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Abstract

Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology

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Objectives: To develop and validate a psychometrically rigorous measure of health-related quality of life (HRQoL) for people with dementia: DEMQOL.

Data sources: Literature review. Expert opinion. Interviews and questionnaires.

Review methods: Gold standard psychometric techniques were used to develop DEMQOL and DEMQOL-Proxy. A conceptual framework was generated from a review of the literature, qualitative interviews with people with dementia and their carers, expert opinion and team discussion. Items for each component of the conceptual framework were drafted and piloted to produce questionnaires for the person with dementia (DEMQOL) and carer (DEMQOL-Proxy). An extensive two-stage field-testing was then undertaken of both measures in large samples of people with dementia ($n = 130$) and their carers ($n = 126$) representing a range of severity and care arrangements. In the first field test, items with poor psychometric performance were eliminated separately for DEMQOL and DEMQOL-Proxy to produce two shorter, more scientifically robust instruments. In the second field test, the item-reduced questionnaires were evaluated along with other validating measures ($n = 101$ people with dementia, $n = 99$ carers) to assess acceptability, reliability and validity.

Results: Rigorous evaluation in two-stage field testing with 241 people with dementia and 225 carers demonstrated that in psychometric terms: (1) DEMQOL is comparable to the best available dementia-specific HRQoL measures in mild to moderate dementia, but is not appropriate for use in severe dementia [Mini Mental State Examination (MMSE) <10]; and (2) DEMQOL-Proxy is comparable to the best available proxy measure in mild to moderate dementia, and shows promise in severe dementia. In addition, the DEMQOL system has been validated in the UK in a large sample of people with dementia and their carers, and it provides separate measures for self-report and proxy report, which allows outcomes assessment across a wide range of severity in dementia.

Conclusions: The 28-item DEMQOL and 31-item DEMQOL-Proxy provide a method for evaluating HRQoL in dementia. The new measures show comparable psychometric properties to the best available dementia-specific measures, provide both self- and proxy-report versions for people with dementia and their carers, are appropriate for use in mild/moderate dementia (MMSE ≥ 10) and are suitable for use in the UK. DEMQOL-Proxy also shows promise in severe dementia. As DEMQOL and DEMQOL-Proxy give different but complementary perspectives on quality of life in dementia, the use of both measures together is recommended. In severe dementia, only DEMQOL-Proxy should be used. Further research with

DEMQOL is needed to confirm these findings in an independent sample, evaluate responsiveness, investigate the feasibility of use in specific subgroups and in economic evaluation, and develop population norms. Additional research is needed to address the psychometric challenges of self-report in dementia and validating new dementia-specific HRQoL measures.

Contents

List of abbreviations

AD	Alzheimer's disease
ADAS-Cog	Alzheimer's Disease Assessment Scale – cognitive section
ADL	activities of daily living
ADRQL	Alzheimer's Disease Related Quality of Life measure
AEF	aggregate adjacent endorsement frequency
BS	Bartlett's test of sphericity
CDQLP	Community Dementia Quality of Life Profile
CDR	Clinical Dementia Rating Scale
CGIC	Clinical Global Impression of Change
CIBIC-plus	Clinician Interview Based Impression of Change-plus
DQOL	Dementia Quality of Life Instrument
DSM	Diagnostic and Statistical Manual of the American Psychiatric Association
GDS-30	Geriatric Depression Scale 30-item version
GHQ-12	12-item version of the General Health Questionnaire
HRQoL	health-related quality of life
HUI	Health Utilities Index
IADL	instrumental activities of daily living
ICC	intraclass correlation
ICD-10	International Classification of Diseases (10th revision)
KMO	Kaiser–Meyer–Olkin statistic
LREC	local research ethics committee
MCS	Mental Component Summary Score (of SF-12)
MEF	Maximum endorsement frequency
MHOA	Mental Health for Older Adults
MMSE	Mini-Mental State Examination
NICE	National Institute for Clinical Excellence
NSF	National Service Framework
ns	not significant
ONS	Office of National Statistics
PCS	Physical Component Summary Score (of SF-12)
PDS	Progressive Deterioration Scale
QOLAD	Quality of Life in Alzheimer's Disease
QOLAS	Quality of Life Assessment Schedule
QOL-D	Quality of Life in Dementia scale
RCT	randomised controlled trial
SEIQOL	Schedule for the Evaluation of Individual Quality of Life
SF-12	Short Form-12 Health Survey
SF-36	Short Form-36 Health Survey

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.

Executive summary

Background

Dementia is one of the most common and serious disorders in later life. It causes irreversible decline in global intellectual and physical functioning, and has a significant personal, social, health and economic impact on people with dementia, their family carers, and health and social services. Although measures of cognitive, functional and behavioural outcomes are widely used to evaluate interventions for dementia, the challenge of measuring broader outcomes such as health-related quality of life (HRQoL) has only recently begun to be addressed. This presents challenges about how to assess the subjective perceptions and experiences of the person with dementia in a reliable and valid way. This report describes the development of a new measure (DEMQOL) to evaluate HRQoL in people with dementia. The new measure is designed to address limitations and/or gaps that were identified in existing dementia-specific measures.

Objectives

The purpose of this study was to develop and validate a psychometrically rigorous measure of HRQoL for people with dementia. The measure was intended to be: (1) suitable for use in the UK; (2) available in self- and proxy-report versions for people with dementia and their carers, respectively; and (3) appropriate for use in mild/moderate and severe dementia. The aim was to keep the perspective of the person with dementia central in all stages of questionnaire development and evaluation.

Methods

Gold-standard psychometric techniques were used to develop DEMQOL and DEMQOL-Proxy. First, a conceptual framework was generated from a review of the literature, qualitative interviews with people with dementia and their carers, expert opinion and team discussion. Items for each component of the conceptual framework were drafted and piloted to produce questionnaires for the person with dementia (DEMQOL) and carer (DEMQOL-Proxy). Extensive two-stage field testing of both measures was then undertaken in large samples of people with dementia (n = 130) and their carers (n = 126), representing a range of severity and care arrangements. In the first field test, items with poor psychometric performance were eliminated separately for DEMQOL and DEMQOL-Proxy to produce two shorter, more scientifically robust instruments. In the second field test, the item-reduced questionnaires were evaluated along with other validating measures (n = 101 people with dementia, n = 99 carers) to assess acceptability, reliability and validity.

Results

The conceptual framework included five domains: daily activities and looking after yourself, health and well-being, cognitive functioning, social relationships and self-concept. The preliminary field test versions of DEMQOL and DEMQOL-Proxy contained 73 questions representing the five domains and a global question about overall quality of life. Item reduction analyses resulted in a 28-item DEMQOL and a 31-item DEMQOL-Proxy.

Rigorous evaluation in two-stage field testing with 241 people with dementia and 225 carers demonstrated that in psychometric terms: (1) DEMQOL is comparable to the best available dementia-specific HRQoL measures in mild to moderate dementia, but is not appropriate for use in severe dementia [Mini Mental State Examination (MMSE) <10]; and (2) DEMQOL-Proxy is comparable to the best available proxy measure in mild to moderate dementia, and shows promise in severe dementia. In addition, the DEMQOL system has been validated in the UK in a large sample of people with dementia and their carers, and it provides separate measures for self-report and proxy report, which allows outcomes assessment across a wide range of severity in dementia.

Conclusions

The 28-item DEMQOL and 31-item DEMQOL-Proxy provide a method for evaluating HRQoL in

dementia. The new measures show comparable psychometric properties to the best available dementia-specific measures, provide both self- and proxy-report versions for people with dementia and their carers, are appropriate for use in mild to moderate dementia (MMSE ≥ 10) and are suitable for use in the UK. DEMQOL-Proxy also shows promise in severe dementia. As DEMQOL and DEMQOL-Proxy give different but complementary perspectives on quality of life in dementia, it is recommended that both measures are used together. In severe dementia, only DEMQOL-Proxy should be used.

Further research with DEMQOL is needed to: (1) confirm these findings in an independent sample; (2) evaluate responsiveness; (3) investigate the feasibility of use in specific subgroups and in economic evaluation; and (4) develop population norms. Additional research is needed to address the psychometric challenges of self-report in dementia and validating new dementia-specific HRQoL measures.

Chapter 1
Introduction

Dementia is one of the most common and serious disorders in later life. It causes irreversible decline in global intellectual and physical functioning and has a significant personal, social, health and economic impact on people with dementia, their family carers, and health and social services. The National Service Framework (NSF) for older people[1] identified dementia as a health policy priority, citing the need to ensure early diagnosis, access to treatment, effective planning of care and support to carers. Implementation of these priorities requires rigorous evidence about the impact of dementia and the effectiveness of treatments on a range of outcomes.

Although measures of cognitive, functional and behavioural outcomes are widely used to evaluate interventions for dementia, the challenge of measuring broader psychosocial outcomes such as health-related quality of life (HRQoL) in dementia has only recently begun to be addressed. This study addresses some of these challenges in developing a new measure of HRQoL for people with dementia. HRQoL is generally assessed by directly asking the individual about his or her views. In people with dementia, however, difficulties with memory, attention, communication, judgement, insight and behaviour present an enormous challenge when evaluating HRQoL. The main concern is how to assess the subjective perceptions and experiences of the person with dementia in a reliable and valid way. Although proxy reports are sometimes used, patient–proxy agreement in dementia is moderate at best and better for observable behaviours than for subjective experiences. Both self-report and proxy report present unique methodological challenges in dementia.

Characteristics and natural history of dementia

The syndrome of dementia includes a sustained decline in memory and other intellectual functions occurring in clear consciousness, and changes in behaviour (excess and deficits), emotional control and social functioning. The criteria for dementia in the International Classification of Diseases (ICD-10)[2] are summarised as follows.

- A syndrome due to disease of the brain, usually chronic (over 6 months in duration) and progressive. Disturbance of memory and one or more other higher cortical functions (e.g. thinking, orientation, comprehension, calculation, learning, language and judgement).
- No clouding of consciousness.
- Commonly accompanied by deterioration in emotional control, social behaviour and/or motivation.
- Interference with activities of daily living.

The course and particular symptoms of dementia depend on the underlying diagnosis, the environment and patient characteristics such as co-morbid physical disorder and personality. At presentation patients may complain of forgetfulness, decline in mental functioning or feeling depressed, but may also be unaware of memory loss. Patients and family may sometimes deny or be unaware of the severity of memory loss and other deteriorations in functioning. The diagnosis of dementia may be the result of families asking for help because of failing memory, disorientation, self-care, change in personality or behaviour, or may be an incidental finding after investigation of another acute or chronic health problem. It is not possible to predict the course or timescale of cognitive impairment in an individual with dementia, other than an overall decrease in function over time. Equally, there is no clear or predictable association between time, cognitive impairment, and particular behavioural and psychological symptoms in dementia.

Subtypes of dementia

The four most common disease processes that cause dementia are Alzheimer's disease (AD), vascular dementia, Lewy body dementia and frontal or frontotemporal dementia. There is strong evidence of overlap between these specific subtypes. This may be incidental (e.g. vascular disease, Parkinsonism and AD are all relatively common in older people) or may reflect shared aetiology (e.g. vascular risk factors for AD). It is important to recognise that the course and prognosis of the disorder in an individual may be impossible to predict. Despite advances in neuroimaging, the definitive diagnosis of the particular subtype of dementia will usually only be possible at post-

mortem by neuropathology of brain tissue, and only then if appropriate techniques are used. The vast majority of people dying with dementia do not, however, undergo post-mortem examination.

Epidemiology of dementia

Dementia has a prevalence of 6% and an incidence of 2% per year in the over-65s.[3,4] In the UK dementia therefore affects around 600,000 people at any one time, with 200,000 new cases every year. It is strongly associated with increasing age, with prevalence of dementia (and of the most common subtype, AD) increasing exponentially with increasing age. The EURODEM consortium meta-analysis[3] for European population-based studies applying the dementia criteria of the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-III)[5] reported the following rates: 1% (65–69 years), 4% (70–74 years), 6% (75–79 years), 13% (80–84 years), 22% (85–89 years) and 32% (90–94 years). As with prevalence, the annual incidence risk for dementia (and AD) increases exponentially with increasing age.

Variations in dementia prevalence between countries

The consensus until recently has been that there are no important regional differences in the frequency of dementia or AD. Jorm and colleagues[6] reviewed 47 studies of the prevalence of dementia published between 1945 and 1985. Much of the variability in prevalence between studies was explained by the different methods used by the investigators, in particular: sampling, inclusion and exclusion criteria, research instruments and diagnostic criteria. Corrada and colleagues[7] reviewed AD prevalence surveys published between 1984 and 1993, with a very similar pattern of findings. Since then the research methods for these investigations have been increasingly refined and standardised. The EURODEM consortium found that among European studies using similar methodologies and diagnostic criteria, there were only trivial differences in the age-specific prevalence of dementia (12 studies)[3] and AD (six centres),[8] concluding that ecological comparisons were unlikely to be informative about aetiology. However, the large majority of these studies have been carried out in urban settings in developed countries.

Other evidence suggests that AD may be less common in rural than in urban areas, and in developing compared with developed regions. A recent review of population-based dementia prevalence studies in the developing world by the 10/66 Dementia Research Group[9] identified a large variation in the age-adjusted prevalence of dementia, from 1.3 to 5.3% for all those aged 60 years or over and from 1.7 to 5.2% for all those aged 65 and over. This may represent genuine differences in dementia prevalence, or may simply be an artefact of the methodological differences between the studies. Two of the studies from developing countries[10,11] reported a strikingly low prevalence of dementia. These are the two studies from developing countries with the most rigorously developed culture- and education-fair dementia diagnostic procedures, which had been harmonised for use in US–Nigeria and US–India trans-national studies. The Nigerian study supported earlier observations on the rarity of AD in Ibadan, and on the absence of amyloid plaques and neurofibrillary tangles in an unselected brain autopsy series.[12] From these and other studies, there seems to be a general trend for the dementia prevalence estimates from the developing world, age-adjusted, to be lower than those for the developed world.

In addition to the possibility of true differences in the prevalence of dementia there is the possibility of other explanations. First, diagnostic procedures for psychiatric disorders that have been standardised in one setting cannot be applied indiscriminately to another. They may turn out to be culturally biased, giving a misleadingly high or low estimate of the prevalence of the disease. Second, other methodological differences between studies, for example in sampling procedures and in inclusion and exclusion criteria, may have important effects on prevalence estimates. Third, the observed low prevalence in the developing world may be accounted for either by selective out-migration of susceptible persons, or by in-migration of those unlikely to develop the disorder, and vice versa for high prevalence. Finally, prevalence is the product of incidence and duration, low prevalence rates may indicate a high recovery rate (unlikely in dementia) or a low survival rate for those with the disorder, rather than a true difference in incidence. So the low prevalence of dementia and AD seen in Nigeria and in India may reflect a particularly high mortality rate among people with dementia, or those at risk of dementia in developing countries.

Variations in dementia prevalence over time

Two epidemiological programmes have continued to survey the residents of the same area over long

periods, and are therefore in the unusual position of being able to comment on the trends in the prevalence of dementia over time. The Lundby study in Sweden[13] reported no significant change in the prevalence or incidence of either multi-infarct dementia or what was described at the time as "senile dementia" (now most probably AD) over the period from 1947 to 1972. In Rochester in the USA,[14] the meticulously maintained healthcare register suggested no change in the prevalence of either AD or dementia between 1975 and 1980. However, despite the recent stability of prevalence rates one cannot exclude the possibility that dementia is a more common disease nowadays than say 100 or even 50 years ago, at a time when developed countries were still developing. Accounts of typical cases of AD are to be found in historical sources, centuries before Alois Alzheimer's description of early-onset cases. However, there are no hard data on prevalence that would allow valid comparison with modern studies.

The recent findings of a substantial prospective association between both established vascular disease and its risk factors and risk for AD and dementia, suggest that efforts to prevent vascular disease may also reduce incidence rates for dementia and AD. Changes in vascular risk exposures, particularly reduction in smoking together with improvements in treatment of hypertension and established vascular disease, have led to a reduction in cardiovascular and cerebrovascular morbidity and mortality in many populations in the developed world. It will be both interesting and important in the future to monitor whether these changes have a discernable effect on the age-specific incidence of dementia and AD. Recent standardisation of research methods and the establishment of precise baseline estimates in large population-based samples will assist such future secular comparisons. Any reductions in age-specific incidence rates are still likely to be accompanied by an increase in the absolute numbers of those with dementia, because of the continuing ageing of the population in developed and developing countries.

Treatment for dementia

The challenges presented in planning and providing services for the person with dementia are daunting. Particular difficulties arise in attempting to take account of patient views when the disorder itself, and the nature of the consequent problems, may be unacknowledged by the patient. Equally, the disorder may render people with dementia unable to formulate and articulate needs and preferences. Government policy across the developed world has become increasingly focused on meeting the challenges of caring for an ageing population in general and, in particular, people with dementia.

Given the nature of the impairments and impacts of dementia it is important to bear in mind the potential scope of intervention in dementia. Interventions include those with a psychological (e.g. cognitive retraining), social (e.g. provision of home help) or biological (e.g. drugs to treat behavioural and psychological symptoms in dementia) focus. Interventions delivered at an individual level focus on people with dementia (e.g. drugs to improve cognition), family carers (e.g. carer cognitive behavioural therapy to improve the quality of life for the person with dementia) or service providers (e.g. training to improve quality of care in nursing homes). Other interventions may be delivered at a group (e.g. support groups for people with dementia or carers), community (e.g. development of good quality dementia assessment and care services), national (e.g. NSFs or focused financial incentives for primary care identification) or international (e.g. the work of Alzheimer's Disease International in developing and supporting national Alzheimer's associations) level. These levels of complexity substantiate the need to evaluate the broad impact of interventions using scientifically robust measures of HRQoL in dementia.

The exponential growth of psychological and social interventions for dementia in addition to drug treatment makes clear the need for rigorous evaluation of these new interventions. This requires outcome measures that are tailored to the particular challenges presented by dementia which can assess the comparative efficacy and effectiveness of different treatment strategies.

Alongside the development of psychological and social interventions, there is an immense growth of work using emerging neurobiological aetiological insights to develop drug treatments for dementia. The first group of compounds to be introduced was the acetylcholinesterase inhibitors. Donepezil was licensed for use in the UK in April 1997,[15] followed by rivastigmine and galantamine. More recently, memantine, a compound that targets the glutaminergic rather than the cholinergic system, has been licensed. While there is no evidence that these drugs modify the underlying disease processes in dementia, they appear to show some

efficacy in terms of time-limited improvement and/or maintenance of cognitive function. The most important advantage in terms of the cost–benefit equation for patients and carers is their benign side-effect profile and the extremely low frequency of severe adverse events. Although data on these medications remain limited, especially with respect to real-time clinical effectiveness, impact on quality of life and economics, the National Institute for Clinical Excellence (NICE)[16] has endorsed their use. While the effects of the current compounds may be relatively modest, there is significant continuing investment in the development of new drugs to treat the dementias.

Evaluating treatment

Most studies of treatments for dementia have evaluated the outcome of treatment on the basis of cognitive functioning, using either the Alzheimer's Disease Assessment Scale–cognitive section (ADAS-Cog)[17] or Mini-Mental State Examination (MMSE)[18], or one of several clinician-rated global measures of change such as the Clinical Global Impression of Change (CGIC)[19] or the Clinician Interview Based Impression of Change-plus (CIBIC-plus).[20] The majority of drug trials have used the ADAS-Cog[15,21–24] to measure cognitive function, although many studies have also continued to use the ubiquitous MMSE.[25] For global change, most trials have used the CIBIC-plus.[15,23,26,27] Increasingly, studies have attempted to acknowledge the inherent complexity in dementia by including a wider range of outcomes, including activities of daily living (ADL),[15] instrumental activities of daily living (IADL)[28] and quality of care.[29,30] Although one trial purported to measure quality of life outcome,[31] it has been suggested that the instrument used, the Progressive Deterioration Scale (PDS), is in fact a measure of activity limitation.[32] It is now clearly acknowledged that the narrow assessment of cognition and functional ability is insufficient for clinical decision-making and policy development, and that measures of HRQoL[33] and carer outcomes[34] are vital.

Costs of care

More systematic assessment is also needed to evaluate the impact of interventions on costs in the whole system of health and social care. The cost of caring for people with dementia is immense, including the costs of 'informal' family care (direct costs and the opportunity costs of taking on the caring role), healthcare (both primary and secondary services) and social services (home care, day care and institutional care). It has been estimated that the direct costs of dementia are between £7.1 billion and £14.9 billion in the UK alone,[35] which is substantially greater than stroke (£3.2 billion), heart disease (£4.1 billion) and cancer (£1.6 billion). Our understanding of how these costs may be affected by interventions is very limited at present, but the extent of spending makes clear the value of attending to this issue.

While the economics are striking, the negative impact of dementia in terms of deteriorating function and high carer stress, burden and mental disorder associated with taking on the caring role[36,37] is also enormous. Current models of service provision in Mental Health for Older Adults (MHOA) may be seen to be failing to address the needs of the vast majority of people with dementia, as only 15–20% ever have contact with specialist MHOA services[38] at any stage of their illness. Given that the needs of the other 80% may not be adequately met, it is essential to be able to identify and assess people with dementia and to do this earlier in their illness.[1] In addition, there is a need to improve the quality and consistency of care for older people with dementia. This includes increasing the appropriate prescription of antidementia drugs, and the use of psychological and social management strategies for people with dementia and their carers. This points to the need to develop and evaluate different models of service provision for people with dementia and their family carers so that potentially beneficial interventions can be offered.

Impact of dementia on quality of life

Clinical descriptions often cite the impact of dementia on psychosocial outcomes such as depression, isolation and fear,[39] loss of responsibilities, control and status,[40] loss of ability to engage in enjoyable activities[41] and negative affect.[42] The potential impact on the carer is also well recognised.[43] However, relatively little research has systematically investigated the type and magnitude of the effect of dementia on psychosocial outcomes including HRQoL. In part, this reflects the lack of appropriate measures of HRQoL in dementia, although this is now beginning to change.

Cross-sectional studies have generally not compared HRQoL in clinical groups with either age-matched normative data or a general

population control group. There are also few longitudinal or cohort studies of HRQoL in dementia. Gonzalez-Salvador and colleagues[44] found that assisted-living residents with dementia reported consistently better HRQoL than those living in skilled nursing facilities, although the former group also had higher MMSE scores (mean 9.5 compared with 2.6). Ballard and colleagues[45] studied the impact of behaviour, ADL and taking psychotropic drugs on quality of life. The study has methodological problems, but lower performance on ADL and taking psychotropic drugs were both reported to be associated with lower well-being, increased social withdrawal and decreased engagement in activities. The authors also reported that behavioural symptoms were not associated with reduced quality of life. One of the few available longitudinal studies of psychosocial outcomes in dementia[46] provides a baseline profile of people with dementia in terms of activity, confinement to home and affect. Longitudinal data collected at 6-monthly intervals for 4 or more years suggested that when severity of dementia increased over follow-up, subjects were more likely to experience poor quality of life (indicated by reduced activity, reduced positive affect and increased confinement).

The lack of data comparing HRQoL in people with dementia with age-matched normative data or controls means that it is difficult to draw conclusions about whether the impact on HRQoL is due to dementia or reflects a more general age-related pattern. It is important to document these disease effects because a treatment could not, in general, be expected to improve HRQoL unless it was known that the disease itself has a negative impact on HRQoL. Furthermore, it is important to know the magnitude of the disease effect. Treatment effects are likely to be smaller than disease effects, so knowledge of the magnitude of the disease effect can inform estimation of the expected treatment effect, thus enabling more accurate power calculations for evaluation studies and clinical trials.

Impact on carers

As dementia progresses, people with dementia require more help with self-care and other aspects of daily functioning. The burden of care usually falls on close family members, typically co-resident spouses or daughters, with most of the caring carried out by one relative,[47] and with the tasks rarely equally shared. Caring for people with dementia is stressful; carers have been found to have poorer physical and mental health than age-matched controls.[48]

The impact on carers depends on the characteristics of the carer as well as the person with dementia. Levin and colleagues[49] have usefully defined four main sources of stress and burden:

- practical: need for help with personal care and housework
- behavioural: including active problems (e.g. aggression, wandering, night disturbance, incontinence) and passive problems (e.g. apathy, decreased social interaction), which may be particularly difficult to deal with
- interpersonal: difficulty in communication and change in the nature of the relationship with the person with dementia
- social: restrictions on the carer leaving the home, socialising or going to work.

Logiudice and colleagues[50] found that the psychosocial health of carers of people with dementia was impaired, although in a different way to chronically ill patients, with social interaction and recreation most affected. It has also been suggested that carers who are co-resident with the person with dementia, socially isolated and/or who have previously had a poor relationship are at increased risk of distress.[51]

Conceptual models of HRQoL in dementia

HRQoL is a multidimensional concept that reflects the individual's subjective perception of the impact of a health condition on everyday living.[52] This was the working definition of HRQoL used in the current study. It is distinct from the broader concept of quality of life as it includes only the aspects of quality of life that are affected by a health condition. HRQoL is related to, but not conceptually equivalent to, symptom impact and functional status.

General models of HRQoL

The WHO[53,54] definition recognises health as a multidimensional concept that includes physical, mental and social well-being. Autonomy has more recently been added as a fourth component.[55] Most general models of HRQoL reflect the importance of physical, psychological and social functioning, often including the ability to perform usual roles within each of these domains. In addition, several models[56–59] include general health perceptions as a domain of HRQoL. Some models also include another potentially important component – 'opportunity for health'[56,57] or 'health potential'[60] – that is, the ability to withstand

stress and the extent to which an individual has physiological reserves. The construct HRQoL is therefore sometimes described as having elements of 'positive health', which includes the ability to fulfil potential, in addition to the absence of illness and the ability to function adequately. These positive aspects of health and HRQoL are difficult to measure and are rarely included in instruments to measure HRQoL.

Well-established generic measures of HRQoL and health status such as the Short Form 36 (SF-36),[61] Health Utilities Index (HUI),[62] EQ-5D[63] and WHOQOL[64] may also include additional domains such as pain, general health perceptions, energy, independence, environment and spirituality. Most conceptual work on HRQoL has aimed to provide a description of the construct, but few studies have explored the relationship between different domains of HRQoL or between HRQoL and other relevant constructs.[59]

Dementia-specific models of HRQoL

Conceptual work to identify the specific domains of HRQoL that are relevant to people with dementia is still relatively under-developed. There is an emerging body of literature that suggests that people with dementia have a meaningful experience of HRQoL and are able to report this subjective experience.[39,65,66] Most studies of HRQoL in dementia are descriptive; few have compared findings with general models or explored the relationship among different aspects of HRQoL or between HRQoL and other relevant variables.

