# MEASURING INFORMAL CARER QUALITY OF LIFE IN ECONOMIC EVALUATION

by

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# Abstract

Carer quality of life (QoL) is recommended for inclusion in economic evaluation, but little is known about the relative performance of different QoL measures with informal carers. This thesis investigates, for the first time, the psychometric performance, in terms of validity and responsiveness, of different preference-based measures of carer QoL for different groups of informal carers. The study focuses on one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, ASCOT-Carer) QoL measures. Construct validity, responsiveness, feasibility, content validity, and face validity were investigated through primary survey work with 573 informal carers of adults with dementia, recovery from stroke, a mental health condition, or rheumatoid arthritis.

A baseline questionnaire containing the five QoL measures was posted to informal carers and a follow-up questionnaire was posted 12 months later to informal carers who responded at baseline. Hypotheses regarding anticipated associations between constructs related to the QoL of informal carers and QoL measures scores were developed and tested to investigate construct validity and responsiveness. Think-aloud and semi-structured interviews with 24 informal carers were carried out and a thematic analysis was conducted to assess the content validity, feasibility, and face validity of each QoL measure.

Taken together, the results of the quantitative and qualitative analyses indicate that each of the five QoL measures can be considered, in general, valid and feasible for use with informal carers in economic evaluation. Where the focus is on health maximisation, the results suggest that the EQ-5D-5L has relatively encouraging validity as an outcome measure with informal carers. However, the results show that when including informal carers in economic evaluation health-related QoL (HRQoL) may be a limiting measurement as it does not capture the full impacts of providing informal care. Where there is more flexibility in the economic evaluation, the findings show that the ICECAP-A and measures of care-related QoL (CRQoL), in particular, the ASCOT-Carer, can be used in addition or instead of a HRQoL measure, in view of their performance.

# Dedication

For Joe and Tom, my joy.

# Acknowledgements

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# Table of contents

# List of tables

# List of figures

# Introduction

The world's population is ageing and because of this we can expect to see the number of people living with chronic illness and disability rise in the coming years [1-4]. This will lead to a 'care gap' because the number of people able and willing to provide informal care is unlikely to meet the projected demand.

Informal care is often not included in economic evaluation where the focus is typically on the patient as an isolated individual. However, there is a growing interest in including in the evaluative scope in economic evaluation the wider, or spillover, effects of a given intervention on a patient's informal carer(s). To include informal care in economic evaluation in a way that is meaningful to decision makers, we must be able to demonstrate confidence in the tools we use to measure and value carer impacts. While the literature on the validity of outcome measures with informal carers is initially promising [5-19], there is still ambiguity over which outcome measure to use in economic evaluations that involve informal carers. The focus of this thesis is on comparing the psychometric performance of different quality of life (QoL) measures at measuring informal carer QoL. This PhD work was conducted as part of a wider programme of research for a NIHR career development fellowship awarded to Hareth Al-Janabi.

Chapter 1 describes the scope and impact of informal care, with particular focus on carers in the UK. The chapter begins by looking at how the role of informal care is defined in legislation, policy, and academic literature. It then looks at trends in informal care and the impact providing care can have on the informal carer. The chapter finishes by outlining how policy and legislation are constantly evolving to effectively support informal carers to continue in their role.

Chapter 2 explores how the impacts of providing informal care can be identified, measured, and valued so that it might be included in economic evaluation in a way that is meaningful to decision makers. The chapter begins by providing a theoretical basis for how resource allocation decisions are made, how economic evaluation can assist in making difficult choices and the frameworks used for conducting economic analysis. The chapter continues by highlighting that the evaluative scope must be broadened to include the spillover effects of a given intervention. This includes the impacts of providing informal care. The chapter then introduces a number of preference-based QoL measures that can be used in economic evaluations involving informal carers.

Chapter 3 builds on the previous two chapters and explores how the validity of QoL measures for informal carers can be assessed. The chapter begins by looking at the theoretical background to validity and responsiveness, defining the types of validity and how they can be tested. The chapter concludes by outlining the gaps in our knowledge and why further testing is required to strengthen our confidence in the ability of certain outcome measures used with informal carers, to be used in economic evaluation.

Chapter 4 describes the methods used to assess the construct validity and responsiveness of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures. The chapter begins by describing how participants were identified through a wider programme of work to which this PhD is linked, and further detail is provided on the conditions included in the research for this thesis. Briefly, the research for this thesis is focused on high prevalence chronic health conditions associated with diverse impacts on informal carers' lives, specifically dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis. The chapter then details how two postal questionnaires were developed and how data was collected and analysed to test the validity and responsiveness of the five QoL measures. This involved developing evidence-based hypotheses which were subjected to rigorous testing, and the development of an anchor-based approach to test whether there was an 'important' change in measure score when compared, or anchored, to changes in the anchoring item.

Chapter 5 presents the results of the quantitative analysis. The chapter begins by describing the characteristics of the participants who responded to the baseline and follow-up questionnaires. The chapter then outlines the results of the construct validity analysis beginning with the convergent validity analysis, followed by four tests of discriminative analysis. The first three analyses look at QoL measure score for all conditions pooled together, for individual conditions, and for condition specific health difficulties. The fourth analysis looks at individual QoL measure items for all conditions pooled together. Finally, the results of the responsiveness analysis exploring changes within a year in care recipient health status or hours of care provided per week are presented. The quantitative work presented in Chapters 4 and 5 represents a comprehensive analysis of the validity and responsiveness of multiple QoL measures across multiple conditions, and this work has been published [20].

Chapter 6 describes the methods for the qualitative study of the feasibility, content validity and face validity of the same five QoL measures. To meet this objective two qualitative approaches; a think-aloud interview, and semi-structured interview, were used to identify response process issues and to explore how and why respondents arrive at their answer when completing an outcome measure. The chapter describes the recruitment of participants and shows how rigour was applied at each stage of the interview process. The chapter then describes the methods for handling and analysing the data.

Chapter 7 presents the results of the qualitative analysis. The chapter begins by describing the characteristics of the participants who consented to being interviewed. This chapter then outlines the results of the think-aloud analysis which are structured to look at the key issues by cognitive process, by QoL measure, by theoretical domain, and by care recipient condition. Finally, the results from the semi-structured interview are presented.

This study investigates, for the first time, the psychometric performance, in terms of validity and responsiveness, of different preference-based measures of carer QoL for different groups of informal carers. An overall discussion of the empirical work is presented in Chapter 8. The key findings of the work, and its strengths and weaknesses are discussed, along with potential directions for future research.

# 1. The role of informal care

## 1.1. Introduction

This chapter explores the scope and impact of informal care. As world populations age, we can expect to see an increase in the number of people at risk for chronic illness and disability that impact on their ability to care for themselves [1-4]. These demographic changes are driving an increased demand for care that will continue to rise. Part of this growing demand is likely to be met by informal care. In the UK, informal care plays a crucial role in meeting the demand for care and the volume of informal carers is already relatively large [21]. The impact of providing informal care is considerable and multidimensional and can have negative and positive impacts on the carer simultaneously. This chapter will look in detail at the different impacts providing care can have on the informal carer. By exploring these impacts, we can hope to better understand the dimensions of QoL affected by providing care.

The chapter begins by looking at how informal carers and the role of providing informal care are defined in policy and legislation in a selection of twelve countries: Australia, Canada, Denmark, Finland, France, Ireland, Germany, Italy, The Netherlands, Sweden, USA, and the UK (Section 1.2). Section 1.2 will then explore how informal care is defined in the academic literature. From this we can draw out the key traits of informal care. We see that informal care is widely accepted to be an unpaid role, the care is provided to somebody with an illness or disability, and the care is provided by a non-professional person with no training, usually a family member. The chapter will then progress to consider the prevalence of informal care in the UK (Section 1.3), and the projected demographic changes that are likely to cause an increase in the demand for informal care. This section focuses on the UK as this is where the empirical research for this thesis was conducted. Particular attention is paid to the 'care gap' that is anticipated in the coming decades as the supply of informal carers fails to keep pace with the growing demand in caring responsibilities.

In Section 1.4 the focus turns to the impacts of providing informal care. The section will look at the impact on the carer's health and wellbeing, the impact the relationship between the carer and care recipient has on the carer's QoL, and the specific impacts of caring for somebody with a chronic condition. By understanding that these impacts influence the carers' willingness and ability to provide care and to sustain their role we can appreciate how important it is that carers are supported through policy and practice to continue in their role. How informal carers have been included in policy and legislation to date in the UK is then considered in Section 1.5.

Finally, the conclusion to this chapter summarises the role and impact of informal care and the importance of sustaining informal carers in their role to address the projected 'care gap' in the UK.

## 1.2. Defining informal care

There are two types of care that can be provided: formal care, and informal care. Formal care is described in the literature as "…*remunerated support provided by professional caregivers working in the health sector*" [22]. The services provided are "…*publicly or privately controlled and involve contracts specifying care-based responsibilities and working regulations*" [23]. In contrast, the key traits of informal care are that it is an unpaid role, the care is provided to somebody with an illness or disability, and the care is provided by a non-professional person with no training, usually a family member.

Countries have adopted different definitions of informal care and the role of informal care in legislation and policy. Nevertheless, there are key points common to most definitions. Table 1.1 looks at the definitions for a selection of twelve countries: Australia, Canada, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Sweden, the UK, and the USA. The countries included were selected based on their connection to the QoL measures investigated in this thesis. More detail is provided in Chapter 4 on the individual measures. Briefly, the measures chosen were the CES, CarerQoL-7D, ASCOT-Carer, ICECAP-A, and EQ-5D-5L. The countries where these measures were developed and/or where investigations into their validity were conducted were used to frame the review that follows.

Relevant literature regarding definitions of informal care and the role of informal care in legislation and policy in the various countries was sought from legislation and government resources (websites and reports). Additionally, websites for national carers organisation (both formal and informal) in each country were included in the search. The inclusion of information on a definition for informal care was based on a hierarchy of evidence in terms of the origin of the definition. Where available, the legal definition for informal care was included. If this was not present, government sources were searched, and finally national carers websites. Some countries specify that the care is voluntary in nature using words such as "non-professional" (Germany, France), "unpaid" (USA, Sweden, Ireland), "without pay" (Canada) or "voluntary" (Italy, Sweden). Each of the selected countries defines the relationship between the carer and care recipient. The definitions include family members (UK, USA, Finland, Denmark, Canada, Australia, Sweden, Ireland), friends (UK, USA, Canada, Australia, Sweden, Ireland) or neighbours (UK, Australia, Sweden, Ireland). In Finland they also include the phrase "*other loved ones*", and legislation in Italy uses a broad statement to define the relationship as "*a person for whom* [the carer] *feels affection*". The relationship between carer and care recipient is defined by other countries based on who the carer is, for example "*someone in the care recipients immediate social setting*" (the Netherlands), or "[an] *ally*" (France). In Canada the carer is defined as somebody who is a "*primary or secondary caregiver or part of an informal network of multiple informal carers*".

Some countries elaborate on what condition the care recipient may have that requires assistance, for example physical, cognitive, or mental ill health or disability (UK, Germany, the Netherlands, Sweden, Finland, Denmark, Canada, Ireland), problems related to old age (UK, Ireland) or frailty (the Netherlands). The definitions also elaborate on the tasks the care recipient may need support with, for example to cope with the activities of daily living (Italy, Finland, France, USA). Other countries provide more general text on the type of care, for example "*all help*" (the Netherlands), "c*are and assistance*" (Australia), "*help or support*" (UK), "*personal help or support*" (Ireland), and "*a variety of emotional and practical help*" (Sweden).

Only one country (Germany) specifies that the care provided should be "*long-term*", though the Australian definition states the care provided should be "*regular*" and "*sustained*". The definitions used in the USA and Denmark comment on the living situation between the carer and care recipient stating that "*The nursing can be provided in the carer or care recipients home"* (Denmark), and *"This adult need not live with you*" (USA).

**Table 1.1.** Definitions of informal care used in legislation and policy

| Country | Definition | Source |
|---|---|---|
| Australia | A person, such as a family member, friend, or neighbour, who provides regular and sustained care and assistance to the person requiring support | Australian Institute of Health and Welfare, 1998 [24] |
| Canada | Individuals who provide ongoing care and assistance, without pay, for family members and friends in need of support due to physical, cognitive, or mental conditions. They can be primary or secondary caregivers or part of an informal network of multiple informal carers. | Canadian Caregiver Coalition, 2001 [25] |
| Denmark | A person caring for a close relative with a disability or serious illness. The nursing can be provided in the carer or care recipient's home. | The Law of Service (3, §118), 2019 [26] |
| Finland | A person who takes care of his/her family member or other loved one who cannot cope independently with everyday activities due to an illness, disability, or other special need for care. | The Finnish Network for Organisations Supporting Family Caring, 2015 [27] |
| France | The Proches Aidants (carers) of an elder person are: their spouse, the partner with whom they have concluded a civil solidarity pact, a cohabitant, a parent, or 'ally' defined as family carers, or a person living with them and with whom they maintain a close and stable relationship, who provides them with regular and frequent care, in a non-professional capacity, to carry out all or part of the activities of daily living. | The Act on Adapting Society to an Ageing Population, article 51, 2015 [28] |
| Germany | People who provide non-professional home care to other people in need of long-term care, due to a physical, mental, or emotional illness or disability. | Social law XI §19 [29] |
| Ireland | People who provide regular, unpaid personal help or support to a family member, neighbour or friend with a long-term illness, health issue, an issue related to old age or disability | Central Statistics Office, 2022 [30] |
| Italy | Individuals who take care in a continuously, voluntary, and free way of a person for whom she/he feels affection who is not able to perform daily tasks by herself/himself | Provisions for the recognition and support of the family caregiver, 2019 [31] |
| Netherlands | All help provided to a sick, disabled, or frail person by someone in their immediate social setting | The Netherlands Institute for Social Research, 2020 [32] |
| Sweden | Family, close friends, significant others, or neighbours, in short – anyone who provides a variety of emotional and practical help, support or care to people that suffer from a long-term illness or disability. This caring is generally unpaid and carried out on a voluntary basis. | The Swedish Family Care Competence Centre, 2008 [33] |
| UK | People who look after or give help or support to family members, friends, neighbours, or | UK Office for National Statistics, 2021 [34] |

| | | |
|---|---|---|
| | others because of long-term physical or mental ill health or disability, or problems related to old age. | |
| USA | Those who provide unpaid care to a relative or friend 18 years or older to help them take care of themselves. This may include helping with personal needs or household chores. It might be managing a person’s finances, arranging for outside services, or visiting regularly to see how they are doing. This adult need not live with you. | US National Family Caregiving Survey, 2019 [35] |

In looking at how informal care is defined in both the academic literature and in legislation and policy, we can see that there are more similarities in the definitions than there are differences. The definitions in the academic literature follow the formal definitions used in legislation and policy discussed in that the most distinctive features of informal care are defined as follows:

- it is an unpaid role
- the care is provided to somebody with an illness or disability
- the care is provided by a non-professional person with no training, usually a family member or person with whom the care recipient has a social relationship [3, 4, 22, 23, 36-41].

