.

Evaluations of carer interventions have been extensively reviewed. Schulz and colleagues identified nine systematic reviews prior to their own. The varying methodologies used for the systematic review have led to significant differences in conclusions about the quantity and quality of research, yet there is consensus that carer intervention research has historically been of questionable quality, and that poor study design has contributed to inconclusive findings. Interventions showing greatest impact have generally been comprehensive and intensive. Cognitive behavioural interventions have been shown to be effective in reducing carer stress, but the provision of such interventions is expensive and often not available owing to a lack of appropriately trained therapists within dementia care or carer support services.

Only a fraction of psychological support is provided by psychological therapists, and there is much in common between informal and formal helping, such as empathy, positive regard and genuineness. Faust and Zlotnick found that, for mild to moderate mental health problems, the benefits of informal helping by mental health paraprofessionals, such as clergy and family doctors, are roughly the same as those of professional, formal helping, carried out by psychiatrists and psychologists.

A range of social support interventions has been devised and evaluated, but reviews of the evidence base of social support interventions generally highlight a lack of methodological rigour. Within the voluntary sector, a commonly used model of social support is ‘befriending’. There are many befriending schemes in the UK, most particularly in the voluntary and charitable sector. The role of befrienders varies widely from project to project, and the characteristics of the befrienders also vary, including both volunteers and paid staff. Befriending has the potential to foster friendship, with the reciprocities entailed in this and concomitant gains experienced by peer-befrienders. For befrienees, a volunteer visit may be experienced as very different from that of a professional, perhaps without fear of institutional intervention in their family or care choices, which may be especially welcomed by older people trying to maintain their independence. In addition, empathic, non-directive befriending was as effective as structured cognitive behavioural therapy (CBT) in the short term for people with treatment-resistant schizophrenia, although CBT was superior at 9-month follow-up. An analysis of session content indicated that the befriending was distinct from CBT, and a conclusion was drawn that social support is “no mere placebo”.

During protocol development for the Befriending and Costs of Caring (BECCA) project, a literature search was undertaken for befriending schemes for family carers of people with dementia. No quantitative research trials were found for the use of befriending volunteers to support carers. The closest trial was Harris and colleagues, evaluation of a volunteer befriending intervention for women with chronic depression in inner London. With additional searching using a broader range of search terms, two randomised controlled trials (RCTs) were identified which evaluate ‘friendly visiting’ for isolated elders. Macintyre and colleagues found improved life satisfaction, worth and social integration, and concluded that volunteer visitors made a difference for elderly people in the community. Most recently, a report has been published of a peer-support intervention for carers of people with Alzheimer’s disease, but there was no evidence of a beneficial effect, possibly because of the short time-frame.
Cost-effectiveness of support for carers

The Carers Special Grant was established to support the implementation of the National Carers Strategy, with ring-fenced funding of £140 million made available to local authorities to help them to develop a wider range of services to give carers a break from their caring responsibilities. However, there is evidence for managers wishing to commission cost-effective interventions.

In an RCT, Patel and colleagues\(^3\) evaluated the cost-effectiveness of a training programme for carers of stroke patients and found that costs were significantly lower in the training group, while improving overall quality of life of carers at 1 year. Similarly, the economic evaluation of a training programme for carers of people with dementia\(^4\) reported cost savings of Aus $7967 (US $5975) per patient, with improved patient survival at home and decreased carer morbidity. Drummond and colleagues\(^5\) evaluated a support programme for carers (RCT) which showed improved quality of life with incremental cost per quality-adjusted life-year (QALY) gained of Can $20,000. The evaluation of a daily living programme (RCT) by Knapp and colleagues\(^6\) found that it was more cost-effective than hospital-based care. Similarly, Donaldson and Gregson\(^7\) reported that a community support intervention resulted in prolonged life at home for the elderly and concluded that the intervention will be cost-effective if the cost of long-term institutional care averted is included in the calculations. Payton and colleagues,\(^8\) in their cost analysis of a community health information network for carers of people with Alzheimer’s disease, concluded that it provides social and economic benefit to their users.

Economic methods in carer intervention evaluations

The cost-effectiveness literature for carers has used a range of costing methodologies and there is presently no consensus. Considerations include: whether to cost for the carer, care recipient or both; whether to take cross-sectional snapshots of service receipt or try to build up a longitudinal picture of costs; and costing informal care.

Options for costing informal care include: the market price method, the contingent valuation method and the opportunity cost method.\(^9\) Theoretical and practical challenges of evaluating carer time have previously been acknowledged.\(^10\) Wimo and colleagues\(^11\) recommend that the valuation be based on the opportunity costs of time sacrificed on each type of time-use. This would necessitate data collection on the specific nature of time sacrificed; for example, time spent in caring, nursing and supervision; loss of time in work; and impact on leisure activities. Distinguishing between ‘care activities’ and ‘normal household duties’ can be especially challenging for spouse carers where the carer is also the person who has had a long-term responsibility for the domestic household duties.

From a societal perspective, the value of informal care may be recognised by considering the cost of its replacement. Should individuals be unwilling or unable to undertake the role of carer, society would have little choice but to fund formal care. This would involve diverting resources away from other uses; the opportunity cost of those resources – the forgone benefit – determines the cost of informal care. The value of the resources diverted is a measure of the cost of informal care and is known as ‘replacement cost’. From the perspective of the individual carer, the opportunity cost of caring may be understood in terms of the alternatives forgone as a result of taking on this role, which may include employment opportunities, other unpaid work, such as caring for other family members, and leisure activities, including holidays, social activities and relaxation. Whether employment opportunities should be valued is the subject of considerable debate and scepticism,\(^12\) as inclusion of economically active individuals’ time will be valued more highly than the time of those who are economically inactive, and this may lead to an exacerbation of existing inequalities in the provision of care or support.

Summary

Family carers of people with dementia report high burden and stress. Demands of time and lack of understanding among family and friends can lead to reduced social contact and social supports. A wide range of psychosocial interventions has been devised, including one-to-one social support interventions such as befriending, but no rigorous studies of cost-effectiveness exist for befriending.

Aim and objectives

The aim of this report is to address this gap in the evidence base by evaluating the cost-effectiveness
of befriending schemes for carers of people with dementia alongside an RCT. The objectives of the trial were as follows.

- To determine whether a social support intervention (access to an employed befriending facilitator in addition to usual care) is effective compared with usual care alone, through randomly allocating carers of people with dementia to one of two groups (intervention versus usual care control) and follow-up for 2 years postrandomisation.
- To document direct and indirect costs in both the intervention and control groups, and to establish incremental cost-effectiveness, calculating the costs from the perspectives of the statutory and voluntary sectors and from a societal perspective.
Chapter 2

Methods

Design

An RCT design was used to compare usual care plus a social support intervention [access to a befriender facilitator (BF)] with control (usual care) for carers of people with dementia. Data collection points were at 6, 15 and 24 months from the date of randomisation, with the main end-point being at 15 months. The primary perspective of the economic evaluation was societal.

Ethics approval

A protocol was submitted for ethical scrutiny by the multisite research ethics committee (MREC) in 2001. The submission described the methodology approved by peer reviewers for the HTA programme, and included a Zelen randomisation procedure. The protocol was rejected on the grounds of the Zelen design, and also concerns for the safety of carers put in contact with lay intervention providers. The proposed methodology was revised to use a standard RCT design, and with additional information on the recommended good practice for the involvement of volunteers in the provision of health and social care. Ethical approval was received in November 2001 with the proviso that a pilot be carried out in not more than three local research ethics committee (LREC) districts before the implementation of the full trial. The aim of the pilot was to ensure that procedures for the research interviews and befriending scheme were feasible and appropriate. LREC approval was subsequently received from all five LRECs in Norfolk and Suffolk, plus the London Borough of Havering. Trust research and development (R&D) approval was also sought where recruitment was planned within secondary care, and from primary care groupings that had R&D approval procedures during the recruitment phase of the trial.

There were consent procedures for both family carers and potential befriending volunteers. The PwD was not involved in interviews and was not the intended recipient of the befriending intervention, and was not therefore involved in the consent procedures.

Intervention and control conditions

The befriending schemes were organised and administered separately from the research interviews. The befriending intervention comprised access to an employed BF, and the offer of contact with a trained volunteer befriender for the duration of the befriending schemes. The expectation was that befriending visits by the trained volunteer befrienders would be weekly home visits (dose) for at least 6 months (duration), with variations in location, duration and frequency of contact negotiated as necessary by each carer–volunteer pairing, overseen by the BF.

The remit of the befriending volunteers was to provide companionship and conversation. Their role was to be a listening ear; that is, to provide emotional support to the carer. Some informational support or ‘signposting’ was also permissible in appropriate circumstances. The boundaries of the role specifically excluded giving advice and carrying out practical caring tasks that would otherwise be carried out by a paid worker such as a nurse or home care worker. Further details of the befriending intervention are given in Chapter 3.

The intervention was offered as an addition to usual care, and was not a replacement for any other service (health, social or voluntary). In the study areas, typical health services for the care recipient included diagnostic clinics for memory impairment and dementia (memory clinics) and community support for challenging behaviours through community psychiatric nurses (CPNs). Typical social services for carers included short-term and longer term respite in the form of day centres and residential or nursing home stays, and assistance with washing, dressing and eating for more dependent care recipients. Typical voluntary sector provision included carer information and support groups, and luncheon clubs. All carers randomised into the trial were sent locally relevant information on services for caring for people with dementia by the research interviewer.
Study population

The BECCA project was carried out in the UK, in the East Anglian counties of Norfolk and Suffolk, and in the London Borough of Havering, with recruitment between April 2002 and July 2004.

The HTA call for bids had specified that participants should be the carers of people with Alzheimer’s type dementia. However, Alzheimer’s disease can only be diagnosed with certainty post-mortem, and the diagnosis of Alzheimer’s disease in vivo is made by exclusion of evidence of other possible causes, and on a possible or probable basis only. Alzheimer’s type pathology commonly co-occurs with other dementia-causing pathologies, and the symptom profiles are not generally distinguished within primary care. Therefore, carers in this study are of people with a primary progressive dementia in general, rather than specifically Alzheimer’s disease.

Eligibility criteria

Inclusion

The main inclusion criteria were that participants must be family carers aged 18 years or older, caring for a person with a primary progressive dementia. Carers should either be cohabiting with the PwD, or spending an average of 20 hours or more per week on care-related tasks such as supervision and assistance in activities of daily living (ADL).

Exclusion

Carers with significant congenital or acquired cognitive impairment were excluded, as were those with terminal illness. Carers of people in permanent residential, nursing or long-stay hospital accommodation were also excluded.

Sample size

During the planning stages of the trial there were no published trials of befriending for carers of people with dementia. Therefore, sample size calculations were based on the effect size seen in befriending interventions with different client groups, that is, 0.42–0.45. It was anticipated that retention of carers postrandomisation would be high, based on the experience of Aneshensel and colleagues in a 3-year longitudinal study of caring (without an intervention), 82% of carers were followed up to 3 years.

Using nQuery and making an assumption of a normal distribution, to achieve 90% power at the 5% significance level (two-tailed), 150 carers were needed for each group, for postrandomisation dropout of 20% at 6 months. Making an assumption that between 30% and 60% of people invited to take part would not respond, a target of 750 was set for carer invitations. In the course of the trial, targets were recalculated on the grounds that fewer carers were being lost to follow-up than had been anticipated. For a postrandomisation dropout of 7%, it was calculated that adequate precision and power should be gained from a sample size of between 225 and 235 carers.

Recruitment procedures

A significant proportion of the population in Norfolk and Suffolk lives in rural areas. Rural carers are considered “hard to reach” and dissemination of information can be difficult owing to there being very few contact points. Therefore, a recruitment strategy was needed that would maximise equality of access to the trial, irrespective of urban or rural location. Given that most gerontological research work involves gatekeepers such as health and social service practitioners, it was hoped that there would be less sample bias from primary care than from a secondary care population. Therefore, general practices were approached to identify surgeries that would be happy to send out invitations to participate. It was hoped that this would be acceptable to practices given that the Government’s National Priorities Guidance for health and social services in England had asked primary care teams to take a lead and identify carers by April 2000.

Unfortunately, initial recruitment was slow and after 6 months, only 13 responses had been received from practices in the pilot area. In keeping with the picture in the rest of the UK, practices had neither carers’ registers nor straightforward means for identifying informal carers in either computerised or paper records. Only around half of practices expressed willingness to send out invitations, even though funding was available from the project to reimburse administration time and postage costs. It was clear that additional recruitment strategies would be necessary if targets were to be met in the full trial, so strategies were developed for media and other publicity, and for wider dissemination of information through gatekeepers in social services, secondary care and the voluntary sector.

- Mailouts of publicity posters and leaflets: these went to all libraries in Suffolk and Norfolk, in addition to social services, mental health services for older people, pharmacies, day services, supermarkets and voluntary organisations.
• **Media publicity**: radio interviews and various articles were arranged with local press.

• **Voluntary-sector mailouts**: some voluntary and charitable organisations were willing to circulate invitations akin to those used in primary care to all on their mailing lists. This was the only strategy used in the London Borough of Havering, and mailing by Suffolk Carers provided a significant response in Suffolk.

• **Presentations to potential participants and to gatekeepers**: presentations were devised for carers’ groups, and for health-, social- and voluntary-sector personnel who may act as gatekeepers.

All recruiters were briefed on the inclusion and exclusion criteria for the trial, and the importance of avoiding inappropriate approaches (e.g. to family members who are unaware of their relative’s suspected diagnosis) was emphasised. All used standard letters of invitation and approved participant information leaflets.

Potential participants expressed their interest in participating in the research by completing and returning a response form in a prepaid envelope to the researchers. Recruitment strategies were kept under continuous review, including monitoring of productivity.

Following receipt of a response form (expression of interest), research associates made contact with carers by telephone (or e-mail if this was requested) to provide further information about the trial, and where appropriate to carry out initial screening. The purpose of the initial screening was to check eligibility (see the section ‘Eligibility criteria’, p. 6).

For eligible carers who expressed continued interest after this initial contact, arrangements were made for a face-to-face interview. Times and venues for face-to-face interviews were organised as flexibly as possible to accommodate interviewees’ caring responsibilities. All contact with carers aimed to be sensitive to their needs, and appropriately responsive to disclosure of circumstances that present significant risk to the well-being of the carer or care recipient (e.g. abuse, suicidal or homicidal intent). Constraints such as pressures on carers’ time and transport difficulties were acknowledged. The importance of considering transportation has also been highlighted in previous recruitment literature. For this project, it was anticipated that most carers would prefer home visits, or interviews based at a neutral location within their locality, rather than travel to a research base. Therefore, the study protocol and budget included transport costs for interviewers to travel throughout the counties on a regular basis. Interviewers endeavoured to meet all carers’ preferences for days and times of day.

Once carers had contacted the research team expressing interest in participation, they were contacted by telephone, given the opportunity to ask questions, and sent a full information booklet. Written consent was taken at the first face-to-face interview, after researchers had given an oral overview of the trial and answered any questions on the content of the information booklet.

Information about the trial clearly explained randomisation, and made it clear to participants that they were free to withdraw at any time without giving a reason and without this affecting the services available to the current or future carer, or the care recipient.

### Randomisation

#### Sequence generation

Randomisation lists were drawn up by the trial statistician. Randomisation was stratified by kinship between carer and PwD (either vertical or horizontal) and also by region of residence (urban or rural). Blocked randomisation (block length of six) was used. For the stratification by kinship, spouses, long-term partners, cousins of the same generation and siblings were designated a ‘horizontal bond’, whereas adult offspring (sons and daughters) and sons- and daughters-in-law were classified as having a ‘vertical bond’. It was anticipated that this stratification for kinship would increase the likelihood of the two groups matching in terms of gender balance and age, since adult children carers are more commonly women, whereas there is a more even gender balance among spouse carers. Urban and rural areas were classified on the basis of population density, with densities of 10,000 per km² and above classified as urban.

#### Allocation concealment

Team members involved in carer consent and interviews were not involved in the randomisation process. The randomisation lists were drawn up before the start of recruitment by the trial statistician, and held by the research administrator.