Kitwood's Dementia Care Mapping approach[67] suggests that there are four sentient states relevant to quality of life in dementia:

- sense of personal growth
- sense of agency
- social confidence
- hope.

Parse[68] describes four emerging dimensions of quality of life based on interviews with people with dementia:

- calm/turbulence
- freedom/restriction
- certainty/uncertainty
- togetherness/aloneness.

Brod and colleagues[69] conducted three focus groups: one with five co-resident carers of people with dementia, one with six service providers, and one with six people in the early stages of dementia who were regular participants in a support group. They then proposed a conceptual framework that includes:

- aesthetics (including enjoying/appreciating beauty, nature and surroundings)
- positive affect (including humour, feeling happy, content and hopeful)
- absence of negative affect (including worry, frustration, depression, anxiety, sadness, loneliness, fear, irritability, nervousness, embarrassment and anger)
- self-esteem (including feeling accomplished, confident or satisfied with self, able to make own decisions)
- feelings of belonging (feeling loveable, liked and useful).

These three models conceptualise HRQoL in terms of subjective components. The Brod model,[69] which builds on the generic conceptual models of Lawton[70–72] and Wilson and Cleary,[59] proposes a conceptual model of the relationship between domains of HRQoL and other areas of impact in dementia. Further work is needed to test the hypothesised relationships between these aspects of health.

An alternative perspective[72] suggests that quality of life in dementia includes both subjective and physical/social-normative components. The subjective component includes perceived quality of self (psychological well-being) and the environment (the person's own evaluation of housing, income, leisure activities). The physical/social-normative component includes behavioural competence (ADL, cognitive performance and social behaviour) and the quality of the external environment (observer ratings of the living environment or amount of private space or homeliness). Lawton argues that because people with dementia who are beyond the early stages of the condition are not able reliably to report verbally on their subjective experience, the external or observable components are often the only aspect of quality of life that can be assessed. Other authors have suggested that this reliance on external observations does not allow for the individual nature of values, needs and ability to adapt.[69]

Evaluating quality of life in dementia

Approaches to the measurement of HRQoL in dementia

Current conceptual frameworks form the basis of

instruments to measure HRQoL. Instruments can be either self-rated or proxy-rated, self-administered or interviewer-administered, generic or disease-specific. The choice between self- and proxy-rated instruments depends on the construct being measured and the characteristics of the population under investigation. Subjective constructs such as HRQoL are usually best measured by self-report, but this may be more difficult with people with dementia. This is discussed further below (in the section 'Methodological challenges in measuring HQoL in dementia', p. 7). The decision between self- and interviewer-administered instruments is mainly a practical one and is often a trade-off between the participants' level of functioning and financial and time constraints. Generic and disease-specific measures can be used to evaluate HRQoL. Generic measures have the advantage of allowing the same instrument to be used in a variety of different conditions so that results can be compared on the same scale. This is an important consideration for applications such as health economics or monitoring population health. Generic scales may, however, be insensitive to some domains that are important in a specific condition.

Because disease-specific measures are designed to be relevant to a particular condition, they are generally more sensitive in detecting change following an intervention. The disadvantage of disease-specific instruments is that they do not allow comparisons across different conditions. Ideally, the evaluation of HRQoL should include both generic and disease-specific instruments, although the additional respondent burden imposed by administering an extra questionnaire may make this unfeasible.

Generic measures

Several generic measures have been evaluated for their appropriateness for use in dementia. The Duke Health Profile, SF-12, Nottingham Health Profile, EQ-5D and the Schedule for the Evaluation of Individual Quality of Life (SEIQOL) have all been shown to have important limitations when used with people with dementia. For example, the SEIQOL has been reported to be too cognitively complex for people with dementia.[73] The Duke Health Profile does not meet standard criteria for reliability when tested with people with dementia (Cronbach's alpha and test–retest <0.7 for several subscales).[74] The validity of the Nottingham Health Profile, SF-12 and EQ-5D for people with dementia is also questionable.[75–77] The content, format and instructions of HRQoL instruments must be appropriate to people with dementia, given their cognitive difficulties. By definition, generic measures are not necessarily designed in a way that makes them easy for a person with dementia to complete. The nature of the disease may also make it difficult for the person with dementia to communicate with family and carers, and for family and carers to give accurate proxy reports.

Few studies have directly compared generic and disease-specific measures in people with dementia. One recent study[78] compared qualitative reports of HRQoL given by people with dementia and their carers with three generic utility-based HRQoL measures (EQ-5D, Quality of Well-being Scale and HUI). The authors concluded that none of the three generic measures had adequate content validity to assess HRQoL in dementia, although the Quality of Well-being Scale performed best.

Disease-specific measures

Major advances have been made in evaluating disease-specific, patient-based health outcomes such as HRQoL. Several disease-specific instruments are available for use in a wide range of conditions.[79–82] In dementia, however, the development of patient-based measures of HRQoL has been slower and more limited. This lag is likely to be due to the methodological challenges in measuring patient-reported outcomes such as HRQoL in dementia. Between 1996 and 2002, seven new measures of HRQoL in dementia were developed,[83–89] in addition to an earlier measure.[90] These are reviewed below (section 'Critical review of measures of HRQoL in dementia', p. 9).

Methodological challenges in measuring HRQoL in dementia

The main methodological challenge in measuring HRQoL in dementia is to determine a reliable and valid method for obtaining information from people with dementia. This includes identifying who is the most appropriate person to report on HRQoL. Where possible, this should be the person with dementia, but if he or she cannot self-report then proxy report is an alternative method. Both self-report and proxy report in dementia present unique methodological challenges.

Use of self-reports

The dementias are a complex set of disorders that result in progressive specific and global impairment of intellectual and cognitive functioning. Some have asserted that people with dementia "cannot comprehend questions or report on subjective

states",[91] or more pejoratively that they "approach more closely the condition of animals than normal adult humans in their psychological capacities".[92] Alongside this, it has been argued that the only valid method of assessing quality of life is by the subjective definition of the person experiencing it.[93] Even if a less absolutist stance is adopted, given the centrality of subjective evaluation in the concept of quality of life, there are particular problems when the effects of the disease process itself can interfere with the effective and accurate self-assessment of HRQoL, as in dementia. These disease-related factors will vary from case to case, and over the course of the illness, from presymptomatic stages through increasing dementia severity to death.

The main mechanisms of complication in the assessment of HRQoL in dementia include the following:

- Disorders of memory, especially for recent events, can lead to difficulties in generating accurate self-assessment and integrating that assessment into an evaluation of changes in HRQoL over time.
- Disorders of attention may limit the ability of the person with dementia to focus on being interviewed about their HRQoL.
- Disorders of language, both expressive and receptive, are common in dementia; therefore, full participation in discussion (especially complex discussion) about HRQoL may be limited.
- Disorders of insight of varying severity are also often present in dementia, with some patients entirely unaware of their impairments and therefore denying them, and others minimising them.
- Disorders of making judgements are also complicating factors, with people with dementia having difficulties in establishing goals, developing plans and evaluating outcome; such executive dysfunction may limit the validity of HRQoL judgements.
- Disorders of behaviour may also be present, such as agitation, anxiety, depression or psychosis, each of which may compromise accurate self-assessment.
- Dementia is a progressive disorder with deterioration over time, which may mean that the nature of HRQoL and the methodology needed to assess it will vary from early to terminal stages of the illness.

The potential limitations of self-reported HRQoL in dementia need to be balanced with the continuing abilities and competencies of people with dementia. Brod and Stewart[94] and Lawton,[95] among others, have argued for the importance of not excluding self-reported quality of life in dementia. Much of the argument is ideologically polarised and based on assertion or inference rather than empirical evidence, with some important exceptions as described above. The project reported here is underpinned by an acknowledgment of the central importance of self-report in assessing HRQoL without excluding the potential insights of family carers where these may be of use.

Validity of proxy reports

Proxy reports from carers, family members or healthcare professionals provide an alternative method for evaluating HRQoL in people with dementia who are unable to self-report. An early review of the general HRQoL literature indicated that agreement between proxy reports and self-reports is far from optimal.[96] However, a recent review,[97] which included studies using more robust measures of HRQoL, showed that moderate to high levels of patient–proxy agreement can be achieved and that proxy ratings are reasonably accurate. Findings indicate that patient–proxy agreement tends to be higher for physical than psychosocial domains of HRQoL and for significant others than for healthcare providers. Proxy raters tend to report more problems than patients' self-report. However, these differences may actually be less than is reported as they are often based on small samples.

Studies of patient–proxy agreement in elderly or cognitively impaired people have generally assessed functional ability rather than HRQoL per se. Work in this area has shown that agreement is higher for simpler and more observable ADL tasks[98,99] and that proxies generally report more impairment on complex ADL tasks, functional independence and physical health.[100–103] Several factors influence the level of (dis)agreement between self-reports and proxy reports. For example, agreement is higher among proxies who live with the patient, but lower when the patient has poor cognitive or affective status.[100] Proxies with a close relationship with patients (e.g. spouses) or who have more frequent contact with the person with dementia are more likely to overestimate disability.[101]

In dementia, patient–proxy agreement has been shown to be moderate at best.[85,104] Novella and colleagues[105] investigated agreement between patient and proxy reports of quality of life using

the Duke Health Profile. Associations between patient and proxy reports were reported to be poor to moderate [intraclass correlations (ICCs) between 0.00 and 0.61]. Bias in proxy reports may in part reflect a difference between the proxy's own view of the HRQoL of the person with dementia and the response that the proxy thinks the person with dementia would give.[106]

Poor agreement between self-reports and proxy reports may be the result of methodological problems related to response precision and response bias.[107,108] As it has been shown that patient–proxy agreement is lower in studies with a small sample size,[97] response precision can be improved by increasing sample size to reduce the standard error. Response bias is less easy to eliminate, although several strategies have been suggested to minimise it. For example, asking proxies to report on observable, objective constructs increases agreement with self-reports. The use of proxy reports throughout the course of a longitudinal study, rather than substituting them only when the person with dementia becomes unable to report part way through a study, reduces bias over time.

Several methods have been proposed to understand and control for proxy response bias. For behavioural outcomes, proxy reports can be verified against an externally observed gold standard, but for constructs such as HRQoL such gold standards are not available. Some studies have used a weighted combination of both self-reports and proxy reports,[85] but there is little evidence for determining the relative importance of these different sources of information. Some authors have suggested that proxies may be more accurate in particular domains and that proxy reports may be complementary to self-reports.[109] However, this is hard to reconcile with the definition of quality of life as an individual's own subjective perceptions of well-being.

Observer rating

Direct observation is an alternative method of proxy reporting. Proxy ratings of apparent affect or pleasant events[110,111] provide a way of assessing emotion in circumstances where self-reports may not be feasible. However, direct observation is also prone to reporting bias. Even with careful training of observers it is uncertain whether the observed behaviours represent the most important and relevant aspects of HRQoL, as HRQoL is defined as a person's subjective perceptions. Observer ratings are therefore likely to provide a very limited assessment of HRQoL.

Critical review of measures of HRQoL in dementia

To date, five reviews of measures of dementia-specific HRQoL have been published.[112–116] The structure, administration method and target population for each measure are described here and summarised in *Table 1*. Using the criteria described in Chapter 2, an updated critical review of eight published measures is presented.

The PDS[90] consists of 27 items rated on visual analogue scales. It is proxy reported and self-administered by carers. It was developed for use with people with AD in the USA. It has high test–retest reliability and limited evidence of validity.

The Pleasant Events Schedule-AD[83] is a proxy-report measure developed in the USA for use in mild dementia. It consists of 21 items covering two domains (activity and affect). It is quick to administer, but has no available information on reliability and limited evidence of validity.

The Dementia Quality of Life Instrument (DQOL)[84] consists of 29 items with five domains (aesthetics, positive affect, absence of negative affect, self-esteem and feelings of belonging). It is a self-report measure developed in the USA for people with mild/moderate dementia (MMSE ≥ 12) that is administered by interview. The DQOL is relatively quick to administer, though participants must successfully complete two of three screening questions before completing it. The DQOL has good reliability, and good evidence of content, convergent and known groups difference validity. Subscales have also been confirmed by factor analysis.

The Quality of Life in Alzheimer's Disease (QOLAD)[85,104] consists of 13 items. It can either be self-reported by the person with dementia when interviewer administered or proxy reported by the carer when self-administered. It was developed for use with people with AD and their carers in the USA. The QOLAD is reported to be most appropriate for use with people with MMSE >10. It has high internal consistency and test–retest reliability, and good content and convergent validity. Known groups difference validity has also been shown for the patient-reported version.

The Alzheimer's Disease Related Quality of Life measure (ADRQL)[86,117] includes 47 items covering five domains (social integration, awareness of self, feelings and mood, enjoyment of activities and

TABLE 1 *Description of instruments*

Name of instrument	Description	Mode of administration	Target population	Language
Progressive Deterioration Scale (PDS)[90]	27 items covering 11 domains rated on visual analogue scales	Proxy report, self-administered by caregivers	US population with AD	US English
Dementia Quality of Life Instrument (DQoL)[84]	29 items covering five domains (aesthetics, positive affect, absence of negative affect, self-esteem, feelings of belonging) rated on five-point response scales of enjoyment (not at all to a lot) or frequency (never to very often). Generates five domain scores (self-esteem, positive affect/humour, absence of negative affect, feelings of belonging, sense of aesthetics). Also includes an optional overall quality of life item rated on a five-point scale (bad to excellent)	Self-report administered by interview	US population with mild/moderate dementia (MMSE ≥ 12)	US English
Quality of Life-AD (QOLAD)[85]	13 items rated on a four-point scale (poor to excellent). Overall scores from self- and proxy-reported versions can be calculated separately or combined to form a single composite score	Self-report administered by interview and proxy report self-administered by caregivers	US population with AD and their carers	US English
Alzheimer's Disease Related Quality of Life (ADRQL)[86,117]	47 items covering five domains (social integration, awareness of self, feelings and mood, enjoyment of activities, response to surroundings) rated on a dichotomous scale (agree to disagree). Generates an overall score	Proxy report by caregivers, interviewer administered	US population of carers of people with AD	US English
Quality of Life Assessment Schedule (QOLAS)[87]	Individualised assessment based on five domains (physical functioning, psychological/emotional status, social and family life, economic/employment status, cognitive abilities). Respondents generate two constructs within each domain that are personally meaningful and rate the extent to which each is a problem on a six-point scale (no problem to it could not be worse). Generates an overall score and five domain scores (physical, psychological, social/family, work, cognitive)	Self-report administered by interview or proxy report administered by interview	UK population with mild/moderate dementia (MMSE ≥ 11)	UK English

continued

TABLE 1 *Description of instruments (cont'd)*

Name of instrument	Description	Mode of administration	Target population	Language
Community Dementia Quality of Life Profile (CDQLP)[88,118,119]	Includes separate components about the person with dementia (part 1) and about the carer (part 2). Part 1 includes 33 items covering four dimensions (thinking and behaviour, family and social life, physical activities and other aspects of daily life). Part 2 includes 13 items assessing the carer's quality of life and stress. All items are rated on a four-point Likert-type scale (not at all to always). Generates two overall summary scores (patient's and carer's QoL)	Proxy report self-administered by caregivers	UK population of people with dementia, cared for in the community, and their carers	UK English
Pleasant Events Schedule – AD[83]	21 items covering two domains (activity and affect). 15 activity items rated on a three-point scale (frequently to never) and six affect items rated on a five-point scale (≥ 3 times/day). Generates three summary scores (activity, positive affect and negative affect). Also an overall score of QoL	Proxy report	US population with mild dementia	US English
Quality of Life in Dementia Scale (QOL-D)[89]	31 items covering six domains (three positive and three negative)	Proxy report by nursing staff or family carers	Japanese population with moderate to severe dementia	Japanese

QoL, quality of life.

response to surroundings). It is proxy reported by the caregiver and interviewer administered. It was developed for use with carers of people with AD in the USA. The ADRQL has high internal consistency, content and convergent validity, but no evidence of test–retest reliability has been reported.

The Quality of Life Assessment Schedule (QOLAS)[87] is an individualised assessment based on five domains (physical functioning, psychological/emotional status, social and family life, economic/employment status and cognitive abilities). Respondents generate two constructs within each domain that are personally meaningful and rate the extent to which each is a problem. It is either self-reported or proxy-reported and is interviewer-administered. It was developed for use with people with mild to moderate dementia (MMSE ≥ 11). The QOLAS has good internal consistency, content, convergent and known groups difference validity, although test–retest reliability has not been demonstrated and only limited evidence of criterion-related validity has been published.

The Community Dementia Quality of Life Profile (CDQLP)[88,118,119] consists of 33 items covering four domains (thinking and behaviour, family and social life, physical activities and other aspects of daily life) about the person with dementia and 13 items about the carer. Both sections are proxy-reported and self-administered by the caregiver. It was developed for use with people with dementia who are cared for in the community and their carers in the UK. It has high internal consistency and test–retest reliability, and good content validity, but limited evidence of convergent validity. Subscales have been confirmed using factor analysis.

Finally, the Quality of Life in Dementia scale (QOL-D)[89] consists of 31 items covering six domains (positive affect, ability for communication, negative affect/negative action, spontaneity/activity, restlessness and attachment to others). The questionnaire is reported by a proxy (either nursing staff or a family carer). The questionnaire was developed for use with moderate to severe dementia in Japan. It has high internal consistency and good inter-rater reliability, but test–retest reliability has not been assessed. Good evidence of convergent validity has been published.

There are currently two other projects underway in the UK (in Bath and Bristol) to develop new measures of HRQoL in dementia. However, to the authors' knowledge neither instrument has yet been published.

Table 2 summarises the psychometric performance of each of the published measures according to criteria that are described in detail in Chapter 2. All eight measures provide at least some evidence of reliability and validity. None, however, has evaluated responsiveness and all require further tests of validity, particularly discriminant validity. Four of the currently available measures[83,86,89,90] are not appropriate for self-report as they were developed exclusively for proxy report. Only two of the currently available self-report measures[87,89] have been validated outside the USA and only one has been validated in the UK.[87] None of the published scales is applicable across the wide range of severity and care arrangements in dementia. Although the QOLAS is an interesting instrument, it is based on an individualised assessment technique in which respondents rate self-nominated problems. The lack of a standardised content may limit comparisons across respondents.

Aims and objectives

The review of existing measures confirms the need for a scientifically rigorous, self-report measure of HRQoL in dementia for use in clinical trials, epidemiological studies and audit. Although several of the existing measures have begun to address the methodological challenges of assessing HRQoL in people with dementia, all have limitations that compromise the value of their use and only two have been developed for use in the UK. The methodological challenge of keeping the perspective of the person with dementia central despite cognitive decline is well recognised.

The purpose of this study was to develop and validate a new measure of HRQoL for people with dementia that keeps the perspective of the person with dementia central in all stages of questionnaire development and evaluation.

Overview of the report

This report describes the development and validation of a new measure of HRQoL in dementia (DEMQOL). The researchers built on previous work (Chapter 1), used gold standard psychometric methods (Chapter 2) and developed a conceptual framework (Chapter 3) to develop

TABLE 2 *Summary of psychometric properties of instruments*

	PDS	Pleasant Events Schedule – AD	DQOL	QOL-AD		ADRQL	QOLAS	CDQLP	QOL-D
				Patient	Proxy				
Conceptual model	0	+	+++	0	0	+++	++	+	+
Acceptability	0	0	++	0	0	0	0	0	++
Reliability									
Internal consistency	0	0	++	+++	+++	+++	++	+++	+++
Test–retest	+++	0	++	+++	+++	0	0	+++	0
Inter-rater reliability	0	0	NA	NA	0	0	NA	0	++
Validity									
Content	+	0	+++	+++	+++	+++	+++	+++	++
Criterion-related	0	0	0	0	0	0	+	0	0
Construct									
Convergent validity	0	+	++	+++	+++	+++	+++	+	++
Discriminant validity	0	0	0	0	0	0	0	0	0
Known groups differences	+	0	++	+++	0	0	+++	0	0
Experimental intervention	0	0	0	0	0	0	0	0	0
Factor analysis	0	0	+++	0	0	0	0	++	++
Responsiveness	0	0	0	0	0	0	0	0	0
Respondent burden	0	++	+++	+++	+++	0	0	+++	0
Cultural and language adaptations	0	0	0	+	+	+	0	0	0

0, no evidence or not tested; +, some limited evidence; ++, some good evidence, but some aspects do not meet criteria or some aspects not tested/reported; +++, good evidence; NA, not applicable.

and evaluate DEMQOL in extensive two-stage field testing in large samples of people with dementia and their family carers representing a range of severity and care arrangements. In the preliminary field test (item reduction), items with poor psychometric performance were eliminated to produce a shorter, more scientifically robust version of DEMQOL (Chapter 4), which was then comprehensively evaluated in a final independent field test (Chapter 5). The psychometric properties of separate questionnaires for the person with dementia (DEMQOL) and carers (DEMQOL-Proxy) are reported in Chapter 6 and findings, study strengths and limitations, future directions, and application in research practice and policy are discussed in Chapter 7.

Chapter 2

Developing and validating health outcome measures

This chapter introduces the psychometric concepts and methods used in the development and validation of health outcome measures. Rigorous psychometric methods were used to guide the development and evaluation of DEMQOL. These gold-standard scientific methods,[120,121] borrowed from the social sciences for application in healthcare,[122–124] allow regulatory bodies, clinicians, researchers and patient advocacy groups to determine whether an instrument is a 'good' measure that provides scientifically credible information.

Developing questionnaires

Best practice guidelines for questionnaire design[124–128] provide clear recommendations about the content and format of questionnaires. Questionnaire items and response scales should be simply and clearly phrased to minimise ambiguity and bias, easy-to-follow instructions should be given, a clearly defined time-frame with a short recall period should be used, and response options should be mutually exclusive.

In the following section, questionnaire bias and techniques for minimising bias are discussed. The practical difficulties in applying these methods in developing self-report questionnaires for people with dementia are discussed in Chapter 3.

Types of bias

Several types of bias are known to affect questionnaire responses.[121,129] Among the most common are:

- halo effects:[130] observer ratings about specific characteristics of a person are influenced by the rater's overall impression of the person
- acquiescence bias or 'yea-saying':[131] the tendency of respondents to give positive responses (such as 'yes', 'true' or 'often')
- framing effects:[132] responses are influenced by how the question is phrased and by information presented in preceding questions
- social desirability or 'faking good':[133] the tendency of respondents to give the most socially acceptable answer
- end-aversion or central tendency bias:[121] tendency for respondents to avoid using the end-points of a response scale.

Techniques to minimise bias

Specific techniques have been developed to minimise bias when developing questionnaires. For example, the use of behaviourally anchored rating scales,[134] that is, response scales based on specific, concrete behaviours, can help to reduce halo effects. A mix of positive and negative questions can help to avoid acquiescence bias. Framing effects can be minimised by placing questions that may influence each other in different sections of the questionnaire. Social desirability bias can be measured[135] and then controlled statistically. End-aversion bias can be minimised using response scales that do not have absolute end-points (e.g. using end-points of 'almost always' instead of 'always').

Pilot testing and pre-testing

Careful pilot testing and pre-testing of questionnaires provide an additional check for ambiguity and potential bias. Pilot testing is usually done by interview to identify parts of the questionnaire that are unclear or difficult. Interviewers note questions and/or response scales that are unclear, open to misinterpretation, uncomfortable or awkward to answer, or about which respondents would like to say more.

Pre-testing is carried out to evaluate whether respondents understand and interpret questions in the way that was intended, and often focuses on a subset of items. Three specific techniques can be used to pre-test questions.[136] First, respondents can be asked to rephrase the question in their own words.[137] The respondent's interpretations are recorded verbatim and later coded for accuracy against the original intention of the question. Second, the double-interview technique[138] can be used. After each question, follow-up questions are asked to elicit respondents' understanding of the key ideas in the question. This can be achieved by asking respondents how they arrived at their answer, with the interviewer probing for further detail as necessary. The third technique involves asking respondents to think aloud as they complete questionnaire items.[139,140] Respondents' verbalisations are recorded by the interviewer and

later independently coded according to the type of difficulty reported. Following pre-testing, modifications are made and the revised questionnaire is re-evaluated.

Evaluating the psychometric properties of health outcome measures

Psychometrics[120] is a well-established scientific field concerned with the measurement of subjective judgements using numerical scales and the evaluation of the measurement properties of scales (e.g. reliability, validity, responsiveness). Established over 100 years ago as a subdiscipline in psychology, psychometrics defines the classic theories and methods for constructing measures, scaling responses and evaluating the quality of measurement scales that have been developed to assess abstract psychological concepts such as intelligence, personality, attitudes, and other social and behavioural phenomena. The scientific methods used in psychometrics grew out of the rigorous laboratory methods used by psychophysicists in the mid-nineteenth century to study brain–behaviour relationships, specifically to develop mathematical formulae to model people's subjective judgements about physical stimuli such as light, sound and weight. The same psychometric methods[120] used to develop numerous tests of intelligence, personality, aptitude and personnel selection over the past ten decades have now been applied in healthcare to develop scientifically rigorous measures of patient-based outcomes[121–123] The relatively new field of health measurement[121] developed specifically in response to the need for rigorous measurement of patient-based outcomes in evaluating healthcare.

Rigorous scientific criteria are available for evaluating the psychometric rigour of measuring instruments. For example, gold-standard review criteria have been published to evaluate the scientific and practical aspects of health outcome measures.[141] Guidelines for the development, testing and dissemination of health measures have also been produced.[142,143] The present authors[144–153] and others (see refs 79–81 for reviews) have used these methods extensively to develop and validate outcome measures across areas of clinical medicine.

Psychometric tests and criteria

The scientific evaluation of a measuring instrument involves carrying out tests of various psychometric properties to determine whether the questionnaire meets standard criteria in order to be considered a scientifically robust measure. During the field testing of a new instrument, three main psychometric properties are evaluated: reliability, validity and responsiveness.

- **Reliability** is the degree to which an instrument is free from error. A reliable instrument is internally consistent and produces stable, repeatable results. There are four types of reliability: internal consistency, test–retest reliability, inter-rater reliability and parallel (alternative) forms reliability.
- **Validity** is the extent to which an instrument measures what it is intended to measure. There are three types of validity: content, criterion-related and construct validity. Validity concerns the level of confidence that can be placed in inferences drawn from scores.
- **Responsiveness** is the degree to which an instrument is able to detect clinically significant change over time.

The evaluation of each of these psychometric properties involves applying specific tests to determine whether the instrument meets standard criteria. These psychometric tests and criteria are described in *Table 3*.

Psychometric field testing

The psychometric evaluation of a measure is ideally carried out in two-stage field testing. In the first field test (item reduction), a long version of the questionnaire is evaluated that includes all items generated during the questionnaire development stage. The purpose of the first field test is to determine response rate, confirm the acceptability of the questionnaire, and identify and retain items with strong measurement properties. On the basis of psychometric tests, items with poor measurement properties are then eliminated to produce a shorter, item-reduced version of the questionnaire. Another purpose of the first field test is to develop subscales by testing scaling assumptions. A preliminary evaluation of the psychometric properties of the item-reduced version of the questionnaire is also undertaken at this stage.