The importance of the role has also been included in the definitions provided, as seen in Akgun-Citak et al [4] where informal care is defined as "…*unpaid care provided by family, friends, or volunteers and plays a crucial role in the caregiving process*".

Other authors provide detail on the activities that might be associated with the informal caregiving role. For example, Weatherly et al [36] and Oliva-Moreno et al [23] both speak of how heterogeneous informal care can be and how this heterogeneity is associated with differences in the duration of care, the tasks that informal carers might provide, and the time that carers may spend on these tasks. Both authors give examples of tasks in their definition, such as "…*personal care such as washing and dressing, domestic tasks such as cooking and cleaning,* *administrative tasks such as organising finances and coordinating care, and assisting the care recipient to be involved in the community and leisure activities*" [36]. Oliva-Moreno et al [23] also lists personal care, administrative, and household work. They broaden the definition to also include "*supervision tasks, companionship and emotional support*".

Finally, other authors have commented in their definition on how informal care can complement or substitute the formal care patients receive [37], and how the care provided informally can constitute a substantial part of total healthcare provided [38].

The research on informal care, and how informal care is defined, has evolved over time. In short, the literature has traditionally highlighted the negative consequences on carer's physical and mental health, by focusing on the stress and burden associated with providing informal care [42]. More recently however, the literature has shifted to identify the positive aspects of providing care which contribute to the informal carer's sense of wellbeing [43-45]. This topic is explored in more detail in Section 1.4.1.

How carers are perceived in policy and legislation has also evolved over time. Section 1.5 looks at this from the UK perspective and details how the inclusion of informal care has evolved from informal carers being viewed as the default source of care with the focus of support on the care recipient, to informal carers being viewed as individuals with the focus of support on the carers needs [46].

## 1.3. Prevalence of informal care in society

Accepting the chronological age of 60 years as a definition of 'elderly', figures from the World Health Organization (WHO) show that by 2050, 16% of the world's population will be elderly [47]. Across OECD member countries, between 2017 and 2050, the proportion of elderly people is expected to increase from 17% to 27% [48]. In the UK, it is predicted that by 2050, one in four people will be elderly and over 10% of the population will be aged 80+ [48].

As populations age, we can expect to see an increase in the number of people at risk for chronic illness and disability that impact on their ability to care for themselves over a prolonged period [4, 49]. These demographic changes are one of the key drivers for an increased demand for care that will keep rising in the decades to come [1-4, 22, 48, 50]. Part of this growing demand is likely to be met by informal care [1-4]. Informal care constitutes a substantial part of total healthcare provided, especially in the context of the chronically ill or disabled [4, 37, 38, 49-51]. For example, Hoffmann and Rodriques [52] estimated that informal care of adults living with chronic illness or disability comprised 80% of all long-term care provided across Europe.

In the UK, informal care plays a crucial role in meeting the demand for care and the volume of informal carers is already relatively large. In 2017, more than 18% of the population aged 50+ provided informal care in contrast to the OECD average of

13.5% [53]. Based on 2011 Census data[1], there are currently 6.5 million adults providing informal care for a family member in the UK. This shows an increase of 11% over 10 years since the 2001 Census [21]. Meanwhile, research using different datasets suggests that the number of informal carers in the UK is larger than the Census figures suggest. Using population projections from the Office for National Statistics (ONS) and polling by Carers UK, it is estimated that up to 8.8 million adults are currently providing informal care [21]. In 2015, Carers UK estimated that the economic value of the contribution made by informal carers in the UK was £132 billion per year, almost double its value in 2001 [54].

Informal care is seen from a governmental perspective as a low-cost alternative to formal care [48]. However, the research shows that Governments should be cautious in their reliance on informal carers to compensate for professional care [3]. Along with an ageing population, other societal developments such as decreased family size [2], women's increased participation in the labour market [3], and rising retirement age [52] are projected to contribute to a 'care gap' in the coming decades as the supply of informal carers fails to keep pace with the growing demand.

## 1.4. The impacts of providing informal care

The impact of providing informal care is considerable and multidimensional and can have negative and positive impacts on the carer simultaneously. This section

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[1] Census 2021 data was not available at the time of writing.

examines the different ways in which providing informal care can impact on the carer and how those impacts can affect the carer’s QoL. Specifically, the section will look at the impacts on the carer’s health and wellbeing (Section 1.4.1), the impact the relationship between the carer and care recipient has on the carer’s QoL (Section 1.4.2), and the impacts of caring for somebody with a chronic condition (Section 1.4.3). In looking at these impacts we can understand the importance of sustaining informal carers in their role to address the ‘care gap’ discussed in the Section 1.3.

### *1.4.1. Impacts on the informal carer’s health and wellbeing*

In a landmark study Zarit et al [42] looked at the impacts of providing informal care and suggested that informal carers fare worse than their non caring peers with respect to five indicators of physical and mental health: stress, depression, subjective wellbeing, physical health, and self-efficacy. In this context, self-efficacy relates to the carers confidence in their ability to exert control over their motivation and social environment [42]. However, caring can also be an important source of happiness in people’s lives with many individuals choosing to become informal carers and to continue providing care [44, 45, 55]. Oliva-Moreno et al [23] point to the fact that providing care can bring a sense of enjoyment of the role that can enhance the informal carers overall wellbeing. For some, their role as an informal carer may provide them with a sense of satisfaction, and it can bring them closer to the person they are caring for [44]. The literature points to factors such as control over the caring process, and stress attached to the caring role as having a strong impact in how providing care impacts on a carer’s overall health and wellbeing [43-45]. Van

Exel et al [56] noted that it is the characteristics of the carer, the care recipient, and the caregiving situation that will dictate what impacts may occur, and whether these impacts are positive, negative, or both.

In terms of physical health, the number of tasks an informal carer might have to perform, the time required for each task, and the physical nature of some of these tasks - such as assisting a care recipient out of bed - can be physically straining and this can lead to a deterioration in carer physical health [45, 57]. Meanwhile, a substantial literature base shows that providing informal care also impacts on the informal carer’s mental health. Again, this is because of the number of tasks required and the time required for each task [57] but also the social isolation [44], stress [1, 44], and uncertainty of the care recipients condition [44, 48]. This is found to be especially true in the context of providing care for the chronically ill or disabled because of the progressive nature of the care recipient’s illness [44]. The findings from one study indicate that the mental health effects of providing informal care seem to persist throughout the care trajectory meaning that informal carers do not adapt over time [48].

The literature has expanded beyond looking at the physical and mental health impacts of providing care to also look at how the impact of providing care can also influence a carer’s overall wellbeing [1, 43-45, 48, 55, 58-61]. For example, providing care often restricts the personal life, social life and employment of the informal carer [44, 57]. Many carers can experience problems with managing their caregiving tasks along with their paid employment which can lead to carers leaving their employment or reducing their paid working hours [52]. This in turn can have an impact on the carer's financial situation, along with the day-to-day costs of providing informal care such as travel to medical appointments etc.

Providing care can also impact on the carer's relationships and social activity as they may have less time to spend with friends, or to pursue leisure activities. The act of providing and receiving care can also result in a change in dynamic between the carer and the care recipient and this can have a massive impact on their relationship [44]. While these impacts can be negative, studies also show that this change in dynamic can provide both the carer and the recipient with an enhanced sense of companionship [23].

### *1.4.2. Impacts because of the relationship between carer and care recipient*

The presence and intensity of the impacts of caring differ greatly amongst different sub-groups of informal carers. For example, research shows that female carers, especially those providing a high intensity of caring, experience larger negative caregiving effects on mental health than their male counterparts [1, 48]. This may be because females are more often the primary caregiver and are more likely to experience social pressure to become an informal carer [44], or they have additional responsibilities on top of caregiving duties and are therefore more strongly impacted by the caregiving tasks [1, 48].

In the UK, most informal care is directed towards parents and spouses, with on average 40% of informal carers caring for their parents or parents-in-law, and 26% caring for their spouse or partner [21]. The evidence shows differences between these subgroups of carers regarding both their level of subjective burden, and the type of problems this burden can lead to [1]. Specifically, the evidence shows that caring for a spouse can result in larger negative caregiving effects compared to caring for a parent [44, 51, 55, 60, 62, 63]. This may be because, given their age, spousal carers might have the additional burden of suffering from their own mental and physical health issues [64]. They are also more likely to live with the care recipient and will therefore provide more hours of informal care [1]. However, most spousal carers are of retirement age and as such, do not have to combine their care tasks with other responsibilities such as paid work [65]. The research shows that, in contrast, adult-child caregivers can experience problems with managing their caregiving tasks along with their paid employment and other responsibilities [64].

### *1.4.3. Impacts because of the care recipient's condition*

As discussed in Section 1.3 as populations age, we can expect to see an increase in the number of people living with chronic illnesses or disabilities that require additional care. Chapter 4 will provide further detail on the conditions included in the research for this thesis. Briefly, the research is focused on high prevalence chronic conditions associated with diverse impacts on informal carer's lives, specifically dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis. Dementia is a degenerative condition associated with long care hours and physically demanding caregiving [66-68]. Mental health conditions are generally chronic with acute episodes that can require hospitalisation [59]. For mental health conditions, this research will focus on nonorganic mental disorders (most commonly anxiety disorders, delusional disorders such as schizophrenia, and mood disorders such as depression). Recovery from stroke and rheumatoid arthritis often involve younger carers, and the impacts of providing care are often related to the severity of the condition [69].

Section 1.4.1 looked at the impact providing care may have on the informal carer's health and wellbeing. It touched on the fact that chronic conditions can have a sustained negative impact on the carer, due to the progressive nature of the care recipient's illness [44, 48]. The literature shows that problematic behaviour, impaired cognitive ability, and increased daily dependencies are associated with increased carer burden [49, 61, 70]. This is true for caring for chronic conditions like dementia, recovery from stroke, mental health conditions, rheumatoid arthritis, and caring in general. However, it is the frequency of behavioural difficulties - difficulties that are directly influenced by the cognitive and functional impairment of the care recipient - that are the strongest predictor of carer burden and stress [61]. Research shows that for informal carers of people with dementia or a mental health condition, the presence of behavioural difficulties, such as antisocial behaviour, disorientation, hallucinations, wandering, and agitation have a negative impact on the carer's stress levels [44, 59]. Specifically, it is the uncontrollable and unpredictable character of the behavioural difficulties that influences their levels of stress and burden [59]. For carers of people recovering from stroke and rheumatoid arthritis it is the reduced functional capacity of the care recipient that has been linked to higher carer burden [69]. Reduced functional capacity impedes the performance of activities of daily living in the care recipient and influences difficulties such as problems with co-ordination and balance, problems with swallowing, communication problems, and over dependence.

This section looked at the positive and negative impacts providing care can have on carer QoL, and how these impacts differ amongst subgroups of informal carers and depending on the care recipient’s condition. By understanding that these impacts influence the carers’ willingness and ability to provide care and to sustain their role we can appreciate how important it is that carers are supported through policy and practice to continue in their role. The next section will address this issue and look at how informal carers have been included in policy and legislation to date in the UK.

## 1.5. Policy and social importance of informal care

Care for people is often provided by informal carers combined with support from professionals in a care triad consisting of the care recipient, informal carer and healthcare and social care professionals. This interaction between informal care and formal care may influence different directions in policy making.

Informal carers are an enormous asset to any healthcare system, it is often preferred by the care recipient and from a governmental perspective it is a low-cost alternative to formal care [48]. The provision of informal care may delay institutionalisation [71], thus significantly reducing the costs of long-term care for health systems [36, 72].

The role of informal carers is therefore a prominent issue at a political, sociological, and economic level. The literature highlights that, to effectively support informal carers to continue in their role, policy makers and healthcare providers must recognise and understand the role of, and burden on, informal carers [1, 4, 23, 45, 50, 73]. The inclusion of the informal care question in the 2001, 2011, and 2021 UK Censuses reflects the importance of informal caring as a public policy issue [73].

How informal carers have been included in policy and legislation to date in the UK is evolving to effectively support informal carers to continue in their role. Twigg and Atkin [46] put forward a framework that can help us to conceptualise how carers are perceived in UK policy:

- Model 1: Carer as resource: Carers are viewed as the default source of care and the focus of support is on the care recipient;
- Model 2: Carer as co-worker: Carers are viewed as working jointly with health providers and they are enabled and encouraged in their role;
- Model 3: Carer as co-client: Carers are viewed as individuals and the focus of support is on the carers needs.

In the UK, prior to 1995 informal carers were viewed in policy and legislation primarily as a resource to provide care (Model 1). This lack of recognition prompted the passage of The Carers (Recognition and Services) Act 1995 to take into consideration the needs of carers on a basic level (Model 2) [74]. The 1995 Act was the first piece of UK legislation to fully recognise the role of informal carers. This has since been expanded in the subsequent three acts, the Carers and Disabled Children Act 2000 [75], the Carers (Equal Opportunities) Act 2004 [76], and the Care Act 2014 [77]. These acts promote the equal rights of carers (Model 3). The 2014 Act also includes a provision that local and public authorities must work together in the planning and delivery of services to support carers in their caring role [77].

The Carers Strategy: Second National Action Plan 2014-2016 [78] was published prior to the implementation of the Carers Act 2014. It builds on the UK Government's vision for carers first published in 2008. The vision for informal carers, detailed in The Action Plan 2014-2016 is that "*carers will be universally recognised and valued as being fundamental to strong families and stable communities. Support will be tailored to meet individuals' needs, enabling carers to maintain a balance between their caring responsibilities and a life outside caring, while enabling the person they support to be a full and equal citizen*." [78]. The Carers strategy also identifies four areas for priority action: identification and recognition, realising and releasing potential, a life alongside caring, and supporting carers to stay healthy.