#### Implementation

After obtaining informed consent and completing a baseline interview, the interviewer put forward the carer’s ID number to the trial administrator. The administrator assigned the carer to
intervention or control on the basis of the sequence laid out in the relevant randomisation list (urban/vertical; urban/horizontal; rural/vertical; rural/horizontal). The administrator was independent of interviews, had no direct contact with study participants and was entirely unaware of participants’ personal circumstances.

Blinding
Over the course of the trial, six researchers were involved in the informed consent and recruitment process. To reduce experimenter bias all outcome measurement was completed with interviewers who were independent from the provision of befriending services. Carer well-being was assessed using self-report inventories, which are less susceptible to experimenter bias than observational measures.

Owing to the nature of the intervention it was not possible to blind trial participants to group allocation. Therefore, it was decided to keep participants fully informed of the outcome of the randomisation process by sending one of two standard letters outlining their allocation to either control or befriending intervention. Letters were sent by the trial administrator responsible for allocation from the randomisation lists. All participants had previously received brief details about the befriending intervention in their information booklet. However, given the quantity of information about using the scheme, full details were only supplied to those carers who were randomised to the befriending intervention.

Measures
All data were collected through interviews with the carer. The care recipient was not interviewed. The main outcomes were carer well-being as measured by the Hospital Anxiety and Depression Scale (HADS) depression and health-related quality of life measured using Euro-Qol 5 Dimensions (EQ-5D). Secondary measures of well-being were HADS anxiety, loneliness, positive affectivity and global health. Measures of structural and perceived social support were used to characterise the sample, as were measures of relationship quality and carer burden. Demographic data and characteristics of the context of caring (e.g. multiple roles, sleep disturbance) were also collected through carer self-report.

Demographic data included age, gender, ethnicity of the carer and PwD, and kin relationship of the carer to the care recipient. Additional characteristics of caring included hours spent caring, sleep disturbance, other caring roles and employment.

Anxiety and depression
The negative aspects of carers’ well-being were assessed by the HADS. On this 14-item scale, seven items assess anxiety (e.g. ‘I feel tense’ or ‘wound up’, ‘Worrying thoughts go through my mind’) and seven items assess depression (e.g. ‘I feel as if I am slowed down’, ‘I have lost interest in my appearance’). Items are scored on a four-point scale ranging from 0 to 3, where the higher scores indicate higher levels of anxiety or depression. Both scales have good internal consistency, with Cronbach’s α of 0.84 for the anxiety subscale at baseline and 0.74 for the depression subscale. Cut-offs have been used to indicate caseness, where a score of 7 or below indicates a non-case for both subscales, a score of 8–10 indicates a doubtful case, and a score of 11 or above indicates a definite case.

Loneliness
A two-item measure of emotional loneliness was used, after Stroebe and colleagues. The questions used were ‘Over the past 7 days, how much have you felt distressed by feeling lonely/feeling lonely even when you are with people?’ Both items were rated on a five-point scale from 0 = not at all to 4 = extremely. Cronbach’s α was 0.86.

Positive and negative affectivity
Positive and negative affectivity were measured using the 20-item Positive and Negative Affect Schedule (PANAS) scale. The measure consists of 20 adjectives, ten of which describe negative moods (e.g. distressed, upset, guilty) and ten describe positive moods (e.g. excited, proud, determined). Respondents indicated on a five-point scale (where 1 = very slightly or not at all and 5 = extremely) the extent to which they have experienced the feelings and emotions stated ‘over the past seven days’. The internal consistency was α = 0.88 for the negative items and 0.84 for the positive items. The instrument was included so that the possibility of an increase in positive affect could be explored should floor effects be found on the HADS (carers scoring within asymptomatic range at baseline, with no room for further improvement).

Burden
The Carers Assessment of Difficulties Index (CADI) frequency scale was used as a measure of objective burden. It is a 30-item instrument.
including statements that describe experiences related to caring (e.g. ‘It is physically tiring’, ‘The person I care for can demand too much of me’). Frequencies of experiences were indicated on a three-point scale from 1 = never applies to me to 3 = always applies to me. Cronbach’s α was 0.89.

**Relationship quality**

The quality of premorbid relationship was assessed using a single five-point scale (0 = very poor, 2 = neither good nor bad, 4 = very good), and also with the ten-item Mutual Communal Behaviours Scale (MCBS), which measures the responsiveness between the carer and care recipient before the onset of illness. The frequency of each behaviour was rated using a four-point scale from 1 = never to 4 = always. A principal components analysis for this study identified two five-item factors (oblimin rotation) with eigenvalues of 5.34 and 1.55, explaining 69% of the variance. All items loaded highly, with factor loadings of 0.7 and above. The first factor contained the five items evaluating the care recipient’s communal behaviour towards the carer (e.g. ‘They seemed to enjoy responding to my needs’, ‘They did things just to please me’) and the second factor containing all items concerning the carer’s communal behaviour towards the care recipient (e.g. ‘If they were feeling bad, I tried to cheer him/her up’, ‘When they had a need, he/she turned to me for help’). Cronbach’s α for the two subscales was 0.91 and 0.84, respectively.

Perceived loss of companionship was assessed using a three-item scale by Aneshensel and colleagues. Each item (‘How much have you lost having someone who knew you well?’) was rated on a four-point scale from 1 = completely to 4 = not at all, giving a range of 3–12, with lower scores indicating the greater perceived loss. However, for ease of interpretation of results, items were recoded such that higher scores indicate greater perceived loss. A principal components analysis on data from carers in this study indicated that all three items loaded heavily on one factor (loadings ranged from 0.82 to 0.89) and accounted for 73.5% of the variance. Reliability of the scale, as indicated by Cronbach’s α was 0.81.

**Social support**

The Practitioner Assessment of Network Type (PANT) scale, which consists of eight items/questions (e.g. ‘If you have any children where does your nearest child live? ’ ‘How often do you see any of your neighbours to have a chat or do something with?’), was developed to identify social support network type. The instrument has been found to correlate highly with a range of demographic variables, level of service use and response to interventions. Items from the Network Typology questionnaire were also used to construct a social isolation index akin to that of Scharf and Smith, summarising contact with family, friends and neighbours. The index provided a measure of social isolation ranging from 0 = not isolated to 3 = extremely isolated (no contact with family, friends or neighbours).

The Multidimensional Scale of Perceived Social Support (MSPSS) is a 12-item measure assessing perceived social support. Each item is rated on a five-point Likert-type scale ranging from 1 = strongly disagree to 5 = strongly agree. The scale was developed to assess perceived social support in relation to the family (e.g. ‘My family really tries to help me’, ‘I can talk about my problems with my family’), friends (e.g. ‘I can count on my friends when things go wrong’, ‘I have friends with whom I can share my joys and sorrows’) and significant other (e.g. ‘There is a special person who is around when I am in need’, ‘I have a special person who is a real source of comfort to me’) source of support, which form the three subscales of the measure. Strong psychometric properties of the measure have been documented previously, including test–retest reliability, with correlation coefficients of \( r = 0.73 \) for the full scale, \( r = 0.73 \) for the friends subscale, \( r = 0.74 \) for the family subscale and \( r = 0.54 \) for the significant other subscale. Cronbach’s α in this study was 0.92, 0.89 and 0.87 for the family, friends and significant other subscales, respectively.

**Coping**

The Brief Coping Orientation for Problem Experience (COPE) is a 28-item measure for multidimensional assessment of coping. Active coping includes the subscales acceptance, emotional support, religion, active coping, planning and positive reframing. Avoidance coping includes the subscales self-distraction, venting, humour, denial, behavioural disengagement and substance use. Items (e.g. ‘I’ve been turning to work or other activities to take my mind off things’, ‘I’ve been saying to myself “this isn’t real”’) assess responses of individuals when confronted with difficult or stressful situations and are scored on a four-point Likert-type scale ranging from 1 = don’t do this at all to 4 = do this a lot.
Life events
The List of Threatening Experiences is a 12-item measure, which states life events (e.g. ‘serious injury or illness to yourself’, ‘Death of a first degree relative including a child or a spouse’). The scale accounts for two-thirds of life events that may have a marked or moderate long-term threat. The occurrence or absence of a life event was scored as Yes or No.

Health-related quality of life
Health-related quality of life was measured in QALYs for both the carer and PwD using the EQ-5D instrument, with the carer providing a proxy measure on behalf of the PwD. The EQ-5D is a standardised instrument designed to measure health outcomes and was recommended for adults by Dixon and co-authors in an HTA review of health status measures for economic evaluation. It is a six-item self-assessment, health state measure of health-related quality of life. The scale includes five items accounting for five dimensions of quality of life (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and a visual analogue ‘thermometer’, ranging from 0 to 100 points, where 100 represents the best possible health state and 0 the worst. The five items/dimensions of quality of life are scored on a three-level scale ranging from 1 = no problem to 3 = extreme problem. Carers were not asked to proxy for the PwD on the visual analogue scale (VAS).

Resource use
Data on resource use were collected through a semi-structured interview devised for this trial influenced by pre-existing interview schedules, namely the Client Service Receipt Inventory (CSRI), the Caregiver Time Questionnaire, the Caregiver Activity Schedule (CAS) and the Resource Utilization in Dementia (RUD) questionnaire. Information was collected on statutory and voluntary sector usage by both carer and PwD. Areas covered included home care (personal care, e.g. bathing and dressing), day care, inpatient admission, use of GP services, use of medication, respite care, aids and adaptations, loss of income, time taken off work and benefits received. The data-collection instrument varied at follow-up depending on whether the PwD remained in the community, had moved permanently into residential or nursing care, or had died.

Support from family and friends
Carers were asked about regular and occasional support from family and friends. Arrangements made with family or friends which occurred on a regular daily or weekly basis were deemed ‘regular support’. Regular support was subdivided into ‘respite support’, where the family member or friend replaced the carer, and ‘assistance’, where the carer remained with the PwD.

Data-collection procedures
Baseline questionnaire data were collected after the carer had consented to take part in the study, with follow-up at 6, 15 and 24 months post-randomisation. A longitudinal picture of resource use was constructed for each carer. Carers interviewed at 6 months were asked about all resource use that occurred between the first (baseline) interview and the ongoing interview. This method was repeated at the 15- and 24-month interviews, so a complete picture of resource use for each carer and carer recipient was available at the end of the final interview. It was anticipated that all data would be collected through face-to-face interviews in carers’ own homes, with the resource-use semi-structured interview being used to gather information from carers’ recall, with the use of their own recording systems such as calendars, diaries and copies of repeat prescriptions. The recommended best practice for drug-use information is to go through the prescription sheets and repeat prescriptions of study participants and take down names of drugs, including the correct dosage and frequency. Where possible this practice was followed. However, where repeat prescription forms were not available, interviewers relied on carer recall. Similarly, where diaries and calendars were available, interviewers encouraged carers to use them to ensure accuracy of frequency of visits and duration of stays; however, in the absence of such prompts, data were again subject to carer recall.

Psychometric questionnaires were completed either as part of a semi-structured interview or as self-completion, depending on the carer’s preference.

To maximise data collection, some variations were made in data-collection methods. For example, in cases where carers were fatigued by the interview process, or their caring responsibilities precluded completion of the interview, either a second appointment was made or, for the psychometric component only, carers were provided with a stamped addressed envelope for return of questionnaires. Where carers did not wish to be interviewed in their own homes, alternative venues
were organised, for example GP surgeries, health centres, or voluntary-sector or university meeting rooms. Where the carer moved away from the catchment area after randomisation, a telephone interview was developed for the resource-use data collection, and psychometric measures were either completed over the telephone, or posted to carers with a return envelope. Over the course of the trial, it became standard procedure for follow-up psychometric questionnaires to be posted out to participants with letters confirming the arrangements for follow-up interview, thus giving carers the option of precompleting all or part of the questionnaire, or waiting to complete with the researcher.

Data checking

Data were entered into the Statistical Package for the Social Sciences (SPSS, version 12.0.2; SPSS, Chicago, IL, USA, 2003) and accuracy checks were carried out. Subscale scores for psychometric measures were both handscored and calculated by SPSS as part of error checking. Other data checks for the psychometric data included checks for out-of-range values. A proportion of the resource-use interview scripts was checked by the lead economics researcher and a second researcher, with any queries resolved with the main project researchers.

Data analysis

Missing data
The proportion of missing psychometric data was generally low (less than 5%), with greater missing data for earlier rather than later interviews. No psychometric scale or subscale was missing for more than 10% of data from interviewer participants. Where individual items were missing within scales or subscales, data were imputed before calculation of the scale or subscale score. For the resource-use data, where five or fewer of the 136 cost data items were missing, or two or fewer of the utility items were missing, data were imputed using Rubin’s multiple imputation method.

Baseline characteristics
As is now recommended, no formal tests were carried out for significant differences in baseline characteristics between the study groups. Data were tabulated for intervention, control and whole sample for both demographic and clinical variables.

Primary effectiveness analysis
The psychometric data were transferred to SAS software for outcome analysis. The intervention group carers were compared with control on the HADS depression scale at 6, 15 and 24 months, using the intention-to-treat (ITT) population. Unadjusted analysis was based on a pooled t-test, and the adjusted analysis based on a generalised linear model (GLM) with baseline HADS depression score and stratification categories (urban/rural location; horizontal/vertical kinship) as covariates.

Secondary effectiveness analyses
The method used for the primary analysis was repeated for the secondary measures of HADS anxiety, loneliness, positive affectivity and the global VAS of the EQ-5D. In addition, the proportion of PwD still in home care compared with those institutionalised was compared between groups.

Subgroup analyses
The primary analysis was repeated on a per-protocol basis (i.e. removing those carers from the intervention group who were not matched with a befriender for at least 6 months and those carers in the control group who ended up matched with a befriender) and also looking at spouse carers only (carers in a horizontal kinship relationship).

Economic analyses

Valuing resource use
The chosen price year was 2005. Resource-use data were multiplied by national unit costs obtained from routine NHS and other data sources such as the national schedule of reference costs. Drug prices were obtained from the British National Formulary. Where unit cost data were not readily available, costs were obtained directly from the relevant agency or estimated separately. Time spent by carers, friends and family in caring for their relative was valued at average UK gross income rates for 2005, derived from Office for National Statistics (ONS). Unit cost data are listed in Appendix 2.

Discounting costs
It is conventional to discount costs (and outcomes) incurred more than 1 year in the future to their ‘present value’. However, it was not possible to identify which costs in the 15-month follow-up data set had been incurred after the 12-month cut-off point. Not discounting costs incurred between 12 and 15 months is unlikely to have a great impact on the results of this analysis, and therefore no attempt was made to do so. Costs
incurred and QALYs accrued between 15 and 24 months were discounted at 3.5%.

**Primary economic analysis**

An economic evaluation was performed from the perspective of society comparing costs with the QALYs gained by carers in intervention versus control after 15 months’ follow-up. The EQ-5D health profiles were converted to utilities using UK general population valuations, and thence to QALYs over the period measured.

To compare costs and effects, an incremental cost-effectiveness ratio (ICER) was calculated, comparing the difference (increment) in costs with the difference in QALYs gained in each arm of the study. The ratio states the cost of buying one extra QALY by enacting the befriending strategy compared with no befriending. Typically, the NHS is willing to pay up to £20,000–30,000 for a QALY. Thus, if the ICER is below this threshold, befriending may be considered good value for money. If it is above this, it may be considered poor value for money.

\[
\text{ICER} = \frac{C_2 - C_1}{E_2 - E_1}
\]

where \(C_2\) is cost per carer–PwD in the befriending arm, \(C_1\) is cost per carer–PwD in the control arm, \(E_2\) = QALYs gained by carer in the befriending arm, and \(E_1\) = QALYs gained by carer in the control arm.

Mean costs and QALYs gained in the intervention and control arms were calculated from trial observations. A non-parametric bootstrap approach of 1000 replications was used to construct distributions around the mean costs and QALYs gained in each arm. The simulations are used to construct 95% confidence intervals (CIs) resulting around mean difference in cost and QALYs between the arms, and the ICERs used to construct a cost-effectiveness acceptability curve (CEAC).

**Alternative economic scenarios**

Further analyses were performed to consider the cost-effectiveness of the intervention within different scenarios.

**Varying the perspective**

The base case was societal, but within that there are different sectors:

- the statutory sector (NHS, social services and other government-funded services)
- the voluntary sector
- the household sector.