A second field test (psychometric evaluation) is then carried out in an independent sample to evaluate the psychometric properties (reliability, validity, responsiveness) of the item-reduced questionnaire.

Item reduction

In this first stage of psychometric evaluation, item reduction analyses are performed to determine

TABLE 3 *Psychometric tests and criteria*

Psychometric property	Definition/test	Criteria for acceptability
Item analysis/reduction	Identification of items for possible elimination owing to weak psychometric performance; assessed on the basis of (1) unrotated principal component factor analysis to determine whether all items are measuring a single factor; and (2) item analyses for all items	**Principal component factor analysis:** All items should load on the first unrotated factor >0.30 **Item analyses (applied to all items):** Missing data <5% No item redundancy (inter-item correlations ≤ 0.75) Item–total correlations >0.25 Maximum endorsement frequencies ≤80% (i.e. the proportion of respondents who endorse each response category), including floor/ceiling effects <80% (i.e. response categories with high endorsement rates at the bottom/top ends of the scale, respectively) Aggregate adjacent endorsement frequencies ≥10%[154]
Acceptability	The quality of data; assessed by completeness of data and score distributions	Missing data for summary scores <5% Even distribution of endorsement frequencies across response categories Floor/ceiling effects for summary scores <10%
Reliability		
Internal consistency	The extent to which items comprising a scale measure the same construct (e.g. homogeneity of the scale); assessed by Cronbach's alpha[155] and item–total correlations	Cronbach's alphas for summary scores ≥0.70[121] Item–total correlations ≥0.20[121]
Test–retest reliability	The stability of a measuring instrument; assessed by administering the instrument to respondents on two different occasions and examining the correlation between test and retest scores	Test–retest reliability correlations for summary scores ≥0.70[141]
Inter-rater reliability	Agreement between independent raters/observers; assessed by ICCs	ICC ≥0.70[141]
Parallel (alternative) forms reliability	Agreement between two or more parallel/alternative forms or different versions of the same measure (e.g. form A/B, short/long form) that indicates that they can be used interchangeably; assessed on the basis of correlations between parallel/alternative forms of a measure	High correlation between parallel/alternative forms of the measure (e.g. between long and short form)

continued

TABLE 3 *Psychometric tests and criteria (cont'd)*

Psychometric property	Definition/test	Criteria for acceptability
Validity		
Content validity	The extent to which the content of a scale is representative of the conceptual domain it is intended to cover; assessed qualitatively during the questionnaire development stage through pre-testing with patients, expert opinion and literature review	Qualitative evidence from pre-testing with patients, expert opinion and literature review that items in the scale are representative of the construct being measured
Criterion-related validity		
Concurrent validity	Evidence that the scale predicts a gold-standard criterion that is measured at the same time; assessed on the basis of correlations between the scale and the criterion measure	High correlation between the scale and the criterion measure
Predictive validity	Evidence that the scale predicts a gold-standard criterion that is measured in the future; assessed on the basis of correlations between the scale and the criterion measure	High correlation between the scale and the criterion measure
Construct validity		
Within-scale analyses	Evidence that a single entity (construct) is being measured and that items can be combined to form a summary score; assessed on the basis of evidence of good internal consistency and correlations between scale scores (which purport to measure related aspects of the construct)	Internal consistency (Cronbach's alpha) $\geq$ 0.70 Moderate to high correlations between scale scores
Analyses against external criteria		
Convergent validity	Evidence that the scale is correlated with other measures of the same or similar constructs; assessed on the basis of correlations between the measure and other similar measures	Correlations are expected to vary according to the degree of similarity between the constructs that are being measured by each instrument. Specific hypotheses are formulated and predictions tested on the basis of correlations
Discriminant validity	Evidence that the scale is not correlated with measures of different constructs; assessed on the basis of correlations with measures of different constructs	Low correlations between the instrument and measures of different constructs
Known groups differences	The ability of a scale to differentiate known groups; assessed by comparing scores for subgroups who are expected to differ on the construct being measured	Significant differences between known groups or difference of expected magnitude
Responsiveness		
	The ability of a scale to detect clinically important change over time; assessed by comparing scores before and after an intervention of known efficacy (on the basis of various methods including *t*-tests,[156] effect sizes,[157,158] standardised response means,[159] or responsiveness statistics[160])	Significant differences between known groups or difference of expected magnitude

Adapted from Lamping and colleagues, 2002.[152]

whether the initial long questionnaire can be reduced to a smaller number of items by selecting items that perform best against psychometric criteria. This involves carrying out analyses of individual items to identify items for possible elimination owing to weak psychometric performance.

An item reduction strategy[152,161] is developed based on standard psychometric tests and criteria. Extensive item analyses are performed (see *Table 3*) to evaluate whether an item should be retained or eliminated. These include an evaluation of missing data, maximum endorsement frequencies (i.e. the proportion of respondents who endorse each response category), including floor/ceiling effects (i.e. response categories with high endorsement rates at the bottom/top ends of the scale, respectively) and aggregate adjacent endorsement frequencies, inter-item correlations (indicating non-redundancy) and item–total correlations. Items that perform poorly in these item analyses are considered for elimination from the item pool.

Tests of scaling assumptions

Tests of scaling assumptions[121,162–165] evaluate whether items are correctly grouped into scales, that items in the same scale measure the same construct and that items can be summed to produce a summary score. Scaling assumptions are evaluated on the basis of:

- equivalence of item variance (e.g. roughly symmetrical item-response distributions and approximately equivalent item means and standard deviations)
- equivalence of corrected item–total correlations
- factor analysis
- tests of item convergent and discriminant validity.

These analyses evaluate the appropriateness of combining a priori groups of items into scales and the potential for further item reduction.

Exploratory factor analysis is used to identify subscales, based on intercorrelated items (factors) that are empirically distinct, and to carry out further item reduction to eliminate items that do not fit in any subscale. Items that load on more than one factor (cross-load) or that do not load on any factor are candidates for elimination.

Analyses of item convergent and discriminant validity[162,164,165] are then used to evaluate scales further. An item should be correlated more highly with its own scale (item convergent validity) than with other scales (item discriminant validity). Item convergent validity is demonstrated when item-own scale correlations exceed item-other scale correlations by at least two standard errors (the standard error of a correlation coefficient = $1/\sqrt{N}$). The extent of item convergent and item-discriminant validity is assessed by calculating scaling success rates. A scaling success indicates that an item correlates significantly more highly, by at least two standard errors, with its own scale than with another scale. A probable scaling success is defined as an item that correlates more highly with its own scale than another scale, but not significantly, that is, by less than two standard errors. A scaling failure indicates that an item correlates significantly more highly, by at least two standard errors, with another scale than with its own scale. A probable scaling failure is defined as an item that correlates more highly with another scale than with its own scale, but not significantly, that is, by less than two standard errors. Items identified as scaling failures or probable scaling failures are candidates for elimination.

Chapter 3

Development of the DEMQOL questionnaire

In this chapter the qualitative methods used to develop a conceptual framework of HRQoL for people with dementia are described. Questionnaire items were generated for each component of the conceptual framework to produce two questionnaires: one for self-report by the person with dementia (DEMQOL) and the other for proxy report by the carer (DEMQOL-Proxy). Preliminary versions of both questionnaires were pre-tested with people with dementia and their carers to clarify ambiguities in wording and to evaluate the appropriateness of the time-frame, question stems and response options.

Development of a conceptual framework

Overview

A conceptual framework of HRQoL in dementia was developed to guide the development of the new questionnaire. This included both 'top–down' (existing literature and expert consensus) and 'bottom-up' (in-depth qualitative interviews) approaches, conducted in parallel (*Figure 1*). First, a working framework and an initial interview guide were developed, then qualitative interviews were conducted with people with dementia and carers using the initial interview guide. In light of results from the first stage of interviews, the working framework and interview guide were revised to produce successive revisions of the framework and a revised interview guide. This was done through team discussion and expert consensus. A second stage of interviews was then conducted, based on the revised framework and interview guide, which led to the final conceptual framework. These steps are described below.

Working framework

On the basis of the review of the literature and expert team consensus, a working framework of HRQoL in dementia was developed. The working framework included seven domains: well-being, perceived satisfaction with daily activities, perceived satisfaction with cognitive ability, quality of social relationships, general health perceptions, energy and sense of aesthetics. The working model was developed iteratively, through review and discussion among subgroups of the multidisciplinary research team, until a consensus view was achieved.

Interview guide

The results of the literature review and expert team consensus were also used to develop an initial interview guide (see Appendix 1A). It covered five areas, with prompts for each: involvement in activities, autonomy and choice, social and family relationships, health and well-being and life satisfaction, plus an open-ended question which asked participants about any other aspects of HRQoL that had not been discussed. The initial interview guide was intended to guide rather than constrain interviews and was revised after the first stage of qualitative interviews (see Appendix 1B).

Qualitative interviews

A purposive sample of 19 people with a clinical diagnosis of dementia (based on ICD-10 criteria) and 20 family carers was recruited from clinical contacts in psychiatry in the South London and Maudsley NHS Trust. Participants were included if they had sufficiently fluent English for the completion of the interview; apart from insufficient spoken English, there were no exclusion criteria. Introductory letters were sent and individuals were followed up by telephone to confirm willingness to participate. Interviews took place in participants' homes, at a mutually convenient time. The age of the people with dementia ranged from 69 to 85 years and 15 (79%) were female. The sample included people across the range of severity (eight mild/moderate, seven moderate, and four moderate/severe or severe, based on experienced interviewers' informal ratings at the time of the interview). All except one person with dementia were living at home and 16 had an identifiable carer (14 spouses, two other relatives or close friends). Four additional carers were also interviewed. Ethical approval was obtained from the relevant local research ethics committee (LREC) and written informed consent obtained from both the person with dementia and the carer. If the person with dementia was not able to give written informed consent, verbal assent was obtained from the person with dementia and written assent from the

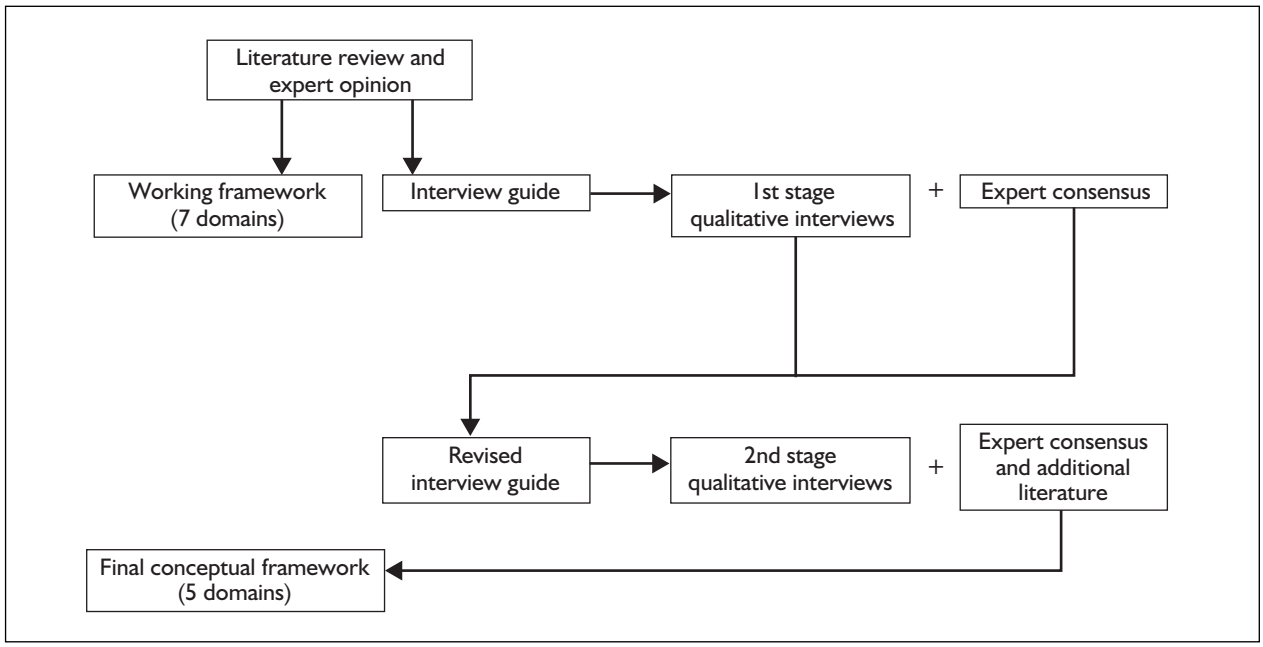

FIGURE 1 *Development of the conceptual framework*

carer. Most interviews lasted for approximately between 40 and 60 minutes and continued until participants were unable to or did not wish to continue.

Interviews, conducted by two experienced researchers, were audiotaped and then transcribed verbatim. Interviews with the person with dementia and his or her carer were conducted simultaneously but separately, to maximise privacy and reduce the potential for bias. When it became apparent that many carers were reporting their own perceptions of the HRQoL of person with dementia, carers were asked to respond to interview questions by providing the views that they thought the person with dementia would give.

Manual thematic analysis was performed, first and then QSR N-Vivo software was used to aid data manipulation. Two researchers independently coded each transcript. Discrepancies were discussed by at least three researchers until consensus was reached. Transcripts were initially coded to the working conceptual framework, which was revised as new domains and components came to light. Coding was always to the current version of the conceptual framework.

Findings that emerged from the qualitative interviews highlighted the differences between patient and carer views. For example, people with dementia gave answers based on their current 'here and now' situation, and often responded by making social comparisons with peers of a similar age. Carers, in contrast, responded on the basis of both the past and current situation and tended to make comparisons between how the person was now and with how he or she used to be. These differences confirmed the need to develop separate versions of the questionnaire for people with dementia and carers. A detailed discussion of these qualitative findings is beyond the psychometric focus of this report, but is the subject of a specific paper (Smith SC, *et al.* What constitutes health related quality of life in dementia? Development of a conceptual framework for people with dementia and their carers. Submitted for publication).

Final framework

On the basis of the qualitative interviews and review and discussion by the expert team, including a focus group with community psychiatric nurses working with people with dementia and a carer's group of family carers, a final framework was developed that included five domains: daily activities and looking after yourself, health and well-being, cognitive functioning, social relationships and self-concept, each with several components (*Table 4*).

Development of the DEMQOL questionnaire

An interviewer-administered format was used to obtain self-reports from people with dementia and

TABLE 4 *Cross-mapping of final conceptual framework and questionnaire items*

Domain	Component	Questionnaire item[a]
Daily activities and looking after yourself	getting around	**Q60** moving about indoors?
		Q61 moving about outdoors?
	keeping yourself clean	**Q54** keeping yourself clean (e.g. washing and bathing)?
	getting dressed	**Q53** getting dressed?
	keeping yourself looking nice	**Q55** keeping yourself looking nice?
	going to the toilet	**Q56** getting to the toilet on time?
	using a knife and fork	**Q59** using cutlery (e.g. a knife, fork and spoon)?
	getting the things you need from the shops	**Q62** getting what you want from the shops?
	getting in touch with people when you need to	**Q67** getting in touch with people?
	getting meals	**Q57** getting what you want to eat?
		Q58 getting food or drink when you want it?
	taking care of the house	**Q66** the way your home is looked after?
	getting where you need to go	**Q63** getting where you want to go?
	taking care of your finances	**Q65** looking after your finances?
	using money to buy everyday things	**Q64** using money to pay for things?
	choice about how you spend your time	**Q71** have you felt you've had enough choice about how you spend your time?
	things that you want to do but can't	**Q73** have you felt there are things that you wanted to do but couldn't?
	being able to enjoy what you do	**Q72** have you been happy with how you've spent the day?
Health and well-being	global health rating	**Q25** your health overall?
		Q22 your physical health?
		Q23 how you feel in yourself?
	happiness–depression (including fluctuations in mood)	**Q18** that life is not worth living
		Q20 fed-up
	contentment–frustration	**Q4** frustrated?
		Q12 content?
	enjoying life–enjoying nothing	**Q3** that you are enjoying life?
	confidence	**Q5** confident?
	embarrassment	**Q6** embarrassed?
	anxiety	**Q2** worried or anxious?
	lively–weary (including slowing down)	**Q14** lively?
		Q68 things take longer than they used to?
		Q7 full of energy?
	loneliness	**Q10** lonely?
	somatic complaints (including pain)	**Q24** how well you sleep?
		Q69 have you enjoyed your food?
		Q70 has pain stopped you from enjoying things?
	feeling safe	**Q17** safe?
	cheerful	**Q1** cheerful?

continued

TABLE 4 *Cross-mapping of final conceptual framework and questionnaire items (cont'd)*

Domain	Component	Questionnaire item[a]
	relaxed	**Q9** calm?
	irritable	**Q15** irritable?
	angry	**Q11** angry?
	resentful	**Q16** bitter?
	sad	**Q8** sad?
	distressed	**Q13** distressed?
Cognitive functioning	memory for recent events	**Q26** your memory in general
		Q28 forgetting things that happened recently?
	memory for distant events	**Q27** forgetting things that happened a long time ago?
	memory for names	**Q29** forgetting people's names?
	concentration	**Q35** poor concentration?
	orientation in time, place and person	**Q30** forgetting who people are?
		Q31 forgetting where you are?
		Q32 forgetting what day it is?
	clarity of thought	**Q33** your thoughts being muddled?
	making your mind up	**Q34** difficulty making decisions?
	communication	**Q36** making yourself understood?
Social relationships	treatment by others (including respect)	**Q40** not having enough privacy?
		Q41 how other people treat you?
		Q42 people not listening to you?
	social interaction	**Q37** how you get on with other people?
	reciprocity	**Q43** not being able to help other people?
	social integration	**Q38** being left out of things?
	companionship	**Q39** not having enough company?
	social support	**Q44** getting help when you need it?
	intimacy and physical affection	**Q45** getting the affection that you want?
	other emotional relationships	**Q46** how you get on with people close to you?
Self-concept	self-esteem	**Q50** not feeling important?
	presentation of self (including keeping up appearances)	**Q49** what other people think of you?
	sense of independence	**Q47** depending too much on others?
	satisfaction with past life	**Q51** the way you have lived your life?
	satisfaction with present life	**Q52** your life nowadays?
	hopes and aspirations for the future	**Q19** hopeful?
		Q21 that you have things to look forward to?
	feeling useful	**Q48** not playing a useful part in things?

[a] Question numbers refer to DEMQOL v3.3 (see Appendices 3A and 3B).

proxy-reports from carers. Items were drafted for each component in the conceptual framework and produced separate questionnaires for the person with dementia (DEMQOL) and carers (DEMQOL-Proxy). Items in the initial versions of the questionnaires used the stem 'How did you feel about …' and one of two response scales: 'Good most of the time/Bad most of the time' or 'Yes most of the time/No most of the time'. For the DEMQOL-Proxy, carers were explicitly asked to give the answer that they thought the person with dementia would give, rather than their own perceptions of the HRQoL of person with dementia.

Questionnaire pre-testing

A purposive sample of 12 people with a diagnosis of dementia (covering a range of severity, as assessed informally by the interviewers) and 11 carers was recruited from clinical contacts in old-age psychiatry in the South London and Maudsley NHS Trust. Introductory letters were sent and individuals were followed up by telephone to confirm willingness to participate. Interviews took place in participants' homes, at a mutually convenient time. Written informed consent was obtained from all participants where possible. If the person with dementia was unable to give written informed consent, verbal assent was obtained from the person with dementia and written assent from the carer. Interviews, conducted by two experienced researchers, were audiotaped and lasted for between 30 and 60 minutes. Interviews continued until participants were unable to or did not want to continue.

The appropriateness of the time-frame, question stem and response scales was assessed, and any additional queries raised by participants were considered. The techniques of 'rephrasing the question' and 'thinking aloud' were considered too complex to use with people with dementia, so a variation on the double-interview technique was used. This involved using follow-up questions where possible to probe the reasons behind each response choice, to ensure that respondents understood the question in the way that was intended.

Revisions to pre-test questionnaire

Pre-testing indicated that some of the standard best practice principles in questionnaire design (e.g. using familiar words or keeping the number of response options to a minimum) did not improve the questionnaire for people with dementia. Therefore, several revisions were made to the initial draft questionnaire (*Table 5*), as well as revisions in wording as indicated by the interview transcripts. The main types of revision are discussed below.

Time-frame

Pre-testing indicated variation among people with dementia in their ability to use a specified time-frame of 1 week. As not all participants commented on the time-frame, it was not possible to distinguish between those who genuinely did not have difficulty with the time-frame and those who were not aware of a problem owing to poor insight. However, some people with dementia appeared to understand the 1-week time-frame, to relate it to their experiences and to generate an answer that combined the two pieces of information (e.g. interviewer: "In the last week have you felt embarrassed about yourself? …"; person with dementia: "Not this week particularly, no"). In contrast, some people with dementia found the short-term time-frame difficult to use (e.g. person with dementia: "… past week? I can remember the past 10, 20, 30 years but the past week … that's hard"). In the final version of the questionnaire a decision was made to use a time-frame of 1 week. Although some people with dementia would be unable to use it reliably, it was felt that it was important to have a specified time-frame for those who could use it, including carers. A period of 1 week was short enough to be practical for people with mild dementia, but also long enough to be meaningful.

Question stem

In choosing a question stem the researchers had two concerns. First, they were concerned about whether participants would use the stem 'How did you feel about …' at all, or whether they would simply respond to the main part of the question and report their actual functional ability rather than how they felt about their ability (or disability). The ability to report reflective feeling, which is central to the construct of HRQoL, is likely to be compromised in some people with dementia. Second, they were concerned about whether respondents had actually understood the question stem. Although it was not always clear whether participants had used the question stem, there was evidence to suggest that some people with dementia did indeed distinguish between functional ability and subjective feeling (e.g. stem about worry, person with dementia: "Oh that occurs quite often. I don't worry, but it does occur, I forget their names").

Varied question stems were pre-tested, including, 'How did you feel about …', 'How satisfied were you with …, How bothered are you by …', 'How happy are you with …', 'How concerned are you about …', and 'How worried have you been about …'. Some participants reported that so-called

TABLE 5 *Pre-testing: revisions to DEMQOL questionnaire*

			Response options	
Version	**Time frame**	**Stem**	**For questions with no stem**	**For questions with a stem**
1.1	In the past week…	How did you feel about…	Yes most of the time/No most of the time	Good most of the time/Bad most of the time
1.2	In the past week…	How have you felt about…	Yes/No	Good/Bad
2.1	In the past week…	How satisfied were you with…	Always/often/sometimes/never	Always/often/sometimes/never
2.1b	In the past week…	How satisfied are you about…	A lot/quite a bit/a little/not at all	Very satisfied/satisfied/dissatisfied/very dissatisfied
2.2	In the past week…	How bothered are you by…	Always/often/sometimes/never	A lot/quite a bit/a little/not at all
2.3a	In the past week…	How happy are you with…	Always/often/sometimes/never	A lot/quite a bit/a little/not at all
2.3b	In the past week…	How concerned are you about…	Always/often/sometimes/never	A lot/quite a bit/a little/not at all
2.4	In the past week…	How bothered are you by…	Always/often/sometimes/never	A lot/quite a bit/a little/not at all
3.1	In the past week…	How bothered are you by…	Always/often/sometimes/never	A lot/quite a bit/a little/not at all
3.2	In the past week…	How worried have you been about…	A lot/quite a bit/a little/not at all	A lot/quite a bit/a little/not at all
3.3	In the past week…	How worried have you been about…	A lot/quite a bit/a little/not at all	A lot/quite a bit/a little/not at all

familiar words were not easy to understand or were ambiguous. One carer spontaneously reported difficulty with the word 'bothered' in the question stem (e.g. carer, "… I think bothered is the wrong word, especially if you are talking about people with memory problems … it needs to be straighter than that, than bothered …"). Difficulty was also expressed with the word 'concern' in the question stem. For some people with dementia it was interpreted as meaning of general importance rather than a specific worry (e.g. interviewer: "How concerned are you about how you get on with people who are important to you?"; person with dementia, "quite a bit"; interviewer: "Do you feel like you do get on with people who are important to you?"; person with dementia "Yes I do"). Although the initial intention was to avoid the use of a negative stem word, pre-testing indicated that the stem that was most easily understood was 'How worried have you been about …'. This is therefore the stem that was used in the final version of the questionnaire.

Response options

Although the researchers had intended to keep the questionnaire simple by using only two response options, participants expressed the need for more response options. When the range of response options was increased to a four-point scale, participants (both people with dementia and carers) appeared to be able to use the full range of response options. Participants also reported difficulty using response options that were based on feelings because people with dementia interpreted the response options quite literally (e.g. response options 'good/bad', interviewer: "… how have you felt about your memory for things that have happened recently?"; person with dementia: "… Er, I haven't felt anything about it"). This may reflect the inappropriateness of the response options or the inability of the person with dementia to reflect. Carers also reported difficulty for people with dementia to reflect (e.g. response options 'very satisfied/satisfied/ dissatisfied/very dissatisfied', interviewer: "… how satisfied is your wife about her memory for things that happened a long time ago?"; carer: "… Well as I said, she wouldn't know"). Response options that were an intensity rating ('a lot/quite a bit/a little/not at all') seemed to be understood most easily and therefore this set of response options was used in the final version of the questionnaire.

There were some occasions when people with dementia were able to give meaningful answers, but did not express them in terms of the response options. This tendency to give long, conversational answers, irrespective of the response scale, highlights the need for a clear set of interviewer guidelines to ensure that the interviewer records the appropriate answer. An interviewer manual was developed (see Appendix 2) which includes specific instructions for dealing with this problem.

DEMQOL questionnaire (preliminary field test v3.3)

The initial long version of the DEMQOL that was evaluated in the preliminary field testing includes 73 items (Appendix 3A) and a global question about overall quality of life (Q74). The DEMQOL-Proxy contains the same 73 items (Appendix 3B), with the pronouns adapted for proxy-report. The overall quality of life item is not scored for either DEMQOL or DEMQOL-Proxy. All other items are scored 1 (a lot) to 4 (not at all), except for the positive items indicated by asterisks in Appendices 3A and 3B. The positive items should be reverse scored. Scored items are summed to produce a total score. A higher score indicates better HRQoL.

Summary

A conceptual framework of HRQoL for people with dementia was developed that includes five domains (daily activities and looking after yourself, health and well-being, cognitive functioning, social relationships and self concept), each with several components. Items were generated for each component to produce two questionnaires: one for self-report by the person with dementia (DEMQOL) and the other for proxy-report by the carer (DEMQOL-Proxy). Preliminary versions of both questionnaires were pre-tested with people with dementia and their carers to clarify ambiguities in wording and to evaluate the appropriateness of the time-frame, question stems and response options. This resulted in 73-item field test versions of both questionnaires.