## 1.6. Chapter summary

This chapter described the scope and impact of informal care, with particular focus on carers in the UK. The chapter explored how the role of informal care is defined in legislation, policy, and academic literature. From this we can see that the key traits of informal care are that it is an unpaid role, the care is provided to somebody with an illness or disability, and the care is provided by a non-professional person with no training, usually a family member. The world's population is ageing and because of this we can expect to see the number of people living with chronic illness and disability rise in the coming years. This will lead to a 'care gap' because the number of people able and willing to provide informal care is unlikely to meet the projected demand. By understanding that the positive and negative impacts of providing care influence the carers' willingness and ability to provide care and to sustain their role we can appreciate how important it is that informal carers are supported through policy and practice to continue in their role. Key to ensuring carers capacity to provide care is sustained is ensuring that the impacts of providing informal care can be identified, measured, and valued within policy-making and resource allocation. The next chapter will explore this economic issue.

# 2. Informal care in economic evaluation

## 2.1. Introduction

Despite the advances in policy and legislation discussed in Chapter 1, because informal care is not directly paid out of healthcare budgets it is often an unnoticed or undervalued part of total healthcare and outcomes for informal carers are often not included in economic evaluation. The limitation of the evaluative scope may lead decision makers to reach different decisions of the cost-effectiveness of an intervention than would be reached if the wider, or spillover, effects of an intervention were considered. This chapter considers how the evaluative scope must be broadened to include the spillover effects of a given intervention on a patient or care recipient. This includes the impacts of providing informal care.

The chapter begins by providing a theoretical basis for how economic evaluation can assist in making difficult choices and the frameworks used for conducting economic analysis (Section 2.2). This section focuses on how informal care can theoretically be included within each of these frameworks by exploring how the costs and effects of providing informal care can be identified, measured, and valued so that they might be included in economic evaluation. This section introduces a number of preference-based QoL measures that can be used in economic evaluations involving informal carers.

Section 2.3 looks at how informal care has been included in economic evaluation to date, paying particular attention to how it has been included in academic literature, the specific challenges of including informal care in economic evaluation, and the importance of guidelines to ensure informal care is included in economic evaluation in an appropriate and meaningful way. This section shows us that despite increasing methodological and applied work, informal care is rarely included in economic evaluation [22, 36, 79].

Finally, the chapter concludes by summarising the current state of play for how informal care is included in economic evaluation and reiterates the importance of being able to demonstrate confidence in the methods we use for identifying, measuring, and including informal care in economic evaluation.

## 2.2. Informal care in economic evaluation: Theory

Despite the advances in policy and legislation discussed in Chapter 1, because informal care is not directly paid out of healthcare budgets it is often an unnoticed or undervalued part of total healthcare [23, 38, 80].

Informal care can be seen as an economic good as the resources required to provide informal care are finite in relation to demand. As such, difficult decisions must be made regarding how best to allocate the limited resources available for maximising population health and wellbeing [81]. Economic evaluation provides a framework for the comparison of the costs and outcomes of alternative interventions, and it is used to determine incremental cost-effectiveness and inform resource allocation decisions [82, 83].

Economic evaluation is rooted in welfare economics where the objective is to provide an ethical framework for making meaningful statements about whether specific changes improve social welfare [84]. There are two main theoretical bases for conducting economic evaluation in healthcare, welfarism and extra welfarism. Welfarism is defined in the literature as "*the systematic analysis of the social desirability of any set of arrangements, for example a state of the world or allocation of resources, solely in terms of the utility obtained by individuals*" [83]. There are four key principles upon which welfarism attempts to achieve economic efficiency [85]. These principles are that: individuals are rational and consistent in their choices and will seek to maximise their own utility; individuals are the best and only judge of their own utility; utility is derived only from the outcomes of a good or service; the appeal of any situation can be judged on the utility obtained by the individuals affected [83].

In terms of its theoretical groundings, there are arguments that the welfarism framework is not appropriate for healthcare decision-making [83, 86, 87]. In response, an alternative approach was developed called 'extra-welfarism'. This approach focuses on providing analysis to maximise health as opposed to overall welfare as the outcome of focus in resource allocation decisions [87, 88]. Brouwer et al [84] identified four ways in which extra-welfarism relaxes the assumptions of welfarism: it permits the use of outcomes other than utility (i.e. health); it permits the use of sources of valuation other than the affected individuals (i.e. general public); it permits the weighting of outcomes (whether utility or not) according to principles that need not be preference-based; it permits interpersonal comparisons of wellbeing in a variety of dimensions. Extra-welfarism, including the focus on the Quality Adjusted Life Year (QALY) as a measure of health, is typically the basis on which economic evaluation is undertaken within the UK and internationally [87, 89, 90]. The QALY combines into one measure the effectiveness of an intervention in relation to survival in terms of life-years and QoL. In terms of QoL, QALYs are weighted using utility values [91]. Utility values in this context reflect the societal preferences for health states and are anchored on a scale from 0 to 1 where 0 represents a health state equal to death, and 1 represents full health, enabling meaningful comparisons between health states. QALYs are then calculated by multiplying the utility value of the health state by the length of time (expressed in years) spent in that health state.

Presently, in terms of resource allocation decision making, the evaluative scope of outcomes is typically focused on the patient (or care recipient) as an isolated individual [56]. However, interventions designed to improve the health and wellbeing of the patient do not impact on the patient alone. One of the important choices in any economic evaluation is which elements of value are to be included in the analysis. Brouwer, 2019 [92] noted that "*in theory, all aspects of value that are relevant to the decision the analysis is trying to support should be included*". This field of research is constantly advancing, and authors have argued for the need to include informal carer health, and other impacts, in economic analyses to consider "*the full spectrum of effects of disease on society*" [93]. Not taking informal care into consideration in economic evaluation might undervalue the economic value of informal care [23, 38, 80]. In turn, it may underestimate the costs and impacts of an intervention intended for the care recipient [93, 94].

The limitation of the evaluative scope may lead decision makers to reach different decisions of the cost-effectiveness of an intervention than would be reached if the wider effects of an intervention were considered [95]. To prevent misallocation of resources the evaluative scope must be broadened to include informal care [37, 96]. To be included in economic evaluation we must first look at how we can measure and value informal carer impacts, and then look at how we can incorporate them into economic evaluation in a way that is meaningful to decision makers.

### *2.2.1. Including informal care costs and effects in economic evaluation*

How informal care is included in an economic evaluation depends on the perspective of the economic evaluation, and the type of economic evaluation that is conducted.

The perspective taken in the economic evaluation influences which costs, and effects on informal carers are relevant for the analysis [80]. The broadest perspective is societal which implies that all costs and effects should be considered, regardless of where these costs and effects occur [97]. If a societal perspective is taken in an economic evaluation, the costs and outcomes associated with informal care should be included [36, 43]. Alternatively, a healthcare sector perspective is narrower and includes the direct costs and effects for the healthcare provider e.g., the NHS in the

UK. From a healthcare perspective all healthcare costs and health effects should be considered, and in theory this should include healthcare costs and health outcomes for informal carers [12, 37, 38, 84].

The different frameworks used to conduct economic evaluation are commonly classified as cost-benefit analysis (CBA), cost-effectiveness analyses (CEA), and cost-utility analysis (CUA). The various frameworks require different information regarding informal care. Each framework similarly measures costs in terms of monetary units using methods described in the next section and incorporates a monetary value of informal care on the cost side on an analysis. The frameworks differ regarding measuring effects and outcomes.

CBA has its theoretical underpinnings in welfarism with both the costs and effects of a healthcare intervention valued in monetary units [81]. The aim of CBA is to estimate monetary values for benefits and compare them with the monetary costs of an intervention. If the benefits outweigh the costs, then the intervention should proceed. Because CBA expresses all costs and effects in monetary value, any effects of informal care should be valued in monetary terms. In CBA, contingent valuation (CV) and conjoint analysis (CA) methods appear to be the best tools for the valuation of informal care [37, 38]. A description of these methods is provided in the section that follows. The results of a CBA can show which intervention would maximise societal welfare within the healthcare sector and across other sectors of the economy thus allowing, for example, the comparison of a health intervention with an education intervention. However, in practice CBA has had limited use in healthcare decision-making due to ethical concerns about the valuing of health benefits in monetary terms [98, 99].

The primary goal of CEA is to determine which of similar interventions can get the most benefit for a specific outcome e.g., to reduce depression, for the lowest cost per unit. All the costs for each intervention are valued in monetary units. The effects of each intervention however will be specific to the intervention and measured in natural units relevant to the interventions, for example cases detected or life years gained [100-102]. The results of a CEA are presented in the form of an incremental cost-effectiveness ratio (ICER). An ICER compares interventions based on the difference in costs divided by the difference in outcomes. This ratio can be used to assess the efficiency of each intervention [103].

CUA is the main evaluation framework of the extra-welfarism theory [104]. It is the most frequently used form of economic analysis for decisions involving health care resource allocation [82], and the preferred evaluation framework of the National Institute for Health and Care Excellence (NICE) in the UK for baseline comparisons across the NHS. CUA focuses on health-related outcomes for healthcare treatments [82]. It builds upon CEA by including preferences and allowing for a generic measure of outcome - health-related utility (a QALY) - that can be applied across many conditions [82, 91]. As with CEA the results of a CUA are expressed in terms of an ICER. The ICER in this case is expressed in terms of the incremental cost to gain an additional QALY. The most cost-effective intervention is considered to be the one where the ICER (compared to the alternative) is below a pre-defined threshold.

### *2.2.2. Measuring and valuing informal care costs*

Two main types of costs of informal care can be distinguished, out-of-pocket expenses, and time. Out-of-pocket expenses, such as travel costs, are costs that can be measured directly by asking informal carers about expenses they have incurred as a direct result of providing care [37]. Time spent providing informal care can be directly measured using different methods such as the diary method and the recall method [37] For the diary method activities are prospectively recorded during a specified time period [105]. In contrast, the recall method involves the carer recording how much time they spend on a list of activities during a previous period, for example a day or week [105].

Once informal care time is measured, this time needs to be valued in monetary terms. A key issue in the monetary valuation of informal care hours is that there is no market price available for informal caring [106]. Therefore, several economic methods exist for valuing an hour of informal care where market prices are not available. These methods can be categorised as revealed preference-based methods and stated preference-based methods. Revealed preference methods are based on values obtained indirectly from preferences revealed in other markets [106]. In contrast, stated preference methods are based on values reported directly by informal carers [106].

In general, revealed preference methods use wages or income data to derive monetary values (Table 2.1). Two approaches are most common, the opportunity cost (OC) method and the proxy good (replacement cost) method. With the OC method monetary values for informal care are based on the assumed opportunity cost of the informal carer for time spent providing care [38, 105]. Time losses are valued based on the value of competing time use, for instance paid labour multiplied by the hours spent providing care [38, 80]. If the informal carer is not in paid employment, an average wage rate for an individual of the same age, sex, and education level can be used [79, 105]. Issues with this method include the heterogeneity in earning potential. Using an average wage rate based on demographics can understate the opportunity cost of time for relatively high earners and overstate it for low earners [105]. Grosse et al [105] also pointed to the decision of whether to use gross wages or net wages in the calculation as another source of heterogeneity in estimates. This method also raises potential issues associated with requiring informal carers to register the amount of time spent providing care. As highlighted by Grosse et al [105] it is possible to compare before and after time use patterns for acute events, but this is more difficult for chronic conditions. The authors suggest that in this instance carers could be asked what they would do with their time if not providing care [105]. Hoefman et al [37] also highlight the difficulty attached in retrospectively asking carers to indicate how much time they have sacrificed because of providing care. They note that carers might find it difficult to distinguish between ‘normal time use’ and informal care activities, especially for those providing care for longer periods of time.

**Table 2.1.** Monetary valuation methods for informal care

| Type of method | Approach | Concept | Valuation methods |
|---|---|---|---|
| Revealed preference | Uses data from decisions taken by individuals regarding goods or services assumed equivalent to informal care. [106]. | Time input<br><br>Wellbeing | OC<br>PG<br>Wellbeing |
| Stated preference | Obtains individual's valuation of a service, by directly asking individuals to state a money value or by asking individuals to make trade-offs between different characteristics of the service, using cost as one characteristic [106]. | WTP<br><br>WTA | CV<br><br>CA |

The proxy good (PG) method values time spent on providing informal care at the price of a (close) market substitute [79, 80]. The value of caregiver time can then differ for different tasks [37 2008]. For example, housework and personal care can be distinguished, with personal care being valued at the market wage rate of a home care nurse and housework being valued at the market wage rate of a housekeeper [37, 38]. The major issue with this method is the underlying assumption that (unpaid) informal care and paid care are perfect substitutes, which is unlikely to be true [37, 105]. This assumes that replacing the informal carer with a paid carer will yield no difference in the quality of care provided or the time spent performing care tasks [37].

The OC and PG approaches are similar in that they both require the measurement of time spent providing informal care, and while both approaches use wages or income data to derive monetary values, they differ in what data they use to arrive at their estimate. However, comparisons between both methods have found minimal differences between the two in the valuation of informal care [38, 79].

A third revealed preference method, the wellbeing method, calculates the monetary amount required to compensate an informal carer for their loss in wellbeing because of providing informal care [37]. This is a two-step approach: first the informal carers wellbeing is defined as a function of income and of the amount of care provided; second, the income required to maintain the informal carers wellbeing if an additional hour of care is provided is estimated [39]. This method assumes that income positively influences wellbeing [37]. An advantage of this approach is that it uses data from informal carers, rather than substitute markets, and it gives a total value of informal care. This total value includes time forgone along with other elements that impact on informal carers as a result of providing care [106].

Stated preference methods seek to obtain the individual carer's valuation of a particular service to estimate shadow prices where market prices do not exist or may not be generalisable (Table 2.1). Two approaches are most common, CV and CA [37, 107]. CV methods assess the value of informal care by presenting informal carers with a hypothetical caregiving situation and asking them to specify the minimum amount of money they are willing to accept (WTA) to provide informal care for an additional hour, or alternatively, the maximum amount they would be willing to pay (WTP) to reduce the amount of informal care they provide by one hour (Table 2.1) [38, 39, 79]. A key issue with CV methods is the potential for bias and strategic answers. Respondents may overstate their WTP when presented with hypothetical situations [105], or they may find it difficult to place a monetary value on their time [38]. Also, informal carers who are satisfied in their role may be less likely to participate in CV assessments than those who are dissatisfied. This would lead to upward bias of WTP/WTA estimates [105].