Each calculation includes only those costs relevant to each sector. For example, the statutory sector analysis includes only costs borne by the NHS and social services, and thus excludes voluntary-sector costs, patients’ and their carers’ out-of-pocket costs, the value of carers’ time, and so on.

**Varying the time-point**

Although 15 months postrandomisation was the main end-point, data were available at 6 months and also at 24 months. The cost–utility analysis is repeated for these time-points.

**Complete case analysis**

This comprised only observations for whom complete cost and outcome data were available at 15 months (30 intervention; 31 control).

**Taking account of both carer and PwD quality of life**

The resource-use data included costs for both the carer and the person with dementia, but in the main utility analysis the health-related quality of life relates to the carer only. This alternative scenario includes the QALYs calculated for the care recipient from the EQ-5D, completed by the carer.

**Summary of changes to protocol**

As already described above, recruitment strategies were amended to include recruitment through the voluntary sector, self-referral and secondary services. The changes to the carer recruitment process also included the addition of Havering as a trial site. To maintain the original project end date, follow-up periodicities were amended such that follow-up occurred at 6, 15 and 24 months rather than at 9, 18 and 36 months. That is, the time-horizon (follow-up period) was reduced from 36 to 24 months owing to the extension of the recruitment period. Low attrition rates in the project facilitated the reduction of recruitment targets as the assumed attrition was not experienced. To maintain maximum follow-up, data-collection methods were also broadened through the course of the trial to include self-completion of the psychometric follow-up and the use of telephone follow-ups for carers who had moved out of the area. Other protocol changes were revisions to the management committees in the light of new governance guidelines and the inclusion of a pilot study as requested by the ethical committee. The latter is described further in Chapter 3.
Chapter 3
Intervention

In this chapter the development and implementation of the befriending intervention are described in detail.

Definition of befriending

Befriending is a form of social support where a supportive other is introduced to, or matched with an individual who would otherwise be socially isolated. The term ‘befriending’ has been used to describe a range of interventions from emotional support to tangible assistance. In the initial protocol for this trial, befriending was conceptualised as offering emotional, informational and practical support. However, through consultation with the potential local providers, the definition of befriending and the planned content of the intervention were amended to focus on the provision of emotional support and also, where appropriate, some ‘signposting’ to information and services. That is, befriending comprised companionship and conversation rather than instrumental support or activities that aimed to increase community participation.

Development of the BECCA befriending schemes

The BECCA project was devised at the University of East Anglia (UEA) in the city of Norwich (population 120,000) in the county of Norfolk (population 800,000), to take place in Norfolk and the adjoining county of Suffolk (population 700,000). The physical size of the two counties made it unfeasible to have a single scheme, and there were no voluntary organisations spanning both Norfolk and Suffolk that could support a suitable befriending scheme. Discussions were held between representatives of the research team (GC and FP) and the Alzheimer’s Society’s national office to determine ways in which the befriending intervention could be set up and managed. Various options were considered, and it was decided that the only feasible option was for a number of small befriending schemes to be set up on a locality basis, with multiple BFs employed by separate organisations, each of which had experience of providing befriending services. As Norwich and its surrounding areas had been identified as the pilot area, further discussions were held with community organisations within the voluntary organisations in Norwich. It was agreed that the first scheme would be hosted by Norwich and Norfolk Voluntary Services (NVS), and a contract was drawn up between UEA and NVS. Following this agreement, and during the process of recruiting to the post of BF, several consultation meetings were held with key stakeholders, with the remit of deciding the appropriate policies and procedures for ensuring the safe involvement of both carers and volunteers in the befriending scheme. Once procedures for recruitment, training and matching of volunteers were in place in Norwich, the scheme was extended to other areas of Norfolk overseen by the same BF. In addition, two further schemes were set up, one with Age Concern Suffolk (ACS) and the smallest with Age Concern Havering (ACH). Consistent with arrangements for the initial Norwich scheme, the BFs were jointly managed by the operations manager from the ‘host’ organisation and the BECCA grantholder with responsibility for managing the befriending intervention (designated ‘intervention manager’).

The contracted host voluntary organisations (NVS, ACS, ACH) agreed to employ a part-time BF, and jointly manage the post with the UEA-based trial intervention manager; register all potential volunteer befrienders in their area, taking informed consent for the volunteers’ involvement in the BECCA research trial; take up references; facilitate Criminal Records Bureau (CRB) disclosures; provide public liability and personal accident insurance; provide BECCA training for volunteers including details of the Code of Conduct and Statement of Confidentiality; and provide ongoing support for the BF and all registered BECCA volunteers. They also had policies in place for volunteer support, complaints, disciplinary action, grievance and the storage of information about volunteers under the Data Protection Act.
Consultation and advisory groups
The initial Norfolk-focused consultation group was made up of representatives of organisations with an interest in carer support, volunteer support and/or people with dementia. This included committee members from branches of the Alzheimer’s Society, Alzheimer’s Society outreach workers, representatives from Age Concern Norwich and Age Concern Norfolk, Pabulum (a Norwich-based project for reminiscence with people with dementia), the Mental Health Service dementia nurse specialist, Norfolk Social Services planning and community development officer and Suffolk Social Services carers grant officer. Discussions within this initial consultation forum included consideration of the boundaries of the intervention, insurance, screening and training, and exit strategies for the end of the project. Members of this group also contributed to the piloting of the befriender training. This initial consultation group was extended to form a broader group which met approximately every 6 months for the duration of the trial, to comment on trial progress and contribute to decision-making on evolving procedures. Similar groups were convened in Suffolk and Havering.

In addition to issues policies, procedures and training, the consultation groups proved particularly helpful in anticipating some problems and in suggesting solutions during the ongoing trial. These included publicity phrasing, placement and timing to fit with local-voluntary sector programmes, and issues to consider in befriending visits to carers’ homes, particularly in considering the carer’s relationship with the PwD.

Befriending scheme procedures
Befriender facilitator recruitment and induction
BF posts were all part-time. They were advertised internally within the host organisation, and where necessary in the local press. The person specification for BFs included the following criteria: prior experience of working in the voluntary sector, working with people with dementia and their carers, and proficiency in training volunteers. The job description was to recruit and screen volunteers, organise training, maintain contact with and support referred carers, match befrienders and carers, monitor ongoing befriending relationships, support endings, facilitate support for befrienders, help support the network of voluntary-sector partner organisations and accurately compile records for the research team.

The initial BF played a key part in the development of policies and procedures for the scheme, in close collaboration with the intervention manager and principal investigator for the BECCA trial. Subsequently employed BFs took part in a full-day training course, which covered the role of the BFs, befriender recruitment and training procedures, volunteer registration and screening, befriender training, initial contact with carers, support across the befriending relationship, reporting procedures, expenses and volunteer time recording and management, risk assessment, and befriender and carer reviews.

Recruitment and screening of potential befriending volunteers
Pilot procedures for volunteer recruitment included dissemination of recruitment posters and leaflets through the network of volunteer bureaux in the Norwich and District area, and through partner organisations represented in the consultation group. Open meetings were organised and advertised so that potentially interested volunteers could, without commitment, hear a short talk about the project and about the role of befrienders. There were attendees at two pilot open meetings held in the City of Norwich (one in a suburb at a venue with parking facilities, and one in the centre of town convenient for public transport). However, a similar meeting arranged in one small market town did not attract any new interest. Early indications were that befrienders would be harder to identify outside the largest centre of population. For the full trial, therefore, opportunities were sought for contact with a greater number of local social-care organisations, in addition to dissemination of recruitment leaflets and posters, and media advertising. Recruitment literature emphasised the importance of a ‘listening ear’ and the ability to provide ‘companionship and conversation’.

Inclusion criteria
Potential befriending volunteers were asked to meet the following criteria before being considered eligible for matching with a family carer.

Attend an open meeting, or individual meeting with the BF
The aim of open meetings was to welcome potential volunteers, to orientate them to the stages to becoming a befriender and to outline the
expectations of befrienders. The meetings also provided volunteers with an opportunity to meet those involved in the befriending scheme and to ask questions before formally registering their interest.

**Read the information for potential befriending volunteers and complete a befriender registration form**

As the BECCA befriending schemes were part of a research trial, the befriending volunteers were considered a form of research participant. Therefore, the information booklet included MREC-approved information relevant to research trial participants, and the registration form also included MREC-approved statements akin to those found on research consent forms. The volunteer registration form was also used to record information on existing skills (e.g. experience as a family carer and/or caring experience, or from training within the helping professions or as a paid carer), and volunteers’ availability (weekdays or weekends; daytime or evening) and preferences for placements (e.g. no pets or smoking; local or away from own community).

The information booklet and registration form had been revised and amended in the light of pilot work which identified the risk of dual roles for befrienders and carers. It had been assumed that all current carers would be too busy to be considering voluntary activity; however, some carers expressed an interest in being befrienders themselves. Indeed, some misinterpreted the carer information sheet used for recruitment of family carers to the project to mean that they were being asked to be befrienders, and they engaged in the research interviews with this express intent. To clarify literature, the information sheets were amended, and some of the terminology was changed to remove any possible ambiguities. A procedure was devised for ensuring that active carers were not taken on as potential befrienders during their time as a research participant, but to value their offer and contribution during later phases of the trial, once their research participation was complete. It was noted that some carers saw themselves as better equipped for the befriending role, and not just in need of care. Feedback from pilot work also showed that befrienders needed to be aware of some aspects of the research design, for example making it clear that carers had contact with research interviewers before entry into the trial, and that referrals could not be taken for the befriending scheme except from within the trial.

**Provide names of referees and complete a CRB standard disclosure form**

Contact details were requested for two character referees (not relatives), and references were taken up by the BF. Potential volunteers were also asked to disclose criminal convictions, including any that were spent, as people over the age of 65 (which many carers were) are considered vulnerable people under the terms of the Rehabilitation of Offenders Act 1974. During the start-up of the project, procedures for police checks were being transferred to the new CRB, and participants were asked to complete the CRB disclosure form. Assistance was provided by the BF where necessary.

**Attend the befriender training course**

The befriender training course consisted of six 2-hour modules, totalling 12 hours of learning (further details on p. 16). The course was compulsory and volunteers were able attend sessions from more than one course as long as all modules were covered. A record of attendance was kept.

**Agree to abide by the Code of Conduct, including the statement of confidentiality**

The Code of Conduct outlined the expectations of the work that befrienders would do on the scheme’s behalf. It included a statement of confidentiality, as organisers had to be able to trust volunteers with personal information about the carers who used its services, and personal information about the cared-for PwD. Volunteers signed to say that they would not pass on confidential information to anyone other than their BF, or supporters nominated by the BF. Volunteers could pass on confidential information if they had been given the permission of the person concerned. The statement of confidentiality also emphasised situations where safety took a higher priority than confidentiality, for example in situations of suspected abuse.

**Availability**

Volunteers were asked to make a minimum commitment to be involved with the scheme for 6 months, at an intensity of an hour per week plus travel.

**Exclusion criteria**

The following exclusion criteria were applied:

- volunteers under the age of 18 years
- volunteers regarded as unsuitable in the light of references or information from standard disclosures from the CRB
- volunteers with special needs that could not be catered for within the scheme, or which
might add to the caring burden of a befriender
- volunteers who failed to declare convictions which later came to light.

The above criteria were in line with the key principles for the safe involvement of volunteers with vulnerable clients. In the event, no volunteers were excluded on the grounds of any of these criteria.

**Befriender training programme**

The training programme was developed specifically for the trial, and delivered by the BFs in conjunction with invited others. The aims of the training were to equip volunteers for their befriending role, and ensure that they were aware of scheme boundaries and guidelines for safe and ethical involvement with carers. Certificates of attendance were provided on completion.

An early version of the training programme was written by a clinical psychologist with experience of working with carers and people with dementia, and of training in the voluntary sector. Some information was drawn from existing training programmes, plus information from organisations such as the Alzheimer’s Society. The training included skills-based work, including listening skills and maintaining boundaries. It also covered key aspects of policies and procedures, including non-discriminatory practice, health and safety when working in other people’s homes, and the balance of confidentiality versus communication of risk. The initial programme was piloted with members of the consultation group, and others nominated by consultation group members. The programme was amended to focus specifically on the befriending role rather than dementia knowledge, and the use of case vignettes was increased. The final 12-hour training programme was organised into six 2-hour units which could be organised into six, three or two sessions. The course curriculum is outlined below.

- **Unit 1: Befriending: what is it, and what it isn’t:** covered the role and responsibilities of befrienders in the BECCA scheme, including confidentiality and safety. Short ‘carer scenarios’ provided a focus for discussion and learning.
- **Unit 2: Listening skills:** theory and practice of good listening, and establishing a good relationship with carers.
- **Unit 3: Carers’ needs; the befriending relationship:** ‘carer scenarios’ from session 1 were developed to highlight the impact of caring for a person with dementia, to raise befrienders’ awareness of needs that befriending can meet. The four stages of the befriending relationship were introduced, and skills developed in stages 1 and 2 (‘breaking the ice’ and ‘getting to know one another’).
- **Unit 4: Working in other people’s homes:** guidelines for health and safety when visiting carers at home, including risk assessment, and what to do in the face of incidents, accidents or untoward situations.
- **Unit 5: Dementia and services:** this session gave information about dementia and signposted volunteers to a variety of information resources to assist in signposting.
- **Unit 6: Later stages of befriending, and looking after yourself:** skills were developed for maintaining companionship (stage 3), including avoiding miscommunication and troubleshooting. Procedures for ending befriending relationship (stage 4) were covered, and the importance of ongoing self-care was emphasised.

**Carer registration**

In parallel with the recruitment, screening and training of befriending volunteers, the BFs also registered carers expressing an interest in receiving visits from a befriending volunteer. All carers in contact with the BFs were put in contact through the BECCA research trial. The BECCA befriending schemes did not accept referrals from outside the research project. In the pilot, carers randomised to intervention were asked to opt in to the befriending scheme by sending an expression of interest form to the BF. However, carers randomised to intervention during the pilot phase did not opt in. The project consultation group suggested that opting in could be perceived by carers as ‘another hurdle to jump’, rather than as protection of their right to choose whether or not to be involved. Therefore, a protocol amendment was sought and approved such that all carers were asked for permission for their contact details to be passed on to the local BF should they be allocated to intervention as a result of the randomisation process. Following the protocol amendment, those carers allocated to the befriending intervention through the randomisation procedure received a letter from the trial administrator informing them of their allocation and enclosing a brief information leaflet about the befriending scheme. Their contact details were forwarded to the relevant BF. The introductory leaflet gave a clear statement that making use of the befriending scheme was optional. On receipt of a carer’s details, the BF would make telephone contact to
introduce themselves, to answer questions on the introductory leaflet and, where appropriate, to arrange to visit the carer. At the initial face-to-face meeting, the BF provided carers with a full information booklet about using the befriending scheme. Carers interested in participating at that stage completed a registration form and those who declined involvement were given an open invitation to change their mind at any time during the life of the project. In accordance with the suggestions of the consultation group, the BF maintained occasional contact with those carers who were not initially interested in having a befriender. The information booklet and registration form for carers using the befriending scheme corresponded to those used with the befriending volunteers.

**Befriender–carer matches**

Matches were made by the BF on the basis of locality and knowledge of both the carer and befriender. Information was used from the registration forms, most particularly befrienders’ and carers’ preferences for time and location of meetings. There were no requirements or restrictions for matches relating to gender, current circumstances or prior experience. The BF organised an initial meeting to introduce the befriender to the carer, to remind both parties of the ground rules for the befriending partnerships, and to set up an informal contract for meeting location, duration and frequency.

**Monitoring of matches**

Both befriender and carer were reminded that the BF would be contacting each of them individually to review the partnership after 1 month, 6 months and every subsequent 6 months, but that they could contact the BF at any time in between.

**Befriender support**

Local peer-support group meetings were organised for befrienders at a minimum of 6-monthly intervals. These provided opportunities for volunteers to support each other on issues that could be raised without breaching confidentiality, and to have further training and topical information about aspects of volunteering or carer support, such as telephone support. Newsletters were circulated, also at 6-monthly intervals, giving information about the BECCA project, volunteer recruitment and signposting issues. The BF maintained individual contact with each volunteer and carer between meetings, usually by telephone, and 6-monthly reviews of the activity and the quality of befriender relationship were routinely carried out. However, both befriender and carer were actively encouraged to contact the BF if they had any concerns about issues within or relating to the befriending activity.