Chapter 4

Preliminary field test: methods and results

The psychometric properties of DEMQOL and DEMQOL-Proxy were evaluated in two independent field tests. The purpose of the preliminary field test (item reduction) was to identify items with poor psychometric performance for possible elimination and to conduct a preliminary evaluation of subscales. The purpose of the final field test (psychometric evaluation) was to evaluate the acceptability, reliability, validity and responsiveness of the item-reduced version of the questionnaires. This chapter describes the methods and results for the preliminary field test.

Methods

Recruitment

Participants were people with a clinical diagnosis of dementia (based on ICD-10 criteria) and their family carers identified from clinical contacts in psychiatry in the South London and Maudsley NHS Trust. Participants with a probable diagnosis of dementia were recruited consecutively by the area in which they lived. No exclusion criteria were applied other than having insufficient spoken English to complete the interview.

Measures

The preliminary field test included the following measures.

Dementia-related quality of life

Interviewers administered the DEMQOL (v3.3) and DEMQOL-Proxy (v3.3) verbatim, according to standardised instructions contained in the interviewer manual.

Disease severity

The MMSE[18] and Clinical Dementia Rating Scale (CDR)[166,167] were used to assess the severity of dementia. The MMSE is widely used in screening for dementia and defining its severity. It generates scores between 0 and 30, with higher scores indicating less impairment.

The CDR assesses six domains: memory, orientation, judgement/problem solving, community affairs, home and hobbies, and personal care. Each domain is scored 0.5, 1, 2 or 3; the final score (0, 0.5, 1, 2 or 3) is derived from these domain scores according to a specified algorithm.[166,167] Higher scores indicate more severe disease. The CDR is designed to be rated by a clinician using information obtained during routine clinical practice. In this study, CDR ratings were made by the interviewer immediately after the interview. The CDR was introduced part way through the preliminary field test after a reasonably high proportion of the sample was encountered who could not complete the MMSE, particularly those with severe dementia. Although Folstein and colleagues[18] argue that a score can be generated for each case, irrespective of the number of items successfully completed, it was decided to supplement this with an additional interviewer rating in the form of the CDR.

Cases were classified as severe if they had an MMSE score less than 10. This identified a subsample of 79 cases with non-severe (mild/moderate) dementia. The rationale for the choice of the MMSE cut-point is discussed in Chapter 5 (section 'Analyses of mild/moderate and severe cases', p. 41).

Disability

The Barthel Index[168] is a widely used measure of disability based on ADL. It consists of ten items about bathing, transfer, dressing, feeding, mobility, stairs, toilet use (including incontinence) and grooming. The original version has been slightly modified for self-completion by postal questionnaire.[169] High scores on the Barthel indicate less dependency.

Procedures

Eligible participants received an introductory letter and information sheet and were then contacted by telephone to confirm willingness to take part. To maximise privacy and reduce potential bias, the person with dementia and the family carer were interviewed simultaneously but separately at the home of the person with dementia. Interviews were conducted at a mutually convenient time. Ethical approval was obtained from the relevant LRECs and written informed consent from both the person with dementia and the carer. If the person with dementia was not able to give written informed consent, verbal assent was

obtained from the person with dementia and written assent from the carer.

All interviews were conducted by two experienced researchers. Interviews lasted for approximately 60 minutes and continued until participants had completed the questionnaires, or were unable to or did not wish to continue.

All measures were administered in the same order. For the person with dementia, the DEMQOL was administered first, followed by the MMSE and CDR (rated by the interviewer immediately after the interview). For the carer, the DEMQOL-Proxy was administered first, followed by the Barthel and background questions about sociodemographic characteristics and the amount of time spent with the person with dementia.

Item reduction and preliminary scale development

The purpose of the preliminary field test (item reduction) was to identify items with poor psychometric performance for possible elimination and to conduct a preliminary evaluation of scales. The item reduction analyses were performed in two stages. First, items were eliminated on the basis of missing data, endorsement frequencies and item redundancy. For the second stage, missing data were imputed for the remaining items and then additional items were eliminated based on item–total correlations. A preliminary evaluation of scales was then carried out, which included additional item reduction, using exploratory factor analysis followed by item convergent and discriminant validity analyses. Finally, the internal consistency of derived scales was evaluated using Cronbach's alpha.

Criteria for item reduction

To identify whether item reduction needed to be carried out separately for DEMQOL and DEMQOL-Proxy, the correlations between self-reports from people with dementia and proxy-reports from carers for each item were examined. Low average association between the self-reported and proxy-reported items would indicate the need to conduct separate item reduction for DEMQOL and DEMQOL-Proxy.

The researchers used the strategy for item reduction developed in their previous work.[152,161] Initial consideration of the data indicated that the rates of missing data were generally high, but particularly for the self-reported data (missing data for DEMQOL: 21.4–34.4%; missing data for DEMQOL-Proxy: 6.1–17.6%). The usual criterion for missing data is 5% and there was concern whether such high rates would provide usable data. Therefore, one modification was made to the criteria used in the Lamping[152] strategy (see *Table 6*, first two columns). The missing data cut-off was considered in 5% increments to identify a more liberal criterion that would allow retention of a reasonable number of items. For DEMQOL, an acceptance criterion of 30% or less was chosen. This criterion allowed elimination of the most extreme items and retention of a sufficient number of items. Plots of percentage missing data by item confirmed this criterion; a natural break in the data occurred at 32% missing. To confirm the appropriateness of this criterion, item reduction analyses were also performed using a more stringent retention criterion of 25% or less and the results compared with the 30% or less criterion. For DEMQOL-Proxy, a criterion of 10% or less was chosen. Plots of percentage missing data by item also confirmed this criterion; a natural break in the data occurred at 12% missing.

Imputation of missing data

As some of the statistical techniques used in item reduction (e.g. item–total correlations, factor analysis) require complete data, missing data for all items that remained after the first stage of elimination were imputed using standard methods.[61,122] For respondents who answered at least 50% of remaining questionnaire items, data for every missing item were imputed using a person-specific mean calculated on the basis of the mean score of non-missing values for that respondent. Missing data were not imputed for respondents who answered less than 50% of the remaining questionnaire items.

Preliminary scale development and further item reduction

To conduct a preliminary evaluation of scales and further item reduction, exploratory factor analysis was performed, followed by item convergent and discriminant validity analyses. Exploratory factor analysis on imputed data was performed to evaluate the a priori scales defined by the conceptual framework. All factor analysis used principal axis factoring and varimax rotation. The Kaiser–Meyer–Olkin (KMO) statistic was examined to ensure that the correlation matrix could be accounted for by a smaller set of factors; a minimum value of 0.5 is required. Bartlett's test of sphericity (BS), which tests the null hypothesis that there is no relationship between any of the variables, was also examined; this should be significant ($p < 0.05$). Several factor-analytic models were examined to identify the number of

TABLE 6 *Item reduction: DEMQOL and DEMQOL-Proxy*

	DEMQOL	
	Criteria for elimination	**Items eliminated[a]**
Item reduction	Missing (>30%)	**21 items failed:** Q9, Q12, Q17, Q19, Q21, Q27, Q28, Q43, Q47, Q48, Q49, Q50, Q51, Q52, Q55, Q63, Q64, Q66, Q68, Q71, Q72
	MEF (>80%)	**19 items failed:** Q24, Q31, Q40, Q41, Q50, Q51, Q53, Q54, Q57, Q58, Q59, Q60, Q62, Q63, Q64, Q65, Q66, Q67, Q70
	AEF (<10%)	**23 items failed:** Q16, Q18, Q24, Q27, Q31, Q37, Q38, Q40, Q41, Q49, Q53, Q54, Q57, Q58, Q59, Q60, Q62, Q63, Q64, Q65, Q66, Q67, Q70
	Redundancy (>0.75)	**1 pair of items failed:** Q26, Q28 (Q26 eliminated) **No. of items eliminated: 39**
		No. of items remaining = 34
Item reduction (after imputation)	Item–total correlations (>0.25)	**0 items failed**
		No. of items remaining = 34
Scale development (after imputation)	Factor analysis (loading <0.4 on all factors; cross-loading ⩾0.4 on more than one factor with a difference between the loadings <0.2)	**6 item failed:** Q11, Q22, Q61, Q69, Q6, Q29
		No. of items eliminated: 6
		No. of items remaining = 28
Scale development (after imputation)	Item convergence/discrimination (probable failures or scaling failures)	**0 items failed**
		No. of items remaining = 28
	DEMQOL-Proxy	
	Criteria for elimination	**Items eliminated[a]**
Item reduction	Missing (>10%)	**26 items failed:** Q3, Q5, Q9, Q10, Q16, Q17, Q18, Q19, Q23, Q35, Q38, Q40, Q41, Q42, Q44, Q45, Q47, Q49, Q50, Q51, Q52, Q63, Q66, Q71, Q72, Q73
	MEF (>80%)	**1 item failed:** Q59
	AEF (<10%)	**9 items failed:** Q6, Q16, Q37, Q40, Q46, Q49, Q51, Q58, Q59
	Redundancy (>0.75)	**1 pair of items failed:** Q29, Q30 (Q30 eliminated) **No. of items eliminated: 32**
		No. of items remaining: 41
Item reduction (after imputation)	Item–total correlations (>0.25)	**2 items failed:** Q11, Q57
		No. of items eliminated: 2
		No. of items remaining: 39
Scale development (after imputation)	Factor analysis (loading <0.4 on all factors; cross loading ⩾0.4 on more than one factor with a difference between the loadings <0.2)	**8 items failed:** Q24, Q53, Q56, Q60, Q61, Q69, Q70, Q25
		No. of items eliminated: 8
		No. of items remaining: 31

continued

TABLE 6 *Item reduction: DEMQOL and DEMQOL-Proxy (cont'd)*

	DEMQOL-Proxy	
	Criteria for elimination	**Items eliminated[a]**
Scale development (after imputation)	Item convergence/discrimination (probable failures or scaling failures)	**0 items failed**
		No. of items remaining: 31

[a] Item numbers refer to initial version of the Questionnaire shown in Appendices 3A and 3B.
AEF, aggregate adjacent endorsement frequency; MEF, maximum endorsement frequency.

factors that provided the best fit. From the best fit model, items were eliminated if they failed to load at least 0.40 on any factor or if they cross-loaded (loading ≥ 0.40 on more than one factor) and the difference between the two loadings was less than 0.20.[170] Although the best fit model was re-run on the remaining items, no further item elimination was performed. Item convergent/discrimination correlations[162,164,165] were used to evaluate further the scales derived by factor analysis. Items are classified as scaling successes if they correlate significantly more highly (i.e. by at least two standard errors) with their own scale than with other scales. Items are classified as probable scaling successes if they correlate more highly with their own scale than with other scales, but not significantly. Items are classified as scaling failures if they correlate significantly more highly (i.e. by at least two standard errors) with another scale than with their own scale. Items are classified as probable scaling failures if they correlate higher with another scale than with their own scale, but not significantly. Items classified as scaling failures or probable failures were considered for elimination.

Results: DEMQOL

Respondent characteristics

A total of 130 people with dementia agreed to be interviewed. As shown in *Table 7*, people with dementia ranged in age from 58 to 95 (mean 79) years and 60% were female. The majority (81%) were living at home or in sheltered accommodation and 19% were in residential or nursing homes. Five people with dementia had no identifiable carer or a carer who did not want to participate.

Agreement between self-reports and proxy reports

Because the distribution of scores on most items was highly skewed, Spearman rather than Pearson correlations were used. Correlations between self-reports and proxy reports were 0.4 or below for all except three items (Q5, Q36 and Q60).

Item reduction

Results of item reduction are summarised in the right-hand column of *Table 6*. A total of 39 items was eliminated for failing one of the criteria of missing data 30% or less, maximum endorsement frequencies 80% or less, aggregate adjacent endorsement frequencies greater than 10% or redundancy (inter-item correlation ≤ 0.75). Of the pair of items that failed the redundancy criterion (Q26 and Q28), Q28 was retained despite its high rate of missing data, as it was the more specific of the two questions and also provided better fit in the factor analysis. No items failed the criterion for item–total correlation (>0.25). At this stage in the item reduction, 34 items remained. Applying the more stringent criterion for missing data (≤ 25%) resulted in only seven items being retained. This criterion was not considered appropriate as content validity is likely to be compromised in such a short scale.

The item reduction analyses were repeated in the subsample of cases with mild/moderate dementia (n = 79). Examination of the distribution of missing data in this mild/moderate subsample suggested a criterion of greater than 10% for missing data. Item reduction analyses resulted in the retention of 39 items. This included 31 of the 34 items retained in the analysis of the whole sample plus eight items that were eliminated in the whole sample analysis but retained in the analyses of the mild/moderate subsample. All eight of these extra items had previously failed the missing criterion. Results were therefore similar to those conducted on the whole sample, but the mild/moderate sample had fewer missing data. By using the whole sample for item reduction the items that were answerable by the widest range of people were retained.

TABLE 7 *Respondent characteristics: preliminary field test*

		Total PWD *n* = 130 **Total carer *n* = 126**
Person with dementia		
Age (years)	Mean (SD)	78.95 (7.99)
	Range (*n*)	58–95 (130)
Gender	Male	52 (40)
	Female	78 (60)
Ethnicity		
White	*n* (%)	117 (90.7)
Caribbean	*n* (%)	6 (4.7)
African	*n* (%)	4 (3.1)
Indian	*n* (%)	2 (1.6)
Other	*n* (%)	1 (0.8)
Social class		
1.1 Large employers/higher managerial occupations	*n* (%)	9 (7.1)
1.2 Higher professional occupations	*n* (%)	11 (8.7)
2 Lower managerial and professional occupations	*n* (%)	15 (11.9)
3 Intermediate occupations	*n* (%)	22 (17.5)
4 Small employers and own account workers	*n* (%)	17 (13.5)
5 Lower supervisory and technical occupations	*n* (%)	16 (12.7)
6 Semi-routine occupations	*n* (%)	21 (16.7)
7 Routine occupations	*n* (%)	15 (11.9)
8 Never worked and long-term unemployed	*n* (%)	0 (0)
MMSE	Mean (SD)	16.8 (7.8)
	Range (*n*)	0–30 (98)
CDR		
0.50	*n* (%)	6 (6.5)
1.00	*n* (%)	51 (54.8)
2.00	*n* (%)	25 (26.9)
3.00	*n* (%)	11 (11.8)
	Median	1.00
Barthel	Mean (SD)	15.29 (4.43)
	Range (*n*)	1–20 (120)
Carer		
Age (years)	Mean (SD)	64.23 (13.26)
	Range (*n*)	28–85 (125)
Gender	Male	41 (32)
	Female	85 (68)
Relationship to patient		
Spouse	*n* (%)	64 (51.2)
Son/daughter (in-law)	*n* (%)	45 (36.0)
Sibling	*n* (%)	3 (2.4)
Other relative	*n* (%)	5 (4)
Friend/neighbour	*n* (%)	7 (5.6)
Other	*n* (%)	1 (0.8)

PWD, person with dementia.

Preliminary scale development

The KMO statistic and BS were both satisfactory, indicating that it was appropriate to conduct factor analysis. Exploratory factor analysis on the 34-item DEMQOL suggested a four-factor model as the best fit model. Further item reduction analyses resulted in a 28-item scale. Four items that did not load at least 0.40 on any factor and two items that cross-loaded were eliminated. The final model for the 28-item scale explained 49.97% of the variance and included four factors which were labelled daily activities, memory, negative emotion and positive emotion. As only one round of item elimination was conducted, the

final model (*Table 8*) contains three items (Q20, Q36 and Q56) that fail one or more of the factor analysis criteria for item retention. The four-factor model is not entirely consistent with the original conceptual framework. That is, although the domain of cognitive functioning is represented by the memory factor, the domain of health and well-being has split into two factors (negative emotion and positive emotion), and the daily activities domain has become a broad factor that includes items from the social relationships, health and well-being and daily activities domains. No items were retained from the self-concept domain.

Item convergent/discriminant validity analyses for the four preliminary scales identified from the factor analyses indicated 48 scaling successes, 35 probable scaling successes and one probable scaling failure (Q73). Although this item was considered for elimination, it was retained because it was a borderline probable scaling failure. Therefore, no additional items were eliminated.

Cronbach's alphas were acceptable for the 28-item overall score (0.94) and for the four preliminary subscales (daily activities 0.84, memory 0.89, negative emotion 0.84 and positive emotion 0.85).

Item-reduced DEMQOL

Item reduction and the preliminary evaluation of scales produced a 28-item shortened version of DEMQOL (v4, Appendix 4A) with four preliminary scales: daily activities, memory, negative emotion and positive emotion.

Results: DEMQOL-Proxy

Respondent characteristics

A total of 126 carers agreed to be interviewed. As shown in *Table 7*, carers ranged in age from 28 to 85 (mean 64.2) years and 68% were female. About half of the carers were spouses (51%), about one-third were sons or daughters (in-law) of the person with dementia (36%) and 12% were other relatives, friends or neighbours. Most carers (59%) lived with the person with dementia. Only one carer was interviewed without a corresponding interview with the person with dementia.

Item reduction

Results are shown in the right-hand column of *Table 6*. A total of 32 items was eliminated for failing one of the criteria of missing data 10% or less, maximum endorsement frequencies 80% or less, aggregate adjacent endorsement frequencies greater than 10% or redundancy (inter-item correlation ≤ 0.75). Two further items failed the item–total correlation criterion (>0.25) and were eliminated. At this stage of item reduction, 39 items remained.

Preliminary scale development

Exploratory factor analysis on the 39-item DEMQOL-Proxy indicated a two-factor model as the best fit model. Further item reduction analyses resulted in a 31-item scale. Seven items that did not load at least 0.40 on any factor and one item that cross-loaded were eliminated. The final model for the 31-item scale accounted for 35.16% of the variance and included two factors which were labelled functioning and emotion. As only one round of item elimination was undertaken, the final model (*Table 9*) contains two items (Q22 and Q39) that fail these criteria. The two-factor model is not entirely consistent with the original conceptual framework. The first factor (functioning) is a combination of the cognitive functioning, social relationships and daily activities domains. The second factor (emotion) consists entirely of items from the health and well-being domain. Only one item was retained from the self-concept domain, which loaded on the first (functioning) factor.

Item convergent/discriminant validity analyses for the two preliminary scales identified in the factor analyses indicated 28 scaling successes and three probable successes. No additional items were eliminated.

Cronbach's alphas were acceptable for the 31-item overall score (0.90) and for both subscales (functioning 0.90 and emotion 0.85).

Item-reduced DEMQOL-Proxy

Item reduction and the preliminary evaluation of scales produced a 31-item shortened version of DEMQOL-Proxy (v4, Appendix 4B) with two preliminary scales, functioning and emotion.

Discussion

Item reduction analyses produced two separate instruments: the 28-item DEMQOL for self-report by people with dementia and the 31-item DEMQOL-Proxy for proxy report by carers. *Table 10* shows the items in both questionnaires, indicating common and unique items. Preliminary scales that showed good internal consistency were identified for both measures.

In general, people with dementia and carers were able to complete the questionnaire. However,

TABLE 8 *Factor loadings: DEMQOL final four-factor model*

Summary description of item[a]	Conceptual framework domain	Factor 1: Daily activities	Factor 2: Memory	Factor 3: Negative emotion	Factor 4: Positive emotion
Q1 cheerful	Health and well-being	0.221	0.115	0.121	**0.748**
Q2 worried/anxious	Health and well-being	0.181	0.185	**0.597**	0.123
Q3 enjoying life	Health and well-being	0.209	0.019	0.213	**0.749**
Q4 frustrated	Health and well-being	0.068	0.191	**0.672**	0.240
Q5 confident	Health and well-being	0.250	0.217	0.232	**0.629**
Q7 full of energy	Health and well-being	0.126	0.166	0.340	**0.555**
Q8 sad	Health and well-being	0.011	0.070	**0.662**	0.353
Q10 lonely	Health and well-being	0.301	–0.107	**0.545**	0.218
Q13 distressed	Health and well-being	0.070	0.323	**0.518**	0.060
Q14 lively	Health and well-being	0.018	0.019	0.178	**0.655**
Q15 irritable	Health and well-being	0.076	0.296	**0.662**	0.201
Q20 [b]fed-up	Health and well-being	*0.212*	*0.169*	*0.358*	*0.339*
Q23 how you feel in yourself	Health and well-being	**0.439**	0.185	0.145	0.423
Q25 your health overall	Health and well-being	**0.506**	0.269	0.059	0.129
Q28 forgetting things that happened recently	Cognitive functioning	0.278	**0.649**	0.399	0.158
Q30 forgetting who people are	Cognitive functioning	0.394	**0.640**	0.223	0.064
Q32 forgetting what day it is	Cognitive functioning	0.083	**0.673**	0.027	0.122
Q33 thoughts being muddled	Cognitive functioning	0.388	**0.638**	0.165	0.145
Q34 difficulty making decisions	Cognitive functioning	0.354	**0.565**	0.323	0.160
Q35 poor concentration	Cognitive functioning	0.186	**0.762**	0.224	0.046
Q36 [c]making self understood	Cognitive functioning	**0.532**	**0.406**	0.306	0.049
Q39 not having enough company	Social relationships	**0.600**	0.073	0.283	0.160
Q42 people not listening to you	Social relationships	**0.642**	0.220	0.040	0.098
Q44 getting help when you need it	Social relationships	**0.692**	0.185	0.132	0.292
Q45 getting the affection you want	Social relationships	**0.452**	0.322	0.033	0.188
Q46 how you get on with people close to you	Social relationships	**0.418**	0.270	0.105	0.029
Q56 [c]getting to the toilet in time	Daily activities	**0.512**	0.056	**0.404**	0.171
Q73 things wanted to do but couldn't	Daily activities	0.341	0.261	**0.403**	0.187

[a] Question numbers refer to initial version of the questionnaire shown in Appendix 3A.
[b] Item fails to load ⩾0.4.on any factor.
[c] Item cross-loads and difference between the two highest loadings is <0.2.

TABLE 9 *Factor loadings: DEMQOL-Proxy final two-factor model*

Summary description of item[a]	Conceptual framework domain	Factor 1: Functioning	Factor 2: Emotion
Q1 cheerful	Health and well-being	–0.048	**0.639**
Q2 worried or anxious	Health and well-being	0.290	**0.565**
Q4 frustrated	Health and well-being	0.101	**0.637**
Q7 full of energy	Health and well-being	–0.009	**0.431**
Q8 sad	Health and well-being	0.160	**0.659**
Q12 content	Health and well-being	0.003	**0.727**
Q13 distressed	Health and well-being	0.150	**0.611**
Q14 lively	Health and well-being	–0.016	**0.519**
Q15 irritable	Health and well-being	–0.036	**0.481**
Q20 fed-up	Health and well-being	0.070	**0.635**
Q21 has things to look forward to	Health and well-being	0.031	**0.426**
Q22 [b]physical health	Health and well-being	*0.342*	*0.382*
Q26 memory overall	Cognitive functioning	**0.696**	0.137
Q27 forgetting things that happened long ago	Cognitive functioning	**0.552**	0.004
Q28 forgetting things that happened recently	Cognitive functioning	**0.640**	0.148
Q29 forgetting people's names	Cognitive functioning	**0.665**	0.020
Q31 forgetting where he/she is	Cognitive functioning	**0.647**	0.145
Q32 forgetting what day it is	Cognitive functioning	**0.635**	–0.098
Q33 thoughts being muddled	Cognitive functioning	**0.708**	0.194
Q34 difficulty making decisions	Cognitive functioning	**0.740**	0.234
Q36 making self understood	Cognitive functioning	**0.519**	0.191
Q39 [b]not having enough company	Social relationships	0.195	0.387
Q43 not being able to help other people	Social relationships	**0.543**	0.269
Q48 not playing a useful part	Self-concept	**0.635**	0.239
Q54 keeping self clean	Daily activities	**0.554**	–0.032
Q55 keeping self looking nice	Daily activities	**0.446**	–0.118
Q62 getting what want from shops	Daily activities	**0.424**	0.051
Q64 using money to pay for things	Daily activities	**0.540**	–0.038
Q65 looking after finances	Daily activities	**0.515**	–0.005
Q67 getting in touch with people	Daily activities	**0.436**	0.107
Q68 things taking longer than they used to	Daily activities	**0.410**	0.340

[a] Question numbers refer to initial version of the questionnaire shown in Appendix 3B.
[b] Item fails to load ⩾0.4 on any factor.

several carers commented on the length of the questionnaire, and there were large amounts of missing data from both people with dementia and carers. Missing data were highest for people with severe dementia. However, as item analyses on the mild/moderate subsample produced a similar item-reduced questionnaire, the reliability of data obtained from people with severe dementia in the final field test was investigated further.

Results of the preliminary field test indicate that there are important differences in how people with dementia and their carers report HRQoL. This was demonstrated by the finding that different items were eliminated or retained in DEMQOL and DEMQOL-Proxy. Of 14 items that are unique to DEMQOL, several are related to social aspects of HRQoL (Q10, Q30, Q42, Q44, Q45, Q46 and Q56; Appendix 3A), although not all of these were originally part of the social relationships domain. People with dementia therefore appear to be more concerned than carers with fitting into social networks and being socially accepted, which may be a vestige of self-concept, despite no self-concept items actually remaining. In contrast, 17 items that were unique to the DEMQOL-Proxy included several related to the cognitive functioning (Q26, Q27, Q29 and Q31; Appendix 3B) and daily activities and looking after yourself (Q54, Q55, Q62, Q64, Q65, Q67 and Q68; Appendix 3B) domains. This suggests that carers may be reflecting on longer term deterioration or that the lack of insight on the part of people with dementia was becoming manifest. Of the 14 items that were common to both questionnaires, correlations between the same items on DEMQOL and DEMQOL-Proxy were consistently low, indicating that there are important differences between self-report and carer-proxy reports. This adds to the body of evidence suggesting that self-

TABLE 10 *Correspondence between DEMQOL and DEMQOL-Proxy items*

Questionnaire item DEMQOL	Questionnaire item DEMQOL-Proxy
cheerful?	cheerful?
worried or anxious?	worried or anxious?
that you are enjoying life?	
frustrated?	frustrated?
confident?	
full of energy?	full of energy?
sad?	sad?
lonely?	
	content?
distressed?	distressed?
lively?	lively?
irritable?	irritable?
fed-up?	fed-up
that there are things that you wanted to do but couldn't?	
	that he/she has things to look forward to?
	his/her memory in general?
	forgetting things that happened a long time ago?
forgetting things that happened recently?	forgetting things that happened recently?
forgetting who people are?	
	forgetting people's names?
	forgetting where he/she is?
forgetting what day it is?	forgetting what day it is?
your thoughts being muddled?	his/her thoughts being muddled?
difficulty making decisions?	difficulty making decisions?
poor concentration?	
not having enough company?	
how you get on with people close to you?	
getting the affection that you want?	
people not listening to you?	
making yourself understood?	making him/herself understood?
	getting in touch with people?
	not having enough company?
	not being able to help other people?
	not playing a useful part in things?
getting help when you need it?	
getting to the toilet in time?	
	keeping him/herself clean (e.g. washing and bathing)?
	keeping him/herself looking nice?
	getting what he/she wants from the shops?
	using money to pay for things?
	looking after his/her finances?
	things taking longer than they used to?
how you feel in yourself?	
your health overall?	
	his/her physical health?
your quality of life overall?	his/her quality of life overall?

reports and carer reports of HRQoL should be considered complementary rather than interchangeable.