With CA methods, respondents are asked to evaluate different hypothetical informal care scenarios [37, 38]. Each scenario has different characteristics, or attributes which can take different values (levels). To derive a monetary value for informal care, one of the attributes should concern money [37, 38, 105]. By having respondents make several choices and varying the levels of the attributes, implied preferences for attributes can be derived [37, 105]. Different CA methods are used for eliciting preferences for scenarios and attributes, including ranking, rating, discrete choice and best-worst scaling [38]. A disadvantage of CA methods is that informal carers may find evaluating multi-attribute scenarios to be cognitively demanding [38].

A key criticism of revealed preference methods is that they do not consider if the informal carer derives benefit (utility) from providing care, which may reduce the monetary compensation required [106]. However, because these methods estimate the monetary impacts of care only the issue of double counting, that is, a situation where the value of an item has been counted more than once [83], is not expected to pose a serious threat [38, 105]. The issue of double counting is discussed in further detail in Section 2.3.2.

### *2.2.3. Measuring and valuing informal care effects*

The impacts of providing informal care extend beyond time contribution and can instead (or additionally) be quantified as an effect in terms of carers' QoL. A literature search identified many outcome instruments designed for use with informal carers - for context a review conducted by Mosquera et al., 2016 of tools used to assess the impact of elderly caregiving on the informal carers' life identified 93 tools [108]. Most tools identified are broad outcome measures of stress or burden, which cannot be used to generate QALY weights and therefore cannot be used in economic evaluation. In contrast, preference-based outcome measures can be used in economic evaluation. The literature shows that there are relatively few preference-based outcome measures available for use with informal carers. The measures discussed in this section are preference-based measures available for use with informal carers that can also be used in economic evaluation. Each measure consists of a self-complete standardised questionnaire and preference weights for all states defined by a classification system. The conceptual bases of the preference-based outcome measures identified in the literature can be broadly categorised as: those that measure HRQoL, those that measure the wellbeing of carers, or those that measure CRQoL. Chapter 4 will provide further detail on the outcome measures chosen for analysis in this study and the rationale for choosing each measure.

#### *2.2.3.1. Measuring health effects*

The HRQoL of caregivers can be assessed using QALYs based on generic HRQoL instruments [36]. HRQoL measurement places more emphasis on physical and mental functioning, focusing only on the areas of life which would be expected to be affected by a health condition or treatment [109]. In calculating QALYs, the EuroQoL five-dimension questionnaire (EQ-5D), a measure of HRQoL, is widely used [110] The EQ-5D is a generic preference-based outcome measure designed for self-completion [111]. The 5-level version (EQ-5D-5L) contains five items believed to impact QoL and linked to health: (i) mobility, (ii) self-care, (iii) usual activities, (iv) pain/discomfort, (v) anxiety/depression. With the EQ-5D-5L each dimension has five response categories. For the items ‘mobility’, ‘self-care’ and ‘usual activities’ these response categories are; no problems, slight problems, moderate problems, severe problems, unable to do. For the item ‘pain/discomfort’ these response categories are; no pain or discomfort, slight pain or discomfort, moderate pain or discomfort, severe pain or discomfort, extreme pain or discomfort. For the item ‘anxiety/depression’ these items are; not anxious or depressed, slightly anxious or depressed, moderately anxious or depressed, severely anxious or depressed, extremely anxious or depressed [112]. Using weights developed from preference studies, these states may be converted into a single summary index value, from 0 (being dead) to 1 (in perfect health) [113]. Used extensively in health research to assess patient utility, the EQ-5D-5L has also been used to assess the HRQoL of informal carers [114-116]. Other authors have used the EQ-5D-5L to assess the overall QoL of informal carers and supplemented this with a care-related measure to assess the caregiving experience [117]. In the UK, NICE recommends the EQ-5D as the preferred measure of QoL in adults and does not specify whether carer utility should be calculated by any other means [118]. The benefits of using the EQ-5D to measure carer QoL is that it can easily be combined with patient QoL. However, given the EQ-5D's focus on health, there are notable limitations to using this instrument for measuring carer QoL.

#### *2.2.3.2. Measuring wellbeing effects*

The ICECAP measures of wellbeing have been designed for use in economic evaluation of health and social care and offer a broader perspective on HRQoL than the EQ-5D [87]. The measures are conceptually based on Sen's capability approach which defines wellbeing in terms of an individual's ability to achieve important functioning's in life [86]. Separate ICECAP measures have been developed for use in the older population [87], for end-of-life care [119], and for the general adult population [120]. The ICECAP-O, developed for use with the older population has been applied to a sample of the older Australian population [121] and samples of the older UK population [41, 43, 122] according to carer status. The ICECAP-A was developed for use with the general adult population. The ICECAP-A contains five attributes believed to impact on QoL: (i) stability, (ii) attachment, (iii) autonomy, (iv) achievement, (v) enjoyment, and each dimension has four response categories ranging from 'no capability' to 'full capability'. In the UK, NICE recommends this measure for use within the evaluation of social care interventions [123]. The

ICECAP-A has been used in economic evaluations mainly in the UK, but also in other English-speaking countries and in Europe, across a wide range of healthcare contexts [124], and with populations of informal carers [19, 43].

#### *2.2.3.3. Measuring CRQoL effects*

In measuring the QoL of informal carers both health-related and wellbeing instruments have been criticised for not capturing attributes relevant to the caring role, and which might impact on informal carer's QoL [125]. Instead, focusing on care-related outcomes for informal carers may be appropriate as they map onto the issues important to them better than HRQoL or wellbeing measures. The Carer Experience Scale (CES) [126], CarerQol [127], and ASCOT-Carer [11] are subjective burden instruments that include both positive and negative items. Other subjective burden instruments identified in the literature such as the Zarit burden interview [42] or the caregiver strain index [70] do not include items on the positive aspects of caregiving and while these measures provide valuable information on the experience of carers, they do not provide an overall valuation of the impacts of caring. The CES, CarerQoL, and ASCOT-Carer have been developed specifically for use within economic evaluation. Each measure has been designed for use alongside the QALY (for carers) in economic evaluation with the intention of providing additional information to standard methods.

The CES was developed in the UK, using a combination of findings from qualitative studies on caring and semi-structured interviews with informal carers of older people (n=16) [41]. These interviews were used to develop the six items included in the measure which capture conceptual attributes of caring: (i) activities outside caring, (ii) support from family and friends, (iii) assistance from organisations and the government, (iv) fulfilment from caring, (v) control over caring, and (vi) getting on with the care recipient. Each item is described on one of three levels: little, some, a lot of. Relative weights attached to each of the six care dimensions are aggregated to provide a preference-based overall score of caring experiences (0 'bottom state' - 100 'top state') [41]. Preference weights are currently available for the UK population only [126]. The CES has been used in studies of carer wellbeing and service evaluation in the UK [43, 72] and Australia [57, 128].

The CarerQol instrument was developed in the Netherlands, based on a review of the domains included in existing burden measures [127]. The measure contains two components: the CarerQol-7D (subjective burden) and the CarerQol-VAS (visual analogue scale) (wellbeing) [127]. The CarerQoL-7D contains seven items - five negative (relational problems, mental health problems, problems combining daily activities with care, financial problems, and physical health problems) and two positive dimensions of caregiving (fulfilment and support). Each domain is described on one of three levels: no, some, a lot of. The domains included were assessed based on a sample of informal carers (n=175) [127]. The seven dimensions can be aggregated and weighted by their severity with a tariff, which is then used to calculate an overall score (0 'worst situation' – 100 'best situation') [127]. To date, tariffs for the Netherlands, Australia, Germany, Sweden, the UK, and the USA have been developed [14, 129]. The CarerQol-VAS measures the happiness of carers on a horizontal VAS ranging from 0 (completely unhappy) to 10 (completely happy) [15]. The CarerQoL has been used extensively in studies examining the wellbeing and economic burden of providing informal care, for example in the Netherlands [130], the UK, Italy, and Germany [131].

The ASCOT-Carer is a preference-based measure of carers' social care related QoL (SCRQoL) and has been designed for use alongside the QALY (for carers) in economic evaluation. In the UK, social care refers to community-based services such as home care and day centres, and residential or nursing care [11]. As with the CES and the CarerQol, the ASCOT-Carer is a survey instrument, designed for self-completion by informal carers, though there is also an interview version available [11]. The measure was developed through focus groups with care managers and informal carers. This work identified seven items of SCRQoL from the carer's perspective: (i) occupation, (ii) control over daily life, (iii) self-care, (iv) personal safety, (v) social participation, (vi) space and time to be yourself, (vii) feeling supported and encouraged [11]. Each item is judged on one of four levels; no, some, adequate, as much as I want. The English scoring algorithm, based on general population preferences, was used to calculate the preference weight and ranges from 0 (worst QoL) to 1 (best QoL) [11, 132]. The ASCOT-Carer has been used in research to explore the SCRQoL of informal carers of people living with dementia [133].

## 2.3. Inclusion of informal care in economic evaluation: Practice

Despite increasing methodological and applied work, research shows that informal care is rarely included in economic evaluation [22, 36, 79]. This may be because of methodological issues and/or the guidelines available for including informal care.

### *2.3.1. The inclusion of informal care in economic evaluation*

Several systematic reviews were identified which explored the inclusion of informal care in economic evaluations, the methods used, and the potential impact of including the costs and effects of informal care on cost-effectiveness results. [80, 94, 95, 134-136]. Table 2.2 shows the key points from the systematic reviews identified.

The number of relevant economic evaluations identified by the authors ranged from 30 [95] to 422 [135]. This broad range is because Goodrich et al [95] and Scope et al [136] only searched for studies that included informal carers (or family members), while the other authors searched, for example, for all economic evaluations related to a specific disease area (Krol et al [80] and Lin et al [94]) and then explored the number of economic evaluations that included informal care in their analysis. Krol et al [80] identified 100 economic evaluations investigating interventions targeted at Alzheimer's disease, metastatic colorectal cancer, Parkinson's disease, and rheumatoid arthritis. Less than a quarter (n=23) of these evaluations included costs and/or effects of informal caregiving. Pennington [135] reviewed all published NICE economic evaluations to identify those that included carer HRQoL. The author identified 422 economic evaluations in their review, of which 17% (n=73) mentioned the term ‘carer’ or ‘caregiver’. Of these, only 16 studies included HRQoL in their analysis. Lavelle et al [134] identified 142 CUAs of which 72% (n=105) considered informal care, and Lin et al [94] identified 63 economic evaluations investigating interventions targeted at Alzheimer’s disease, of which 70% (n=44) considered informal care. Lavelle et al [134] explored how family spillover including costs and effects for parents, siblings, and extended family members are considered in paediatric CUA. This is the only study included in this review that focuses on a paediatric population and does not specify the role of the informal carer.

Each author noted that more recent studies were more likely to include informal care. For example, Pennington [135] found that the first NICE appraisal to include carer HRQoL was in 2007, the next appraisal to include carer HRQoL was not until 2012, and since 2014, more appraisals have included carer HRQoL. Lin et al [94] commented that studies published from 2006 to 2018 were more likely than those published in 2000-2005 to include informal care, and Goodrich et al [95] - who focused their search on economic evaluations that included informal care - noted that despite the search covering a period of 60 years, only 5 studies were published prior to 2000. This is consistent with the emerging international consensus on the importance of including informal care in economic evaluation discussed in Chapter 1.

The country/region where most studies identified were conducted ranged from the UK specifically (n=1), the UK predominantly (n=1), Europe more generally (n=2), and the USA (n=1). The inclusion of informal care in economic evaluation is often dictated by the country guidelines. This is especially true of the perspective taken in the analysis and the limitations this can place. Most studies identified in Lin et al [94] were conducted from the societal perspective (69%) and the authors found that studies conducted from this perspective were more likely that those conducted from a healthcare perspective to include spillover effects. This was true for each of the systematic reviews identified, with most evaluations identified that included informal care taking a societal perspective, either exclusively or in addition to a narrower payer perspective. Goodrich et al [95] commented in their review that "*the decision about how to incorporate informal care in the economic evaluation appears to be driven by the perspective taken and the nature of the intervention*". This reflects the expanded scope of these analyses in comparison to analyses conducted from a healthcare perspective.

Most studies identified in each review that included informal care, except for Pennington [135] were in the field of Alzheimer's disease/dementia. In the Goodrich et al [95] review just over half of all the studies that included informal care were in the field of mental and behaviour disorders including dementia. Krol et al [80] focused their review on four distinct disease areas where informal care is potentially important: Alzheimer's disease, metastatic colorectal cancer, Parkinson's disease, and rheumatoid arthritis. Their review found that the inclusion of informal care differed considerably between diseases. Lin et al [94] focused their analysis on Alzheimer's disease/dementia. This is perhaps reflective of the fact that Alzheimer's disease/dementia has a well-known caregiving burden. This topic is discussed in greater detail in Chapter 4.

The reviews highlighted that most studies that considered informal care included caregiving time costs, with a small number stating that they valued time loss as a productivity loss. Most studies that stated how carers' time input was valued used the OC method and the PG method. Very few studies included caregiver out-of-pocket spending (such as travel expenses), and as noted in Goodrich et al [95] there was no obvious attempt in any study to identify whether joint production had occurred, i.e., whether other activities such as housework were undertaken at the same time as informal care.

Table 2.2 shows that where outcomes for carers were incorporated into the economic evaluation most studies used generic health status measures and calculated QALYs for carers. The EQ-5D was the most used measurement instrument. As discussed in Section 2.2.3 HRQoL may be a limiting measurement that does not capture the full impacts of providing informal care. Other studies used care-related measures of QoL as their primary outcomes. This was evident in the review conducted by Goodrich et al [95] where two studies used measures of carers free time, two used WTP, and two used a mix of clinical questionnaires on health, hope, morale, and satisfaction as outcome measures. In the review conducted by Lin et al [94] three studies reported summary measures of informal carer mental health, and stress, using measures that were not converted into health utilities, such as the Zarit Caregiving Rating Scale. As discussed in Section 2.2.3 using non-preference-based measures such as this does not give a full picture of the impacts of providing care.

The most common analytic approach to incorporating informal care costs and/or effects into the ICER was to sum carer and patient values. For example, in the review conducted by Lavelle et al [134] of the 105 economic evaluations that included informal care, 94 included informal care costs and 90% of these studies added carer costs to patient costs. Ten studies included carer HRQoL and 64% of these studies added carer QALY loss to patient QALYs using a time horizon specific to the patient's condition.