Previous work has recommended that one full-time befriending coordinator could only successfully support 15–20 matched befrienders. Therefore, it was initially intended that the BF would liaise with counterparts in relevant organisations to identify potential befriender contacts, and also work to develop a pyramid of volunteer support in which more experienced volunteers within a community take on the role of local befriending contact, supporting and training new recruits, matching befrienders with care dyads and publicising the befriending scheme. For the Suffolk and Havering schemes, the number of matched did not rise above the recommended ceiling. In Norfolk, the BF worked closely with Alzheimer’s Society outreach workers, with some aspects of the BF role delegated.

**Ending of partnerships**

At the start of their involvement with the scheme, participating carers were told that they could use the befriending scheme as long as there was an appropriate BF. If the carer’s active caring situation changed because the PwD had either moved into long-term care or died, the carer was then given the choice as to whether to continue or terminate a befriending relationship. From the start of the trial, the intervention manager and the BF worked towards an exit strategy to ensure that ongoing matches could be supported beyond the end of the trial-specific schemes.

**Audit and data collection**

Volunteer screening and training procedures were audited by the BF, in conjunction with the intervention manager. Audit data and demographic information on matched befriending volunteers were collated by the BF and sent to the university-based research team in anonymised format. Data included age and gender of befriending volunteers, and whether or not they had previous experience as a carer. Dates of matches and partnership end dates were also collated for use by the research team.

**Volunteer flow**

A total of 124 volunteers approached BF across the three schemes expressing interest in the volunteer befriender role. Of these, 81 (65%) completed a volunteer registration form, 75 (60%) were screened using references and 64 (52%) completed CRB disclosures. In total, 63 (51%) completed the training programme, and 60 (48%)
met all four screening criteria of registration, references, CRB disclosures and completion of befriender training. In other words, two potential volunteers had to be recruited to result in one eligible befriender or, alternatively, one in two potential volunteers was lost through the screening and training process.

Previous descriptions of befriending schemes, for example ‘City Support’ Case Study 6, have found that around 15% of befriending applicants may be considered unsuitable for befriending within healthcare. The BECCA scheme screening procedures did not include any assessment of ‘befriender suitability’. Individual applicants were encouraged to consider this for themselves during the recruitment, screening and training process, and it was indeed the case that some potential volunteers withdrew as they decided for themselves that the befriending role was not right for them. In some cases, BFs were able to direct volunteers to other volunteering opportunities.

Of the 60 volunteers who completed the screening and training process, only 49 became befrienders. As demographic data for volunteers were only passed on to the research team for those who became befrienders (i.e. matched with carers), no information is available on potential differences between those volunteers who become befrienders and those who withdrew earlier in the recruitment, screening and training process, or on those who were eligible to befriend, but not matched. Anecdotally, non-matching of eligible volunteers was often due to mismatches in geographical location between befriender and carer recruitment.

**Costing of befriending services**

Each BECCA befriending scheme was set up specifically for the trial in addition to existing services, and therefore each service was uniquely costed. Cost data were collected from the beginning of the pretrial consultation to the end of the financial year 2005/06. Costs collected included set-up costs, training costs (for staff and volunteers), staff salaries and travel, volunteer time and travel, overhead expenses (administration, stationery, telephone, postage, insurance, CRB disclosures) and running costs (ongoing and recruitment and publicity costs, room hire for support groups).

Half-yearly budget statements were obtained from the host organisations to collect details on staff salaries, travel claims and all expenses related to overheads and running expenses.

**Record of activities**

BFs kept accounts of their own work and budget, and basic records of befrienders’ contact with carers. They also collected the records kept by befrienders and trainers of their time spent and expenses. The precise quantities of befriender time and expenses were recorded on monthly returns. Time, out-of-pocket expenses, use of volunteers’ cars and organisational costs of running the befriending service were all collected routinely.

**Total cost of intervention**

Intervention costs were calculated as a fixed and variable component, specific to each of the three centres (Norfolk, Suffolk and Havering). The fixed cost was divided equally by centre among all those in the intervention arm, and variable costs were divided equally among those who actually received befriending.

**Protocol changes relating to intervention**

As a consequence of ethical review, a limited-area pilot phase was introduced to the project with the aim of piloting procedures for the recruitment and training of befriending volunteers. This had implications for the wider trial timetable, leading in part to the changes to the recruitment process described in the section ‘Summary of changes to protocol’ (p. 12). As a consequence of the pilot, there were changes to the consent procedures for carers, and associated changes to the information and consent forms. At this time the opportunity was taken to amend the terminology used in these forms to conform to best practice, in a changing field.
Participant flow

A summary of participant flow is provided in the CONSORT diagram (Figure 1). Details at each stage are described below.

Expressions of interest and assessment for eligibility

In total, the research team received 316 expressions of interest. Of these, 107 (34%) were received as a result of invitations from GP practices. The greatest proportion of responses (136; 43%) came about as a consequence of carers’ contact with voluntary-sector personnel or invitations received through voluntary-sector mailing lists. Eleven per cent were self-referrals following media publicity. Over the course of recruitment an increasing number of enquiries came by word of mouth.

Of the 316 people initially expressing interest in the trial, 31 (10%) declined involvement. It is not known whether those who declined involvement would have been eligible for the trial. A further 49 people were excluded at the screening stage as they did not meet eligibility criteria for the trial. The most common reasons for exclusion were the PwD living in permanent care or having already passed away. Other reasons included carer ill-health and the care recipient having an illness other than a primary progressive dementia. Reasons for exclusion are shown in Table 1.

No demographic or psychosocial information was collected about potential participants prior to their giving written informed consent to involvement in the trial. Therefore, it is not known whether non-responders systematically differ from responders, nor is it known whether eligible carers had demographic or psychosocial differences compared with those who declined or were excluded.

Randomised allocation

All 236 carers screened as eligible for the trial gave informed consent and were randomised after baseline assessment between April 2000 and August 2004. A total of 116 carers were randomly allocated to intervention and 120 to control.

Of the 116 randomised to intervention, all 116 were offered contact with their local BF. During the initial pilot stage of the trial carers were asked to initiate this contact through the return of a response form. However, following discussion with the consultation group, this was seen as an unnecessary barrier to accessing the service, and a change to protocol was applied for and approved by the MREC such that all carers consented to having their details passed to the BF should they be allocated to intervention. There were 42 carers consented into the trial under the original procedure, with 20 in the intervention arm and 22 in the control. Of the 20 invited to make contact with the BF, 13 did so. For the 96 carers allocated to intervention under the revised consent procedures, all had contact with the BF. In addition, administrative error meant that the names of three carers allocated to control were forwarded to a BF, and therefore were treated by the BF as carers in the intervention.

Follow-up

Follow-up interviews were carried out as soon as could be arranged after the interview due date; that is, 6, 15 and 24 months postrandomisation. Overall retention in the trial over the 2-year follow-up was good at 81% overall (80% intervention and 81% control). Loss to follow-up was proportionately greater in the intervention arm than in the control arm for the first two follow-up interviews (at 6 and 15 months), but was very similar by 24 months. The main reason for loss to follow-up was carer health. Six carers died over the course of the 2-year follow-up. Three carers withdrew from the

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Table 1 Reasons for exclusion at screening

<table>
<thead>
<tr>
<th>Reason for exclusion</th>
<th>n</th>
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</thead>
<tbody>
<tr>
<td>Declined involvement (n = 31)</td>
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</tr>
<tr>
<td>Refused</td>
<td>9</td>
</tr>
<tr>
<td>No reason given</td>
<td>22</td>
</tr>
<tr>
<td>Did not meet study eligibility criteria (n = 49)</td>
<td></td>
</tr>
<tr>
<td>PwD in care, or deceased</td>
<td>19</td>
</tr>
<tr>
<td>Carer ill-health (physical or emotional)</td>
<td>15</td>
</tr>
<tr>
<td>Care recipient not having dementia</td>
<td>8</td>
</tr>
<tr>
<td>Carer spending &lt;20 hours per week caring</td>
<td>4</td>
</tr>
<tr>
<td>Out of catchment area</td>
<td>2</td>
</tr>
<tr>
<td>Paid carer</td>
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</tr>
</tbody>
</table>
Results: characteristics and outcomes

FIGURE 1 CONSORT summary of participant flow. a Intervention was ‘access to a befriender facilitator’. b Three control carers also received intervention. For purposes of analysis they were treated as control carers. c Figures for effectiveness analyses. The data set for 6-, 15- and 24-month economic evaluations comprised data from carers followed up at 6 months, i.e. 218 participants (105 intervention; 113 control). BL, baseline; FU, follow-up.
trial on the grounds that they felt they had ‘moved on with life’ such that they no longer felt they had a carer identity following the death of the PwD or their move into permanent care.

**Analysis**

All carers who were followed up were included in the analyses, with the following exceptions:

- three intervention and two control carers had missing data on the HADS at baseline
- one further intervention carer had missing HADS data at 6-month follow-up, so was excluded from 6-month analyses
- 11 intervention and seven control carers had no resource-use data at 6 months, so were excluded from economic analyses.

**Baseline characteristics of randomised carers**

Baseline data are presented for the complete sample and by group (intervention versus control).

The denominators in the tables reflect the number of carers who answered a given question.

**Demographic information**

Over the whole sample, two-thirds of carers were female (Table 2). The kin relations of the carer to the person with dementia in the sample were: 97 wives, 62 husbands, 39 daughters, 15 sons, 12 daughters or sons-in-law, four siblings, two nieces, one parent, one cousin and two friends of long standing, ‘as if related’. Three in five participants lived in ‘urban’ locations (population density 10,000 or greater). A majority (86%) of the sample were cohabiting with the PwD. All participants except for two identified themselves as white. Two-thirds of the sample were retired. The mean age of carers was 68 years (range 36–91 years) and the mean age of PwD was older, at 78 years. The mean duration of caring was just under 4 years.

Almost the complete sample (97%) was providing some form of assistance to the PwD on a daily basis (Table 3). Two-thirds considered themselves to be ‘on duty’ for 24 hours per day, and over half

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**TABLE 2 Baseline demographic information**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>n/N</td>
</tr>
<tr>
<td>Female carer</td>
<td>152/236 64</td>
<td>76/116 66</td>
<td>76/120 63</td>
</tr>
<tr>
<td>Carer ethnicity: white</td>
<td>232/234 99</td>
<td>116/116 100</td>
<td>116/118 98</td>
</tr>
<tr>
<td>Kinship: spouse</td>
<td>159/236 67</td>
<td>76/116 66</td>
<td>83/120 69</td>
</tr>
<tr>
<td>Urban location</td>
<td>146/236 62</td>
<td>71/116 61</td>
<td>75/120 63</td>
</tr>
<tr>
<td>Cohabiting</td>
<td>204/236 86</td>
<td>99/116 85</td>
<td>105/120 88</td>
</tr>
<tr>
<td>Retired</td>
<td>158/235 67</td>
<td>78/115 67</td>
<td>80/120 66</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carer’s age (years)</td>
<td>236</td>
<td>68.0</td>
<td>11.4</td>
<td>116</td>
<td>68.4</td>
<td>11.3</td>
<td>120</td>
<td>67.6</td>
<td>11.6</td>
</tr>
<tr>
<td>PwD age (years)</td>
<td>236</td>
<td>78.2</td>
<td>8.7</td>
<td>116</td>
<td>78.6</td>
<td>8.9</td>
<td>120</td>
<td>77.8</td>
<td>8.5</td>
</tr>
<tr>
<td>Duration of caring (years)</td>
<td>232</td>
<td>3.8</td>
<td>5.9</td>
<td>114</td>
<td>3.9</td>
<td>7.7</td>
<td>118</td>
<td>3.7</td>
<td>3.5</td>
</tr>
</tbody>
</table>

**TABLE 3 Burden of caring**

<table>
<thead>
<tr>
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<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Daily assistance</td>
<td>226</td>
<td>97</td>
<td>110</td>
</tr>
<tr>
<td>24 hours/day ‘on duty’</td>
<td>139</td>
<td>64</td>
<td>67</td>
</tr>
<tr>
<td>Relative can be left unsupervised</td>
<td>142</td>
<td>61</td>
<td>68</td>
</tr>
<tr>
<td>Sleep disturbance</td>
<td>125</td>
<td>57</td>
<td>60</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective burden (CADI-F)</td>
<td>232</td>
<td>54.1</td>
<td>10.4</td>
<td>114</td>
<td>53.7</td>
<td>11.0</td>
<td>118</td>
<td>54.4</td>
<td>9.9</td>
</tr>
</tbody>
</table>
experienced sleep disturbance on account of the PwD.

Sixteen per cent of carers were caring for another person in addition to a person with dementia and 16% were working, in full- or part-time paid employment, or were self-employed (Table 4). Eighteen carers (89%) identified themselves as being full-time carers. The intervention and control groups were notably similar in terms of demographics, burden of caring and multiple roles.

**Psychological well-being**

The level of psychological morbidity for the participating carers is shown in Table 5. In total, 40 carers (17%) self-reported case levels of depressive symptomology (HADS depression score ≥11), either with or without case levels of anxiety. This proportion is in keeping with the expected prevalence of clinical depression in family carers of PwD (expected range 0.15–0.32). The proportion of carers expressing case levels of anxiety (with or without depression) was higher, with 63 (27%) scoring 11 or above on the HADS anxiety scale. The mean scores on the HADS depression and anxiety subscales are comparable with those found in carers of PwD in day-hospital settings or in contact with community mental health teams (CMHTs).

Baseline scores on other psychometric measures are shown in Table 6. As for the baseline demographics, the intervention and control groups were similar on all measures.

**Support in caring role**

It was anticipated that the availability of support for carers would depend in part on their social network. There were participating carers in each of the social network categories (Table 7), with the largest category being ‘private restricted’. The private restricted network type includes individuals who have no local relative and have very little local contact or informal support.

The network typology questionnaire was also used to generate an index of social isolation based on whether or not the carer has family, friends and contact with neighbours, and whether they see any of them (family, friends and neighbours) less often than once a week. The index does not incorporate information on proximity to family (nearest family/child/sibling), frequency of interaction with family, friends and neighbours, or information on local social ties (participation in social clubs, groups or religious meetings), but has the advantage of creating an ordered scale. On the Social Isolation Index, the carer population was evenly spread across the no-isolation, low- and

**TABLE 4** Multiple roles: concurrent caring and paid employment

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N %</td>
<td>n/N %</td>
<td>n/N %</td>
</tr>
<tr>
<td>Concurrent caring</td>
<td>38/233 16</td>
<td>18/114 16</td>
<td>20/119 17</td>
</tr>
<tr>
<td>Caring for dependant under 18</td>
<td>12/36 33</td>
<td>6/17 35</td>
<td>6/19 32</td>
</tr>
<tr>
<td>Employment:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paid work</td>
<td>38/235 16</td>
<td>20/115 17</td>
<td>18/120 15</td>
</tr>
<tr>
<td>Full-time carer</td>
<td>18/235 8</td>
<td>10/115 9</td>
<td>8/120 7</td>
</tr>
</tbody>
</table>

**TABLE 5** HADS depression and anxiety: caseness (score ≥11) and continuous data

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N %</td>
<td>n/N %</td>
<td>n/N %</td>
</tr>
<tr>
<td>Depression and anxiety</td>
<td>22/231 9</td>
<td>9/113 8</td>
<td>13/118 11</td>
</tr>
<tr>
<td>Depression only</td>
<td>18/231 8</td>
<td>10/113 8</td>
<td>8/118 7</td>
</tr>
<tr>
<td>Anxiety only</td>
<td>41/231 18</td>
<td>20/113 18</td>
<td>21/118 18</td>
</tr>
<tr>
<td>Non-case</td>
<td>150/231 65</td>
<td>74/113 66</td>
<td>76/118 64</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>N Mean SD</th>
<th>n Mean SD</th>
<th>n Mean SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>231 6.8 3.7</td>
<td>113 6.7 3.6</td>
<td>118 6.9 3.9</td>
</tr>
<tr>
<td>Anxiety</td>
<td>231 7.7 4.6</td>
<td>113 7.5 4.5</td>
<td>118 7.9 4.6</td>
</tr>
</tbody>
</table>
moderate-isolation categories, with only 22 (10%) falling into the high-isolation category (Table 8).