The items retained in the item reduction analyses do not clearly match the conceptual framework for either measure. The self-concept domain does not emerge in either DEMQOL or DEMQOL-Proxy (only one item from this domain remained in DEMQOL-Proxy) and there is poor support for the DEMQOL daily activities domain (two items remained) and DEMQOL-Proxy social relationships domain (two items). There may be a trade-off between content validity, represented by the conceptual framework, and better psychometric properties that are likely to result from item reduction. Thus, although the conceptual framework provided a useful basis for questionnaire development, it did not provide a very robust set of scales.

Likewise, some items that failed the item reduction criteria may be considered clinically important. To explore this idea and in consultation with a clinical expert (RH), nine of the items eliminated from DEMQOL (Q49, Q69, Q47, Q55, Q38, Q41, Q66, Q43 and Q11) were identified as clinically important. These were added back into the item pool and factor analyses re-run to determine whether the factor structure was still interpretable and, if so, to which factor these items would contribute. It was found that these additional items did not improve the factor model or increase internal consistency of the subscales, but simply added to the generality of the first factor (daily activities).

The final factor models for both DEMQOL and DEMQOL-Proxy contain a small number of items with highest loading less than 0.40 and the DEMQOL model also includes two items that cross-load with a difference between the loadings of less than 0.20. This is the result of only conducting one round of item elimination from the factor analyses. This approach to the use of factor analysis allowed elimination of the weakest items, but retained a degree of caution in the use of the self-report data from people with dementia, by not over-eliminating items. These preliminary scales are further evaluated in the final field test (Chapters 5 and 6).

Summary

Item reduction analyses resulted in a 28-item DEMQOL and 31-item DEMQOL-Proxy with high internal consistency. Preliminary scales were identified for both instruments, but these did not entirely represent the conceptual domains.

Chapter 5

Final field test: methods

Psychometric evaluations were conducted independently for the item-reduced versions of DEMQOL and DEMQOL-Proxy. This chapter describes the methods used in the final field test of both instruments.

Participants

Participants were people with a clinical diagnosis of dementia and their family carers who were identified from two sources: community mental health teams for older people in the South London and Maudsley Mental Health Trust and at the Nottinghamshire Healthcare NHS Trust, Nottingham. No specific exclusion criteria were applied. A subset was randomly selected from cases recruited in London to assess test–retest reliability. As missing data were high for several of the cases in the test–retest sample, seven additional test–retest cases were recruited from both London and Nottingham using the same criteria outlined above. In Nottingham, newly diagnosed cases or those presenting with a new episode were approached for a second interview after 3 months to assess responsiveness.

Measures

DEMQOL and DEMQOL-Proxy

The 28-item DEMQOL (v4) and 31-item DEMQOL-Proxy (v4) were administered according to the interviewer manual. The DEMQOL was scored and missing data were imputed following the rules described in Chapter 4. Appendix 5 summarises the direction of scoring for all of the measures used in the final field test.

Validating measures

Our approach to the validation of DEMQOL and DEMQOL-Proxy was to evaluate construct validity by examining the relationship between the new measures and three types of validating measures. First, convergent validity was examined by comparing the new measures with other dementia-specific HRQoL measures. These comparisons were considered to be the most robust test of validity. Then, the new measures were compared with a gold-standard generic measure of HRQoL. Finally, the relationship was examined between the new measures and measures of other constructs that were hypothesised to be related to some aspects of HRQoL, such as depression and disability, as well as other constructs that were hypothesised not to be related to HRQoL, such as carer well-being. The latter two types of validity comparisons are of a more exploratory nature, given the limitations outlined below.

Dementia-specific HRQoL

Two existing dementia-specific HRQoL measures were administered: the QOLAD[85,104] and the DQOL.[84] The QOLAD consists of 13 items, each rated on a four-point scale. It is designed to be interviewer administered to the person with dementia (QOLAD) or self-administered to a carer (QOLAD-Carer). It is brief and simple to complete and has been used with people with a range of severity of dementia, although the authors report it to be most appropriate for use with people with an MMSE score of at least 10.[104] Psychometric evaluation of QOLAD is at an early stage, although initial results are promising. For consistency and to minimise method bias, interviewer administration was used for both QOLAD and QOLAD-Carer with permission from authors (Logsdon R: personal communication, July 2001). High QOLAD scores indicate good HRQoL.

DQOL is reported to be suitable for use with patients with mild to moderate dementia (MMSE $\geq$ 12). It is administered by a trained interviewer. Respondents must pass two of three screening questions before being considered eligible for DQOL. The instrument consists of 29 items that are scored to produce five subscales: self-esteem, positive affect, absence of negative affect, feelings of belonging and sense of aesthetics. Psychometric investigation of DQOL is also at an early stage; initial results are promising,[84] but further analyses are required. For all DQOL scales, high scores indicate good HRQoL.

As DEMQOL, QOLAD and DQOL are all dementia-specific HRQoL measures, it was hypothesised that the three measures would be highly correlated.

Generic HRQoL

The researchers considered using the SF-36,[61] but decided that it was too long for use with people with dementia. Therefore, to minimise the respondent burden the SF-12 v2 was used.[171] The SF-12 v2 is a generic measure that assesses HRQoL in eight domains of physical functioning, role – physical, bodily pain, general health, energy/fatigue, social functioning, role–emotional and mental health. These are the same domains as the SF-36. Two summary scores can be produced: physical (PCS) and mental (MCS) component scores. The recently released version 2 of the SF-12 includes some important changes to response options and minor wording changes to some items of the SF-12 v1. As the UK English version of version 2 of the SF-12 is not yet available, the authors' permission was obtained to apply the standardised wording used in the UK version 2 of the SF-36 to produce a UK English version the SF-12 v2 (Gandek B, Health Assessment Lab, Boston: personal communication, July 2001). The SF-12 v2 was administered by interview to both the person with dementia and the carer. Higher scores indicate good HRQoL.

The SF-12 v2 is a generic measure that was not developed or validated for use with people with dementia. Therefore there was concern about its appropriateness for use with people with dementia and particularly whether they would be able to complete it. The SF-12 v2 was adapted for proxy report so that a standard generic measure could be used to evaluate the convergent validity of DEMQOL-Proxy. However, given the uncertainty about the appropriateness of the SF-12 for use with people with dementia, this was included on an exploratory basis in the validation process. It was hypothesised that the disease-specific DEMQOL, QOLAD and DQOL measures would be moderately correlated with the generic SF-12.

Other constructs

Convergent validity was investigated by examining the relationship between DEMQOL and three possibly related constructs: depression, disability and carer psychological well-being.

Depression was assessed using the Geriatric Depression Scale 30-item version (GDS-30),[172] adapted for proxy report by a carer.[41] The GDS-30 is designed as a screening instrument for depression among elderly people. It consists of 30 items, reported on a yes/no scale. The instrument has good reliability and validity.[172] The proxy-reported version has acceptable psychometric properties in carers of people with AD.[41] High GDS-30 scores indicate more severe depression.

Disability was assessed using the postal version of the Barthel Index (described in Chapter 4). High Barthel Index scores indicate a high level of independence.

The psychological well-being of carers was measured using the 12-item version of the General Health Questionnaire (GHQ-12).[173] The GHQ is a self-administered screening instrument for detecting psychiatric distress. Items are rated on a four-point scale. There are several scoring methods for the GHQ; this study used the method in which ratings are dichotomised (to either 0 or 1). The measure has been demonstrated to be reliable and valid.[173] High scores on the GHQ-12 indicate high distress.

The three validating measures described above allowed aspects of validity to be tested in an exploratory but not definitive way. For example, because neither the Barthel Index nor GHQ-12 has been validated for use with people with dementia, there was uncertainty over the robustness of their psychometric properties when used as validating tools in the study sample of people with dementia. Moreover, hypotheses about the expected relationships between dementia-specific HRQoL, depression, disability and carer well-being are tentative at best, given the paucity of research on HRQoL in dementia to date, including knowledge about the relationships between these four constructs in dementia.

The tentative hypotheses were as follows. In assessing construct validity, it was predicted that dementia-specific HRQoL measures, which measure both physical and psychological aspects of functioning, would be moderately correlated with the Barthel, which measures aspects of physical functioning, and the GDS-30, which measures aspects of psychological functioning. In evaluating discriminant validity, the researchers wanted to ensure that dementia-specific HRQoL measures, which are completed by the carer on behalf of the patient, are not correlated with the psychological well-being of the carer (GHQ-12), as this would indicate that carers' ratings of the HRQoL of the person with dementia are biased by their own psychological well-being.

Other measures

Disease severity and socio-demographic variables were also measured.

Disease severity

Disease severity was assessed using the MMSE (described in Chapter 4). High scores indicate less

impairment. The CDR (described in Chapter 4) was used to provide an additional rating of severity. The higher the CDR scores the more severe the dementia.

Socio-demographic variables

Age, gender, social class, ethnicity and amount of time the carer spends with the person with dementia were assessed using a demographic questionnaire designed specifically for this study. Questions on ethnicity and socio-economic status followed the recommended wording from the Office of National Statistics (ONS).

Procedures

As in the preliminary field test, eligible participants in London received an introductory letter and information sheet and were then contacted by telephone to confirm willingness to take part. In Nottingham, eligible participants were initially approached and given the information sheet by the consultant psychiatrist during their clinic visit. If they agreed to take part, the researcher contacted the person by telephone to arrange a home visit. In both sites, the person with dementia and carer were seen simultaneously but separately at the home of the person with dementia. Ethical approval was obtained from the relevant LRECs and written informed consent was obtained from both the person with dementia and the carer. Where the person with dementia was unable to provide written informed consent, verbal assent was obtained from the person with dementia and written assent from the carer. All interviews were conducted by experienced researchers. Measures were administered in the following order: DEMQOL, MMSE, DQOL or QOLAD, SF-12 v2 (person with dementia); DEMQOL-Proxy, QOLAD-Carer or proxy SF-12, GDS-30, Barthel Index, GHQ-12 and demographic questionnaire (carer). The Barthel Index and GHQ-12 were self-completed by the carer. To reduce respondent burden, participants were randomly assigned at baseline to one of two groups. In group A (n = 43), people with dementia were assigned to DEMQOL, MMSE and DQOL (DQOL data were only included from those with MMSE ≥ 12; n = 30) and SF-12, and carers to DEMQOL-Proxy, proxy SF-12, GDS-30, Barthel Index, GHQ-12 and the demographic questionnaire. In group B (n = 58), people with dementia were assigned to DEMQOL, MMSE, QOLAD and SF-12, and carers to DEMQOL-Proxy, QOLAD-Carer, GDS-30, Barthel Index, GHQ-12 and the demographic questionnaire.

Respondents in the test–retest sample completed the DEMQOL or DEMQOL-Proxy 2 weeks later, while respondents in the responsiveness sample completed the same questionnaires at baseline and 3-month follow-up.

Analyses of mild/moderate and severe cases

Separate preliminary psychometric analyses were conducted for people with mild/moderate and severe dementia. However, there is little consensus in the literature about specific MMSE cut-off scores for defining mild/moderate and severe dementia.[174,175] Although many clinical trials have used the criterion of MMSE less than 10 to classify people as having severe dementia,[15,23,26,31,176,177] other researchers have suggested cut-off scores of MMSE less than 12[84] and MMSE less than 8[178] for defining severe dementia. Three different criteria were used in this study, including Brod's liberal estimate (MMSE<12), an estimate based on common practice in clinical trials (MSME<10) and a conservative estimate (MMSE<8).

When these criteria were applied to the sample, preliminary analyses indicated that there were few differences between the three criteria in the number of people defined as having severe dementia (*Table 11*). Therefore, it was decided to use the cut-off of MMSE below 10 to define severe dementia, which is the criterion most frequently used in clinical trials. Mild/moderate and severe dementia were defined on the basis of MMSE at least 10 and less than 10, respectively. Where MMSE scores were missing a CDR rating of 3 was used to define severe cases.

The proportion of missing data for severe (MMSE<10) and mild/moderate (MMSE ≥ 10) cases was then examined. As shown in *Table 11*, missing data for both DEMQOL and DEMQOL-Proxy are substantially higher in people with severe dementia than in those with mild/moderate dementia. For DEMQOL, the sample size in the severe group was not considered sufficiently large to undertake further validation analyses (valid n = 7), so the validity of DEMQOL was evaluated only in people with mild/moderate dementia (MMSE ≥ 10; valid n = 68). For DEMQOL-Proxy, there were fewer missing data so separate validation analyses were performed in people with mild/moderate (valid n = 77) and severe (valid n = 21) dementia.

Psychometric evaluation

The acceptability, reliability, validity and responsiveness of DEMQOL and DEMQOL-Proxy

TABLE 11 *Missing data by severity: DEMQOL and DEMQOL-Proxy*

	Mild/moderate			Severe		
	Valid (%)	Missing (%)	Total	Valid (%)	Missing (%)	Total
DEMQOL						
Conservative estimate (MMSE <8)	69 (84)	13 (16)	82	6 (31)	13 (68)	19
Liberal estimate (MMSE <10)	68 (86)	11 (14)	79	7 (32)	15 (68)	22
Brod's estimate (MMSE <12)	66 (86)	11 (14)	77	9 (37)	15 (62)	24
DEMQOL-Proxy						
Conservative estimate (MMSE <8)	80 (100)	0 (0)	80	18 (95)	1 (5)	19
Liberal estimate (MMSE <10)	77 (100)	0 (0)	77	21 (95)	1 (4)	22
Brod's estimate (MMSE <12)	75 (100)	0 (0)	75	23 (96)	1 (4)	24

scores were evaluated using the methods described in Chapter 2 (*Table 3*). As QOLAD and DQOL are still undergoing psychometric evaluation, the psychometric properties of both instruments were also assessed. The same methods used to validate DEMQOL and DEMQOL-Proxy, described below, were applied. This adds to the body of psychometric evidence for these measures, and ensures the scientific robustness of both measures as validating measures in this study. Missing data in the validating instruments were imputed using the same rule as described for DEMQOL (see Appendix 5 for a summary). Exceptions to this were: MMSE (no imputation), CDR (no imputation), Barthel Index (no imputation), DQOL (using developers' rules for number of completed items required for each scale and imputing with the mean), GHQ-12 (using developers' imputation rules) and SF-12 (using developers' imputation rules).

Acceptability

Acceptability was evaluated by examining missing data and floor/ceiling effects for summary scores. Given the expected higher than usual amount of missing data among people with dementia, and based on rates of missing data reported for existing dementia-specific measures, a more liberal criterion of 20% was adopted for missing data for DEMQOL. As DEMQOL-Proxy is completed by carer proxies, the usual criterion of less than 5% missing data was retained for DEMQOL-Proxy.

Reliability

Reliability was assessed on the basis of internal consistency (Cronbach's alpha ≥ 0.70) and test–retest reliability (criterion ≥ 0.70)

Validity

The validation strategy was based on specific hypotheses about expected relationships between DEMQOL and the other validating measures. The measures described above differ on two dimensions: method of report (self-report versus proxy-report) and type of measure (generic versus disease-specific). Therefore, instruments of the same type and based on the same method of report were expected to be more closely related than instruments that differed on these dimensions. Specific validity hypotheses are described below.

Convergent validity

It was hypothesised that there would be:

- high correlations between dementia-specific measures (DEMQOL, QOLAD, DQOL)
- moderate correlations between dementia-specific (DEMQOL, QOLAD, DQOL) and generic (SF-12) HRQoL measures
- moderate correlations between dementia-specific measures (DEMQOL, QOLAD, DQOL) and depression (GDS-30) and disability (Barthel).

Discriminant validity

It was hypothesised that disease-specific HRQoL measures (DEMQOL, QOLAD, DQOL) would not be correlated with age, gender or social class. For DEMQOL-Proxy, it was also hypothesised that scores would not be correlated with carer psychological well-being (GHQ-12).

Known groups differences

Although previous studies have used disease severity to validate dementia-specific HRQoL measures, the relationship between dementia severity and HRQoL is not well established. Therefore, known groups difference validity was investigated on an exploratory basis, hypothesising that HRQoL would be better in people with mild/moderate than severe dementia.

Factor analysis

Exploratory factor analysis was undertaken to determine the extent of support for subscales identified in the preliminary field test (four subscales for DEMQOL, two for DEMQOL-Proxy). All factor analysis used principal axis factoring and varimax rotation with KMO and BS tested for each model. Preliminary factor analyses were conducted to identify the number of factors in the best fit model. Items with factor loadings of at least 0.40 with no cross-loading on other factors were considered to belong to a factor. Cross-loading was defined as having factor loadings of at least 0.40 on more than one factor with the difference between the two loading values less than 0.20.[170] Factor analyses in the final field test are limited by the relatively small sample size available. These analyses should therefore be considered as exploratory.

Responsiveness

The plan was to evaluate responsiveness using effect sizes and standardised response means as described in Chapter 2.

Correlation between DEMQOL and DEMQOL-Proxy

Correlations between DEMQOL and DEMQOL-Proxy were examined to investigate the agreement between self-report and proxy report. Results are presented in Chapter 6.

Chapter 6

Final field test: results

This chapter presents the results of the evaluation of the psychometric properties (acceptability, reliability, validity and responsiveness) of DEMQOL and DEMQOL-Proxy. For DEMQOL, results are reported for the subsample of people with mild/moderate dementia. People with severe dementia (MMSE <10) were excluded for the reasons described in Chapter 5. For DEMQOL-Proxy, results are reported separately for people with mild/moderate and severe dementia. Results of the evaluation of the psychometric properties of QOLAD, DQOL and QOLAD-Carer in the current sample are also reported.

Psychometric evaluation of DEMQOL

Respondent characteristics

The sample consisted of 101 people with dementia (*Table 12*) but, as described in Chapter 5, validation of DEMQOL was undertaken among the mild/moderate group (MMSE ≥ 10; $n = 79$). The mean age of people with mild/moderate dementia was 79 (range 54–91 years) and just over half (54%) were female. The mean MMSE score was 19.9 (SD 4.5; range 10–29) and the median CDR rating was 1. Most people with dementia lived with their carer (75%). Social class was measured using the full method developed by the ONS[179] and classification was made for each household. All social classes except for the highest (large employers and higher managerial occupations) were represented in the sample.

Concurrent evaluation of QOLAD and DQOL

Before evaluating DEMQOL, the psychometric properties of the two dementia-specific HRQoL instruments that were used as validating measures were examined. This tests the extent to which both instruments are robust measures in the sample, and aids the interpretation of data.

The psychometric evaluation of DQOL may be limited by an error in administration. In one of the data collection sites, the three screening questions were not administered before the administration of DQOL for some cases. As successful completion of two of the screening questions is a criterion for completion of DQOL, the researchers erred on the side of caution and did not score DQOL data for these six cases (i.e. they were treated as missing data). This may have inflated the missing data rates for DQOL. As shown in *Table 13*, missing data for QOLAD met the accepted criterion, whereas missing data for DQOL exceeded the criterion. Floor/ceiling effects and skew were within the acceptable range for both QOLAD and DQOL.

Internal consistency was high for QOLAD, but met the criterion for only three DQOL scales (self-esteem, positive affect and absence of negative affect) (*Table 14*).

In terms of convergent validity, QOLAD was correlated with both the SF-12 and DEMQOL. Correlations for QOLAD were higher with the SF-12, but still in the moderately high range with DEMQOL. QOLAD was moderately highly associated with age, but was not affected by gender or social class.

DQOL was in general, somewhat more highly correlated with DEMQOL than with the SF-12, but the pattern of results varied considerably across DQOL scales. One DQOL scale (self-esteem) showed weak correlations with SF-12 PCS scores: two (positive affect and absence of negative affect) were in the wrong direction and two (feelings of belonging, sense of aesthetics) were not associated with SF-12 PCS scores. One DQOL scale (absence of negative affect) showed high association with SF-12 MCS scores. Four DQOL scales (self-esteem, positive affect, feelings of belonging, sense of aesthetics) showed weak correlations and in the wrong direction with SF-12 MCS scores. DQOL scales showed weak to moderate correlations with DEMQOL, and one (sense of aesthetics) was in the wrong direction. Two DQOL scales (self-esteem and absence of negative affect) were moderately highly correlated with age, and another (sense of aesthetics) was associated with gender, but none was significantly affected by social class.

In summary, QOLAD demonstrated acceptability, internal consistency and validity, although the moderate association with age slightly compromised discriminant validity. Results from

TABLE 12 *Respondent characteristics: DEMQOL – person with dementia*

		Whole sample Total PWD *n* = 101 Total carer *n* = 99	Mild/moderate subsample[a] Total PWD *n* = 79 Total carer *n* = 77	Severe subsample[b] Total PWD *n* = 22 Total carer *n* = 22
Person with dementia				
Age (years)	Mean (SD)	78.65 (8.30)	78.49 (8.32)	79.23 (8.42)
	Range (*n*)	54–93 (101)	54–91 (79)	65–93 (22)
Gender	Male	42 (41.6)	36 (45.6)	6 (27.3)
	Female	59 (58.4)	43 (54.4)	16 (72.7)
Ethnicity				
White British	*n* (%)	80 (79.2)	66 (83.5)	14 (63.6)
White Irish	*n* (%)	3 (3)	3 (3.8)	0 (0)
White other	*n* (%)	5 (5)	3 (3.8)	2 (9.1)
Mixed White and Black Caribbean	*n* (%)	2 (2)	2 (2.5)	0 (0)
Asian British or Asian Indian	*n* (%)	3 (3)	2 (2.5)	1 (4.5)
Black British or Black Caribbean	*n* (%)	6 (5.9)	3 (3.8)	3 (13.6)
Black British or Black African	*n* (%)	2 (2)	0 (0)	2 (9.1)
Social class				
Large employers/higher managerial occupations	*n* (%)	1 (1)	0 (0)	1 (5.3)
Higher professional occupations	*n* (%)	7 (7.2)	6 (7.7)	1 (5.3)
Lower managerial and professional occupations	*n* (%)	33 (34)	28 (35.9)	5 (26.3)
Intermediate occupations	*n* (%)	6 (6.2)	5 (6.4)	1 (5.3)
Small employers and own account workers	*n* (%)	8 (8.2)	4 (5.1)	4 (21.1)
Lower supervisory and technical occupations	*n* (%)	17 (17.5)	15 (19.2)	2 (10.5)
Semi-routine occupations	*n* (%)	14 (14.2)	11 (14.1)	3 (15.8)
Routine occupations	*n* (%)	9 (9.3)	7 (9)	2 (10.5)
Never worked and long-term unemployed	*n* (%)	2 (2.1)	2 (2.6)	0 (0)
MMSE	Mean (SD)	16.01 (8.53)	19.93 (4.84)	2.90 (3.60)
	Range (*n*)	0–29 (87)	10–29 (67)	0–9 (20)
CDR				
0.50	*n* (%)	8 (8.1)	8 (10.3)	0 (0)
1.00	*n* (%)	45 (45.5)	44 (56.4)	1 (4.8)
2.00	*n* (%)	30 (30.3)	24 (30.8)	6 (28.6)
3.00	*n* (%)	16 (16.2)	2 (2.6)	14 (66.7)
	Median	1.00	1.00	3.00
Barthel	Mean (SD)	15.5 (4.5)	16.9 (3.3)	10.7 (5.0)
	Range (*n*)	3–20 (88)	6–20 (68)	3–20 (20)
GDS-30	Mean (SD)	16.60 (5.88)	16.43 (5.94)	17.20 (5.80)
	Range (*n*)	4–28.8 (96)	4–28.8 (75)	7.5–27 (21)

[a] MMSE ≥ 10.
[b] MMSE < 10.

TABLE 13 *Acceptability: DEMQOL and other HRQoL measures – person with dementia*

	Score range			Floor/ceiling effect		
Scale	**% Missing**	**Scale**	**Sample**	**% Floor**	**% Ceiling**	**Skew**
Whole sample[a]						
DEMQOL	25.7	28–112	63–108	0	0	–0.53
QOLAD – PWD	31	13–52	24–45	0	0	–0.21
DQOL self-esteem	43.3	1–5	1–4.75	1	0	–0.92
DQOL positive affect	46.6	1–5	2–4.67	0	0	–0.50
DQOL absence of negative affect	46.6	1–5	1.36–4.27	0	0	0.42
DQOL feelings of belonging	50	1–5	2.33–5	0	2	0.21
DQOL sense of aesthetics	40	1–5	2.40–5	0	1	0.03
SF-12 PCS	46.5	0–100	21.57–60.71	0	0	–0.78
SF-12 MCS	46.5	0–100	23.85–66.46	0	0	–0.64
Mild/moderate (MMSE ≥ 10) subsample[b]						
DEMQOL	13.9	28–112	63–108	0	0	–0.53
QOLAD – PWD	16.7	13–52	24–45	0	0	–0.52
DQOL self-esteem	43.3	1–5	1–4.75	1	0	–0.92
DQOL positive affect	46.6	1–5	2–4.67	0	0	–0.50
DQOL absence of negative affect	46.6	1–5	1.36–4.27	0	0	0.42
DQOL feelings of belonging	50	1–5	2.33–5	0	2	0.21
DQOL sense of aesthetics	40	1–5	2.40–5	0	1	0.03
SF-12 PCS	36.7	0–100	21.57–60.71	0	0	–0.79
SF-12 MCS	36.7	0–100	23.85–63.39	0	0	–0.81

[a] DEMQOL and SF-12 $n = 101$; QOLAD $n = 58$; DQOL $n = 30$.
[b] DEMQOL and SF-12 $n = 79$; QOLAD $n = 42$; DQOL $n = 30$.

DQOL were less consistent. While three of the five DQOL scales (self-esteem, positive affect and absence of negative affect) showed acceptable internal consistency, validity evidence was mixed. However, the samples for both QOLAD and DQOL were relatively small and these results should be replicated with a larger sample.

The following sections describe the psychometric properties of DEMQOL.

Acceptability

As shown in *Table 13*, DEMQOL missing data met the modified criterion and were similar to QOLAD and lower than DQOL. Floor/ceiling effects and skew were within the acceptable range.