Among the studies reporting sufficient information to compare cost-effectiveness results with and without informal care, the authors found that in the majority of cases informal care inclusion had a limited effect on cost-effectiveness outcomes. Where it did have an impact, it typically decreased ICERs or kept the intervention under consideration cost-effective. For example, Lin et al [94] found this was the case in about 85% of the analyses including Alzheimer's disease/dementia informal care cost or health effects. In some studies, the inclusion of informal care changed cost-effectiveness results enough to cross a threshold, though this was not typical of the studies identified in each review. For example, in the review conducted by Krol et al [80] the authors were able to determine that taking a QALY threshold of €50,000 per QALY, informal care inclusion or exclusion would alter decision making in one of the 23 economic evaluations identified.

Each review concluded that informal care is inconsistently included in economic evaluation and that where informal care was incorporated a wide array of methods was used. As noted by Goodrich et al [95] the heterogeneity in methods "…*is likely* *to be partly due to the lack of consensus on the valuation of time and outcomes for carers*". This sentiment is echoed in the reviews conducted by Pennington [135], Lin et al [94] and Krol et al [80] with the authors noting that this heterogeneity "…*confines the comparability of cost-effectiveness outcomes between studies*" [80]. As a result, the interpretation of cost-effectiveness results may be over complicated for decision makers and the usefulness of including informal care in economic evaluation could be called into question. Lin et al [94] also points to the issue of carer HRQoL as measured by the EQ-5D being the most used measure for assessing carer outcomes. The authors comment on the limited nature of using such an outcome measurement for informal care.

The review conducted by Lin et al [94] expanded on the research conducted by Krol et al [80] and this allows the authors to evaluate trends in the inclusion of informal care in the field of Alzheimer's/dementia. The authors found that in the four years since the publication of Krol et al [80] the inclusion of informal care was more frequent (64% of CUAs identified by Krol et al [80] compared to 70% of CUAs identified by Lin et al [94]). Lin et al [94] also noted that the inclusion of informal care was likely to have more of an impact on cost-effectiveness results in the studies they identified compared to the review conducted by Krol et al [80] where the inclusion of informal care was found to have a limited impact on cost-effectiveness results.

The reviews showed that the inclusion of informal care in economic evaluation can have an impact on inferences about the cost-effectiveness of an intervention, and the impact of its inclusion may differ by context, intervention, and disease [80, 94, 95, 134-137]. As noted by Pennington [135] there are "*…no clear trends or rules…*" for when it is relevant to include informal care in economic evaluation, and the methods that should be used to incorporate informal care. The next two subsections will explore some of the methodological issues that can be involved with including informal care in economic evaluation, and the range of guidance that exists to encourage uniformity in the methods.

**Table 2.2.** The inclusion of informal care in economic evaluation

| | **Goodrich et al., 2012** [95] | **Krol et al., 2015** [80] | **Lavelle et al., 2019** [134] | **Lin et al., 2019** [94] | **Pennington, 2020** [135] | **Scope et al., 2022** [136] |
|---|---|---|---|---|---|---|
| Economic evaluations that included informal care (n=) | 30 | 23 | 105 | 44 | 16 | 40 |
| Economic evaluations that included informal care costs (n=) | 13 | 19 | 105 | 32 | Not relevant | Not relevant |
| Economic evaluations that included informal care outcomes (n=) | 5 | 1 | 15 | 2 | 16 | 40 |
| Economic evaluations that included both informal care costs and outcomes (n=) | 12 | 3 | Not specified | 10 | Not relevant | Not relevant |
| Perspective | Societal x 20<br>Healthcare x 8<br>Carer x 2 | Societal x 15<br>Healthcare x 7<br>Payer x 7 | Societal | Societal x 30 | Healthcare | Not specified |
| Method for valuing time | OC or PG methods | OC or PG methods | OC or PG methods | OC methods | Not relevant | Not relevant |
| Method for measuring outcomes | HRQoL x 8, CRQoL x 3, Other x 6 | HRQoL x 1, Other x 3 | HRQoL x 12, Other x 3 | HRQoL x 9, Other x 3 | HRQoL | HRQoL |
| Method for incorporating informal care | Costs and/or outcomes for carers and patients were summed together in 6 cases. | Not specified | Costs and/or outcomes for carers and patients were summed together in 92 cases. | Costs and/or outcomes for carers and patients were summed together in 43 cases. | Carer HRQoL was modelled as a function of the patient's health state in 12 cases | Not specified |

| | | | | | | |
|---|---|---|---|---|---|---|
| Impact of including informal care | Incorporating informal care generally altered the cost-effectiveness of interventions, in some cases changing the key conclusions for health care funding. | In the majority of cases informal care inclusion had a limited effect on cost-effectiveness outcomes | Incorporating spillover generally made interventions more cost-effective or did not change CUA results enough to cross a threshold. | In the majority of cases informal care inclusion decreased ICERs or kept the intervention cost saving. | Including carer HRQoL increased the incremental QALYs and decreased incremental cost-effectiveness ratios in all cases. | Family member QALY estimates, in many cases, were substantial in magnitude and therefore resulted in lower ICERs when included |

Notes: OC: opportunity cost, PG: proxy gamble, HRQoL: health-related quality of life, CRQoL: care-related quality of life, QALY: quality adjusted life year, ICER: incremental cost-effectiveness ratio

### *2.3.2. Methodological issues*

This chapter has so far shown that despite the growing recognition of the need to include informal care in economic evaluation, informal care has rarely been included in economic evaluations to date. This may be due to methodological issues around the broadening of the evaluative scope to include informal care. Issues delaying the more frequent incorporation of informal care into economic evaluation include ignorance over the potential for impacts on carers, and practical issues such as the time consuming and potentially costly nature of identifying informal carers and collecting data. The specific issues considered in this section are the lack of consensus of how costs and outcomes for patients and carers are measured and incorporated together into economic evaluation, along with the potential for double counting.

As detailed in Section 2.2.3 there is a range of options available to measure informal carer outcomes for their inclusion in economic evaluation. The conceptual basis of these measures can be broadly categorised as those that measure HRQoL (e.g., EQ-5D), those that measure wellbeing (e.g., ICECAP), or those that measure CRQoL (e.g., CES, CarerQoL, ASCOT-Carer). Table 2.2 shows that where outcomes for carers were incorporated into the economic evaluation most studies used HRQoL measures and calculated QALYs for carers. Table 2.2 also shows that the most common analytic approach to incorporating informal care costs and/or effects into the ICER was to sum carer and care recipient values.

As discussed in Section 2.2 HRQoL may be a limiting measurement as it does not capture the full impacts of providing informal care. Instead, focusing on care-related outcomes for informal carers may be appropriate as they map onto the issues important to them better than HRQoL. However, aggregating carer and care recipient QoL outcomes when they are in different units is not straightforward [125, 138]. Issues arrive when attempting to aggregate CRQoL outcomes with care recipient generated QALYs as most measures designed for the purpose of generating care recipient QALYs for economic evaluation are health-related measures such as the EQ-5D.

Therefore, the key benefit of using the EQ-5D to measure carer QoL is that it can easily be combined with care recipient QoL. However, as noted by Al-Janabi et al [125] "*there is nothing inherent in the QALY approach that requires life-years to be adjusted by a health-related QoL measure*". This opens the discussion to the potential for a 'middle ground' general wellbeing/QoL option – for example the ICECAP. The ICECAP measures of wellbeing have been designed for use in economic evaluation of health and social care, the measures offer a broader perspective on HRQoL than the EQ-5D, and they can be used to generate QALY types outcomes (time-adjusted capability) for both patients and informal carers [87].

Aside from the issue of what outcome measure to use, and how best to aggregate care recipient and carer outcomes in economic evaluation there is also the potential for double counting to consider when incorporating informal care in economic evaluation. As detailed in Section 2.2 the impact of providing informal care is far reaching and it should be included in economic evaluation in both the estimation of costs and the estimation of effects [37, 95, 139]. This is where the potential for double counting arises. Double counting is a situation where the value of an item has been counted more than once [83]. Double counting can arise in economic evaluation if the same consequence of an intervention is included in both the estimation of costs (numerator) and the estimation of quality weights to construct QALYs (denominator) [140]. For example, it is possible a carer considers their lost income or leisure time when the QoL outcome of an intervention is being measured. Since these losses are already being counted as a cost they would be double counted if incorporated into the outcome as well. To date, empirical studies of double counting have focused on how indirect societal and productivity costs have (or should) be included in economic evaluation to avoid double counting [141-148].

### *2.3.3. Guidelines*

The inclusion of informal care in economic evaluation is strongly conditioned by the rules that each country adapts or recommends [23]. Table 2.3 looks at the guidelines for a selection of twelve countries: Australia, Canada, Denmark, Finland, France, Germany, Italy, Ireland, The Netherlands, Sweden, USA, and the UK.

Recommendations on the inclusion of informal care has changed over time. In 1996, the first US Panel on Cost Effectiveness in Health and Medicine (First Panel) called for the inclusion of informal care time costs in societal perspective analyses [149]. The First Panel also recognised the potential value of including health effects on family members but did not recommend their inclusion in a reference case societal-perspective analysis [105]. The second US Panel on Cost-Effectiveness in Health and Medicine (Second Panel) in 2016 called for the inclusion of both health effects on family members and informal care time costs in societal-perspective analyses. It was recommended that informal care time be included in an inventory of costs and considered for inclusion depending on the study perspective, availability of data, and the likelihood that its inclusion would have a substantial effect on cost estimates [150]. This is also the case in the guidelines for Australia which state that "*In circumstances where the beneficiaries of health or other relevant outcomes are broader than the treated patient population (e.g., community, carers, dependants), include these as supplementary analyses*" [151].

Likewise, although informal carers are not specifically mentioned in the guidelines for Germany [152], Ireland [153] and Italy [154], each country recommends a supplementary analysis can be conducted using a societal perspective. This perspective would allow for the inclusion of the effects of informal care where relevant. The guidelines for the Netherlands [155], Sweden [156], and Denmark [157] recommend a societal perspective in the reference case analysis which would allow for the inclusion of carer impacts. Current guidelines from Canada and NICE in the UK specifically recommend the inclusion of carer effects when relevant. The UK guidelines state that "*Evaluations should consider all health effects for patients, and, when relevant, carers. When presenting health effects for carers, evidence should be provided to show that the condition is associated with a substantial effect on carer's* *health-related quality of life and how the technology affects carers*" [118]. The guidelines for Canada state that "*The target population may include patients and their informal carers (i.e., unpaid carers). Researchers should consider any potential spillover impacts (such as due to changes in the level of care required by patients beyond those individuals for whom the interventions are being targeted)*" [158]. And, although spillover effects and informal carers are not mentioned by name in the guidelines for economic evaluation in France, their inclusion is implied with the following recommendation "*The population concerned can be extended to include other individuals when their health is affected by the interventions studied, even though they were not targeted*" [159]. Of the twelve countries selected, the only guidelines that do not allow for a societal perspective either in the base analysis or as a supplementary analysis, and where no reference to the inclusion of spillover effects or informal carers is made is Finland [160].

The range of guidance reviewed show a lack of uniformity in the methods recommended for including informal care in economic evaluation. This is perhaps unsurprising given the differences in health systems, and in particular differences in the perspective favoured by each country. The impact of this lack of consensus on how to include informal care in economic evaluation is that informal care may not be routinely included in economic evaluation.

**Table 2.3.** Country guidelines for economic evaluation

| Country | Perspective | Preferred analytical technique | Inclusion of informal care in economic evaluation |
|---|---|---|---|
| Australia [151] | Healthcare sector<br>Optional analysis using societal | Cost minimisation analysis (CMA), CUA, CEA or CCA | In circumstances where the beneficiaries of health or other relevant outcomes are broader than the treated patient population (e.g., community, carers, dependants), include these as supplementary analyses |
| Canada [158] | Healthcare sector<br>May deviate depending on the decision problem | CUA | The target population may include patients and their informal carers (i.e., unpaid carers). Researchers should consider any potential spillover impacts (such as due to changes in the level of care required by patients beyond those individuals for whom the interventions are being targeted) |
| Denmark [157] | Societal | CUA or CEA | Not mentioned |
| Finland [160] | Healthcare sector | CUA | Not mentioned |
| France [159] | Sufficiently broad to include all health system stakeholders | CUA and/or CEA | Not mentioned |
| Germany [152] | Healthcare sector<br>Optional analysis using societal | CUA or CEA | Not mentioned |
| Ireland [153] | Healthcare sector<br>Optional analysis using societal | CUA | Not mentioned |
| Italy [154] | Healthcare sector<br>Optional analysis using societal | CUA and/or CEA<br>CMA for limited cases | Not mentioned |
| Netherlands [155] | Societal | CUA | Not mentioned |
| Sweden [156] | Societal | CUA, CEA or CMA | Not mentioned |
| UK [118] | Healthcare sector<br>Societal if justified | CUA | All direct health effects should be included for patients or, when relevant, carers |
| USA [150] | Healthcare sector<br>Optional analysis using societal | CEA or budget impact models (BIM) | Include in supplementary analysis |

## 2.4. Chapter summary

This chapter provided a theoretical basis for informing resource allocation decisions and explores how economic evaluation can assist this process. To prevent misallocation of resources the evaluative scope must be broadened to include informal care. To be included in economic evaluation in a way that is meaningful to decision makers we need to be able to confidently measure and value carer impacts. This chapter introduced a number of preference-based QoL measures that can be used in economic evaluations involving informal carers. To ensure informal care is included in economic evaluation we must be able to demonstrate confidence in these measures for measuring informal carer QoL. The next chapter will explore this topic.

# 3. The validity and responsiveness of outcome measures for use with informal carers

## 3.1. Introduction

Despite the increasing methodological and applied work explored in Chapter 2, we see that informal care is still rarely included in economic evaluation. This chapter will progress the discussion by exploring how we can test the validity and responsiveness of these outcome measures. The chapter begins by looking at the theoretical background to validity and responsiveness, defining the types of validity that can be tested such as construct validity, content validity, and face validity, along with the concepts of feasibility and responsiveness. (Section 3.2).

Establishing the validity and responsiveness of an outcome measure for a particular purpose is an ongoing process, and Section 3.3 looks at the methods that can be used to test validity and responsiveness. This section begins by exploring how we can use both quantitative and qualitative methodology, and why we should use both to strengthen confidence in the conclusions drawn. Along with the methodology employed, the population used is important to ensure a secure judgement on the validity and responsiveness of outcome measures. Section 3.3 concludes by exploring various methodologies for identifying a participant sample.

Section 3.4 discusses the existing literature on the validity and responsiveness of preference-based outcome measures with informal carers, drawing on some wider literature where relevant. This section concludes by outlining the gaps in our knowledge and why further testing is required for outcome measures used with informal carers to strengthen confidence in their ability to be used in economic evaluation.