Support from family and friends is summarised in Table 9. Almost one-third of participants had no support from family or friends. One-quarter had occasional support only. Just over one in five had regular support only, and a similar proportion had both regular and occasional support. Of those carers reporting details of the regular support received, the mean number of hours respite received was only 2.2 hours per week (range 0–23 hours), and the mean number of hours assistance was 8.2 hours per week (range 0–42 hours, excluding an outlier of 168 hours).

In addition to support from family and friends, carers received support and assistance from statutory, private- and voluntary-sector services. A selection of these is shown in Table 10. Carers’ support services were predominantly provided by the voluntary sector, and included sitting services, informational and support groups, lunch clubs and outings. Sixty per cent of participating carers had used some form of carers’ support service. In addition, 50% of care recipients had attended some form of day care (including both day centres and day hospitals). Only 20% were in receipt of assistance with home care and 24% had undertaken residential or nursing respite stays.

<table>
<thead>
<tr>
<th>TABLE 6 Affectivity, loneliness, social support, coping, quality of relationship and life events: mean and SD by group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total (N = 236)</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>n</td>
</tr>
<tr>
<td>Negative affectivity (PANAS)</td>
</tr>
<tr>
<td>Positive affectivity (PANAS)</td>
</tr>
<tr>
<td>Loneliness</td>
</tr>
<tr>
<td>Perceived social support (MSPSS)</td>
</tr>
<tr>
<td>Active coping (COPE)</td>
</tr>
<tr>
<td>Avoidance coping (COPE)</td>
</tr>
<tr>
<td>Loss of companionship</td>
</tr>
<tr>
<td>MCBS (carer towards PwD)</td>
</tr>
<tr>
<td>MCBS (PwD towards carer)</td>
</tr>
<tr>
<td>Quality of premorbid relationship</td>
</tr>
<tr>
<td>Life events</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 7 Social network (PANT) categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total (N = 230)</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>n</td>
</tr>
<tr>
<td>Family dependent</td>
</tr>
<tr>
<td>Locally integrated</td>
</tr>
<tr>
<td>Locally self-contained</td>
</tr>
<tr>
<td>Wider community focused</td>
</tr>
<tr>
<td>Private restricted</td>
</tr>
<tr>
<td>Inconclusive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 8 Social isolation categories</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total (N = 231)</strong></td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>n</td>
</tr>
<tr>
<td>Not isolated</td>
</tr>
<tr>
<td>Low isolation</td>
</tr>
<tr>
<td>Moderate isolation</td>
</tr>
<tr>
<td>High isolation</td>
</tr>
</tbody>
</table>
Summary
The demographic, psychometric and support variables at baseline demonstrate that the population under study is typical of carers of PwD. Comparison of the data for the two groups (intervention and control) demonstrates the success of the use of the urban/rural and horizontal/vertical kinship stratifications.

Main outcomes

Primary analysis
The primary analysis on the ITT population did not demonstrate any evidence of an advantage of intervention over control on the HADS depression subscale (Table 11) at any time-point.

Subgroup analyses
The primary analysis was repeated for two subgroups: first, an analysis of the subgroup of spouse carers (N = 158; 83 control and 75 intervention) and, secondly, a per-protocol analysis comparing those intervention carers who are known to have been matched with a befriender for at least 6 months before the 15-month interview (N = 37) and control carers known not to have had a befriender (N = 177).

Secondary analyses
There is no evidence of any benefit of the intervention with respect to any of the secondary outcomes (HADS anxiety subscale, loneliness, positive affectivity and the global VAS score of the EQ-5D) at any time-point (Tables 14–17).

Admission to long-term care
As disabilities increase for the PwD, the level of dependency on family carers can become unsustainable, and a common outcome is for the person with dementia to move into residential or nursing accommodation, or into NHS continuing care, where such facilities still exist. Whereas all care recipients were living at home at baseline, 32 care recipients had been admitted to permanent care (institutionalised) at 15-month follow-up (Figure 2). The proportion of PwD still in home care was compared with those institutionalised by each time-point (Table 18). Those carers for whom the PwD had died were removed from the analysis. As for other secondary analyses, there is no evidence of any advantage of the intervention over control.

Table 9: Support from family and friends

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/N</td>
<td>n/N %</td>
<td>n/N %</td>
<td>n/N %</td>
</tr>
<tr>
<td>Regular support only</td>
<td>49/226 22%</td>
<td>28/109 26%</td>
<td>21/117 18%</td>
</tr>
<tr>
<td>Occasional support only</td>
<td>59/226 26%</td>
<td>26/109 24%</td>
<td>33/117 28%</td>
</tr>
<tr>
<td>Both regular and occasional</td>
<td>49/226 22%</td>
<td>16/109 15%</td>
<td>33/117 28%</td>
</tr>
<tr>
<td>No support</td>
<td>69/226 31%</td>
<td>39/109 36%</td>
<td>30/117 26%</td>
</tr>
</tbody>
</table>

Table 10: Receipt of support from services

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/N</td>
<td>n/N %</td>
<td>n/N %</td>
<td>n/N %</td>
</tr>
<tr>
<td>Carer services</td>
<td>138/231 60%</td>
<td>71/113 63%</td>
<td>67/118 57%</td>
</tr>
<tr>
<td>Day care</td>
<td>117/234 50%</td>
<td>58/114 51%</td>
<td>59/120 49%</td>
</tr>
<tr>
<td>Home care</td>
<td>61/236 26%</td>
<td>29/116 25%</td>
<td>32/120 27%</td>
</tr>
<tr>
<td>Respite stays</td>
<td>56/232 24%</td>
<td>27/115 23%</td>
<td>29/117 25%</td>
</tr>
</tbody>
</table>

Data include an outlier which was four times greater than the next highest number of hours.
### TABLE 11 HADS depression subscale: primary analysis

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 120)</th>
<th>Intervention (N = 116)</th>
<th>Unadjusted analysis&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Adjusted analysis&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>118&lt;sup&gt;a&lt;/sup&gt;</td>
<td>113&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.96 (3.94)</td>
<td>6.73 (3.62)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>113</td>
<td>104</td>
<td>−0.193 (−1.21 to 0.83)</td>
<td>−0.485 (−1.23 to 0.26)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.84 (3.96)</td>
<td>6.03 (3.63)</td>
<td>p = 0.709</td>
<td>p = 0.201</td>
</tr>
<tr>
<td><strong>15 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>106</td>
<td>96</td>
<td>0.676 (−0.46 to 1.81)</td>
<td>0.468 (−0.50 to 1.44)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.71 (4.18)</td>
<td>6.03 (4.00)</td>
<td>p = 0.241</td>
<td>p = 0.342</td>
</tr>
<tr>
<td><strong>24 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td>93</td>
<td>0.103 (−1.15 to 1.35)</td>
<td>−0.207 (−1.32 to 0.90)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.35 (4.59)</td>
<td>6.25 (4.12)</td>
<td>p = 0.871</td>
<td>p = 0.713</td>
</tr>
</tbody>
</table>

<sup>a</sup> Baseline data missing for two control and three intervention subjects.
<sup>b</sup> Based on a pooled t-test.
<sup>c</sup> Based on a GLM adjusting for area, kinship and baseline HADS score.

### TABLE 12 HADS depression subscale: spouse carers

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 83)</th>
<th>Intervention (N = 75)</th>
<th>Unadjusted analysis&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Adjusted analysis&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>82&lt;sup&gt;a&lt;/sup&gt;</td>
<td>75</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.90 (3.94)</td>
<td>7.07 (3.48)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>78</td>
<td>68</td>
<td>−0.427 (−1.66 to 0.81)</td>
<td>−0.309 (−1.20 to 0.58)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.88 (3.81)</td>
<td>6.30 (3.71)</td>
<td>p = 0.495</td>
<td>p = 0.492</td>
</tr>
<tr>
<td><strong>15 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>73</td>
<td>60</td>
<td>0.043 (−1.39 to 1.48)</td>
<td>0.269 (−0.93 to 1.47)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.48 (4.09)</td>
<td>6.43 (4.24)</td>
<td>p = 0.952</td>
<td>p = 0.659</td>
</tr>
<tr>
<td><strong>24 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>69</td>
<td>57</td>
<td>0.457 (−1.13 to 2.04)</td>
<td>0.493 (−0.87 to 1.85)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.91 (4.80)</td>
<td>6.46 (4.05)</td>
<td>p = 0.570</td>
<td>p = 0.474</td>
</tr>
</tbody>
</table>

<sup>a</sup> Baseline data missing for one control subject.
<sup>b</sup> Based on a pooled t-test.
<sup>c</sup> Based on a GLM adjusting for area, kinship and baseline HADS score.
### TABLE 13 HADS depression subscale: per protocol

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 117)</th>
<th>Intervention (N = 37)</th>
<th>Unadjusted analysis&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Adjusted analysis&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>115&lt;sup&gt;a&lt;/sup&gt;</td>
<td>36&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.98 (3.95)</td>
<td>6.86 (3.54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>111</td>
<td>34</td>
<td>0.383 (–1.11 to 1.87)</td>
<td>0.107 (–1.00 to 1.21)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.86 (3.97)</td>
<td>5.47 (3.37)</td>
<td>p = 0.612</td>
<td>p = 0.848</td>
</tr>
<tr>
<td>15 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>104</td>
<td>31</td>
<td>1.684 (0.04 to 3.32)</td>
<td>1.377 (–0.09 to 2.84)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.75 (4.21)</td>
<td>5.06 (3.45)</td>
<td>p = 0.044</td>
<td>p = 0.966</td>
</tr>
<tr>
<td>24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>95</td>
<td>30</td>
<td>1.402 (–0.47 to 3.27)</td>
<td>1.038 (–0.63 to 2.71)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.37 (4.63)</td>
<td>4.97 (4.11)</td>
<td>p = 0.140</td>
<td>p = 0.220</td>
</tr>
</tbody>
</table>

<sup>a</sup> Baseline data missing for two control subjects and one intervention subject.
<sup>b</sup> Based on a pooled t-test.
<sup>c</sup> Based on a GLM adjusting for area, kinship and baseline HADS score.

### TABLE 14 HADS anxiety subscale

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 120)</th>
<th>Intervention (N = 116)</th>
<th>Unadjusted analysis&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Adjusted analysis&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>118&lt;sup&gt;a&lt;/sup&gt;</td>
<td>113&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>7.97 (4.68)</td>
<td>7.55 (4.58)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>113</td>
<td>104</td>
<td>0.610 (–0.57 to 1.79)</td>
<td>0.218 (–0.43 to 0.97)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.96 (4.37)</td>
<td>6.35 (4.46)</td>
<td>p = 0.311</td>
<td>p = 0.568</td>
</tr>
<tr>
<td>15 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>106</td>
<td>96</td>
<td>1.005 (–0.25 to 2.26)</td>
<td>0.610 (–0.33 to 1.55)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>7.55 (4.47)</td>
<td>6.55 (4.54)</td>
<td>p = 0.115</td>
<td>p = 0.200</td>
</tr>
<tr>
<td>24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td>93</td>
<td>0.419 (–0.87 to 1.71)</td>
<td>–0.037 (–1.10 to 1.03)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>6.97 (4.50)</td>
<td>6.55 (4.49)</td>
<td>p = 0.521</td>
<td>p = 0.946</td>
</tr>
</tbody>
</table>

<sup>a</sup> Baseline data missing for two control and three intervention subjects.
<sup>b</sup> Based on a pooled t-test.
<sup>c</sup> Based on a GLM adjusting for area, kinship and baseline HADS score.
### TABLE 15 PANAS: positive affect

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 120)</th>
<th>Intervention (N = 116)</th>
<th>Unadjusted analysis$^b$</th>
<th>Adjusted analysis$^c$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>111$^a$</td>
<td>108$^a$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>31.7 (4.68)</td>
<td>31.0 (7.50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>111</td>
<td>103</td>
<td>1.40 (–0.82 to 3.62)</td>
<td>0.922 (–0.98 to 2.83)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>31.5 (8.31)</td>
<td>30.1 (8.13)</td>
<td>p = 0.214</td>
<td>p = 0.341</td>
</tr>
<tr>
<td><strong>15 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>106</td>
<td>96</td>
<td>0.03 (–2.22 to 2.29)</td>
<td>–0.079 (–2.13 to 1.97)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>30.5 (8.02)</td>
<td>30.5 (8.22)</td>
<td>p = 0.976</td>
<td>p = 0.940</td>
</tr>
<tr>
<td><strong>24 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>95</td>
<td>92</td>
<td>1.10 (–1.36 to 3.57)</td>
<td>1.17 (–1.26 to 3.59)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>31.2 (8.34)</td>
<td>30.1 (8.73)</td>
<td>p = 0.378</td>
<td>p = 0.344</td>
</tr>
</tbody>
</table>

$^a$ Baseline data missing for nine control and eight intervention subjects.
$^b$ Based on a pooled t-test.
$^c$ Based on a GLM adjusting for area, kinship and baseline positive affect PANAS score.

### TABLE 16 Loneliness scale

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 120)</th>
<th>Intervention (N = 116)</th>
<th>Unadjusted analysis$^b$</th>
<th>Adjusted analysis$^c$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>115$^a$</td>
<td>112$^a$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.29 (2.21)</td>
<td>2.07 (2.28)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>112</td>
<td>104</td>
<td>0.148 (–0.42 to 0.72)</td>
<td>0.016 (–0.41 to 0.45)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.21 (2.21)</td>
<td>2.06 (2.04)</td>
<td>p = 0.611</td>
<td>p = 0.945</td>
</tr>
<tr>
<td><strong>15 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>106</td>
<td>96</td>
<td>0.358 (–0.27 to 0.98)</td>
<td>0.320 (–0.20 to 0.84)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.57 (2.23)</td>
<td>2.21 (2.27)</td>
<td>p = 0.260</td>
<td>p = 0.230</td>
</tr>
<tr>
<td><strong>24 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>97</td>
<td>93</td>
<td>0.392 (–0.28 to 1.06)</td>
<td>0.173 (–0.37 to 0.72)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>2.63 (2.30)</td>
<td>2.24 (2.39)</td>
<td>p = 0.251</td>
<td>p = 0.529</td>
</tr>
</tbody>
</table>

$^a$ Baseline data missing for five control and four intervention subjects.
$^b$ Based on a pooled t-test.
$^c$ Based on a GLM adjusting for area, kinship and baseline Loneliness Scale.
## TABLE 17 EQ-5D global VAS

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 120)</th>
<th>Intervention (N = 116)</th>
<th>Unadjusted analysis(^{b})</th>
<th>Adjusted analysis(^{c})</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n)</td>
<td>114(^a)</td>
<td>112(^a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>73.1 (18.1)</td>
<td>74.0 (16.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n)</td>
<td>112</td>
<td>101</td>
<td>(-2.81) (-7.51 to 1.89)</td>
<td>(-2.06) (-5.51 to 1.38)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>72.9 (17.7)</td>
<td>75.7 (17.0)</td>
<td>(p = 0.240)</td>
<td>(p = 0.239)</td>
</tr>
<tr>
<td><strong>15 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n)</td>
<td>106</td>
<td>95</td>
<td>(-3.87) (-8.94 to 1.19)</td>
<td>(-2.33) (-6.88 to 2.23)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>69.9 (18.1)</td>
<td>73.8 (18.3)</td>
<td>(p = 0.133)</td>
<td>(p = 0.315)</td>
</tr>
<tr>
<td><strong>24 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n)</td>
<td>96</td>
<td>92</td>
<td>(-4.35) (-9.82 to 1.11)</td>
<td>(-3.03) (-8.42 to 2.35)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>68.1 (18.2)</td>
<td>72.5 (19.7)</td>
<td>(p = 0.119)</td>
<td>(p = 0.268)</td>
</tr>
</tbody>
</table>

\(^{a}\) Baseline data missing for five control and four intervention subjects.  
\(^{b}\) Based on a pooled t-test.  
\(^{c}\) Based on a GLM adjusting for area, kinship and baseline EQ-5D global VAS.