Reliability

Internal consistency

Cronbach's alpha for DEMQOL exceeded the standard criterion (*Table 14*). Item–total correlations ranged from 0.19 to 0.65; the mean inter-item correlation was 0.2.

Test-retest reliability

DEMQOL showed good test–retest reliability (*Table 14*).

Validity

Content validity

Content validity was achieved by using a systematically derived conceptual framework to generate questionnaire content for DEMQOL (see Chapter 3). As discussed in Chapter 4, the item-reduced version of DEMQOL includes more items relating to mental than to physical well being. Although four of the five domains in the conceptual framework are represented to some extent in the item-reduced version of DEMQOL, all domains in the conceptual framework may not be fully represented in the final version. However, because some of the eliminated items are correlated with those that were retained, these constructs may still be represented, albeit less directly and not supported by separate subscales in the final version of DEMQOL.

Construct validity

Convergent validity

DEMQOL was moderately associated with QOLAD and three of the five DQOL subscales (self-esteem, positive affect and absence of negative affect) (*Table 14*). DEMQOL had a moderately low association with the feelings of belonging subscale, but for the remaining DQOL scale (sense of aesthetics) the

TABLE 14 *Reliability and validity: DEMQOL and other HRQoL measures – person with dementia*

	DEMQOL (*n*)[a]	DQOL SE self-esteem (*n*)	DQOL PA positive affect (*n*)	DQOL NA absence of negative affect (*n*)	DQOL FB feelings of belonging (*n*)	DQOL SA sense of aesthetics (*n*)	QOLAD-PWD (*n*)	SF-12 PCS-PWD (*n*)	SF-12 MCS-PWD (*n*)	MMSE (*n*)	GDS-30 (*n*)	Barthel (*n*)
Reliability												
Internal consistency[b]	0.87 (75)	0.87 (17)	0.78 (16)	0.83 (16)	0.55 (15)	0.37 (18)	0.84 (40)	–	–	–	0.85 (96)	0.86 (88)
	0.87 (68)	0.87 (17)	0.78 (16)	0.83 (16)	0.55 (15)	0.37 (18)	0.85 (35)	–	–	–	0.85 (75)	0.76 (68)
Test–retest[c]	0.84 (17)	–	–	–	–	–	–	–	–	–	–	–
	0.76 (10)	–	–	–	–	–	–	–	–	–	–	–
Validity[d]												
DEMQOL	–	0.40 (16)	0.45 (16)	0.40 (16)	0.29 (15)	–0.40 (18)	0.55 (36)	0.24 (54)	0.67 (54)	–0.18 (69)	–0.11 (71)	–0.28 (65)
	–	0.40 (16)	0.45 (16)	0.40 (16)	0.29 (15)	–0.40 (18)	0.54 (33)	0.28 (50)	0.65 (50)	–0.23 (62)	–0.17 (64)	–0.28 (58)
DQOL SE	–	–	–	–	–	–	–	0.31 (15)	–0.30 (15)	–0.03 (17)	–0.38 (17)	0.24 (15)
self-esteem	–	–	–	–	–	–	–	0.31 (15)	–0.30 (15)	–0.03 (17)	–0.38 (17)	0.24 (15)
DQOL PA	–	–	–	–	–	–	–	–0.35 (15)	–0.23 (15)	0.05 (16)	–0.16 (16)	–0.32 (14)
positive affect	–	–	–	–	–	–	–	–0.35 (15)	–0.23 (15)	0.05 (16)	–0.16 (16)	–0.32 (14)
DQOL NA	–	–	–	–	–	–	–	–0.44 (15)	0.68 (15)	–0.48 (16)	0.26 (16)	–0.25 (14)
absence of negative affect	–	–	–	–	–	–	–	–0.44 (15)	0.68 (15)	–0.48 (16)	0.26 (16)	–0.25 (14)
DQOL FB	–	–	–	–	–	–	–	0.04 (14)	–0.23 (14)	0.21 (15)	–0.30 (15)	–0.24 (13)
feelings of belonging	–	–	–	–	–	–	–	0.04 (14)	–0.23 (14)	0.21 (15)	–0.30 (15)	–0.24 (13)
DQOL SA	–	–	–	–	–	–	–	–0.04 (16)	–0.28 (16)	0.32 (18)	–0.18 (18)	0.39 (16)
sense of aesthetics	–	–	–	–	–	–	–	–0.04 (16)	–0.28 (16)	0.32 (18)	–0.18 (18)	0.39 (16)
QOLAD-PWD	–	–	–	–	–	–	–	0.72 (26)	0.69 (26)	0.36 (39)	–0.11 (38)	0.40 (35)
	–	–	–	–	–	–	–	0.73 (24)	0.66 (24)	0.14 (34)	–0.09 (33)	0.23 (30)
SF-12 PCS-PWD	–	–	–	–	–	–	–	–	–	0.05 (50)	–0.25 (51)	0.45 (47)
	–	–	–	–	–	–	–	–	–	–0.11 (46)	–0.25 (47)	0.39 (43)
SF-12 MCS-PWD	–	–	–	–	–	–	–	–	–	–0.08 (50)	–0.13 (51)	–0.10 (47)
	–	–	–	–	–	–	–	–	–	–0.17 (46)	–0.16 (47)	–0.18 (43)
Age, PWD	0.36 (75)	0.63 (17)	–0.15 (16)	0.46 (16)	–0.29 (15)	–0.08 (18)	0.54 (40)	0.32 (54)	0.32 (54)	–0.07 (87)	–0.16 (96)	0.05 (88)
	0.39 (68)	0.63 (17)	–0.15 (16)	0.46 (16)	–0.29 (15)	–0.08 (18)	0.57 (35)	0.33 (50)	0.35 (50)	–0.17 (67)	–0.14 (75)	0.03 (68)
Gender, PWD[e]	ns	ns	ns	ns	ns	$p < 0.05$	ns	ns	ns	ns	ns	ns
	ns	ns	ns	ns	ns	$p < 0.05$	ns	ns	ns	ns	ns	ns
Social class[f]	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns
	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns	ns

[a] Whole sample, first line; mild/moderates (MMSE ≥ 10), second line.
[b] Cronbach's alpha.
[c] Intra-class correlation.
[d] Pearson correlation.
[e] *t*-Test.
[f] One-way ANOVA.
ns, not significant.

TABLE 15 *Descriptive statistics: DEMQOL and other HRQoL measures – person with dementia*

		Whole sample Total PWD *n* = 101	Mild/moderate subsample[a] Total PWD *n* = 79	Severe subsample[b] Total PWD *n* = 22[c]
DEMQOL	Mean (SD)	91.22 (11.11)	91.12 (11.21)	–
	Range (*n*)	63–108 (75)	63–108 (68)	–
QOLAD-PWD	Mean (SD)	34.94 (5.68)	35.72 (5.62)	–
	Range (*n*)	24–45 (40)	24–45 (35)	–
DQOL self-esteem	Mean (SD)	3.35 (0.96)	3.35 (0.96)	–
	Range (*n*)	1–4.75 (17)	1–4.75 (17)	–
DEMQOL positive affect	Mean (SD)	3.61 (0.77)	3.61 (0.77)	–
	Range (*n*)	2–4.67 (16)	2–4.67 (16)	–
DQOL absence of negative affect	Mean (SD)	2.53 (0.72)	2.53 (0.72)	–
	Range (*n*)	1.36–4.27 (16)	1.36–4.27 (16)	–
DQOL feelings of belonging	Mean (SD)	3.72 (0.77)	3.72 (0.77)	–
	Range (*n*)	2.33–5 (15)	2.33–5 (15)	–
DQOL sense of aesthetics	Mean (SD)	3.70 (0.71)	3.70 (0.71)	–
	Range (*n*)	2.4–5 (18)	2.4–5 (18)	–
SF-12 PCS-PWD	Mean (SD)	46.28 (9.70)	46.58 (9.55)	–
	Range (*n*)	21.57–60.71 (54)	21.57–60.71 (50)	–
SF-12 MCS-PWD	Mean (SD)	47.17 (11.09)	47.27 (10.84)	–
	Range (*n*)	23.85–66.46 (54)	23.85–63.39 (50)	–

[a] MMSE ≥ 10.
[b] MMSE <10.
[c] Valid *n* too low to complete analysis in sample of people with severe dementia.

association was in the wrong direction. DEMQOL was moderately highly correlated with the SF-12 MCS score, but the correlation with PCS was lower, reflecting the emphasis in DEMQOL on psychosocial aspects of HRQoL. The data do not support the hypothesised relationship between DEMQOL and proxy-reported depression or disability; the correlation with GDS-30 was low and the correlation with Barthel was in the wrong direction. Results indicate moderate convergent validity.

Discriminant validity
DEMQOL was moderately correlated with age, but did not differ significantly with gender or social class, thus providing some support for discriminant validity.

Known groups differences
Due to the small number of cases with severe dementia, known groups differences for DEMQOL could not be evaluated (*Table 15*).

Factor analysis
Table 16 presents the four-factor model for DEMQOL. This solution accounts for 43.3% of the variance, but is conceptually less clear than the model in the preliminary field test. Factors are difficult to interpret. Four items did not load ≥ 0.40 on any factor and two other items loaded (≥ 0.40) on more than one factor. Only two of the six questionable items (fed up and getting to the toilet in time) were also queried in the preliminary field test. As removal of these six items would have necessitated an additional field test (to test the psychometric properties of the further item-reduced version), this was not feasible within the timescale available. Further analyses requesting two, three, five, six, seven and eight factors did not yield satisfactory alternative models.

Responsiveness

The responsiveness of DEMQOL and DEMQOL-Proxy could not be tested in this study. The intention had been to evaluate responsiveness by using DEMQOL in a planned HTA trial of antidementia medication, but this trial did not take place. Because of the lack of additional resource for the follow-up element of the study, 3-month follow-up data could only be collected on 14 cases, which was insufficient to evaluate responsiveness (see the section 'Participants', p. 39).

Discussion

This study was able to validate DEMQOL in people with mild/moderate (MMSE ≥ 10) but not

TABLE 16 *Factor loadings, four-factor model: DEMQOL*

Item number[a]/description	Factor 1	Factor 2	Factor 3	Factor 4
1. cheerful	0.065	–0.085	0.083	**0.460**
2. worried or anxious	**0.509**	0.279	0.335	0.057
3. [b]enjoying life	–0.058	0.231	0.332	0.350
4. frustrated	0.386	0.096	**0.617**	0.039
5. confident	0.067	–0.107	0.335	**0.514**
6. full of energy	–0.021	–0.119	0.272	**0.435**
7. sad	0.120	0.025	**0.682**	0.183
8. lonely	–0.151	**0.476**	0.321	0.047
9. distressed	**0.447**	0.137	0.371	0.230
10.[b]lively	0.114	0.003	0.293	0.115
11. irritable	0.063	0.021	**0.712**	–0.012
12.[c]fed-up	0.200	0.245	**0.405**	**0.484**
13.[b]things wanted to do but couldn't	0.340	0.130	0.180	0.107
14. forgetting things that happened recently	**0.742**	0.007	0.063	0.182
15. forgetting who people are	**0.621**	0.078	0.221	0.031
16. forgetting what day it is	**0.686**	0.134	–0.067	–0.020
17. muddled thoughts	**0.643**	–0.020	0.202	0.174
18. difficulty making decisions	**0.615**	0.100	0.121	0.390
19. poor concentration	**0.586**	0.086	0.120	–0.163
20. not having enough company	0.077	**0.729**	0.104	–0.046
21. [c]how you get on with people close to you	**0.524**	**0.444**	–0.029	–0.336
22. getting the affection you want	0.255	**0.479**	–0.012	–0.324
23. people not listening	0.207	**0.625**	0.034	0.114
24. making self understood	**0.604**	0.339	0.030	0.062
25. getting help when you need it	0.281	**0.711**	–0.129	0.057
26. [b]getting to the toilet in time	0.350	0.116	–0.198	0.302
27. how you feel in yourself	0.281	**0.416**	0.141	0.390
28. health overall	0.182	0.321	–0.164	**0.696**

[a] Item numbers refer to the item-reduced version of DEMQOL in Appendix 4A.
[b] Item does not load ≥ 0.4 on any factor.
[c] Item cross-loads (≥ 0.4) on two factors.

severe dementia. In this group, DEMQOL demonstrates good acceptability, internal consistency and test–retest reliability, and shows modest evidence of convergent and discriminant validity, but responsiveness needs to be evaluated. There is little support for subscales.

Findings confirm the psychometric strengths of DEMQOL. First, the high reliability of DEMQOL is encouraging. The results confirm that people with mild/moderate dementia are able to provide reliable self-reports. Second, on the most robust tests of convergent validity, DEMQOL fares well compared with other dementia-specific instruments. DEMQOL is associated with both the QOLAD and SF-12, and to a lesser extent DQOL, thus providing modest evidence of convergent validity.

However, DEMQOL also shows some psychometric limitations. First, the reliability of self-reports of people with severe dementia (MMSE <10) could not be evaluated. Second, even in the mild/moderate sample scores could not be computed for a significant minority of people (14%) owing to missing data. Third, correlations with other dementia-specific HRQoL instruments (DQOL and QOLAD) were lower than expected, suggesting that these three instruments may measure related but different constructs. Fourth, exploratory convergent validity hypotheses concerning the relationship between dementia-specific measures and disability and depression were not supported. Finally, responsiveness was not evaluated.

When compared with existing dementia-specific HRQoL measures, DEMQOL fares well. In terms of the strength of its psychometric properties, DEMQOL is comparable to QOLAD and both instruments show some advantage over DQOL. However, the fact that convergent validity evidence is not as clear as expected (based on comparisons between the three dementia-specific HRQoL measures, as well as with a generic HRQoL measure and measures of disability, depression and well-being) illustrates some of the difficulties in validating new measures of HRQoL in dementia.

First, although DEMQOL, QOLAD and DQOL all purport to measure dementia-specific HRQoL, results of validity analyses in this sample show that the three measures are not as highly correlated as expected, suggesting that they may be measuring different aspects of dementia-related HRQoL. However, the available *n* for these comparisons was relatively small. Second, the analyses have uncovered some psychometric weaknesses in the validating measures, particularly DQOL, when applied to this UK sample. For DQOL, missing data are high (although possibly partly due to error in administration), two scales demonstrate low internal consistency and validity evidence is mixed. QOLAD generally performs better, but shows a different pattern of validity compared with DQOL and to a lesser extent DEMQOL. As the SF-12, Barthel, GDS and GHQ have not been validated for use with people with dementia, the psychometric properties of these validating measures in people with dementia are unknown. An element of the variation observed may therefore lie in measurement error in the validating instruments. With so few dementia-specific and other measures that have been validated for use in dementia available for evaluating the validity of new measures, the construct validation process remains inherently limited.

These findings reveal some of the psychometric limitations in validating measures of HRQoL in dementia. Interpretation of the validity evidence for DEMQOL is limited by the psychometric strengths and weaknesses of the validating measures. That is, lower than expected convergent validity correlations may be due to inherent psychometric weaknesses in DEMQOL or the validating measures.

The higher than usual non-completion rates for DEMQOL and the other two dementia-specific HRQoL measures point to the limitations in using self-report questionnaires even with people with mild/moderate dementia. This is not surprising, given the cognitive limitations of people with dementia and the length and complexity of the questionnaires.

The desire to maximise reliability and validity while minimising respondent burden leads to a consideration of content validity. Some questionnaire items identified in the qualitative phase were subsequently eliminated during item reduction. Removal of these items meant that some of the domains in the conceptual framework did not produce empirically distinct subscales, but did improve the psychometric properties of DEMQOL. Therefore, a balance between reliability and validity was achieved by retaining items that, the authors believe, represent four of the five originally hypothesised domains, by eliminating redundancy and removing items which performed poorly.

Overall, DEMQOL shows psychometric properties that are as strong as the best available existing dementia-specific HRQoL measures. In this sample, DEMQOL and QOLAD show somewhat better psychometric properties than DQOL.

Psychometric evaluation of DEMQOL-Proxy

Respondent characteristics

The sample included 99 carers (*Table 17*). DEMQOL-Proxy was validated separately for patients with mild/moderate (MMSE ≥ 10; $n = 77$) and severe (MMSE <10; $n = 22$) dementia. In the mild/moderate sample, the mean age of carers was 68 (range 42–87 years) and two-thirds (65%) were female. The majority of carers were spouses of the person with dementia (66%) and one-quarter (26%) were sons or daughters (in-law). The remainder were friends (5%), other (2%) or siblings (1%).

The mean age of carers in the severe sample was lower (66 years; range 42–87 years) than in the mild/moderate sample and just over half (55%) were female. The majority of carers (55%) were spouses and about one-third (32%) were sons or daughters (in-law). The remainder were other relatives (9%) or other (5%). Social class, assessed for the household of the person with dementia, is reported earlier in this chapter (section 'Respondent characteristics', p. 45).

Concurrent evaluation of QOLAD-Carer

QOLAD-Carer showed good acceptability (*Table 18*). Missing data were at or below the accepted criterion for people with mild/moderate and severe dementia. Floor/ceiling effects and skew were within the acceptable range for both subsamples.

Internal consistency for QOLAD-Carer was high in people with mild/moderate dementia (*Table 19*), but fell short of the standard criterion for people with severe dementia.

QOLAD-Carer was moderately correlated with DEMQOL-Proxy in the mild/moderate subsample, but had a lower association in the severe subsample. QOLAD-Carer was not associated with age (of the person with dementia or the carer), gender or social class, but was significantly

TABLE 17 *Respondent characteristics: DEMQOL-Proxy – carers*

		Whole sample Total PWD *n* = 101 Total carer *n* = 99	Mild/moderate subsample[a] Total PWD *n* = 79 Total carer *n* = 77	Severe subsample[b] Total PWD *n* = 22 Total carer *n* = 22
Cover				
Age (years)	Mean(SD)	67.51 (11.60)	67.96 (11.15)	65.91 (13.21)
	Range (*n*)	42–87 (99)	42–87 (77)	42–87 (22)
Gender	Male	37 (37.4)	27 (35.1)	10 (45.4)
	Female	62 (62.6)	50 (64.9)	12 (54.5)
Relationship to patient				
Spouse	*n* (%)	63 (63.6)	51 (66.2)	12 (54.5)
Son/daughter (in-law)	*n* (%)	27 (27.2)	20 (26)	7 (31.8)
Sibling	*n* (%)	1 (1)	1 (1.3)	0 (0)
Other relative	*n* (%)	2 (2)	0 (0)	2 (9.1)
Friend/neighbour	*n* (%)	4 (4)	4 (5.2)	0 (0)
Other	*n* (%)	2 (2)	1 (1.3)	1 (4.5)
GHQ-12	Mean (SD)	3.35 (3.24)	3.31 (3.30)	3.50 (3.09)
	Range (*n*)	0–12 (90)	0–12 (70)	0–9 (20)

[a] MMSE ≥ 10.
[b] MMSE <10.

TABLE 18 *Acceptability: DEMQOL-Proxy and other HRQoL measures – carers*

	Score range			Floor/ceiling effect		
Scale	**% Missing**	**Scale**	**Sample**	**% Floor**	**% Ceiling**	**Skew**
Whole sample[a]						
DEMQOL-Proxy	1	31–124	55.8–118.83	0	0	–0.48
QOLAD-Carer	3.5	13–52	14.3–45	0	0	0.16
SF-12 PCS-Carer	28.6	0–100	12.77–56.52	0	0	–0.70
SF-12 MCS-Carer	28.6	0–100	19.32–60.57	0	0	–0.20
Mild/moderate (MMSE ≥ 10) subsample (*n* = 77)[b]						
DEMQOL-Proxy	2.5	31–124	55.8–118.83	0	0	–0.53
QOLAD-Carer	5	13 – 52	15.6–45	0	0	0.04
SF-12 PCS-Carer	24.3	0 – 100	13.48–56.52	0	0	–0.56
SF-12 MCS-Carer	24.3	0 – 100	19.32–60.45	0	0	–0.36
Severe (MMSE <10) subsample (*n* = 22)[c]						
DEMQOL-Proxy	4.5	31–124	56.83–118	0	0	–0.48
QOLAD-Carer	0	13–52	14.30–35	0	0	–0.46
SF-12 PCS-Carer	60	0–100	12.77–49.38	0	0	[d]
SF-12 MCS-Carer	60	0–100	25.46–60.57	0	0	[d]

[a] DEMQOL *n* = 99; SF-12 *n* = 42; QOLAD-Carer *n* = 57.
[b] DEMQOL *n* = 79; SF-12 *n* = 37; QOLAD-Carer *n* = 40.
[c] DEMQOL *n* = 22; SF-12 *n* = 5; QOLAD-Carer *n* = 17.
[d] Too few cases to compute.

affected by the gender of the person with dementia in the severe subsample. There was also a weak association between QOLAD-Carer and carers' psychological well-being (GHQ-12).

In summary, QOLAD-Carer performed better in people with mild/moderate than severe dementia. In the mild/moderate subsample, QOLAD-Carer demonstrated internal consistency and validity, whereas in the severe subsample QOLAD-Carer showed lower internal consistency and validity.

The following sections describe the psychometric properties of DEMQOL-Proxy.

Acceptability

As shown in *Table 18*, DEMQOL-Proxy met all criteria for acceptability in people with mild/moderate and severe dementia.

Reliability

Internal consistency

Cronbach's alpha for DEMQOL-Proxy exceeded the acceptable criterion (*Table 19*) in both the mild/moderate and severe subsamples. Item–total ranged from 0.02 to 0.68 (mean inter-item correlations 0.18) in people with mild/moderate dementia and 0.11 to 0.76 (mean inter-item correlations 0.28) in people with severe dementia.

Test-retest reliability

Test–retest reliability fell just short of the criterion for people with mild/moderate dementia. Examination of the scatterplot revealed that the low correlation was due to a single outlier. The test–retest correlation increased to 0.82 when this case was removed. Test–retest reliability met the criterion in the severe sample, but there were only five cases in this sample.

Validity

Content validity

As for DEMQOL, content validity of DEMQOL-Proxy was achieved by using a systematically derived conceptual framework to generate questionnaire content (see Chapter 3). Although the item-reduced version of DEMQOL-Proxy includes more physical items than DEMQOL, it still includes more items relating to mental than to physical well-being. All five conceptual domains are represented, but for one domain (self-concept) there is only one item.

Construct validity

Convergent validity

DEMQOL-Proxy was moderately correlated with QOLAD-Carer in people with mild/moderate dementia and more weakly associated in people with severe dementia. In people with mild/moderate dementia, DEMQOL-Proxy showed a moderately low correlation with SF-12 MCS scores and a low correlation with PCS scores. There were too few cases in the severe subsample to examine the association between DEMQOL-Proxy and the SF-12 (*Table 19*).

In people with mild moderate/dementia, DEMQOL-Proxy was moderately highly correlated with proxy-reported depression (GDS-30), but was not associated with disability (Barthel). In the severe group, DEMQOL-Proxy was highly correlated with proxy-reported depression, but was not associated with disability.

Discriminant validity

DEMQOL-Proxy was moderately correlated with the age of the person with dementia, but not of carers. It was not significantly affected by gender (of the person with dementia or carer) or social class. DEMQOL-Proxy was weakly associated with carers' psychological well-being (GHQ-12).

Known groups differences

As shown in *Table 20*, people with severe dementia show marginally better HRQoL than those with mild/moderate dementia (effect size = –0.10). In comparison, people with severe dementia showed poorer HRQoL as measured by SF-12 PCS (effect size = 0.92) and QOLAD-Carer (effect size = 0.63), but slightly better HRQoL as measured by SF-12 MCS (effect size = –0.16).

Factor analysis

Table 21 presents the two-factor model for DEMQOL-Proxy with people with mild/moderate dementia. There were too few cases to run an equivalent analysis in people with severe dementia. The two-factor solution accounted for 33.3% of the variance, but is conceptually weak. Although the two-factor model is similar to that obtained in the preliminary field test, it includes five items that do not load at least 0.40 on any factor. Only one of these items was queried in the preliminary field test, indicating that the two-factor solution may not be robust. Further analyses requesting two, three, five, six, seven and eight factors did not yield satisfactory alternative models.

Responsiveness

For the reasons discussed in the psychometric evaluation of DEMQOL, an evaluation of the responsiveness of DEMQOL-Proxy could not be completed.

Correlation with DEMQOL

Correlations between DEMQOL and DEMQOL-Proxy overall scores were moderate for people with mild/moderate dementia ($r = 0.36$; $n = 66$) and low for people with severe dementia ($r = –0.15$; $n = 7$).