## 3.2. Overview of validity and responsiveness concepts

The scientific field of psychometrics is concerned with assessing the measurement characteristics of scales and involves such properties as practicality, reliability, and validity [161-163]. Practicality refers to the acceptability of the content and administration method to participants while reliability assesses the degree to which a result remains unchanged upon test and retest (when no change is expected) or between different methods of administration [161, 162]. Validity has been defined as "*the extent to which an instrument measures what it is intended to measure*"

[161]. There are many different types of validity testing. For example, criterion validity investigates how the instrument compares to an external ‘gold standard’ [164]. However, in social sciences it is often the case that such a gold standard does not exist [165]. In the absence of a gold standard for QoL, psychometricians have developed various indirect ways of establishing validity [161]. These include construct validity, content validity, face validity, and feasibility. Finally, the appropriateness of an outcome measure is not only determined by its validity. Research highlights the importance of an instruments ability to be sensitive to detecting change in the outcome it is measuring e.g. QoL [166]. The concept of responsiveness is closely linked to validity and is a key psychometric performance indicator [161].

As defined by Brazier [161] construct validity is “*a series of procedures concerned with assessing the extent to which the dimension scores of an instrument correlate with other hypothesized measures or indicators of the health concept or concepts of interest*”. A construct refers to a concept that cannot be directly measured but can be measured by observing other indicators that are associated with it. For example, a person’s QoL cannot be directly measured, but a QoL measure can measure the elements that contribute to a person’s QoL. When assessing construct validity for QoL measures the goal is to ascertain if the overall measure represents the thing researchers are interested in measuring i.e., does the tool really measure the construct of QoL or is it measuring something else.

There are two commonly used approaches for assessing construct validity [161]. The first is known as convergent validity which looks at "*the extent to which a measure correlates with another measure of the same concept*" [161]. When assessing convergent validity for preference-based QoL measures this would involve using another preference-based QoL measure as a comparator. The second approach is known as discriminative validity which involves group comparisons where "*a measure is judged in terms of its ability to differentiate between groups thought to differ in terms of their health*" [161]. Assessment of construct validity involves the development of evidence-based hypotheses. These hypotheses should be formulated based on past empirical research and theoretical work where possible. The stated hypotheses are then subjected to rigorous testing. The results of the analysis can then be interpreted to build an argument for an outcome measures validity.

Content validity is the measurement property that assesses "*the extent to which one can generalise from a particular collection of items to all possible items in a broader domain of item*"[163]. Claims for content validity typically rest on the comprehensiveness of the instrument and the methods used to generate its dimensions and items [161, 167]. When assessing content validity for QoL measures the goal is to ascertain if the items of each measure are "*relevant and important"* [168] to the participants, and to gauge whether there are additional areas of interest that are not covered in the existing measure [167, 168]. Furthermore, assessment of content validity can provide evidence "*that the conceptual framework, content of items and overall measurement approach are consistent*" [167]. Face validity looks at whether a measure appears to be valid and acceptable to users [169]. It describes how well an instrument appears to measure what researchers intend the instrument to measure [163]. When assessing face validity for QoL measures the goal is to ascertain if the dimensions of a measure are comprehensive and if they adequately reflect the perspective for the population of interest.

Assessment of content and face validity is largely based on the judgements of individuals – patients, public or research professionals [162]. The methodology employed to assess content and face validity should be documented and transparent, the research should be grounded in the data, and the analysis should be iterative, thematic and constantly comparative [170, 171]. The literature also highlights that the most appropriate way to collect data to support content validity is through direct communication with participants using qualitative data collection techniques such as individual interviews, focus groups and observations [167, 168]. The use of qualitative methods to assess validity is discussed in further detail in Section 3.3.

The feasibility of a QoL measure can also be described as the measure’s ease of completion [172, 173]. It provides evidence that the measure is practically useable in the relevant context. Indicators of the feasibility of a QoL measure include rates of missing responses and administration time [172, 174]. Feasibility can be assessed through both quantitative and qualitative methodology which will be discussed in Section 3.3.

Finally, responsiveness refers to the ability of an instrument to measure important or meaningful change [162] and is a key psychometric property of an outcome measure [100]. When assessing the responsiveness of QoL measures the goal is to ascertain if the measure is sensitive enough to detect actual changes that have occurred in respondent QoL.

There are two distinct methodological approaches available for assessing responsiveness, distribution-based and anchor-based [175]. The distribution-based approach is a set of methods for estimating change based on a statistical parameter of the population or sample [175]. This statistical parameter is the relationship between the magnitude of effect and some observed variation within the sample [176]. There are two frequently used distribution-based approaches: effect size and standard response mean [175, 176]. A key criticism of the distribution-based approach is that it is 'anchor free' with no external reference point [177].

Anchor-based methods explore the association between the targeted concept of an outcome measure e.g. CRQoL and the same or similar concept measured by an independent and external anchor(s) [175]. Changes in the outcome measure score (either improved or worsened) are compared, or anchored, to changes in the anchoring item [175, 176]. It is recommended that multiple anchors are used when completing an anchor-based responsiveness analysis and anchors should have a theoretical or proven association with the outcome measure under investigation [175, 178, 179]. An acceptable minimum magnitude of the association between the change in outcome measure score and the anchor is taken to be 0.3 [175, 176].

## 3.3. Empirical considerations for assessing the validity and responsiveness of outcome measures for economic evaluation

As detailed in the previous section establishing the validity and responsiveness of an outcome measure for a particular purpose is an ongoing process, requiring both qualitative and quantitative approaches. It is not possible to arrive at the level of 100% certainty, however, using a combination of qualitative and quantitative data can improve an evaluation of an outcome measure by ensuring that the limitations of one type of data are balanced by the strengths of another [168, 180].

The strengths of quantitative methods are that they produce factual, reliable outcome data. These methods are suited to establishing cause-and-effect relationships, to testing hypotheses, and to determining the opinions and practices of a large population [180]. In contrast, the strengths of qualitative methods are that they generate rich, context specific data based on the participant's perspectives and interpretations. These methods are best suited to describing processes such as decision making [180]. The main point of difference in quantitative and qualitative approached can be said to be that qualitative studies try to answer questions about the 'what', 'how' or 'why' of a phenomenon, rather than questions about 'how many' or 'how much' [181]. Therefore, methods such as cognitive interviewing and observation, rather than surveys and experiments, are used to add depth and nuance to the evaluation of an outcome measure.

Cognitive interviewing enables an in-depth exploration into how and why respondents arrive at their answer when completing an outcome measure [167]. There are two main techniques of cognitive interviewing: verbal probing and 'think-aloud' interviewing [182]. Verbal probing requires the interviewer to ask the respondent specific questions or probes which are designed to elicit how they went about answering a particular question [183]. The main difficulty with verbal probing is that it may influence and interfere with the respondents thought processes [184].

In contrast, 'think-aloud' interviews are respondent driven and designed not to alter the interview dynamic in any significant way that might affect comparability with the instrument's "*normal*" usage [184]. In think-aloud interviews, respondents are asked to verbalise their thoughts on the survey questions without interference from the interviewer [182, 183]. There are two main think-aloud approaches, retrospective, where participants complete the tasks in silence and verbalise their thoughts at the end of the session, and concurrent, where respondents verbalise their thoughts while completing the task. Concurrent think-aloud interviews have been shown to generate more information and insights into decision making processes than retrospective methods [185]. Both think-aloud and semi-structured interviews can be used individually [186-188] or combined [19, 189-191]. The semi-structured portion of the cognitive interview is typically aimed at eliciting the participants experiences of completing the survey questions and their reaction to the survey questions [190].

Along with the methodology employed, the population used is important to ensure a secure judgement on the validity and responsiveness of an outcome measure and various methodologies exist for identifying a participant sample. As detailed by Brod [167] the characteristics of the sample should reflect as closely as possible the population to be included in future studies that will incorporate the measure and within this range, as wide a distribution as possible of age, ethnicity, and socioeconomic status is necessary to capture "*variations within a common group*". The sampling strategy chosen may depend on the research aims and the analysis process [192].

A convenience sampling strategy involves the selection of the most accessible participants and is regarded as the least rigorous technique because it does not represent any specific population of interest [193]. Instead, the literature points to purposive sampling as being the best method for achieving a variety within the participant sample, or to achieve a selection of participants based on the same characteristic [194, 195]. Purposive sampling is a judgement sampling strategy, to purposively select people who are 'typical' of the phenomena under study [196]. This methodology focuses on choosing 'information-rich' cases "*from which one can learn a great deal about issues of central importance to the purpose of the inquiry*" [194]. A strategy such as snowball sampling can also be used to identify additional participants. Snowball sampling involves asking existing informants to recommend individuals whose experiences are related to the research [197]. This strategy can be used to identify hard to reach groups.

The sample size may depend on the analysis process. For example, the sample size of qualitative work compared to quantitative analysis is generally small due to diminishing returns and rich data [171, 198]. Characteristics of the sample should reflect as closely as possible the patient population to be included in future studies that will incorporate the outcome measure [167]. However, within this range, as wide a distribution as possible of age, ethnicity and socioeconomic status is necessary to achieve a quasi-stratified, purposeful sampling where the sample is purposefully picked to represent a wide range of cases that demonstrate variation on both dimensions of interest and variations within a common group [194]. In both quantitative and qualitative research 'saturation' has become the gold standard by which purposive sample sizes are determined [199]. This is the point whereby additional participants are not expected to yield new or valuable information. Unfortunately, there are no clear-cut rules on when "*enough is enough*" [167].

## 3.4. The validity and responsiveness of preference-based measures with informal carers

Chapter 2 identified various outcome measures that can be used to measure informal carers' QoL. The conceptual bases of the preference-based measures identified in the literature can be broadly categorised as: those that measure HRQoL (e.g., EQ-5D), those that measure wellbeing (e.g., ICECAP), or those that measure CRQoL (e.g., CES, CarerQoL, ASCOT-Carer). This chapter has, so far, explored the importance of demonstrating confidence in the performance of preference-based QoL measures to be able to include informal care in a meaningful way in economic evaluation. As discussed in Section 3.2. given the absence of a gold standard measure for QoL [165], it can be challenging to demonstrate that a preference-based QoL measure is valid or not, given it is usually a question of degree. This also raises the question of whether to test the validity and or responsiveness of the measure score, or the individual item responses. This section will discuss the literature specifically on the validity and responsiveness of the EQ-5D, ICECAP, CES, CarerQoL, and ASCOT-Carer in studies involving informal carers.

A plethora of literature exists on the use of the EQ-5D and ICECAP across conditions and participant profiles. For example, a systematic review conducted by Afentou et al [124] identified studies that have explored the psychometric properties of the ICECAP-A and its use in economic evaluation. This review identified sixteen studies that assessed the ICECAP-A's psychometric properties, four full economic evaluations that incorporated the ICECAP-A, along with five feasibility studies and two studies exploring issues around prioritisation and resource allocation. Of the 27 studies identified in this review, only one study involved informal carers [19]. Another systematic review, conducted by Feng et al [200] summarises the available published evidence on the psychometric properties of the EQ-5D-5L. This review included 99 studies with only one study identified that included informal carers of children with meningitis [12].

The evidence summary that follows is not an exhaustive review of all literature available on the psychometric properties of the EQ-5D, ICECAP, CES, CarerQoL, and ASCOT-Carer, but rather a comprehensive summary of the published evidence on the psychometric properties of each measure in studies involving informal carers, drawing on some wider literature where relevant. The literature was identified with a systematic search of published peer-reviewed articles. A narrow search strategy was used to retrieve articles relevant to the psychometric properties of the EQ-5D, ICECAP, CES, CarerQoL, and ASCOT-Carer in studies involving informal carers. Table 3.1 shows the key characteristics and results from each study included.

**Table 3.1.** The validity and responsiveness of QoL measures in studies involving informal carers

| Study | Country where data was collected | Sample size | Study population & clinical area | QoL measure | Psychometric properties analysed | Administration method | Key findings |
|---|---|---|---|---|---|---|---|
| Perry-Duxbury et al., 2020 [5] | Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Sweden, UK | 451 | Informal carers of adults with dementia | ICECAP-O<br>EQ-5D-5L | Construct validity | Face-to-face interview<br>Written survey | ICECAP-O was significantly associated with EQ-5D-5L score of patient, the patients age, carer-patient relationship |
| Voormolen et al., 2020 [6] | Germany, Ireland, Italy, the Netherlands, Norway, Portugal, Sweden, UK | 451 | Informal carers of adults with dementia | CarerQoL<br>ICECAP-O<br>EQ-5D-5L | Construct validity | Face-to-face interview<br>Written survey | Moderate to strong correlations with the CarerQoL-VAS, ICECAP-O and EQ-5D score. Various characteristics of the caregiver, patient and situation associated with carer outcomes |
| Baji et al., 2020 [7] | Hungary | 149 | Informal carers – general population | CarerQoL | Construct validity | Written survey | Confirmed validity of Hungarian version of the CarerQoL |
| McCaffrey et al., 2020 [8] | Australia | 500 | Informal carers – general population | Ascot-Carer<br>CES<br>CarerQoL | Construct validity<br>Feasibility<br>Reliability | Online survey | Each measure performed well psychometrically. ASCOT-Carer exhibited the best psychometric properties overall |
| Engel et al., 2020 [9] | UK | Carers n=17<br>Care recipient n=9 | Community-dwelling individuals with dementia and carers of people with dementia | EQ-5D-5L<br>AQoL-8D<br>ICECAP-O<br>ASCOT<br>DEMQOL-U<br>AD-5D | Content validity<br>Face validity | Semi-structured interview<br>Focus group | There was no clear preference for one of the six measures explored; participants identified advantages and disadvantages across all measures |
| Rand et al., | England | 387 | Informal carers | Ascot-Carer | Construct | Written survey | The instruments captured separate |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 2019 [10] | | | of adults using long-term care support | CES | validity | | constructs of SCRQoL and carer experience with overlap in the domains of activities outside caring and social support. |
| Bhadhuri et al., 2017 [12] | UK | Carers n=199<br>Non carers n=648 | Family members of children with meningitis, with and without an informal care role | EQ-5D-5L<br>SF-6D | Construct validity<br>Responsiveness | Written survey | Non carers: both measures exhibited construct validity. There was less clear evidence of responsiveness of the measures<br>Carers: EQ-5D-5L exhibited greater construct validity, as well as responsiveness |
| Bailey et al., 2016 [19] | UK | Study 1: 33<br>Study 2: 22<br>Study 3: 17 | Patients receiving palliative care, close persons, healthcare professionals | ICECAP-SCM<br>ICECAP-A<br>EQ-5D-5L | Feasibility | Concurrent think-aloud<br>Semi-structured interview | Among patients the ICECAP-SCM had the lowest proportion of errors. Among close persons there was little variation in error rates between the three measures. Among health professionals error rates were highest for ICECAP-SCM |
| Rand et al., 2015 [11] | England | 387 | Informal carers – general population | ASCOT-Carer | Construct validity<br>Reliability<br>Acceptance | Face-to-face or telephone interview | Construct validity was supported by significant relationships between SCRQoL and scores on instruments of related constructs, as well as with characteristics of the carer and patient |
| Lutomski et al., 2014 [13] | the Netherlands | 3269 | Informal carers - general population | CarerQoL | Construct validity | Face-to-face interview or written survey | The findings support the construct validity of the CarerQoL. Caution required when pooling data collected using mixed modes of collection |
| Goranitis et al., 2014 [18] | England | 730 | Informal carers – general population | CES | Construct validity | Written survey | Evidence the CES captures the caring experience in a valid way |
| Hoefman et | Australia | 97 | Informal carers | CarerQoL | Construct | Written survey | Patient health status and duration |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| al., 2015 [15] | | | of people receiving palliative care | CES | validity | | of caring negatively associated with caring experience with both measures |
| Hoefman et al., 2013 [14] | the Netherlands | 1244 | Informal carers – general population | CarerQoL | Construct validity | Online survey | Positive associations of CarerQol-VAS with two positive CarerQol-7D items and negative associations with five negative CarerQol-7D items |
| Hoefman et al., 2011 [17] | the Netherlands | 230 | Informal carers – general population | CarerQoL | Construct validity | Written survey | Results confirmed earlier tests of construct validity. Items of CarerQol-7D significantly explained differences in CarerQol-VAS scores |
| Hoefman et al., 2011 [16] | the Netherlands | 108 | Informal carers of people in a long-term care facility | CarerQoL | Construct validity<br>Feasibility<br>Reliability | Written survey | The findings support the CarerQoL as a feasible, valid, and reliable instrument. CarerQol-VAS was positively associated with caregivers' age and health |