---

### FIGURE 2  Status of PwD at each follow-up. C, control group; I, intervention group; T, total.
TABLE 18 Location of PwD by 6, 15 or 24 months

<table>
<thead>
<tr>
<th></th>
<th>Control (N = 116)</th>
<th>Intervention (N = 120)</th>
<th>Unadjusted analysis&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Adjusted analysis&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N&lt;sup&gt;a&lt;/sup&gt;</td>
<td>103</td>
<td>100</td>
<td>OR = 1.25</td>
<td>OR = 1.18</td>
</tr>
<tr>
<td>PwD at home</td>
<td>92 (89%)</td>
<td>87 (87%)</td>
<td>(0.53 to 2.94)</td>
<td>(0.49 to 2.86)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>p = 0.609</td>
<td>p = 0.717</td>
</tr>
<tr>
<td>15 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N&lt;sup&gt;a&lt;/sup&gt;</td>
<td>80</td>
<td>82</td>
<td>OR = 1.42</td>
<td>OR = 1.41</td>
</tr>
<tr>
<td>PwD at home</td>
<td>67 (83%)</td>
<td>63 (77%)</td>
<td>(0.66 to 3.08)</td>
<td>(0.65 to 3.08)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>p = 0.372</td>
<td>p = 0.388</td>
</tr>
<tr>
<td>24 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N&lt;sup&gt;a&lt;/sup&gt;</td>
<td>63</td>
<td>71</td>
<td>OR = 1.14</td>
<td>OR = 1.05</td>
</tr>
<tr>
<td>PwD at home</td>
<td>46 (73%)</td>
<td>50 (70%)</td>
<td>(0.53 to 2.42)</td>
<td>(0.48 to 2.26)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>p = 0.740</td>
<td>p = 0.911</td>
</tr>
</tbody>
</table>

<sup>a</sup> Excluding those subjects lost to follow-up and where the PwD had died.

<sup>b</sup> Odds ratio (OR) estimated using a logistic regression model with group alone as an explanatory variable.

<sup>c</sup> Odds ratio estimated using a logistic regression model with group, kinship and area as explanatory variables.
Chapter 5

Results: overall costs and economic analysis

Costs

Total costs are summarised in Table 19. Full cost tables and quantities are in Appendices 3 and 4.

Quality-adjusted life-years

Total QALYs gained for the intervention and control for carers, PwD and the sum of each are presented in Table 20.

Cost–utility analysis

The total cost from a societal point of view was £1813 greater in the intervention arm, although this was not statistically significant. The quality of life of the carer was slightly higher at +0.017 QALYs, although this was not statistically significant either (Table 21). Based on these point estimates, the extra cost per extra QALY gained is £105,954.

TABLE 19 Total cost summary at 15 months per participating carer (£ sterling 2005 prices; 105 intervention; 113 control)

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Median</th>
<th>Max.</th>
<th>Min.</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention cost</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>£1,138</td>
<td>£907</td>
<td>£1,722</td>
<td>£589</td>
<td>£395</td>
</tr>
<tr>
<td>Control</td>
<td>£11</td>
<td>0</td>
<td>318</td>
<td>0</td>
<td>65</td>
</tr>
<tr>
<td><strong>PwD and carer resource use</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>£13,580</td>
<td>£8,839</td>
<td>£48,471</td>
<td>1,113</td>
<td>£13,426</td>
</tr>
<tr>
<td>Control</td>
<td>£13,583</td>
<td>£10,427</td>
<td>£43,758</td>
<td>2,482</td>
<td>£12,037</td>
</tr>
<tr>
<td><strong>PwD care following admission to care/nursing home</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>£4,176</td>
<td>0</td>
<td>44,205</td>
<td>0</td>
<td>12,306</td>
</tr>
<tr>
<td>Control</td>
<td>£2,174</td>
<td>0</td>
<td>34,826</td>
<td>0</td>
<td>7,894</td>
</tr>
<tr>
<td><strong>Miscellaneous other costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>£374</td>
<td>0</td>
<td>2,283</td>
<td>0</td>
<td>2,080</td>
</tr>
<tr>
<td>Control</td>
<td>£166</td>
<td>0</td>
<td>1,299</td>
<td>0</td>
<td>714</td>
</tr>
<tr>
<td><strong>Time spent caring for PwD by carer and family and friends, and time spent befriending</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>£103,398</td>
<td>£119,322</td>
<td>£153,288</td>
<td>10,118</td>
<td>46,625</td>
</tr>
<tr>
<td>Control</td>
<td>£104,918</td>
<td>£122,176</td>
<td>£151,230</td>
<td>9,455</td>
<td>46,708</td>
</tr>
<tr>
<td><strong>Grand total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>£122,665</td>
<td>£137,134</td>
<td>£194,926</td>
<td>19,932</td>
<td>46,843</td>
</tr>
<tr>
<td>Control</td>
<td>£120,852</td>
<td>£134,852</td>
<td>£203,977</td>
<td>22,014</td>
<td>45,778</td>
</tr>
</tbody>
</table>

a Three control care had contact with the BF.

TABLE 20 QALYs (based on EQ-SD) at 15 months

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Median</th>
<th>Max.</th>
<th>Min.</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Carer QALYs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>0.946</td>
<td>0.980</td>
<td>1.270</td>
<td>-0.020</td>
<td>0.245</td>
</tr>
<tr>
<td>Control</td>
<td>0.929</td>
<td>0.980</td>
<td>1.250</td>
<td>0.010</td>
<td>0.260</td>
</tr>
<tr>
<td><strong>PwD QALYs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>0.365</td>
<td>0.330</td>
<td>1.070</td>
<td>-0.330</td>
<td>0.292</td>
</tr>
<tr>
<td>Control</td>
<td>0.314</td>
<td>0.290</td>
<td>1.040</td>
<td>-0.450</td>
<td>0.317</td>
</tr>
<tr>
<td><strong>Carer + PwD QALYs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>1.311</td>
<td>1.330</td>
<td>2.150</td>
<td>0.088</td>
<td>0.416</td>
</tr>
<tr>
<td>Control</td>
<td>1.243</td>
<td>1.270</td>
<td>2.283</td>
<td>-0.320</td>
<td>0.449</td>
</tr>
</tbody>
</table>

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Results: overall costs and economic analysis

The scatterplot of bootstrapped increments in cost and QALYs (Figure 3) shows points in all four quadrants of the cost-effectiveness plane, although the majority are to the east of the y-axis, and somewhat to the north of the x-axis, suggesting a trend towards befriending being both more effective and more expensive than control. The resulting CEAC (Figure 4) suggests only a 42.2% probability that the ICER is below a typical willingness to pay of £30,000 per QALY gained.

An alternative means of presenting these results is as a net monetary benefit chart (Figure 5). This suggests that there is unlikely to be a net benefit from the intervention, even when the willingness to pay for a QALY is above £100,000. However, there is a wide confidence interval around the point estimates.

### Alternative scenarios

#### Varying perspectives

A comparison of the results from the perspectives of the statutory sector, voluntary sector and household sectors is shown in Table 22.

The societal perspective costs are much higher than the statutory, voluntary or household costs, as societal costs include the indirect costs valuing carers’, family and friends’ time, which are the biggest single component of resource input, when valued as described earlier (see Table 19).

It should be noted that none of the cost or QALY differences reached statistical significance at a level of 95%. Nevertheless, the intervention appears to show a trend towards being slightly

---

**Table 21** Cost–utility analysis (societal perspective, 15-month time-horizon, carer quality of life only)

<table>
<thead>
<tr>
<th></th>
<th>£/carer–PwD</th>
<th>QALYs/carer</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>£122,665</td>
<td>0.946</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>£120,852</td>
<td>0.929</td>
<td></td>
</tr>
<tr>
<td>Increment</td>
<td>£1,813</td>
<td>0.017</td>
<td>£105,954</td>
</tr>
<tr>
<td>(95% CI of increment, from bootstrap)</td>
<td>(–£11,312 to £14,984)</td>
<td>(–0.051 to 0.083)</td>
<td>NA</td>
</tr>
</tbody>
</table>

---

**Figure 3** Scatterplot of increments (societal perspective, 15-month time-horizon, carer quality of life only)
FIGURE 4 CEAC (societal perspective, 15-month time-horizon, carer quality of life only)

FIGURE 5 Net monetary benefit per carer–PwD (mean and 95% CI, societal perspective, 15-month time-horizon, carer quality of life only)
more costly than the control from all perspectives. Given a typical willingness to pay of £30,000 per QALY gained, there is a less than 50% probability that befriending is ‘cost-effective’ from every perspective except for the voluntary sector. This is because the voluntary sector bears only a small proportion of the total costs. Note that this analysis only includes direct costs borne by the voluntary sector. The value of volunteers’ time in caring and befriending (indirect cost) is incorporated in the societal perspective.

**Varying time-horizon**

As the time-horizon extends, the cost-effectiveness of the befriending intervention deteriorates (Table 23). This is because while the QALY increment increases over time, the cost increment increases at a faster rate, and thus the cost-effectiveness deteriorates. In general, a longer time-horizon is preferable to a shorter one as it allows for longer term costs and benefits to be accrued. These results suggest that over the longer term, befriending is not cost-effective at conventional thresholds.

**Complete case analysis**

The results from the complete case analysis are in marked contrast to the imputed analysis results, suggesting a positive cost-effectiveness ratio (the intervention is both less costly and

<table>
<thead>
<tr>
<th>TABLE 22</th>
<th>Cost–utility analysis from societal, statutory, voluntary and household perspectives (15-month time-horizon, carer quality of life only)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perspective</strong></td>
<td><strong>Cost</strong></td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
</tr>
<tr>
<td>Societal (basecase)</td>
<td>£122,665</td>
</tr>
<tr>
<td>Statutory</td>
<td>£13,740</td>
</tr>
<tr>
<td>Voluntary</td>
<td>£716</td>
</tr>
<tr>
<td>Household</td>
<td>£4,811</td>
</tr>
</tbody>
</table>

\( ^a \) Probability intervention is cost-effective at a willingness to pay of £30,000.

\( ^b \) Confidence intervals estimated using non-parametric bootstrap, therefore differences between scenarios is due to random variation.

<table>
<thead>
<tr>
<th>TABLE 23</th>
<th>Cost–utility analysis from a societal perspective at 6, 15 and 24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time-horizon</strong></td>
<td><strong>Cost</strong></td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
</tr>
<tr>
<td>6 months</td>
<td>£54,509</td>
</tr>
<tr>
<td>15 months (basecase)</td>
<td>£122,665</td>
</tr>
<tr>
<td>24 months</td>
<td>£188,683</td>
</tr>
</tbody>
</table>

\( ^a \) Probability intervention is cost-effective at a willingness to pay of £30,000.
more effective than control, with 87.7% probability that the ICER is below £30,000 per QALY gained) (Table 24). However, these results are based on only 61 observations (versus 218 in the imputed data set), and are likely biased owing to potential correlations between health status (and hence resource use) and probability of providing complete responses to all questions.

**Incorporating PwD quality of life**

When the quality of life of the PwD is taken into account as well as that of the carer, the point estimate ICER is £26,848, which is within the conventionally accepted threshold of cost-effectiveness (Table 25). Taking into account uncertainty, the authors estimate a 51.4% probability that the ICER is below £30,000 per QALY gained. Therefore, when including PwD quality of life too, befriending may be a cost-effective intervention.

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**Summary of cost-effectiveness analyses**

There are trends towards both increased quality of life and higher costs to society among carers randomised to intervention, although neither trend is statistically significant. The point estimate of the ICER is £106,000 per QALY gained. This is above conventionally accepted thresholds of cost-effectiveness (approximately £20,000–30,000 per QALY gained). Indeed, there is only an estimated 42.2% probability that the ICER is below £30,000 per QALY gained.

From the point of view of the statutory sector, ‘access to a BF’ has an even lower probability of being the cost-effective choice. This is due to the statutory sector bearing a greater proportion of the incremental cost.

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**TABLE 24** Cost–utility analysis: comparison of imputed data versus complete case analysis (societal perspective, 15-month time-horizon, carer quality of life only)

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Cost</th>
<th>Carer QALYs</th>
<th>Increments (95% CI)</th>
<th>ICER</th>
<th>p (cost-effective)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
<td>Cost</td>
</tr>
<tr>
<td>Imputed data (basecase)</td>
<td>£122,665</td>
<td>£120,852</td>
<td>0.946</td>
<td>0.929</td>
<td>£1,813</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(–£11,312 to £14,984)</td>
</tr>
<tr>
<td>Complete case analysis</td>
<td>£121,615</td>
<td>£132,717</td>
<td>0.900</td>
<td>0.872</td>
<td>–£11,103</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(–£31,469 to £8,755)</td>
</tr>
</tbody>
</table>

* Probability intervention is cost-effective at a willingness to pay of £30,000.

* N = 30 + 31.

**TABLE 25** Cost–utility analysis: comparison of base case versus inclusion of PwD quality of life (societal perspective, 15-month time-horizon)

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Cost</th>
<th>Carer QALYs</th>
<th>Increments (95% CI)</th>
<th>ICER</th>
<th>p (cost-effective)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention</td>
<td>Control</td>
<td>Intervention</td>
<td>Control</td>
<td>Cost</td>
</tr>
<tr>
<td>Carer QALYs only (basecase)</td>
<td>£122,665</td>
<td>£120,852</td>
<td>0.946</td>
<td>0.929</td>
<td>£1,813</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(–£11,312 to £14,984)</td>
</tr>
<tr>
<td>Carer and PwD QALYs</td>
<td>£122,665</td>
<td>£120,852</td>
<td>1.311</td>
<td>1.243</td>
<td>£1,813</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(–£11,163 to £15,024)</td>
</tr>
</tbody>
</table>

* Probability intervention is cost-effective at a willingness to pay of £30,000.
The results from the voluntary sector perspective are in contrast to other sectors, for which there is an estimated 69.9% probability that the ICER will be below £30,000. However, this is because the voluntary sector bears only a small proportion of the overall costs of caring for carers or PwD. [Note that this analysis only includes direct costs borne by the voluntary sector. The value of volunteers’ time in caring and befriending (indirect cost) is incorporated in the societal perspective.] This result underlines the importance of considering cost-effectiveness from the societal perspective, as an intervention can appear cost-effective to one individual or sector; when in fact this is simply an artefact of arbitrary budgetary boundaries. From the household perspective, there is an estimated 29.8% probability that access to a BF is a cost-effective intervention (at a threshold of £30,000 per QALY gained). It is questionable, however, whether this is an appropriate analysis for evaluating cost-effectiveness from a household perspective. Cost–utility analysis is a useful tool to assist population-level rationing decisions, and the threshold is a general rule of thumb as to whether the benefits (generating a statistical QALY) are worth the cost, thus leading to more equitable distribution of finite societal resources. An individual’s willingness to pay for a QALY for a named relative or friend is likely to be very different. Furthermore, the relevant budget constraint is the household’s, not a ‘community chest’. The household may therefore value health gains to a specific person much more highly than those to society as a whole. Again, this emphasises the need to consider the societal perspective when making societal resource allocation decisions.

As the time-horizon extended, the cost-effectiveness deteriorated. Whereas the intervention was in a dominant situation at 6 months (intervention appeared to result in health-related quality of life gains and be less costly), at 24 months the point estimate ICER was £381,000 per QALY gained. The apparent deterioration in cost-effectiveness is because the costs were increasing at a faster rate than the corresponding health gain; therefore, the cost-effectiveness deteriorates.

Complete data were available for only 61 out of 218 care dyads included in the economic evaluation. The results from this limited analysis were strongly in favour of befriending; however, the authors believe this to be a biased analysis as, first, only a small proportion of the valid data was used in this analysis and, secondly, the probability of a respondent providing a complete data set is likely to be related to the health status of the carer and/or PwD. Therefore, the imputed data set is likely to provide a more appropriate representation of costs and outcomes.

When taking into account quality of life of the PwD as well as the carers, the analysis found slightly in favour of befriending: the point estimate ICER was approximately £27,000 per QALY gained, with a 51% probability of being under £30,000.
Chapter 6
Discussion and conclusions

The BECCA trial evaluated the impact of access to a befriender facilitator for family carers of people with dementia. The trial represents the largest RCT of befriending for carers of PwD, and involved an ambitious framework for costing care for carers of PwD.