Discussion

This study was able to validate DEMQOL-Proxy in people with mild/moderate and severe dementia. However, given the small sample size of people with severe dementia, further evidence is needed to confirm the results reported here. In people with mild/moderate and severe dementia, DEMQOL-Proxy demonstrates good acceptability and internal consistency. Results for test–retest

TABLE 19 *Reliability and validity: DEMQOL-Proxy and other HRQoL measures – carers*

	DEMQOL-Proxy (*n*)[a]	QOLAD-Carer (*n*)	SF-12 PCS-Carer (*n*)	SF-12 MCS-Carer (*n*)	MMSE (*n*)	GDS-30 (*n*)	Barthel (*n*)	Carer GHQ-12 (*n*)
Reliability								
Internal consistency[b]	0.89 (98)	0.84 (55)	–	–	–	0.85 (96)	0.86 (88)	0.86 (90)
	0.87 (77)	0.86 (38)	–	–	–	0.85 (75)	0.76 (68)	0.87 (70)
	0.92 (21)	0.64 (17)	–	–	–	0.85 (21)	0.85 (20)	0.80 (20)
Test-retest[c]	0.75 (23)	–	–	–	–	–	–	–
	0.67 (13)[e]	–	–	–	–	–	–	–
	0.84 (5)	–	–	–	–	–	–	–
Validity[d]								
DEMQOL-Proxy	–	0.44 (55)	0.06 (30)	0.41 (30)	–0.03 (84)	–0.66 (96)	–0.01 (87)	–0.21 (90)
	–	0.52 (38)	0.20 (28)	0.32 (28)	–0.11 (65)	–0.61 (75)	–0.05 (68)	–0.21 (70)
	–	0.29 (17)	Too few cases	Too few cases	0.13 (19)	–0.81 (21)	0.09 (19)	–0.24 (20)
QOLAD-Carer	–	–	–	–	0.45 (48)	–0.59 (55)	0.40 (48)	–0.29 (53)
	–	–	–	–	0.28 (33)	–0.67 (38)	0.35 (33)	–0.36 (36)
	–	–	–	–	0.45 (15)	–0.43 (17)	0.31 (15)	–0.20 (17)
SF-12 PCS-Carer	–	–	–	–	0.31 (25)	–0.51 (30)	0.61 (27)	–0.22 (29)
	–	–	–	–	0.12 (23)	–0.58 (28)	0.70 (25)	–0.11 (27)
	–	–	–	–	Too few cases	Too few cases	Too few cases	Too few cases
SF-12 MCS-Carer	–	–	–	–	0.04 (25)	–0.67 (30)	0.10 (27)	–0.05 (29)
	–	–	–	–	0.21 (23)	–0.71 (28)	0.09 (25)	–0.17 (27)
	–	–	–	–	Too few cases	Too few cases	Too few cases	Too few cases
Age, PWD	0.33 (98)	0.10 (55)	–0.02 (30)	–0.35 (30)	–0.07 (87)	–0.16 (96)	0.05 (88)	–0.18 (90)
	0.34 (77)	0.18 (38)	–0.12 (28)	–0.30 (28)	–0.17 (67)	–0.14 (75)	0.03 (68)	–0.20 (70)
	0.32 (21)	–0.23 (17)	Too few cases	Too few cases	0.20 (20)	–0.22 (21)	0.12 (20)	–0.06 (20)
Gender, PWD	ns	ns	ns	ns	ns	ns	ns	$p < 0.001$
	ns	ns	ns	ns	ns	ns	ns	$p < 0.001$
	ns	$p < 0.05$	Too few cases	Too few cases	ns	ns	ns	ns
Age, carer	–0.02 (98)	0.17 (55)	–0.01 (30)	0.10 (30)	0.21 (85)	–0.09 (96)	0.05 (88)	–0.04 (90)
	0.01 (77)	0.14 (38)	–0.04 (28)	0.17 (28)	0.31 (65)	–0.19 (75)	–0.02 (68)	–0.17 (70)
	–0.09 (21)	0.15 (17)	Too few cases	Too few cases	0.16 (20)	0.26 (21)	0.13 (20)	0.22 (20)
Gender, carer[e]	ns	ns	ns	ns	ns	ns	ns	$p < 0.05$
	ns	ns	ns	ns	ns	ns	ns	$p < 0.05$
	ns	ns	Too few cases	Too few cases	ns	ns	ns	ns
Social class[f]	ns	ns	ns	ns	ns	ns	ns	ns
	ns	ns	ns	ns	ns	ns	ns	ns
	ns	ns	Too few cases	Too few cases	ns	ns	ns	ns

[a] Whole sample, first line; mild/moderate (MMSE ≥ 10), second line; severe (MMSE <10), third line.
[b] Cronbach's alpha.
[c] Intraclass correlation.
[d] Pearson correlation.
[e] *t*-Test.
[f] One-way ANOVA.
ns, not significant.

TABLE 20 *Descriptive statistics: DEMQOL-Proxy and other HRQoL measures – carers*

		Whole sample Total Carer *n* = 99	Mild/moderate subsample[a] Total carer *n* = 77	Severe subsample[b] Total carer *n* = 22
DEMQOL-Proxy	Mean (SD) Range (*n*)	92.41 (13.65) 55.8–118.83 (98)	92.14 (12.92) 55.8–118.83 (77)	93.39 (16.37) 56.83–118.00 (21)
QOLAD-Carer	Mean (SD) Range (*n*)	28.97 (6.55) 14.3–45 (55)	30.30 (6.76) 15.6–45 (38)	26.01 (5.07) 14.3–35 (17)
SF-12 PCS-Carer	Mean (SD) Range (*n*)	40.89 (12.29) 12.77–56.52 (30)	41.59 (11.40) 13.48–56.52 (28)	31.07 (25.89) 12.77–49.38 (2)
SF-12 MCS-Carer	Mean (SD) Range (*n*)	41.47 (10.77) 19.32–60.57 (30)	41.36 (10.08) 19.32–60.45 (28)	43.01 (24.83) 25.46–60.57 (2)

[a] MMSE ≥ 10.
[b] MMSE <10.

TABLE 21 *Factor loadings, two-factor model: DEMQOL-Proxy*

Summary description of item[a]	Factor 1	Factor 2
1. cheerful	–0.065	**0.678**
2. worried or anxious	0.189	**0.562**
3. frustrated	0.373	**0.409**
4. full of energy	–0.255	**0.421**
5. sad	0.015	**0.590**
6. content	–0.028	**0.598**
7. distressed	0.192	**0.779**
8. lively	–0.019	**0.551**
9. irritable	0.058	**0.584**
10. fed-up	0.135	**0.609**
11. [b]having things to look forward to	–0.035	0.362
12. memory in general	**0.530**	0.146
13. [b]forgetting things that happened long ago	0.367	0.028
14. forgetting things that happened recently	**0.594**	–0.068
15. forgetting people's names	**0.656**	–0.014
16. forgetting where he/she is	**0.474**	–0.027
17. forgetting what day it is	**0.713**	0.029
18. thoughts being muddled	**0.648**	0.050
19. difficulty making decisions	**0.597**	–0.038
20. making self understood	**0.549**	0.215
21. keeping self clean	**0.447**	0.044
22. [b]keeping self looking nice	0.255	–0.030
23. getting what want from shops	**0.653**	–0.044
24. using money to pay for things	**0.409**	–0.221
25. looking after finances	**0.606**	0.075
26. things taking longer than they used to	**0.564**	0.186
27. getting in touch with people	**0.578**	0.195
28. [b]not having enough company	0.133	0.397
29. not being able to help other people	**0.653**	–0.024
30. not playing a useful part in things	**0.698**	0.238
31. [b]physical health	0.356	0.265

[a] Item numbers refer to the item-reduced version of DEMQOL in Appendix 4B.
[b] Item does not load ⩾0.4 on any factor.

reliability are encouraging, but need further evaluation. Evidence for convergent and discriminant validity is generally moderate but mixed. In terms of convergent validity, DEMQOL-Proxy was correlated with QOLAD-Carer, but not as highly as expected, and with SF-12 MCS but not PCS, and was associated with proxy-reported depression but not disability. In terms of discriminant validity, DEMQOL-Proxy was moderately correlated with the age of the person with dementia and weakly associated with carers' psychological well-being, but not with the age of carers or with gender (person with dementia or carer) or social class. Evidence of convergent validity (QOLAD-Carer) was weaker in the severe subsample. The responsiveness of DEMQOL-Proxy has not been evaluated. There is little support for subscales.

The associations between DEMQOL-Proxy and the validating measures are broadly similar to the pattern for DEMQOL. One exception is that unlike DEMQOL, DEMQOL-Proxy and QOLAD-Carer are both correlated with proxy-reported depression. This may reflect method bias as both are proxy reported. It is possible that carers are not able to give accurate reports on behalf of the person with dementia about subjective aspects of well-being such as HRQoL and depression. Alternatively, it may be that proxy reports are more accurate than self-reports in this patient group.

DEMQOL-Proxy was not associated with disability (Barthel), but QOLAD-Carer and SF-12 PCS were. This is expected, given the low proportion of physical items in DEMQOL-Proxy relative to QOLAD-Carer and SF-12 PCS.

Although DEMQOL-Proxy was correlated with QOLAD-Carer, the convergent validity correlation between the two dementia-specific measures was lower than expected. This suggests that the two instruments are measuring related but not the same constructs. DEMQOL-Proxy was also correlated with SF-12 PCS but not MCS, but there was no similar comparison between QOLAD-Carer and SF-12.

Overall, DEMQOL-Proxy shows reasonable psychometric properties in people with mild/moderate dementia that are as strong as the best available proxy measure. Findings are also promising for people with severe dementia, but these results need to be confirmed in a larger sample. DEMQOL-Proxy provides an evaluation of carers' views about how they believe the person with dementia would report on their own HRQoL, but assesses a different aspect of outcome than does DEMQOL.

Chapter 7
Discussion

Summary

A method has been developed for measuring HRQoL in dementia that comprises two measures, one for the person with dementia (DEMQOL) and a companion measure completed by carers (DEMQOL-Proxy). Rigorous, best practice methods were used throughout the development and validation of both measures.

Gold-standard psychometric techniques were used to develop DEMQOL and DEMQOL-Proxy. First, a conceptual framework was generated from themes generated from a review of the literature, in-depth qualitative interviews with people with dementia and their carers, expert opinion and team discussion. The conceptual framework included five domains: daily activities and looking after yourself, health and well-being, cognitive functioning, social relationships and self-concept. Items for each component of the conceptual framework were drafted and piloted to produce questionnaires for the person with dementia (DEMQOL) and carer (DEMQOL-Proxy). The preliminary field test versions of DEMQOL and DEMQOL-Proxy contained 73 questions representing the five domains and a global question about overall quality of life.

Extensive two-stage field testing was undertaken of both measures in large samples of people with dementia and their carers, representing a range of severity and care arrangements. In the first field test (n = 130 people with dementia, n = 126 carers) items with poor psychometric performance were eliminated separately for DEMQOL and DEMQOL-Proxy to produce two shorter, more scientifically robust instruments. Item reduction analyses resulted in a 28-item DEMQOL and 31-item DEMQOL-Proxy. In the second field test, the item reduced questionnaires were evaluated along with other validating measures (n = 101 people with dementia, n = 99 carers) to assess acceptability, reliability and validity.

Rigorous evaluation with 241 people with dementia and 225 carers demonstrated that in psychometric terms: (1) DEMQOL is comparable to the best available dementia-specific HRQoL measures in mild to moderate dementia, but is not appropriate for use in severe dementia (MMSE <10); and (2) DEMQOL-Proxy is comparable to the best available proxy measure in mild to moderate dementia, and shows promise in severe dementia. Other features of the DEMQOL system are that it: (1) has been validated in the UK in a large sample of people with dementia and their carers; and (2) provides separate measures for self-report and proxy-report, which allows outcomes assessment across a wide range of severity in dementia.

Conceptual and methodological challenges in validating dementia-specific HRQoL measures

HRQoL in dementia: whose perspective?

There is no universally accepted definition of HRQoL, despite the growing interest in this concept and its increasing use in clinical studies. This study used Bullinger and colleagues' definition:[52] "… the impact of a perceived health state on an individual's potential to live a subjectively fulfilling life". Central to this and most definitions is that HRQoL reflects an individual's subjective perceptions. At all stages of the development and validation of the new measures, the perspective of the person with dementia was kept central.

The researchers were aware from the start that this definition raised some difficult issues in the context of dementia. Dementia is a multifaceted condition characterised by a progressive loss of abilities across the whole range of cognitive functions. In particular, loss of memory, insight and judgement, perception of time, ability to reflect, abstract and communicate may make it difficult to give a valid subjective perception. Moreover, the extent to which reliable and valid self-report can be achieved is likely to vary over time as the dementia progresses.

To avoid presuppositions, these assumptions were checked empirically during interviews. It was not possible to elicit information from some people with severe dementia, because of cognitive

impairment, poor concentration and, in some cases, somnolence. In the majority of cases, however, is was possible to elicit useful data from people with dementia. This is an important finding in itself. Moreover, there was reasonable consensus about the important domains of HRQoL.

It became clear, however, that there were differences in the way people that with dementia and their carers perceived HRQoL. People with dementia tended to concentrate on the 'here and now' and were inclined to be concrete in their thinking and examples. However, they tended to be positive, were accepting of their limitations and compared themselves, often favourably, with others. Carers were more reflective, emphasised how things had changed, were more negative, and described limitations and their own frustrations. These systematic differences, and the impairments inherent in dementia, are likely to account for the next important finding: that different items were needed for the measures developed for the person with dementia (DEMQOL) and carers (DEMQOL-Proxy). This need for separate item reduction and selection raises questions concerning other dementia-specific instruments in which the same questions are used to assess HRQoL in people with dementia and family carers.

HRQoL was measured from more than one perspective to take account of these intrinsic and fundamental difficulties. The moderately low correlation between DEMQOL and DEMQOL-Proxy indicates that the differences in perspective between people with dementia and their carers illustrated in the qualitative data are supported by the quantitative data. This is contrary to the findings of Sneeuw and colleagues,[97] who suggest that, in general, moderate to high levels of patient–proxy agreement can be achieved and proxy ratings are reasonably accurate. However, examination of the data suggests that this result may be influenced by a small proportion of respondents whose self-reports indicated very good HRQoL, in contrast to proxy reports of relatively poor HRQoL. The authors recommend that DEMQOL and DEMQOL-Proxy should be used together.

Validating dementia-specific HRQoL measures

The measurement system developed in this study has psychometric properties that are as strong as the best available scales. Nevertheless, validity evidence for all dementia-specific HRQoL measures, including DEMQOL, DEMQOL-Proxy, QOLAD and DQOL, must be interpreted with some caution. This is because of the inherent difficulty in differentiating HRQoL from related constructs such as disability, depression and carer well-being in dementia. Such gaps in knowledge about the nomological net for the construct of HRQoL in dementia limit the ability to develop strong hypotheses to evaluate construct validity.

Study strengths

DEMQOL and DEMQOL-Proxy were rigorously developed and validated using gold-standard psychometric methods. The questionnaire was developed using a systematically derived conceptual framework, carefully pre-tested items and response scales, and well-established tests and criteria were used for item reduction and to evaluate psychometric properties. For DEMQOL, although a more liberal criterion was adopted for missing data during item reduction, this trade-off was considered acceptable in trying to achieve the goal of delivering a reliable and valid *self-report* measure of HRQoL in dementia.

The psychometric evaluation of DEMQOL and DEMQOL-Proxy was carried out in large samples of patients and carers and in a two-stage process of item reduction followed by psychometric evaluation in an independent sample. Another unique aspect of this study was that DEMQOL and DEMQOL-Proxy were validated on community samples of people with dementia and carers recruited from secondary care (79% were living in owned or rented flats or houses and 21% were living in residential, nursing, sheltered or dual-registered homes).

The perspective of the person with dementia was kept central in developing the content of the questionnaire. Questions and response scales were presented in a format that is easy for people with dementia to understand and use. The use of a single response scale reduces the cognitive demand for people with dementia, which makes it a user-friendly assessment tool.

There is an inherent tension between reducing respondent burden by using shorter instruments and the importance of maximising reliability and validity. Some of the items that were identified as important in the qualitative phase were eliminated during item reduction. This meant that some aspects of the conceptual framework were not represented in the final, item-reduced instrument, which is why the study was unable to identify meaningful, coherent subscales to support the

conceptual framework. However, removing these items inevitably improved the psychometric performance of the measure. A balance was achieved by retaining items that represented four of the five a priori domains, eliminating redundancy and removing poorly performing items.

Study limitations

Sampling bias

Recruitment was from only two centres in the UK (London and Nottingham), using a sampling frame defined by people in contact with secondary care services. Although this is an efficient sampling method, not all people with dementia are known to their GP and of these only a minority are referred to secondary care. It is therefore unlikely that the study samples are representative of the population of people with dementia.

Although 13% of respondents were from ethnic minority groups, results for this group could not be analysed separately because of the small sample size, so the findings cannot generalise to these groups. The sample included few younger people with dementia, who are generally referred to neurology rather than psychiatry, so results cannot be generalised to people with dementia under 60 years of age. The reliability and validity of DEMQOL has not been established for use with people with severe dementia (MMSE <10) owing to the relatively small numbers with severe dementia in the sample. However, as it was ensured that the perspective of this group was included during all stages of questionnaire development it would be appropriate to evaluate DEMQOL with this group in the future.

Like most other patient-based health outcome measures, DEMQOL and DEMQOL-Proxy are appropriate for use in group comparisons rather than in individual decision-making. The acceptable psychometric properties of both measures confirm their suitability for use in epidemiological studies, clinical trials, audit and service evaluation, but their validity for use in individual decision-making would require further investigation.

Qualitative methods

In the qualitative phase of questionnaire development, in-depth interviews were used to develop and refine the content of the questionnaires. Additional qualitative methods such as focus groups and/or card-sorting exercises with people with dementia and their carers may have provided a further opportunity to triangulate findings. However, the qualitative interviews were continued to the point at which no new themes were emerging to ensure that the conceptual framework adequately covered the relevant domains. The fact that the framework that emerged from the qualitative work showed similarities to other conceptual models of dementia-specific HRQoL supports the adequacy of this qualitative method.

Missing data

Given that the respondents were people with dementia, it was considered justifiable to make two methodological compromises during the quantitative phase to minimise respondent burden while aiming to achieve psychometric rigour. During item reduction, a more liberal criterion for missing data was adopted and data were imputed for missing values. Although item reduction is generally done without imputation to maximise the validity of the item selection, the amount of missing data precluded the use of some of the statistical techniques needed to validate the questionnaire (e.g. item–total correlations and factor analysis). Nevertheless, the amount of missing data for the item-reduced version of DEMQOL is comparable with other dementia-specific measures.

One possible solution to the problem of missing data might be to develop a method for allowing interviewer ratings to be substituted for self-report (as used, for example, in the SHORT-CARE[180]). This would undoubtedly be a compromise, given that HRQoL is an inherently subjective perception. Ultimately, a combination of methods is needed that considers both the subjective perceptions of the person with dementia and the views of proxies and trained observers. A protocol that emphasises strict non-interpretation of responses elicited from the person with dementia may do this less well than one in which well-trained interviewers and observers are permitted to use some judgement in interpreting responses. In the interim, the recommendation to use carer proxy-reports in addition to a self-report compensates to some extent for the limitations in eliciting reliable information from some people with dementia. For this reason, proxy-reports are likely to continue to play an important role in evaluating HRQoL in people with dementia.

Using DEMQOL and DEMQOL-Proxy

The DEMQOL system is designed to be used across the range of severity and types of dementia

and different care arrangements. The instruments and technical information necessary for administration, data entry, coding and scoring are available in a user's manual available on the website of the Institute of Psychiatry (http://hsr.iop.kcl.ac.uk/ageing). The questionnaires should be administered using the guide in Appendix 2. Imputation of missing data can be undertaken provided the case has at least 50% of the items complete. For these cases missing data should be imputed using the person-specific mean of the completed items.[61,122] Cases with less than 50% data complete are excluded. The overall quality of life question is not included in the score for either DEMQOL or DEMQOL-Proxy. All other items are scored 1 (a lot) to 4 (not at all), except for the positive items indicated by asterisks in Appendices 4A and 4B. The positive items should be reverse scored. Scored items are summed to produce a total score. A higher score indicates better HRQoL.

In the large majority of studies, the use of both DEMQOL and DEMQOL-Proxy is recommended as the two systems are complementary. In studies of people with severe dementia, only DEMQOL-Proxy should be used in light of the high proportion of missing data for DEMQOL in people with severe dementia. In mild/moderate dementia, the use of both measures is recommended to maximise data completeness. DEMQOL-Proxy responses should not be substituted for missing DEMQOL responses or vice versa.

Research recommendations

The authors identified a need for further research in three areas: (1) further development and evaluation of DEMQOL and DEMQOL-Proxy; (2) methodological research; and (3) evaluative research. These are listed in order of priority.

Further development and evaluation of DEMQOL and DEMQOL-Proxy

Evaluation of psychometric properties in independent samples

Further psychometric evaluation and replication is a basic requirement for any new instrument. Although all the results require replication, test–retest reliability in particular should be evaluated in a larger sample, and further consideration should be given to the factor structure of the instrument. No support was found for subscales in either DEMQOL or DEMQOL-Proxy, even though the conceptual framework suggested separate domains.

Evaluation of responsiveness

Responsiveness needs to be evaluated in future research. Although the researchers intended to evaluate the responsiveness of DEMQOL in a planned drug trial, they were unable to do so as the trial did not take place. Determining sensitivity to change is essential if the instrument is to be used to evaluate any type of intervention. None of the published measures of HRQoL in dementia has evaluated responsiveness. This is likely to be due to the lack of a treatment of known efficacy in improving HRQoL, a requirement for assessing responsiveness. Clinical trials have demonstrated some improvement with drug treatment in selected outcomes (e.g. disease severity, ADL, global ratings of change), but the effect on HRQoL is largely unknown. In terms of the WHO framework for outcomes assessment,[181] interventions to improve cognitive function are unlikely to have a large effect on activities (person level) or participation (contextual level), whereas psychological or social interventions may have a wider impact on several domains.

Use of DEMQOL-Proxy in severe dementia

People with severe dementia have been largely overlooked in research studies, despite the fact that there are considerable numbers who present a major challenge to health and social services. The greatest detrimental impact on the person with dementia, family carers and society is concentrated in those with severe dementia, who constitute between 17 and 28% of the population of people with dementia over 65.[182] Interventions need to be developed and tested to address their multiple complex needs. Such work requires the development of a quality of life measure for use in severe dementia. There is preliminary evidence that DEMQOL-Proxy has the characteristics of a good measure in this group, but this requires further evaluation. This should include assessment of acceptability, reliability and validity in large samples.

Use of DEMQOL-Proxy with formal carers

This project has focused on using DEMQOL-Proxy with family carers. However, as not all people with dementia have a family carer who could provide a proxy report, it is important to know whether formal and professional carers (e.g. home helps, care staff in residential homes) can make reliable and valid proxy assessments of HRQoL. DEMQOL-Proxy presents an opportunity to investigate this.

Cross-cultural use of DEMQOL and DEMQOL-Proxy

Relatively few of the participants in this study were from minority ethnic groups. Given the cultural

diversity of the UK and the ageing of these minority populations, there is a need to be able to judge the effectiveness of interventions in older people with dementia from minority ethnic groups. Moreover, there is a need for instruments that can be used in cross-national studies such as multicentre randomised controlled trials (RCTs). This requires further work on the translations and cross-cultural adaptation of DEMQOL and DEMQOL-Proxy for use in these groups.

Development of population norms

Population norms for instruments such as DEMQOL and DEMQOL-Proxy facilitate the interpretation of results by allowing comparisons by age, gender, dementia severity, ethnicity and so on. The development of population norms requires data from large, representative samples of the population.

Use of DEMQOL and DEMQOL-Proxy in other groups

There is a strong rationale for specific work to evaluate the instruments in the following groups: people with early-onset dementia (i.e. before the age of 65 years), people with dementia in primary care, people in care homes and people with rare forms of dementia.

Use in economic evaluation

There is a need for an instrument for use in economic evaluations of interventions for people with dementia. As it stands, the number of items and response levels in DEMQOL would generate an unmanageable number of health scenarios. Further work should address the feasibility of generating utility weights for DEMQOL for use in economic evaluation.

Methodological research

Relationship between self-report and proxy-report of HRQoL in dementia

In other medical conditions patient–proxy agreement has been shown to be acceptable;[97] however, dementia is likely to create discrepancies between self-reports and proxy-reports owing to the nature of the condition. The data from this study reveal a number of differences between the reports of HRQoL by people with dementia and their carers that suggest avenues for further research. This needs to include an investigation of the magnitude of the difference between self-reports and proxy reports. Of particular importance are the factors that moderate this relationship, such as severity of dementia, premorbid relationship with carer, type of care arrangement, carer characteristics and domain of quality of life. This requires independent investigation in large samples.

Feasibility of self-report of HRQoL in dementia

There is a need to understand in more detail the effect of dementia severity and other factors affecting the validity of self-report measures of outcomes such as HRQoL. With respect to severity, an MMSE cut-off point of 10 was used to indicate the point below which people could not reliably self-report. This decision was based on cut-points used in previous studies, but none has been empirically validated. This is a difficult area, since for many purposes there will be no valid absolute cut-points. There will be a proportion of misinterpreted, poorly remembered, peculiar or case-specific responses in cognitively normal people. There will be a greater proportion in mild dementia, greater still in moderate dementia, and so on. There will be progressively greater uncertainty about validity as severity progresses, rather than a cut-point at which meaningfulness is lost. This will be a particular problem in longitudinal or long-term follow-up studies regardless of which measures are used. Other factors that are likely to interfere with self-report include dysphasia and lack of insight.

Novel approaches to assessing HRQoL in dementia

Given the difficulties of both self-reports and proxy reports of HRQoL in dementia, there may be a role for an objective measure based on behavioural observation. For example, a professionally rated observation scale could be used in conjunction with self- and proxy-rated scales. Further research could develop this type of scale, building on the methods developed by Kitwood in Dementia Care Mapping.[67] However, it is important to note that one can never directly observe quality of life, and behavioural observation can therefore only approximate the subjective construct. Such work would need to establish the relationship between the observed construct and HRQoL.

Evaluative research

RCTs of interventions in dementia

Broad measures of outcome are increasingly acknowledged as being of primary importance in the evaluation of interventions by RCTs. Given the complexity of the impact of the disorder, this is of particular importance in dementia. The requirement for measures used in trials to have strong psychometric properties has meant that it has not been possible to measure the HRQoL impacts of interventions in dementia. No scale has

published responsiveness data to date. DEMQOL and DEMQOL-Proxy are good potential candidates for inclusion in such trials subject to further replication and demonstration of responsiveness.

Non-RCT evaluations of interventions and services

Any evaluation requires good outcome measurement. The complexity of dementia often requires complex intervention and intervention at a service level as well as at the level of the individual. Depending on the nature of the evaluation DEMQOL and DEMQOL-Proxy are good potential candidates for inclusion in such studies, subject to the further research detailed earlier in this chapter (section 'Further development and evaluation of DEMQOL and DEMQOL-Proxy', p. 60).

Cross-sectional studies of associations with HRQoL in dementia

There has to date been little study of what is associated with HRQoL in dementia. The instruments developed allow for the investigation of how quality of life varies with other factors related to the person with dementia (e.g. type of dementia, severity, other psychosocial factors), their family carer (e.g. depression, nature of relationship, quality of premorbid relationship) and other factors (e.g. type of placement, services provided). This is again contingent upon appropriate development work as described earlier, and proxy issues may be of particular importance.

Cohort studies and the determinants of HRQoL in dementia

There is a similar lack of prospective studies measuring changes in HRQoL over time. Such studies would allow for the identification of factors predicting higher and lower quality of life. In addition, the impact of carer and patient factors and of events such as transitions in care could be determined. Again, this is contingent upon appropriate development work as detailed above.

Conclusions

The 28-item DEMQOL and 31-item DEMQOL-Proxy provide a method for evaluating HRQoL in dementia. The new measures show comparable psychometric properties to the best available dementia-specific measures, provide both self- and proxy-report versions for people with dementia and their carers, are appropriate for use in mild/moderate dementia (MMSE ≥ 10) and are suitable for use in the UK. DEMQOL-Proxy also shows promise in severe dementia. As DEMQOL and DEMQOL-Proxy give different but complementary perspectives on quality of life in dementia, the authors recommend the use of both measures together. In severe dementia, only DEMQOL-Proxy should be used.

Further research with DEMQOL is needed to: (1) confirm these findings in an independent sample; (2) evaluate responsiveness; (3) investigate the feasibility of use in specific subgroups and in economic evaluation; and (4) develop population norms. Additional research is needed to address the psychometric challenges of self-report in dementia and validating new dementia-specific HRQoL measures.

These findings raise issues for policy and practice in dementia care. The NSF for older people has introduced a single assessment process across health and social care for older people, including those with dementia. Measurement of HRQoL in these groups referred to services is an essential and desirable component of this assessment. Indeed, it is possible to argue that it is the single most important measure of the impact of care in dementia. This study shows that the large majority of people with dementia can be included in the assessment and that carers can provide useful data across the range of dementia severity. With training, systematic assessment can be completed.