Various psychometric properties were assessed in the studies identified in this review. The studies assessed the validity and responsiveness of multiple QoL measures [5, 6, 8-10, 12, 14, 19], and some studies focused on a single QoL measure [7, 11, 13, 14, 16-18]. The identified studies were conducted in England or the UK [10-12, 18], the Netherlands [5, 6, 13, 14, 16, 17], Australia [8, 15], and Hungary [7]. Two studies also conducted their research in Germany, Ireland, Italy, Norway, Portugal, and Sweden [5, 6]. Studies were published between the years 2011 [16] and 2020 [5-8]. Other psychometrics properties explored in the studies were content and face validity [9], feasibility [8, 17, 19], and responsiveness [12]. Each of the studies included in this review included multiple QoL measures, therefore the sections that follow are structured to discuss the studies by QoL concept, rather than by individual measure.

### Health related QoL measures

Bhadhuri et al [12] assessed the construct validity and responsiveness of the EQ-5D-5L and SF-6D in a population of informal carers of children after meningitis, in which a variety of physical and mental health problems create a range of caring contexts. Quantitative methods were used for the analysis, and data was collected through a written questionnaire [12]. Amongst informal carers the EQ-5D-5L exhibited greater construct validity, as well as responsiveness.

Engel et al [9] used qualitative methodology to explore the content and face validity of the EQ-5D, ICECAP-O, ASCOT, AQoL-8D, DEMQOL-U and AD-5D. Semi-structured interviews and focus groups were used, in a population of informal carers for adults with dementia in the UK. This study found that there was no clear preference for one of the six measures explored, participants identified advantages and disadvantages across all measures [9].

Of the studies identified in this review only one study exploring feasibility did so using qualitative methods. Bailey et al [19] conducted three analyses exploring the feasibility of the EQ-5D-5L and ICECAP-SCM with one focusing on ‘close persons’ of adults receiving palliative care in the UK. This study used qualitative methodology: concurrent think-aloud methods followed by semi-structured interview.

### Wellbeing measures

Bailey et al [19] assessed the feasibility of the EQ-5D, ICECAP-SCM, and ICECAP-A instruments in a population of informal carers for adults receiving palliative care by coding interview transcripts to identify where respondents encountered a problem in the process of completing each item of the measure – either an error or a struggle. The results show that the measures were comparable in terms of their feasibility with some errors in completion of each instrument. Close persons reported that the ICECAP-SCM was most appropriate for measuring their QoL. It appeared more meaningful, easier to complete and had fewest errors (4.5%) compared to EQ-5D-5L (5.5%). Of note, the ICECAP-SCM preparation question which focuses on being prepared, financial affairs and funeral plans, was perceived as problematic for some close persons.

Perry-Duxbury et al [5] assessed the construct validity of the ICECAP-O measure in a population of informal carers with dementia. The results showed that the ICECAP-O was at least as reliable as the EQ-5D measure and was associated with aspects of QoL broader than health. The authors concluded that the ICECAP-O may therefore be useful as an outcome measure in economic evaluations of interventions aimed at informal carers of adults with dementia, when the aim is to improve wellbeing beyond health. Engel et al [9] explored the content and face validity of the ICECAP-O in a population of informal carers for adults with dementia, with the authors finding that participants identified advantages and disadvantages to the measure. Bailey et al [19] explored the feasibility of the ICECAP-SCM in a population of informal carers and close persons of adults receiving palliative care. This study found that close persons reported that the ICECAP-SCM was most appropriate for measuring their QoL. Perry-Duxbury et al [5] collected data for construct validity analysis through a face-to-face survey, while both Engel et al [9] and Bailey et al [19] used qualitative methodology to explore content and face validity [9] and feasibility [19].

### Care related QoL measures

Validity and responsiveness of the CES, CarerQoL, and ASCOT-Carer was assessed amongst informal carers of adults with dementia [6] and in the general population with no condition specified in the analysis [7, 10, 11, 13, 14, 16-18]. Studies assessing construct validity and feasibility focused on the CES [8, 10, 15, 18], CarerQoL [6-8, 13-17], and ASCOT-Carer [8, 10, 11]. Rand et al [10] also assessed the construct validity of the EQ-5D-3L. Of note, no studies were identified that assessed the content and/or face validity, or the responsiveness of care-related QoL measures. When assessing construct validity of the CES, CarerQoL, and ASCOT-Carer, measures, quantitative methods were used for the analysis and data was collected either through a written [7, 10, 15, 16, 18] or web-based [8, 14] questionnaire. Other studies collected data for construct validity analysis through a face-to-face or telephone administered survey [6, 11, 13].

When assessing construct validity of a range of measures in a population of informal carers of adults with dementia Voormolen et al [6] found moderate to strong correlations with the CarerQoL-7D instrument and the CarerQoL-VAS, ICECAP-O and EQ-5D health problems score of the caregiver.

Hoefman et al [15] assessed the construct validity of both the CES and the CarerQoL-7D and found that both measures were associated in the expected positive direction with less strain from caregiving and more positive care experiences for informal carers of adults receiving palliative care. These findings add to previous research conducted by Hoefman et al [14, 16, 17] on the construct validity of the CarerQoL instrument in the general population of informal carers. These studies found that construct validity was supported by positive associations of CarerQol-VAS with the two positive CarerQol-7D dimensions and negative associations with the five negative CarerQol-7D dimensions [14], and that CarerQol-VAS was positively associated with caregivers' age and health [17]. The construct validity of the CarerQoL is also supported by studies conducted with informal carers for non-specific conditions by Lutomski et al [13], and Baji et al [7] who confirmed the validity of the Hungarian language version of the CarerQoL.

Other QoL measures also displayed validity amongst a general population of informal carers. For example, when assessing the construct validity of the CES measure, Goranitis et al [18] found associations between variables hypothesised to relate to the caring experience and the CES were largely as expected, providing evidence that the CES captures the caring experience in a valid way.

When assessing the construct validity of the ASCOT-Carer instrument amongst a general population of informal carers, McCaffrey et al [8] also assessed the construct validity of the CES and CarerQoL, finding that each measure performed reasonably well psychometrically, and the ASCOT-Carer exhibited the best psychometric properties overall. Rand et al [10] also assessed the construct validity of the CES alongside the ASCOT-Carer. The authors found that the instruments largely captured separate constructs of SCRQoL (ASCOT-Carer), and carer experience (CES), demonstrating overlap in relation to the domains of activities outside caring and social support [10]. This builds on research conducted by Rand et al [11] where they assessed the construct validity of the ASCOT-Carer and found that construct validity was supported by statistically significant relationships between SCRQoL and characteristics of the carer and care recipient.

McCaffrey et al [8], and Hoefman et al [16] assessed the feasibility of the ASCOT-Carer, CES [8], and CarerQoL [8, 16] amongst a general population of informal carers by assessing the percentages of respondents with missing values. McCaffrey et al [8] found that virtually all respondents completed each item on the instruments (ASCOT-Carer, 99.5 %; CarerQol-7D, 98.1%; CES, 98.9%), while Hoefman et al [16] found that approximately 3% did not answer at least one of the CarerQoL-7D dimensions. Of note, Goranitis et al [18] listed as a potential limitation to their study, the fact that around 25% of individuals who reported being informal carers did not fully complete the CES measure. The authors recommend that future research may examine whether some groups of informal carers feel certain questions on the CES do not apply to them [18].

## 3.5. Gaps in our knowledge

This thesis has so far described the scope and impact of informal care, with particular focus on informal carers in the UK (Chapter 1). Chapter 2 explored the economic issue of including informal carers in economic evaluation, noting that to be included in economic evaluation in a way that is meaningful to decision makers we need to be able to display confidence in the tools we use to measure and value informal carer impacts. Chapter 3 has so far described how we can test the validity and responsiveness of outcome measures to ensure confidence in our ability to include informal care in economic evaluation. The literature review in Section 3.4 looked at the published evidence to date on the validity and responsiveness of the EQ-5D, ICECAP, CES, CarerQoL and ASCOT-Carer in studies involving informal carers. This review provides a snapshot of how these outcome measures have been tested amongst informal carers to date. However, there are still gaps that exist in our knowledge which are clarified below, and which this PhD hopes to address.

Of the studies identified in the literature review, the majority explored the psychometric property of construct validity. Only one study identified assessed content and face validity, and one study looked at responsiveness. There was also no instance where a study looked at each psychometric property i.e., construct validity, content validity, face validity, feasibility, responsiveness, for any of the identified outcome measures. Of note no studies were identified that assessed the content and/or face validity, or the responsiveness of CRQoL measures such as the CES, CarerQoL, or ASCOT-Carer. This highlights the need for further analysis of each psychometric property with each outcome measure in a population of informal carers.

The review also identified that the validity and responsiveness of the measures have been assessed separately in a population of informal carers for adults with dementia, adults receiving palliative care, children with meningitis, and adults in general with no condition specified. No study was identified that assessed the validity and responsiveness of any one of the outcome measures across a range of common conditions that may be particularly relevant to the QoL of informal carers, and no study provided a head-to-head comparison of QoL measures across common conditions.

Ultimately, while the literature on the validity and responsiveness of QoL measures with informal carers is initially promising, there is still ambiguity over which QoL measure to use in economic evaluations that involve informal carers, and little is known about the relative performance of different QoL measures for measuring carer QoL across a range of common conditions. Similarly, evidence on the psychometric properties of preference-based health or wellbeing QoL measures with informal carers is limited.

The aim of this thesis is to address these gaps in our knowledge, through a comprehensive multi-instrument, multi-disease study of different psychometric properties. The next four chapters will present the methods and results for two distinct studies. They are:

- a quantitative study of the construct validity and responsiveness of the CES, CarerQoL-7D, ASCOT-Carer, ICECAP-A, and EQ-5D-5L amongst informal carers for adults with dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis
- a qualitative study of the feasibility, content validity and face validity of the CES, CarerQoL-7D, ASCOT-Carer, ICECAP-A, and EQ-5D-5L amongst informal carers for adults with dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis.

## 3.6. Chapter summary

This chapter described how we can test the validity and responsiveness of QoL measures to ensure confidence in our ability to include informal care in economic evaluation. The explored the theoretical background to validity and responsiveness, and the methods that can be used to test validity and responsiveness. Section 3.3 highlighted that establishing the validity and responsiveness of a QoL measure for a particular purpose requires both qualitative and quantitative approaches to ensure that the limitations of one type of data are balanced by the strengths of another. The chapter concluded by outlining the gaps in our knowledge and why further testing is required to strengthen our confidence in the ability of certain outcome measures used with informal carers, to be used in economic evaluation. The chapters that follow will present the methods and results for the two studies conducted to address this issue.

# 4. Quantitative study of the validity and responsiveness of health-related, wellbeing and care-related measures for estimating carer quality of life: Methods

## 4.1. Introduction

The first three chapters of this thesis have established that there is a need to establish the validity of QoL measures amongst informal carers. The aim of this thesis is to address this topic. The next two chapters will present the methods and results for a quantitative study of the validity and responsiveness of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures with informal carers across a range of conditions, specifically dementia, recovery from stroke, mental health condition, and rheumatoid arthritis. First, the sampling strategy used to recruit participants is outlined in Section 4.2 Then, a description of the QoL measures included in this study is provided in Section 4.3 along with a rationale for the choice of conditions included in the study (Section 4.4).

The aim of this study was to test the validity and responsiveness of the five QoL measures. To meet this objective evidence-based hypotheses were developed which would be subjected to rigorous testing. This process is detailed in Section 4.5 and 4.6. To test these hypotheses participants were required to complete two questionnaires at different time points which included the five QoL measures along with contextual constructs. A description of how the questionnaires were developed is provided in Section 4.7, followed by a description of the data collection process. Finally, the statistical methods used to analyse the data is provided in Section 4.8 and how ethical issues were addressed is presented in Section 4.9.

As stated in the introduction to this thesis, the quantitative work presented in the next two chapters has been published [20]. By including multiple QoL measures across multiple conditions, this study represents a comprehensive analysis in relation to the published evidence on the validity and responsiveness of QoL measures with informal carers detailed in Chapter 3.

## 4.2. The sample frame for the survey work

This PhD work was conducted by the PhD researcher, Carol McLoughlin (CM) as part of a wider programme of research for a NIHR career development fellowship (award number CDF-2015-08-025; awarded to Hareth Al-Janabi (HA)). Identification and recruitment of eligible informal carers for the PhD work was conducted as part of this wider project, although the validity survey work and analysis presented in this thesis was conducted by CM in her role as a researcher on the project.