Main findings

The primary cost and cost-effectiveness analyses did not show any benefit of intervention over control in terms of psychological well-being or cost. That is, at 15 months post-randomisation, access to a BF in the context of usual care did not significantly improve carer well-being as measured by HADS depression, and was associated with a trend towards higher costs to society. There was a trend towards increased health-related quality of life for those randomised to intervention, but this was not statistically significant. In terms of the main outcomes for the ITT analyses, therefore, this is a strongly negative study.

Secondary analyses on measures of carer anxiety, loneliness, positive affect and perceived global health showed no significant benefits for intervention over control, and similarly there were no differences between intervention and control on either a subgroup analysis with spouse carers or a comparison of proportions of people with dementia entering residential or nursing care. Looking from alternative perspectives (statutory, household and voluntary sector) did not offer any convincing evidence for the value of the intervention, and extending the time-frame strengthened the evidence against the intervention.

However, two further analyses that suggest the negative findings may be due to methodological limitations. First, a cost-utility analysis using the QALYs for the PwD in addition to the carer indicated that access to a BF may be a cost-effective intervention. Given the importance of care recipient well-being to family carers, it could be argued that health economic analyses of interventions for family carers should include care recipient quality of life as part of the primary analysis. Secondly, a per-protocol subgroup analysis comparing control carers with the small number of intervention carers who engaged with befrienders for at least 6 months before 15-month follow-up reported a difference in HADS depression scores that approached statistical significance in favour of the intervention. While providing only weak evidence of any beneficial effect, this finding indicates that if uptake can be improved, positive findings in the ITT population are more likely.

Implications for healthcare

Should befriending interventions be withdrawn?

Given the largely negative findings, should befriending still be provided as a support intervention for carers? It should be emphasised that the negative results reported here are for the intervention ‘access to a befriender facilitator’ and not ‘receipt of befriending’. Given that only around half of the carers offered befriending chose to take up the offer, should it be concluded that befriending is not a service that carers want? Lack of service uptake by carers is well known for both standard services and research interventions. Although awareness is a vital precursor to service use, awareness alone does not account for whether or not carers uptake services. Other factors include work status, socio-economic status and level of burden. Lack of time is associated with non-uptake, although increased burden, depression or distress may increase uptake. It is apparent that no one service is appropriate for all carers, and that each carer may have differing needs over the years spent supporting the care recipient. In their work on the ‘caregiving career’, Aneshensel and colleagues suggested that different interventions are appropriate at different stages of the care recipient’s illness, for example, before and after diagnosis, during in-home care, before and after admission of the care recipient into long-term residential or nursing care, and after the death of the care recipient. This research had been expected to show that a social support intervention would be of greatest relevance to those carers for whom the demands of caring had impacted adversely on their social networks, but were still providing care for the PwD.
at home. This study used the ‘time spent caring’ marker of 20 hours or more per week to increase the chance that participants were immersed in the caring role. Further analysis of the demographic, psychological and social characteristics of carers who did and did not take up the offer of befriending may inform the inclusion or exclusion criteria for any future research on befriending interventions or referral criteria for befriending services.

An important consideration for provision of befriending services and funding of befriending schemes is the ‘minimum effective dose’ of befriending. When drawing up the protocol, the researchers proposed providing befriending weekly for 6 months. For the 60 carers who were matched with befrienders, 42 (71%) were befriended for at least 6 months before the end of the befriending scheme (37 before 15-month follow-up). Many carers found weekly commitment difficult in the context of their caring role. A large proportion opted for fortnightly contact, but there was no frequency that suited all participants. Once relationships were established, they endured, with 39 matches lasting over 1 year, and 30 matched carers continuing to meet their befriender beyond the end of the befriending scheme. Of these, 22 became informal friendships and moved away from ‘managed’ befriending schemes. That is, 37% befriending relationships became friendships (22 out of 60 matched carers) over the course of the intervention. The remaining eight remained ‘formal’ befriending relationships, transferred to being supported within other ongoing befriending schemes. The percentage of matches lasting for at least 6 months was slightly below expectation, whereas the percentage lasting for 1 year was within the expected range. As a comparison, the UK-wide survey of 234 general befriending services indicated that 89% of befriending relationships lasted for over 6 months. For befriending services for older people, 96% of befriending relationships lasted for 6 months and 87% lasted for over 1 year, whereas for people with mental ill-health the corresponding figures were 90% and 54%. For matches lasting for at least 6 months, the mean duration of match (to the end of the relationship or the end of the befriending schemes, whichever was sooner) was 677 days (just under 1 year and 10 months), ranging from 6 months and 13 days to 3 years and 6 months for one of the earliest matches. The duration is in keeping with other schemes. For example, in the Norfolk befriending audit, users received services for between 1 and 4 years.

**Is the cost of intervention data generalisable to locally commissioned schemes?**

The mean cost of the intervention was £1138 per carer at 15 months. Costs varied by scheme, with the largest and longest running scheme having lower costs per carer than the smaller schemes. There are economies of scale for both fixed and running costs, but once a scheme grows beyond the size at which a BF can support the befrienders and carers within it, additional staff costs will be necessary.

The BECCA befriending schemes were set up specifically for the research trial. The local voluntary organisations involved in setting up the county-wide BECCA befriending services commented on the difference between the scope of these services and the more localised scope of the services that they would usually run. Factors that would increase the expense of the intervention include the ratio of carers to befrienders, the travel distances involved and criteria for matching.

In terms of carer to befriender ratios, 49 befriending volunteers were matched with carers, giving a ratio of 1.2 to 1. Nationally, the average number of users to volunteers is 170 to 52 (3.3 to 1) for befriending services to older people, with an average of 44 users and 32 volunteers (1.4 to 1) for people with mental health difficulties. In a Norfolk-wide audit of befriending schemes for people who are aged 65 and over, the average number of users and volunteers was 210 and 42, respectively (5 to 1). In a befriending scheme specifically for carers of people with dementia, ten volunteers support 50 family carers (Mid-Essex Alzheimer’s Society befriending programme, personal communication). In this context, the BECCA schemes required more trained volunteers per scheme user than any of the previously reported schemes, and would therefore be more costly per carer. This, in part, was due to a policy decision to require all volunteers to establish one match before volunteering for a second match, so that they could assess for themselves the level of emotional demand that they experienced in their befriending role.

Voluntary sector-generated befriending services would more often cover a town and its immediate rural hinterland in order to minimise volunteer travel costs and times. Some BECCA volunteers living in rural areas sometimes had to travel for up to an hour each way to undertake their befriending task. In some instances this led to
decisions to minimise volunteer travel by mixing face-to-face meetings with telephone befriending or to meet fortnightly rather than weekly, but for 2 hours rather than 1 hour. This will also have meant that initial face-to-face assessment and introductory visits by BFs would have entailed more travel than non-BECCA befriending schemes might have entailed. For these reasons, costs for the BECCA befriending service may have been higher than in a more usual locally implemented befriending service.

**Is it safe to involve volunteers?**

Overall, few risk issues arose. Active steps were taken to follow guidelines on good practice in supporting volunteers working in settings with potentially vulnerable people.90,91 A code of confidentiality was maintained, risk assessments carried out by BFs, and health and safety guidelines were developed in partnership with the voluntary organisations helping to provide the befriending services. Written information and training were provided to ensure that volunteers were fully informed about these issues and about how they needed to be applied in practice.

There were a few occasions where issues affecting the safety of befrienders as well as the safety of carers, people cared for or other family members had to be explicitly considered and responded to by the BF. These usually followed instances where the carer sought to step outside the boundaries of the befriending relationship in some way. These were picked up at an early stage by the befriender, who brought them to the attention of the BF. It was found that the early development of a risk-assessment procedure as well as befriender training in risk management proved useful in deciding how to respond to such incidents, and responses ranged from BF reminders to the carer involved about their agreement to respect boundaries to changes in the terms of the befriender arrangement. These, on two occasions, included a change of befriender and type of contact from face-to-face visits to telephone befriending. In all such cases, good working relationships were successfully maintained.

**User involvement**

The local consultation groups were formed to support and develop the befriending scheme intervention. However, their remit soon expanded to include consultation on aspects of research design and project literature. The authors would strongly endorse the involvement of carers and their representatives from the early stages of project development, including opportunity to comment on project information sheets and in planning recruitment strategies. Consultation groups can also suggest local links and small area initiatives. Such microknowledge is useful in all areas, but especially so in rural areas, where the difficulties with disseminating information to hidden communities has already been highlighted.

**Volunteer support**

Many of the volunteers were above retirement age and there were instances where befriending arrangements needed also to take account of volunteer health. Some had episodes of ill-health which in some cases prevented them from driving to visit carers or meant that they had to withdraw from volunteering completely. Both volunteers and carers were supported by the BF through such episodes to maintain the continuity of the befriending relationship according to the wishes of the participants. Recent studies such as that of older volunteers in Newcastle92 have illustrated how older people have valued their own engagement as befrienders of frailer elders, in which they were able to connect meaningfully with previous roles in which they had been able to make a contribution.

**Factors to consider in carer support research**

**Recruitment**

Recruitment to the project was one of the main challenges for BECCA, and led to both the extension of the recruitment period and the consequent changes in follow-up schedule. There were considerable difficulties in recruiting only through primary care, and the recognition of carers in primary care is an ongoing area of concern.93 A move towards multiple strategies, as recommended by Adams and colleagues94 and DiBartolo and McCrone,95 improved overall recruitment, but barriers remained, including non-identification with the term ‘carer’, non-facilitative gatekeepers, burden of written information and a disperse client group.96

Reflecting on the recruitment activity, from the identification of potential participants through to randomisation, it appears that the recruitment strategy that produced the highest number of expressions of interest was not necessarily the most productive strategy for identifying eligible participants. Twenty-seven out of 54 GP practices (20 out of 35 in Norfolk; seven out of 19 in Suffolk) sent out a total of 484 standard invitation letters and approved participant information
sheets. There were 107 responses to the research team, representing a response rate of 22% in primary care. Of the 107 respondees, 86 were randomised; that is, 18% of invitees and 80% of respondees were randomised. From the figures available from some of the voluntary- and charitable-sector organisations (especially in Havering and Suffolk), 303 invitations resulted in 45 responses (response rate of 15%) and 25 randomisations; that is, 8% invitees and 55% respondees were randomised. Figures from the voluntary- and charitable-sector mailings do not represent all of the organisations involved, but seem to indicate that although most expressions of interest for the trial arose from recruitment activity within the voluntary sector, activity within primary care produced a higher proportion of eligible carers from those expressing interest.

**Improving uptake**

The issue of intervention uptake arises in much of the research on carer intervention. A possible strategy for increasing uptake could be to use a patient preference design, or to use eligibility criteria that narrow the participating population to those most likely to take up the intervention offered. Both strategies would reduce the generalisability to the total carer population, but increase specificity. In the BECCA trial, the researchers sought the opinion of the user consultation group on the reasons for low uptake. The term ‘befriending’ was seen as offputting, in that it could imply that a carer was unable to make friends and needed to have one provided. Other schemes have used terms such as ‘friendly visiting’ or ‘peer support’. Another point made was the time taken by carers to choose to take up a service. Lack of initial uptake does not mean that the service is not wanted, simply that it is not wanted at that time. In the BECCA trial, a proportion of carers did indeed take up the service some time after it was initially offered; on one occasion a carer came back to the facilitator after 2 years. The befriending scheme was still running, but it was after the completion of the research interviews for that individual.

**Measures and data collection**

Costs reported include PwD and carer medication, primary and secondary care use, day-care services, home-care and other service use such as meals on wheels, specialist consultant, nurse or other healthcare professional visits to the home, respite stays, aids and adaptations, and time spent caring for the PwD by carer and friends and family. However, questions on PwD visits from other professionals (counsellor, chiropodist or other), continence and complementary therapy, carer use of support services such as telephone helplines and support groups, visits to professionals (counsellor, chiropodist or other) and childcare costs were excluded. The costs associated with lost employment to care for a PwD were also excluded, for two reasons: first, approximately 66% of carers were retired and therefore had zero cost of lost employment and, secondly, caring time was valued at a shadow price equal to the average gross wage rate. Therefore, forgoing employment to care for a PwD does not represent a loss of productivity to society, merely a transfer of direct cost from the household (lost wages) to indirect benefit (value of care given). Thus, there is no net change in productivity from a societal perspective, although this would have impacts on the analysis from a household perspective.

The value of carer time was calculated on the basis of the simple question: “how many hours in a 24-hour day are you “on duty” to care for your relative?” Many carers responded ‘24 hours per day’. This is undoubtedly the case for many, but for others this was interpreted as being available on the telephone at any time. This is not the same as actually being present for 24 hours, and thus the value of the time may be overestimated.

To obtain a societal cost within the BECCA trial, the aim was to measure resource use in the key sectors affected, namely statutory services (health and social care), voluntary sector and the household. Data were collected for service use by both the carer and the PwD, as difficulties arise in identifying the boundaries of costs between family carers and care recipients, and the aim was to construct a comprehensive longitudinal model of costs, rather than taking repeated cross-sectional snapshots of services at the time of each follow-up. Carer and PwD resource-use data were collected through carer interview, and therefore the data are subject to the vagaries of the individual carer’s recall. Data were not collected from agencies’ records, given the large number of agencies potentially involved, sensitivity to data protection issues and the limitations of using primary care records to measure secondary and tertiary care use. The economic data were collected alongside clinical data and therefore a balance had to be found between comprehensive data collection and the need to minimise interview burden on carers. Resource-use diaries were not used in this trial as it was thought that face-to-face interviewers would be more engaging for participants in a longitudinal trial. Diaries form
part of the methodology for the Canadian Outcomes Study in Dementia (COSID). Analysis of the economic data for the COSID trial was hampered by the non-return of the monthly diaries, with 22% of participants failing to return at least six out of 12 diaries over the course of the year.98

**Measures**

The main quality of life measure for the trial was the EQ-5D. Given the limited information on reliability and validity of the EQ5D with the carer population, and the measure being limited to health-related quality of life, broader measures of quality of life should be considered in any future research. The HTA review panel recommended use of the Carer Generated Index of Quality of Life (CGI-QoL) as a user-defined outcome in addition to a measure of health-related quality of life. The CGI-QoL was still under development at the start of 2002. Its use was piloted within the BECCA project and found to be very time-consuming, leading to interviewee burden. It was therefore dropped from the interview schedule. Health-related quality of life for the PwD also relied on the EQ-5D, using proxy ratings by the carer. Although the EQ-5D has better measurement qualities than some other health-related quality of life measures when carers are used as proxies,99 proxy ratings are known to differ from patients’ ratings.99,100 Given the suggestion that cost-effectiveness analyses should take account of the outcomes for both the carer and PwD, future carer intervention research should include direct measurement of the clinical characteristics of the PwD, including behavioural and psychological symptoms.

**Impact of interviewers**

In carer intervention research, good relations between the interviewers and carers were vital to ensure completion of interviews at each time-point, and retention in the study over time. In the BECCA trial, many participating carers expressed an appreciation of having the space to talk with someone about their caring experiences. While there are advantages to carers feeling positive about their interview involvement, this also leads to the potential narrowing of the difference between intervention and control conditions in a low-level social support trial.

**Blinding**

Although interviewers did not ask directly about befriending, it was not possible for interviewers to remain blind to group when carers specifically commented on their befriending receipt.

**Recommendations for future research**

This research is strongly suggestive that further research into access to a befriender facilitator is redundant. However, the weak evidence of efficacy in the analysis of befrienders receiving at least 6 months’ intervention may suggest that further research into befriending as a form of carer support is warranted. Based on the per-protocol analysis, the effect size was 0.51. A future study with 90% power at 5% significance would need around 220 participants per group. In addition, the befriending interventions could be used as a control for more formal psychotherapeutic interventions for carers.

Before undertaking further intervention research on befriending, it would be of value to establish the characteristics of carers most likely to take up befriending and the befriender–carer characteristics of successful matches. Information relevant to these areas could be derived from further analysis of the BECCA data.