This study demonstrates that quality of life can be measured in dementia and provides an instrument with which to carry out such assessments. These are the first two steps to ensuring that services are developed which can deliver the treatment, care and support needed by people with dementia and their carers. The goal of all dementia care must be to enhance and maintain the quality of life of people with dementia. Subject to further development as detailed above, DEMQOL is a tool with which to evaluate whether the interventions and services achieve this.

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The views expressed are those of the authors.

Contributions of authors

The application and first protocol was generated by S Banerjee (Professor of Mental Health and Ageing), D Lamping (Reader in Psychology) and M Prince (Professor of Epidemiology). S Smith (Lecturer), S Banerjee, D Lamping, J Murray (Senior Lecturer in Social Research), M Prince, R Harwood (Consultant Physician), E Levin (Senior Research Fellow), A Mann (Professor of Epidemiological Psychiatry) and M Knapp (Professor of Health Economics) all contributed the final protocol and to the oversight of the project. S Banerjee was the principal investigator, he took overall responsibility for the project with D Lamping providing senior psychometric input. The fieldwork was carried out by B Foley (Research Worker), J Cook (Research Worker) and P Smith (Research Worker). S Smith was responsible for the day-to-day running of the study, the analyses and preparation of the first draft of the report supervised by S Banerjee and D Lamping. All authors contributed to and commented on the final report. S Banerjee is the guarantor of the study.

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Appendix 1A

Initial interview guide

Domains and constructs for the interview guide for people with dementia and their caregiver.

I. Involvement in activities

Engagement: how do they spend their time: what is a typical day?
What activities do they take part in nowadays?
Can they fill their time?

Continuity: lifetime interests, hobbies, activities, pastimes, sources of happiness.
Are they still enjoyed?
What have been the changes, when and why?

Dementia/Health Related?

II. Autonomy and choice

Decision making: what decisions/choices do they make nowadays (e.g. activities, meals, travel, driving, handling finances, accommodation)?
How has this changed?

Living arrangements: how do they feel about their present accommodation?
Are they content with the people they live with/living alone?

Can they choose who they mix with; can they choose to be alone? Do they feel the staff know them as individuals?

Confidence, security: do they feel confident nowadays in doing things that they used to do? (everyday things)

Independence: how independent do they feel in looking after themselves?
What assistances do they receive?
How do they feel about being helped now and their likely future needs?

Can they choose who they mix with; can they choose to be alone? Do they feel the staff know them as individuals?

Dementia/Health Related?

III. Social and family relationships

Friendship and Intimacy: what relationships are important to them and in what way?
Do they feel they are listened to?
Do they have someone they can confide in?
Who do they most like to be with and why?

Do they ever feel left out or lonely?
How does that feel?

Dementia/Health Related?
Negative relationships: have they lost any important relationships/have any relationships deteriorated?
How do they feel about these?
Do they have any conflict with those around them?

Dementia/Health Related?

Social integration: now and in the past.
Do they feel part of a neighbourhood/residential home?
Do they feel they belong to any groups nowadays? (e.g. religious, social, special interest, political)
Has this changed recently?

Dementia/Health Related?

IV. Health and well-being

Self-appraisal: how would they describe their current health?
What changes have they noticed in recent years?
(Probes: mobility, energy, mood, sensory abilities, thinking, remembering)
What bothers them most about their health?
Does it prevent them doing anything?
How does their health compare with others of their age?

Dementia/Health Related?

V. Life satisfaction

The past: have they achieved most of what they hoped to?
What have been the most important things in their life? (health, happiness, home, family, friends, work, money)? How has this changed in recent years?
Is there anything they would change about their life if they had their time again?

The present: how do they feel about themselves overall?
What makes them feel good/bad nowadays?

The future: how do they feel about the future (hopes and fears)?
What do they look forward to (e.g. social and family events; mealtimes)?

Dementia/Health Related?

Appendix 1B

Revised interview guide

1. DAILY LIFE

a. Doing things I want to do
How do they spend their time? What's a typical day?
Are they happy with the way they spend their time?
What do they enjoy nowadays?
Are there other things they would like to do?
Is there anything that prevents them from doing what they want to do?

b. ADL
How independent are they in looking after themselves?
– getting about
– washing bathing
– shaving/doing hair
– dressing
– going to the toilet
– eating and drinking
How do they feel about it?

c. IADL
How independent are they in running their lives?
– shopping
– preparing meals
– using the phone
– handling money
– getting out and about
How do they feel about these?

2. HEALTH

How would they describe their health? (Overall rating)
What changes have they noticed in the last few years?
How does their health compare with others of their age?
How do they feel in themselves? How are their spirits?
– contentment/happiness
– enjoyment of life
– worry/anxiety
– confidence

3. MEMORY AND THINKING

How are they finding their memory?
What about:
– remembering recent events
– remembering what they are supposed to be doing?
– holding a conversation

– concentrating on TV/newspaper
– making their mind up
– thinking things through
– understanding what's happening around them
– getting muddled about who people are
What about their memory for things that happened in the past?

4. RELATIONSHIPS

Who are the most important people in their life?
Has this changed?
Who do they most like to be with?
Is there anyone you can cuddle nowadays?

How do they feel about the way people treat them?
Do they ever feel left out or lonely?
Do they feel they are listened to?
Do they belong to any groups?
– religious
– social clubs
– day centres

Do they have some one they can turn to if they need to?
– talk over worries
– practical help
Are they able to help other people nowadays?

5. HOW I SEE MYSELF AND MY LIFE

Have they achieved most of what they hoped for?
Is there anything they would change about their life if they had their time again?
What have been the most important things in their life?
How do they think you have changed over the years?
– Does he/she ever feel embarrassed about anything he/she has said or done?

How do they feel about the future?
What do they look forward to?
– hopes/aspirations

Appendix 2

DEMQOL interviewer manual

Instructions for administration

You will need a copy of the DEMQOL questionnaire for each interviewee and a separate card with the response scales printed large scale.

1. Introducing the questionnaire:

1.1 Ensure that the person with dementia/carer is comfortable and happy to participate.

1.2 If the carer is also present during the interview with the person with dementia, explain that it is the *person with dementia's* feelings and understandings that you are interested in. Reiterate that there are no right or wrong answers.

1.3 Explain that you are interested in how people feel about things that happen everyday. Explain that you will ask some questions, for example about the activities that people do during a day, how they feel, their relationships.

1.4 Show the person with dementia/carer the response card and encourage the patient to hold it if appropriate.

1.5 Read verbatim the instructions on the front of the questionnaire.

1.6 Read aloud the practice question. Point to each response option on the response card as it is said. Ask the person with dementia/carer to either say or point to the response he or she has chosen. Probe the response using the suggested probe questions to check whether the respondent has understood the question. If the practice question is successfully completed then continue with the rest of the questionnaire. If the person with dementia/carer cannot complete the practice question, then attempt the first five questions. If the person with dementia/carer is still struggling, suggest that you take a break for 10 minutes. When the interview is resumed start at the top of the next section. If the person with dementia/carer is still struggling after five questions then stop the interview.

1.7 If the person with dementia/carer successfully completes the practice question, but cannot do the questions in the first section of the questionnaire, then attempt the first five questions. If the person with dementia/carer is still struggling, suggest that you take a break for 10 minutes. When the interview is resumed start at the top of the next section. If the person with dementia/carer is still struggling after five questions then stop the interview.

2. Administering the questionnaire items:

2.1 Read each question *exactly* as it is written. If there is an example in the question, this must always be read too. Read aloud each response option, pointing to each response as you say it.

2.2 When the person with dementia/carer has indicated his or her response, mark it on the questionnaire. Mark only one response for each question. If the patient does not or cannot answer an item (for any reason), record the response as missing.

2.3 Try not to prompt with the phrase 'so that doesn't worry you at all?' as this encourages a yes/no answer. Instead use the phrase 'how much does that worry you?' and repeat the four response options.

2.4 For each question read both the stem and the item content. If the person has difficulty with an item repeat both the stem and the item verbatim. If they still have difficulty then repeat second part of the stem (e.g '… are you worried about') and the item content.

2.5 At the end of the interview go back to any missed items and if appropriate ask the person with dementia/carer to complete them.

3. Debriefing after the interview:

3.1 Explain that all the questions have now been answered.

3.2 Ask whether the person with dementia/carer has any questions that he or she would like to ask. Answer any questions and thank the person with dementia/carer for taking part.

4. Possible queries and responses – general

4.1 Doesn't want to complete the questionnaire
Tell the person with dementia/carer that participation is entirely voluntary. They are being asked to complete the questionnaire because it will help us to *understand more about what people think is important for quality of life*. If they still do not want to participate stop the interview and thank the person with dementia/carer.

4.2 Stops completing the questionnaire because he/she does not understand
Specific prompts for not understanding or querying are given on the next page. In general if the person with dementia/carer does not understand a particular question, re-read it verbatim, but *do not rephrase the question*. If the person with dementia/carer does not understand the response options, re-read the response options verbatim *but do not rephrase them*. The question and the response options can be re-read as many times as is necessary, but if it is clear that the patient or carer does not understand then do not continue.

4.3 Is concerned that someone will look at his/her answers
Reassure the person with dementia/carer that all of his/her responses will be kept confidential to the research team. Explain that names will be replaced by a study number so that the questionnaires are completely confidential.

4.4 Asks you to interpret a question
Specific prompts for not understanding or querying are given on the next page. In general re-read the item verbatim. Do not try to explain an item. Suggest that the person with dementia/carer base his/her answer on what *he/she* thinks the question means. Rephrasing or interpreting a question can bias results. *It is very important that the questions are read verbatim and only the standard prompts are used (see specific prompts given on next page).*

4.5 Answers 'don't know' or wants to miss out a question
Acknowledge that it can be hard to choose a response, but encourage the person with dementia/carer to choose the response option that *most applies to him/her*. If a person with dementia/carer wants to miss out an item, explain to the patient/carer that all the questions are very important. They should try to answer all of the questions. If the person with dementia/carer still does not want to answer a particular item, assure them that it is alright, then go on to the next item.

4.6 Wants to know the meaning of his/her answers
Tell the person with dementia/carer that all information is helpful and that there are no right or wrong answers. Remind the person with dementia/carer that all the information is kept confidential and that we will look at what everybody says together rather than anybody's questionnaire on its own.

4.7 Asks why both patient and carer must complete the questionnaire
Explain that sometimes person with dementia and carers have a different view. Both are useful and by asking questions to both carer and the person with dementia we can get a more complete picture of how people feel.

5. Possible queries and responses – specific:

5.1 If person answers simply 'yes' instead of choosing one of the four response options:
- repeat the response options and ask him/her to choose one
- if the person still says 'yes', ask him/her to choose from one of the three positive response options (i.e. *a lot*, *quite a bit* or *a little*) and record the one that they choose
- if still not clear which response option he/she means, repeat the three positive options again and record the one that he/she chooses
- if the person says two positive response options ask them to choose one and record it
- if necessary repeat the question verbatim.

5.2 If person answers simply 'no' instead of choosing one of the four response options:
- repeat the response options and ask him/her to choose
- if the person still just says 'no' check with him/her if that would be '*not at all*'
- if necessary repeat the question verbatim.

5.3 If person responds using their own phrase or form of words that is not one of the response options:
- repeat the question and the response options verbatim and ask them to choose one of the response options

- if they still don't use one of the response options but are answering in a way that is relevant to the question, reiterate that they need to choose one of the four response options
- if they still don't choose one of the response options, then accept their answer, but don't score it, mark the questionnaire as missing and move on to the next questions.

5.4 If person responds using the phrase 'not a lot':
- ask if they mean 'a little' or 'not at all' and record the answer given
- if the person is unable to choose between these two options then accept their response but don't score it. Record the item as missing and allocate the appropriate code. Move on to the next question.

5.5 If person misunderstands question (i.e. answering something else entirely):
- repeat question and response options
- if the person still appears not to understand the question go on to the next question.

5.6 If person explicitly queries what a question means:
- do not rephrase or interpret any question
- repeat question and response options verbatim
- suggest that *he/she* bases their answer on what he/she think it means
- if the person is still querying or appears not to understand go on to the next question and reassure him/her that they're doing very well and it's fine to go on to the next question.

5.7 If person refuses to answer a question:
- accept his/her refusal and reassure the person that it is alright not to answer. Go on to the next question.

5.8 If person answers in terms of ability/functioning rather than subjective perception:
- accept his/her answer and then ask how much he/she worries about that particular activity and repeat the response options.

5.9 If carer queries a 'feeling' question saying that they cannot know:
- tell the carer that there is probably no one else who knows the person better. They should just give the answer that best describes how they think their relative has felt.

5.10 If person doesn't understand the general QoL question at the end:
- repeat descriptive sentence in question book and repeat question
- if the person still appears not to understand say *'In the last week how would you rate your quality of life overall?'*
- if the person still appears not to understand say *'thinking about your life in the last week would you say it was … very good, good, fair or poor?'*
- if still not able to answer accept the non-response, assure the person that it is alright and thank him/her for taking part.

Appendix 3A

Preliminary field test DEMQOL (v3.3b)

Study reference number

DEMQOL
(version 3.3b)

I would like to ask you about your life. Don't be concerned if some questions appear not to apply to you. We have to ask the same questions of everybody. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week.
Before we start we'll do a practice question, that's one that doesn't count.

In the last week, how much have you enjoyed watching television?

a lot **quite a bit** **a little** **not at all**

Why is that?
Tell me a bit more about that.

For all of the questions I'm going to ask you I want you to think about the last week.

First I'm going to ask about <u>your feelings</u> in the last week. Have you felt …

1. cheerful? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
2. worried or anxious?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
3. that you are enjoying life? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
4. frustrated?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
5. confident? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
6. embarrassed about yourself?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
7. full of energy? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
8. sad?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
9. calm? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
10. lonely?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
11. angry?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
12. content? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
13. distressed?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
14. lively? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
15. irritable?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
16. bitter?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
17. safe? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
18. that life is not worth living?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
19. hopeful? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
20. fed-up?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
21. that you have things to look forward to? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask you about <u>your health</u>. In the last week how worried have you been about …

22. your physical health?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
23. how you feel in yourself?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
24. how well you sleep?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
25. your health overall?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask you about <u>your memory</u>. In the last week how worried have you been about …

26. your memory in general?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
27. forgetting things that happened a long time ago?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
28. forgetting things that happened recently?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
29. forgetting people's names?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
30. forgetting who people are?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
31. forgetting where you are?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
32. forgetting what day it is?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
33. your thoughts being muddled?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
34. difficulty making decisions?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
35. poor concentration?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
36. making yourself understood?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask about <u>people around you</u>. In the last week how worried have you been about …

37. how you get on with other people?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
38. being left out of things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
39. not having enough company?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
40. not having enough privacy?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
41. how other people treat you?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
42. people not listening to you?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
43. not being able to help other people?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
44. getting help when you need it?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
45. getting the affection that you want?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
46. how you get on with people close to you?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask about <u>how you see yourself</u>. In the last week how worried have you been about …

47. depending too much on others?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
48. not playing a useful part in things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
49. what other people think of you?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
50. not feeling important?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
51. the way you have lived your life?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
52. your life nowadays?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask you about <u>everyday tasks</u>. In the last week how worried have you been about …

53. getting dressed?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
54. keeping yourself clean (e.g. washing and bathing)?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
55. keeping yourself looking nice?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
56. getting to the toilet in time?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
57. getting what you want to eat?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
58. getting food or drink when you want it?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
59. using cutlery (e.g. a knife, fork or spoon)?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
60. getting about indoors?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
61. getting about outdoors?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
62. getting what you want from the shops?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
63. going where you want to go?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
64. using money to pay for things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
65. looking after your finances?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
66. the way your home is looked after?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
67. getting in touch with people?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
68. things taking longer to do than they used to?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

I'm going to ask you about <u>how much you enjoy things</u>. In the last week …

69. have you enjoyed your food? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
70. has pain stopped you from enjoying things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
71. have you felt you had enough choice about what you do? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
72. have you been happy with how you've spent your day? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
73. have you felt that there are things that you wanted to do but couldn't?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

We've already talked about lots of things: your health, feelings, memory, people around you and things you do. Thinking about all of these things in the last week, how would you rate …

74. your quality of life overall? **	very good ☐	good ☐	fair ☐	poor ☐

** items that need to be reversed before scoring

Appendix 3B

Preliminary field test DEMQOL-Proxy (v3.3b)

Study reference number

DEMQOL
Proxy version
(version 3.3b)

I would like to ask you about your (relative's) life, as you are the person who knows them best. Don't be concerned if some questions appear not to apply to your (relative). We have to ask the same questions of everybody. There are no right or wrong answers. Just give the answer that best describes how he or she has felt in the last week. If possible try and give the answer that you think your (relative) would give.
Before we start we'll do a practice question, that's one that doesn't count.

In the last week how much has your (relative) enjoyed watching the television?

a lot **quite a bit** **a little** **not at all**

Why is that?
Tell me a bit more about that.

For all of the questions I'm going to ask you I want you to think about the last week.

First I'm going to ask you about <u>your (relative's) feelings</u> in the last week.
Has your (relative) felt …

1. cheerful? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
2. worried or anxious?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
3. that they are enjoying life? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
4. frustrated?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
5. confident? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
6. embarrassed about him/herself?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
7. full of energy? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
8. sad?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
9. calm? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
10. lonely?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
11. angry?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
12. content? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
13. distressed?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
14. lively? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
15. irritable?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
16. bitter?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
17. safe? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
18. that life is not worth living?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
19. hopeful? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
20. fed-up	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
21. that he/she has things to look forward to? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask about <u>your (relative's) health</u>. In the last week how worried has your (relative) been about …

22. his/her physical health?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
23. how he/she feels in him/herself?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
24. how well he/she sleeps?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
25. his/her health overall?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask you about <u>your (relative's) memory</u>. In the last week how worried has your (relative) been about …

26. his/her memory in general?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
27. forgetting things that happened a long time ago?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
28. forgetting things that happened recently?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
29. forgetting people's names?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
30. forgetting who people are?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
31. forgetting where he/she is?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
32. forgetting what day it is?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
33. his/her thoughts being muddled?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
34. difficulty making decisions?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
35. poor concentration?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
36. making him/herself understood?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask about <u>people around your (relative)</u>. In the last week how worried has your (relative) been about …

37. how he/she gets on with people?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
38. being left out of things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
39. not having enough company?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
40. not having enough privacy?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
41. how other people treat him/her?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
42. people not listening to him/her?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
43. not being able to help other people?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

44. getting help when he/she needs it?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
45. getting the affection that he/she wants?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
46. how he/she gets on with people close to him/her?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask you about <u>how your (relative) sees him/herself</u>. In the last week how worried has your (relative) been about …

47. depending too much on others?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
48. not playing a useful part in things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
49. what other people think of him/her?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
50. not feeling important?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
51. the way he/she has lived their life?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
52. his/her life nowadays?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

Now I'm going to ask about <u>everyday tasks</u>. In the last week how worried has your (relative) been about …

53. getting dressed?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
54. keeping him/herself clean (e.g. washing and bathing)?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
55. keeping him/herself looking nice?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
56. getting to the toilet on time?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
57. getting what he/she wants to eat?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
58. getting food or drink when he/she wants it?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
59. using cutlery (e.g. a knife, fork or spoon)?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
60. getting about indoors?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
61. getting about outdoors?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
62. getting what he/she wants from the shops?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
63. going where he/she wants to go?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
64. using money to pay for things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
65. looking after his/her finances?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
66. the way his/her home is looked after?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
67. getting in touch with people?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
68. things taking longer than they used to?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

I'm going to ask you <u>how much your (relative) enjoys things</u>. In the last week …

69. has your (relative) enjoyed his/her food? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
70. has pain stopped your (relative) enjoying things?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
71. has your (relative) felt he/she had enough choice about what he/she does? **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
72. has your (relative) been happy with how he/she spends the day **	a lot ☐	quite a bit ☐	a little ☐	not at all ☐
73. have there been things that your (relative) wanted to do but couldn't?	a lot ☐	quite a bit ☐	a little ☐	not at all ☐

We've already talked about lots of things: your (relative's) health, feelings, memory, people around him/her and things he/she does. Thinking about all of these things in the last week, how would your (relative) rate …

74. his/her quality of life overall? **	very good ☐	good ☐	fair ☐	poor ☐

** items that need to be reversed before scoring

Appendix 4A

Final field test item-reduced DEMQOL (v4)

Study ID □□□□□

DEMQOL (version 4)

To be used with interviewer manual

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about your life. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week. Don't worry if some questions appear not to apply to you. We have to ask the same questions of everybody.

Before we start we'll do a practice question; that's one that doesn't count. (*Show the response card and ask respondent to say or point to the answer.*) In the last week, how much have you enjoyed watching television?

a lot **quite a bit** **a little** **not at all**

Follow up with a prompt question: **Why is that?** ***or*** **Tell me a bit more about that.**

For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask about <u>your feelings</u>. In the last week, have you felt …

1. **cheerful? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
2. **worried or anxious?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
3. **that you are enjoying life? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
4. **frustrated?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
5. **confident? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
6. **full of energy? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
7. **sad?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
8. **lonely?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
9. **distressed?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
10. **lively? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
11. **irritable?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
12. **fed-up?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
13. **that there are things that you wanted to do but couldn't?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

Next, I'm going to ask you about <u>your memory</u>. In the last week, how worried have you been about …

14. **forgetting things that happened recently?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
15. **forgetting who people are?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
16. **forgetting what day it is?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
17. **your thoughts being muddled?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
18. **difficulty making decisions?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
19. **poor concentration?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about …

20. **not having enough company?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
21. **how you get on with people close to you?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
22. **getting the affection that you want?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
23. **people not listening to you?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
24. **making yourself understood?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
25. **getting help when you need it?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
26. **getting to the toilet in time?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
27. **how you feel in yourself?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
28. **your health overall?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate …

29. **your quality of life overall? ****	☐ very good	☐ good	☐ fair	☐ poor

** items that need to be reversed before scoring

Appendix 4B

Final field test item-reduced DEMQOL-Proxy (v4)

Study ID □□□□□

DEMQOL-Proxy (version 4)

To be used with interviewer manual

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about _____ (*your relative's*) life, as you are the person who knows him/her best. There are no right or wrong answers. Just give the answer that best describes how _____ (*your relative*) has felt in the last week. If possible try and give the answer that you think _____ (*your relative*) would give. Don't worry if some questions appear not to apply to _____ (*your relative*). We have to ask the same questions of everybody.

Before we start we'll do a practice question; that's one that doesn't count. (*Show the response card and ask respondent to say or point to the answer.*) In the last week how much has _____ (*your relative*) enjoyed watching television?

a lot **quite a bit** **a little** **not at all**

Follow up with a prompt question: **Why is that?** ***or*** **Tell me a bit more about that.**

For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask you about _____ (*your relative's*) <u>feelings</u>. In the last week, would you say that _____ (*your relative*) has felt …

1. **cheerful? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
2. **worried or anxious?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
3. **frustrated?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
4. **full of energy? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
5. **sad?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
6. **content? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
7. **distressed?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
8. **lively? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
9. **irritable?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
10. **fed-up**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
11. **that he/she has things to look forward to? ****	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

Next, I'm going to ask you about _____ (*your relative's*) <u>memory</u>. In the last week, how worried would you say _____ (*your relative*) has been about …

12. **his/her memory in general?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
13. **forgetting things that happened a long time ago?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
14. **forgetting things that happened recently?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
15. **forgetting people's names?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
16. **forgetting where he/she is?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
17. **forgetting what day it is?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
18. **his/her thoughts being muddled?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
19. **difficulty making decisions?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
20. **making him/herself understood?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

Now, I'm going to ask about _____ (*your relative's*) <u>everyday life</u>. In the last week, how worried would you say _____ (*your relative*) has been about …

21. **keeping him/herself clean (e.g. washing and bathing)?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
22. **keeping him/herself looking nice?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
23. **getting what he/she wants from the shops?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
24. **using money to pay for things?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
25. **looking after his/her finances?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
26. **things taking longer than they used to?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
27. **getting in touch with people?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
28. **not having enough company?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
29. **not being able to help other people?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
30. **not playing a useful part in things?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
31. **his/her physical health?**	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

We've already talked about lots of things: _____ (*your relative's*) feelings, memory and everyday life. Thinking about all of these things in the last week, how would you say _____ (*your relative*) would rate …

32. **his/her quality of life overall? ****	☐ very good	☐ good	☐ fair	☐ poor

** items that need to be reversed before scoring

Appendix 5

Rules for scoring and imputing missing data

Direction of coding

DEMQOL PWD self-report	higher = better HRQoL
DQOL self-esteem PWD self-report	higher = better HRQoL
DQOL positive affect PWD self-report	higher = better HRQoL
DQOL absence of negative affect PWD self-report	higher = better HRQoL
DQOL sense of belonging PWD self-report	higher = better HRQoL
DQOL sense of aesthetics PWD self-report	higher = better HRQoL
QOLAD PWD self-report	higher = better HRQoL
MMSE	higher = less severe
SF-12 PCS	higher = better HRQoL
SF-12 MCS	higher = better HRQoL
DEMQOL carer proxy report	higher = better HRQoL
GDS-30 carer proxy report	higher = worse depression
BARTHEL carer proxy report	higher = less dependent
CDR interviewer report	higher = worse dementia
GHQ carer self-report	higher = more distressed

Use of imputation

DEMQOL PWD self-report	If at least 50% of items are complete, impute with person-specific mean of completed items
DQOL self-esteem PWD self-report	If <2 items missing, impute with person-specific mean of completed items
DQOL positive affect PWD self-report	If <3 items missing, impute with person-specific mean of completed items
DQOL absence of negative affect PWD self-report	If <3 items missing, impute with person-specific mean of completed items
DQOL sense of belonging PWD self-report	If <2 items missing, impute with person-specific mean of completed items
DQOL sense of aesthetics PWD self-report	If <2 items missing, impute with person-specific mean of completed items
QOLAD PWD self report	If at least 50% of the data are complete, impute with person-specific mean of completed items
SF-12 PCS	For scales with 2 items and only one item complete, impute missing item with the complete item
SF-12 MCS	For scales with 2 items and only one item complete, impute missing item with the complete item
MMSE	None
DEMQOL carer proxy report	If at least 50% of items are complete, impute with person-specific mean of completed items
GDS-30 carer proxy report	If at least 50% of items are complete, impute with person-specific mean of completed items
BARTHEL carer proxy report	None
CDR interviewer report	None
GHQ carer self-report	If <3 items missing impute with 0, otherwise exclude the case

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The HTA Programme and the authors would like to know your views about this report.

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We look forward to hearing from you.

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