Carer intervention research is complicated by the wide range of services offered to and used by carers over the course of the dementia. The service receipt of carers is often not fully taken into account, nor is the interplay between statutory and voluntary support services and support from families. Greater knowledge of the interaction between formal and informal care is needed.101 The BECCA database could be exploited to explore the interplay of statutory and voluntary sectors and the family, and indeed a Small Grant has been provided by the Economic and Social Research Council (ESRC) to do so. A further complication in carer intervention research is assessing well-being in the context of receipt of befriending and placement of the care recipient in long-term residential or nursing care. The BECCA trial completed follow-up irrespective of location of the PwD, as carers were keen to see support continue beyond their life as a hands-on carer. Such ongoing support should be considered in other carer interventions.

Future cost-effectiveness evaluations of carer support should include outcomes for both the carer and care recipient, and further work is required on economic methods for carer intervention research, including:

- explorations of the relationship between health-related quality of life measures and other outcome measures
• identification of methods for minimising work for respondents and interviewers of resource-use data collection in economic studies
• methods for measuring and valuing carer time and other informal care inputs for economic analysis
• additional work to confirm or refute the cost-effectiveness of befriending from a societal point of view.

Conclusions

Access to a befriender facilitator is neither an effective nor a cost-effective intervention in the support of carers of people with dementia, although there is a suggestion of cost-effectiveness for the care dyad (carer and care recipient). In common with many services for carers of PwD, uptake of befriending services was not high. However, the small number of carers who engaged with befrienders for 6 months or more reported a reduction in scores on HADS depression that approached statistical significance compared with controls. Although this study provides only weak evidence of any beneficial effect, further research into befriending interventions for carers is warranted.
The Befriending and Costs of Caring (BECCA) project (ISRCTN 08130075) was funded by the Health Technology Assessment (HTA) Programme (project 99/34/07) granted to Charlesworth (University College London), Mugford, Poland, Harvey, Price, Reynolds and Shepstone (University of East Anglia). Befriender expenses were funded by Norfolk and Suffolk Social Services, the King’s Lynn and West Norfolk Branch of the Alzheimer’s Society and an AdHoc grant from the Department of Health to North East London Mental Health Trust.

The views expressed in this report do not necessarily reflect those of the funders.

The Project Management Group met throughout the project, and included the Grantholders Shirley Reynolds (Professor in Clinical Psychology, UEA) David Price (University of Aberdeen) and Ian Harvey (in addition to the authors contributing to this report).

The befriender facilitators in the three host schemes are thanked for their support of carers and volunteers. The BFs were: Susan Vaughan (Norwich and Norfolk Voluntary Services), Carol Higgins, Wendy Herber and Thelma Wingfield (Age Concern Suffolk), and Jacqui Burke, Lyn Taylor and Elizabeth Palfreman (Age Concern Havering).

Research staff on the project included Sylvia Morley, Liz Hooper, Kim Shutt, Sandra Picken and Nicky Knights at UEA; Hilary Clarke and Amy Bartlett in North East London Mental Health Trust (London Borough of Havering) and Xanthippe Tzimoula at UCL, with additional support from Jamie Murdoch (SAND), Nick Healey (UEA) and Sarah Pennington (UEA).

The staff and volunteers from the contributing voluntary organisations (Appendix 1) are thanked, especially those who contributed to the consultation groups and in befriender training and support, as are all the participating family carers.

The Steering and Advisory Group is also thanked for their support throughout the project, and included Emeritus Professor Tom Arie (Chair), whose suggestion inspired the project, and Ionne Hammond (formerly of the Alzheimer’s Society, Eastern Region).

Administrative support was provided by Lesley Barrett, Lynne Wright, Claire Powell and Helen Sayer at different stages of the project.

**Contribution of authors**

Georgina Charlesworth (Lecturer in Clinical and Health Psychology of Old Age) had overall responsibility for all aspects of the trial including drafting of the final report. Miranda Mugford (Professor in Health Economics) had overall responsibility for economic evaluation and its reporting. Lee Shepstone (Lecturer in Medical Statistics) carried out the efficacy analysis. Edward Wilson (Health Foundation Research Training Fellow) carried out and reported the economic analyses. Mariamma Thalanany (Research Associate) drew up the resource-use data collection instrument, identified unit costs and designed the costing of the befriending intervention. Fiona Poland (Senior Lecturer in Therapy Research) held overall responsibility for the befriending intervention.

**Papers published in other peer-reviewed journals relating to this research**


References

References


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Appendix I
Organisations involved in the trial

ACCESS, Age Concern Suffolk
ACCESS, Younger People with Dementia, Age Concern Suffolk
Age Concern, Havering, London
Age Concern, Norfolk
Alzheimer’s Society
Beccles Volunteer Bureau, Beccles, Suffolk
Bury Volunteer Group, Bury St Edmunds, Suffolk
Community Mental Health Nursing Services, Norwich
Experience Corps, Cambridge
Hadleigh Volunteer Centre, Suffolk
Halesworth Volunteer Group, Suffolk
Health Centre, Ipswich, Suffolk
Ipswich Volunteer Centre, Suffolk
Ixworth GP Surgery, Ixworth, Suffolk
Julian Hospital, Norwich
Lowestoft Volunteer Group, Suffolk
Norfolk Social Services
Norwich & Norfolk Voluntary Services (NVS)
Norwich & District Carers Forum, Norwich
Nursing & Patient Services, Ipswich Hospital NHS Trust, Suffolk
Pabulum Project, Norwich
Rethink Disability, Stowmarket, Suffolk
Rookery Medical Centre, Newmarket, Suffolk
Suffolk Social Services
Stowmarket Volunteer Centre, Stowmarket, Suffolk
Suffolk Acre, Ipswich, Suffolk
Suffolk Association Voluntary Organisation (SAVO)
Suffolk Carers, Suffolk
Waveney Primary Care Trust, Suffolk
The SAND group of practices (Thorpewood Surgery; Manor Farm Close, Drayton; Bacon Road Medical Centre; Orchard St 1; Botesdale H/C, Diss; Bungay) is thanked for their assistance in recruitment, as are the following: Acle, Coastal Villages Practices (Mensby, Ormesby, Caister, Martham), King Street, Great Yarmouth; Central Surgery, Great Yarmouth; Aldborough; Holt Medical Practice; Old Palace Medical Practice; Castle Partnership; Trinity St (& Bowthorpe); Oak St Medical Practice; Manor Dr, Litcham; Watlington Medical Centre; Carole Brown H/C, Dersingham; Gayton Road; Grimston Medical Centre, Kings Lynn; Woodbridge Road, Ipswich; Chesterfield Drive, Ipswich; Dr Jones & Partners, Bury.
## Appendix 2

**Unit costs and sources**

<table>
<thead>
<tr>
<th>Item</th>
<th>Unit</th>
<th>Cost</th>
<th>Source/notes</th>
</tr>
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<tr>
<td><strong>Hospital visits</strong></td>
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<tr>
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<td>2002 cost of £273 inflated to 2005 (PSSRU, 2002)102</td>
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<td>NHS A&amp;E attendance</td>
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<td>NHS reference costs 2005,103 NHS trust and PCT combined schedule, TOPS FA, code 180</td>
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<tr>
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<td>Per surgery consultation lasting 10 minutes (PSSRU, 2005, P133)104</td>
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<td>GP home visit</td>
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<td>£69.00</td>
<td>Per home visit lasting 13.2 minutes +12 minutes travel (PSSRU 2005, P133)104</td>
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<td>Per telephone conversation lasting 10.8 minutes (PSSRU, 2005, P133)104</td>
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<td>National Audit Office report on NHS Direct in England, 2002, inflated to 2005105</td>
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<td>Assumed same as nurse surgery visit</td>
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<td>Assumed same as nurse surgery visit</td>
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<td>Private car</td>
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<td>AA motoring costs (2005)106</td>
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<td>Community transport</td>
<td>per mile</td>
<td>£1.75</td>
<td>Trial data, average patient transport service journey</td>
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<td><strong>Visits to other professionals</strong></td>
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<td>NHS counsellor, home visit</td>
<td>per visit</td>
<td>£167.81</td>
<td>NHS psychologist domiciliary visit (NHS reference costs, 2005)102</td>
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</tr>
<tr>
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<td>Per clinic visit, community chiropodist (PSSRU, 2005, P120)104</td>
</tr>
<tr>
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<td>Assumed same as chiropodist</td>
</tr>
<tr>
<td>NHS other, clinic visit</td>
<td>per visit</td>
<td>£11.00</td>
<td>Assumed same as chiropodist</td>
</tr>
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<td></td>
</tr>
<tr>
<td>Local authority day care</td>
<td>per day</td>
<td>£38.00</td>
<td>Per day, local authority social services day care for people with mental health problems (PSSRU, 2005, P58)104</td>
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continued
<table>
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<th>Item</th>
<th>Unit</th>
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<th>Source/notes</th>
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<td>Home care</td>
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<td>Mean cost of five agencies in Torbay</td>
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<tr>
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<td>per weekday</td>
<td>£13.00</td>
<td>Local authority home care worker (PSSRU, 2005, P141)</td>
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<tr>
<td>Other</td>
<td>per session</td>
<td>£12.25</td>
<td>Assumed mean of sitting service and home care service</td>
</tr>
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<td>Other services</td>
<td>per meal</td>
<td>£2.27</td>
<td>Mean cost of ten councils (Haringey, Trafford, Manchester, Powys, Isle of Man, Northamptonshire, Medway, North Tyneside, Birmingham, Tameside)</td>
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<td>Other</td>
<td>per unit</td>
<td>£13.00</td>
<td>1 hour of housework, local authority care worker (PSSRU, 2005, P141)</td>
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<td>District nurse home visit (PSSRU, 2005, P125)</td>
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<td>NHS district nurse, clinic visit</td>
<td>per visit</td>
<td>£46.00</td>
<td>District nurse per hour in clinic (PSSRU, 2005, P125)</td>
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<td>NHS district nurse, telephone contact</td>
<td>per call</td>
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<td>Assumed same as clinic cost</td>
</tr>
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<td>NHS occupational therapist, home visit</td>
<td>per visit</td>
<td>£54.00</td>
<td>Per home visit, NHS community occupational therapist (PSSRU, 2005, P118)</td>
</tr>
<tr>
<td>NHS occupational therapist, clinic visit</td>
<td>per visit</td>
<td>£20.00</td>
<td>Per clinic visit, NHS community occupational therapist (PSSRU, 2005, P118)</td>
</tr>
<tr>
<td>NHS occupational therapist, telephone contact</td>
<td>per call</td>
<td>£20.00</td>
<td>Assumed same as clinic cost</td>
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<td>NHS psychiatrist, home visit</td>
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<td>NHS psychologist, home visit</td>
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<td>Domiciliary visit, clinical/consultant psychologist (NHS reference, costs, 2005)</td>
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<td>NHS psychologist, clinic visit</td>
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<td>Per professional chargeable hour, clinic psychologist (PSSRU, 2005, P121)</td>
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<td>NHS psychologist, telephone contact</td>
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<td>NHS CPN, home visit</td>
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<td>Per home visit, including qualification costs (PSSRU, 2005, P126)</td>
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<td>NHS CPN, clinic visit</td>
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<td>Per hour clinic contact, including qualification costs (PSSRU, 2005, P126)</td>
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<tr>
<td>NHS CPN, telephone contact</td>
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<td>£64.00</td>
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</tr>
<tr>
<td>Social worker, home visit</td>
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<td>£58.00</td>
<td>Per hour of home visiting (PSSRU, 2005, P139)</td>
</tr>
<tr>
<td>Social worker, clinic visit</td>
<td>per visit</td>
<td>£35.00</td>
<td>Per hour of client-related work (PSSRU, 2005, P139)</td>
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<tr>
<td>NHS physiotherapist, home visit</td>
<td>per visit</td>
<td>£54.00</td>
<td>Per physiotherapist home visit, including qualification cost (PSSRU, 2005, P117)</td>
</tr>
</tbody>
</table>

continued
<table>
<thead>
<tr>
<th>Item</th>
<th>Unit</th>
<th>Cost</th>
<th>Source/notes</th>
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<tbody>
<tr>
<td>NHS physiotherapist, clinic visit</td>
<td>per visit</td>
<td>£20.00</td>
<td>Per physiotherapist clinic visit, including qualification cost (PSSRU, 2005, P117)</td>
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<tr>
<td>NHS physiotherapist, telephone contact</td>
<td>per call</td>
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<td>Assumed same as clinic cost</td>
</tr>
<tr>
<td>NHS other, home visit</td>
<td>per visit</td>
<td>£23.00</td>
<td>Assumed same as district nurse</td>
</tr>
<tr>
<td>NHS other, clinic visit</td>
<td>per visit</td>
<td>£46.00</td>
<td>Assumed same as district nurse</td>
</tr>
<tr>
<td>NHS other, telephone contact</td>
<td>per call</td>
<td>£46.00</td>
<td>Assumed same as district nurse</td>
</tr>
<tr>
<td>Respite stays and care-home admission</td>
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<td>NHS residential care</td>
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<td>Local authority residential care, based on weekly rate/7 (PSSRU, 2005, P49)</td>
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<td>NHS respite care</td>
<td>per day</td>
<td>£62.43</td>
<td>Assumed same as residential care</td>
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<tr>
<td>NHS nursing care</td>
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<td>£75.14</td>
<td>Private nursing home for older people, based on weekly rate/7 (PSSRU, 2005, P31)</td>
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<td>Psychiatric reprovision package, nursing home placement, weekly rate/7 (PSSRU, 2005, P64)</td>
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<td>£55.00</td>
<td>Voluntary agency residential care, based on weekly rate/7 (PSSRU, 2005, P51)</td>
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<tr>
<td>Voluntary respite care</td>
<td>per day</td>
<td>£62.43</td>
<td>Assumed same as NHS residential care</td>
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<tr>
<td>Voluntary nursing care</td>
<td>per day</td>
<td>£75.14</td>
<td>Assumed same as NHS nursing care</td>
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<tr>
<td>Voluntary EMI care</td>
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<td>£175.14</td>
<td>Assumed same as NHS EMI care</td>
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<td>Dual registered</td>
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<td>Complementary therapy</td>
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<td>£35.00</td>
<td>Notional average cost of range of interventions costing between £20 and £65 per session, collected from Internet price lists from range of clinics</td>
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<td>Carer’s assessment</td>
<td>per assessment</td>
<td>£74.25</td>
<td>Community mental health team per hour of patient contact, including travel costs (PSSRU, 2005, P150)</td>
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<tr>
<td>Social support</td>
<td>per session</td>
<td>£10.00</td>
<td>Notional cost, e.g. of yoga class, outings, tea dance club</td>
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<tr>
<td>Indirect costs – value of caring time</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Gross average wage rate</td>
<td>per hour</td>
<td>£13.11</td>
<td>Gross hourly rate for women and men, UK, 2005 (ONS)</td>
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</table>

EMI, elderly mentally infirm; PSSRU, Personal Social Services Research Unit.
### Appendix 3

**Resource-use quantities at 15 months (complete case analysis)**

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
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<th>Control</th>
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<th>Difference in mean</th>
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<td>Mean</td>
<td>SD</td>
<td>Valid <em>n</em></td>
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<td>6.89</td>
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<td>A&amp;E visit</td>
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<td>Outpatient visit</td>
<td>visits</td>
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<td>1.78</td>
<td>2.73</td>
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<td>Day care</td>
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<td>0.13</td>
<td>0.58</td>
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<td><strong>PwD GP surgery visits</strong></td>
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<td></td>
</tr>
<tr>
<td>Surgery visits</td>
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<td>4.32</td>
<td>6.46</td>
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<td>1.54</td>
<td>4.18</td>
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<tr>
<td>visits</td>
<td>visits</td>
<td>94</td>
<td>54.97</td>
<td>86.27</td>
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<td>185.80</td>
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<td>Other service private</td>
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<td><strong>PwD occasional visits to home</strong></td>
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<td>5.87</td>
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<td>16.11</td>
<td>104</td>
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Appendix 4

Detailed breakdown of per-carer/person with dementia costs at 15 months
## Appendix 4

### Intervention group

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### Control group

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### Value of time spent caring for PwD

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### Value of time in help/support from family/friends

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### Intervention cost

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March 2008