The process of recruiting carer participants began in July 2016. NatCen, a social research institute, were commissioned to draw a sample of informal family carers from across the UK (excl. Northern Ireland) to take part in the study as they hold the names and addresses of all respondents to the Family Resources Survey (FRS). The FRS is a continuous household survey which collects information on the income and circumstances of a representative sample of private households in the UK [201].

Informal carers were sampled from the FRS as informal carers are difficult to identify in the community and recruit to research studies without bias in response [202, 203]. The sample of carers for this study was drawn across the (then) three most recent waves (2013/14, 2014/15 or 2015/16). Individuals who met the following inclusion criteria were included in the study:

- they currently had caring responsibilities
- they did not receive payment for their caring responsibilities
- they were aged 18 or over
- the person they cared for was aged 18 or over.

These broad inclusion criteria were based on data that is collected by the FRS. This resulted in a potential sample of up to 3,800 carers.

Figure 4.1 displays a flow chart of the NatCen screening process. An opt-out letter including information about the purpose of the study was posted on July 27th, 2016, to all individuals in the sample. Individuals who did not opt-out of the study by the opt-out deadline of August 5th, 2016 (n=3,393) were contacted by NatCen for a short telephone interview to assess their eligibility. During the telephone screen, undertaken between August 8th and September 18th, 2016, participants were given a brief overview of the study followed by questions to ascertain whether: they currently had caring responsibilities for somebody aged 18 or over; they did not receive payment for caring responsibilities; the health condition of the person they cared for; they were willing to have their contact details passed on to the University of Birmingham for this study. A dataset of 1,004 eligible and willing carers, including their contact details was delivered by NatCen on September 26th, 2016.

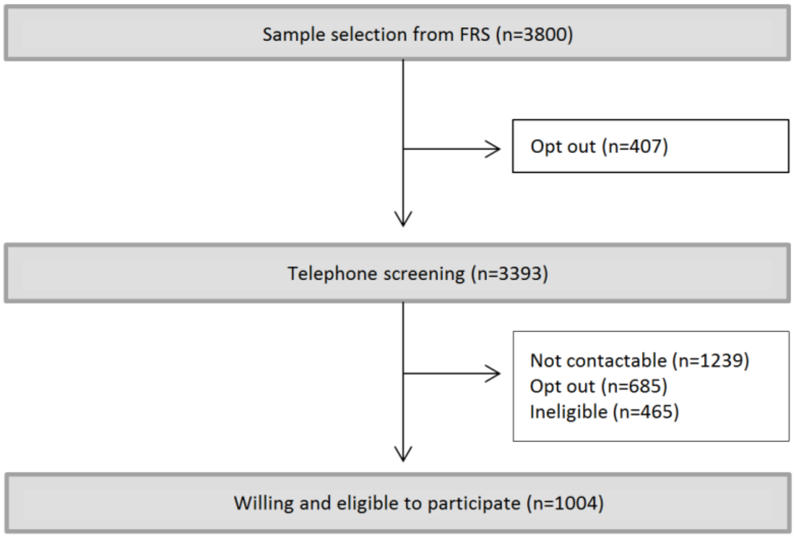

**Figure 4.1.** NatCen screening process

**Figure 4.2.** Geographical coverage of participants

Figure 4.2 shows the density of geographical coverage of willing and eligible participants. The lighter green shade represents a greater concentration of participants, and the dark green represents a lower concentration. The map indicates a wide spread of geographical locations with the main concentration of participants in urban areas for example, in London, Birmingham, Manchester, Edinburgh and Glasgow.

A second dataset of 2,389 ineligible, unwilling or not contactable individuals was also delivered. 685 respondents opted out of the study with 48% (n=335) not providing a reason for this decision. Of those who provided a reason for opting out, the reasons given included that the carer was too ill to take part (n=16), or too busy to take part in the research (n=11). Of the 465 ineligible respondents identified, the main reason for ineligibility was that the respondent was not currently caring for somebody (n=197). A detailed list can be found in Table 4.1 The dataset of 1,004 eligible and willing carers were sent a questionnaire to complete as part of the validity analysis.

As detailed in Chapter 3, responsiveness refers to the ability of an outcome measure to measure important or meaningful change between two relevant time points [162, 175, 176]. Given a lack of information in the literature regarding what is considered 'relevant time points', it was decided to test the responsiveness of the QoL measures included in this study over a 12-month period. This period was chosen as it has been used in a previous study analysing the responsiveness of the EQ-5D-5L [12]. It was also expected that a period of 12 months would allow enough time to pass where the informal carers' situation might have changed so as to impact on their QoL in a meaningful way. To get participants to complete the follow-up questionnaire as close to 12 months after the initial questionnaire as possible the responsiveness questionnaire (see Section 4.7 for further detail) was sent to participants in two separate batches. Participants who responded to the baseline questionnaire in November 2016 (n=468) were posted the responsiveness questionnaire at the end of October 2017 so their responses would be received in November 2017. Participants who responded to the baseline questionnaire from December 2016 onwards (n=108) were posted the follow-up questionnaire in January 2018.

**Table 4.1.** NatCen screening process

| Potential participants | n | Further information | n (%) [1] |
|---|---|---|---|
| Sample selection from the FRS | 3,800 | | |
| Opt out letter sent to NatCen | (407) | No reason given for opting out | |
| Contacted by telephone | 3,393 | | |
| Not contactable | (1,239) | Answer phone | 587 (47) |
| | | Line dead | 291 (24) |
| | | Rings out | 196 (16) |
| | | New details not available | 107 (9) |
| | | Away during screening | 26 (2) |
| | | Call blocking | 18 (1) |
| | | Engaged | 11 (0.8) |
| | | Fax/modem/data line | 3 (0.2) |
| Opt out | (685) | Respondent refused (no reason given) | 335 (49) |
| | | Late opt out letter | 203 (30) |
| | | Respondent refused (further reason given) | 66 (10) |
| | | Proxy refused | 43 (6) |
| | | Carer too ill to take part | 16 (2) |
| | | Other (no further information available) | 14 (2) |
| | | Language barrier | 8 (1) |
| Ineligible | (465) | Not currently caring for anyone (no further information available) | 197 (42) |
| | | No longer caring for anyone (no further information available) | 85 (18) |
| | | Carer deceased | 57 (12) |
| | | No longer caring for anyone (care recipient deceased) | 52 (11) |
| | | Does not provide care/never had a caring role | 50 (11) |
| | | Incapable (no further information available) | 23 (5) |
| | | Carer under 18 | 1 (1) |
| Willing and eligible* | 1,004 | Rheumatoid arthritis | 269 |
| | | Mental health condition | 211 |
| | | Dementia | 206 |
| | | Stroke | 163 |
| | | Heart condition | 146 |
| | | Learning disability | 75 |
| | | Other | 327 |

*No percentage is provided for the 'willing and eligible' participants as there is significant overlap in the conditions i.e., participants reported caring for somebody who has more than one of the listed conditions

## 4.3. Quality of life measures included in the questionnaire

As detailed in Chapter 2 there are currently three instruments that offer preference-based scores of CRQoL for subjective burden – the CES [126], CarerQoL-7D [127], and ASCOT-Carer [11]. These measures have been designed for use alongside the QALY in economic evaluation with the intention of providing additional information to standard methods, or in CUA when the measure of output is CRQoL. While the primary focus of this study was on CRQoL, the EQ-5D-5L [112] and ICECAP-A [123] were also included in the analysis as QoL measures that might also be used with informal carers in economic evaluation.

For the EQ-5D-5L participants were asked to think about the health of the person they care about, and themselves 'today'. Weights developed from preference studies were used to convert answers into a single summary index value, from 0 (being dead) to 1 (in perfect health) [113]. The ICECAP-A asks participants to indicate which statements best describe their overall QoL 'at the moment'. Weights developed in the UK were used and values could range from 0 (no capability) to 1 (full capability).

When completing the CES participants were asked to think about their 'current' experience when answering the questions. Relative weights were attached to each of the six care dimensions and aggregated to provide a preference-based overall score of caring experiences (0 'bottom state' - 100 'top state') [41][126]. The CarerQoL-7D also asks participants to think about their 'current' experience of caring for the care recipient. The seven dimensions were aggregated and weighted by their severity with a UK tariff, which was then used to calculate an overall score (0 'worst situation' – 100 'best situation') [14, 127]. Finally, the ASCOT-Carer also asks participants to think about their 'current' experience. The English scoring algorithm, based on general population preferences, was used to calculate the preference weight and ranges from 0 (worst QoL) to 1 (best QoL) [11, 132].

The individual items of the five QoL measures included in the survey are presented and conceptually mapped across 12 domains in Table 4.2 The conceptual mapping provides a structured framework against which the relationship between individual items of the five QoL measures and contextual variables can be assessed (see Section 4.5).

**Table 4.2.** Conceptual mapping of domains in the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L, and ICECAP-A

| Domain | CES | CarerQoL-7D | ASCOT-Carer | EQ-5D-5L | ICECAP-A |
|---|---|---|---|---|---|
| Occupation | Activities outside caring | Problems with combining care tasks with daily activities | Occupation in valuable or enjoyable activities | Usual activities | |
| Support | Support from family and friends<br>Assistance from organisations and government | Support with carrying out care tasks, as needed | Feeling supported and encouraged | | Love, friendship, and support |
| Fulfilment | Fulfilment from caring | Fulfilment from carrying out care tasks | | | Enjoyment and pleasure |
| Control | Control over caring | | Control over daily life | | Being independent |
| Relationship | Getting on with the person you care for | Relational problems with the care receiver | | | |
| Social Participation | Included under "activities outside of caring" | | Social contact with people you like | | |
| Physical health | | Problems with physical health | | Pain/ discomfort<br>Mobility | |
| Mental health | | Problems with mental health | | Anxiety/depression | |
| Self-care | | | How well you look after yourself | Self-care | |
| Safety and stability | | | How safe you feel | | Feeling settled and secure |
| Finances | | Financial problems due to care tasks | | | |
| Achievement | | | | | Achievement and progress |

## 4.4. Conditions included in the study

Chapter 1 touched on the conditions included in this study. This research was initially focused on carers associated with three conditions: dementia, recovery from stroke, and mental health conditions. These conditions were chosen, as part of the wider project this PhD work is linked to, as high prevalence conditions associated with diverse impacts on carers' lives [67]. In the NatCen telephone interview individuals were asked what condition the person they care for has and this answer was recorded. The dataset of eligible and willing carers (n=1,004) showed that many were caring for people with a condition other than dementia, recovery from stroke, mental health conditions (see Table 4.1). Rheumatoid arthritis emerged as a fourth prevalent condition with 269 respondents (27%) providing care associated with this condition. 498 (49%) of the sample responded that they were providing care associated with a different condition, for example heart failure, Parkinson's disease, multiple sclerosis. Given that people are more likely to complete a questionnaire if it covers issues relevant to them [204], and the importance of capturing the QoL of a representative sample of informal carers, the pilot questionnaire was revised to include a question aimed at those caring for people with rheumatoid arthritis and a free text box and generic list of disease symptoms was included for respondents caring for a person with any other condition.

A literature search was conducted to gather information on difficulties associated with dementia, recovery from stroke, mental health conditions and rheumatoid arthritis which may impact on carer QoL [205-209]. This was used to inform the construct validity analysis (Section 4.5). This literature search was focused on these four major conditions so it would be possible to draw any disease specific inferences in the analysis.

Sorensen et al [68] developed a model of carer stress and burden and identified a list of primary stressors or "*hardships and problems anchored directly in caregiving*" categorised under three headings:

A. Patient characteristics

B. Care situation

C. Carer

The subheadings under patient characteristics: cognitive impairment; functional ability; problem behaviour, were used to develop questions that might identify challenges in these three areas.

### ***4.4.1. Cognitive impairment***

Pearlin et al., 1990, encourages the use of the mini-mental state examination (MMSE), a set of eleven simple questions, to evaluate cognitive impairment [49, 210]. The questions are grouped into seven cognitive domains: orientation to time; orientation to place; registration of three words; attention and calculation; recall of three words; language; visual construction. These groups  were adapted and used in the baseline questionnaire (Appendix 1) to evaluate cognitive impairment for each condition. The questionnaire asked participants to tick any specific cognitive difficulties that the person they care for has from the following list: orientation to time or place; remembering words; understanding simple instructions; attention or calculation; speaking sentences; recognition of familiar faces. Given the MMSE was adapted a formal evaluation framework was not used. Instead, the items were summed from 0-6 to provide an overview of the extent of the care recipients cognitive impairment.

### *4.4.2. Functional ability*

A modified version of The Barthel assistance with daily living (ADL) index was used to evaluate the care recipient's functional ability. This index measures performance in ten activities of daily living [211]. To keep the baseline questionnaire length as short as possible and manageable for participants to complete the ten activities were condensed into seven (for example 'bowels', 'bladder', and 'toilet use' were merged into one activity 'toilet use or incontinence'). Given that the ADL index had been modified for inclusion in the baseline questionnaire a formal evaluation framework was not used to assess the participants response to this question. Rather, the items were summed from 0-7 to provide an overview of the extent of the care recipients function ability.

### *4.4.3. Problem behaviour*

In the baseline questionnaire (Appendix 1) the presence of problem behaviours was evaluated separately for each condition. For dementia a modified list of behaviours that might impact on carer QoL developed by Pruchno and Resch [209] was included. For recovery from stroke a modified list of common problems many stroke survivors experience was included [208]. For mental health conditions the questionnaire focused on organic mental disorders such as anxiety disorder, delusional disorders such as schizophrenia, and mood disorders such as depression [206]. A modified list of complications linked to these mental health conditions [205] was included in the questionnaire. A list of difficulties associated with rheumatoid arthritis was developed based on information provided by the National Rheumatoid Arthritis Society [207]. Finally, a free text box and a list of general difficulties, for example 'changes to emotions' were included for respondents caring for a person with any condition other than dementia, recovery from stroke, mental health conditions, or rheumatoid arthritis.

## 4.5. Analysis methods for assessing validity

As detailed in Chapter 3 best practice states that validation should be investigated by developing evidence-based hypotheses and subjecting these hypotheses to rigorous testing [212]. In this study construct validity of care-related (CES, CarerQoL-7D, ASCOT-Carer), wellbeing (ICECAP-A) and health-related (EQ-5D-5L) QoL measures were assessed using convergent and discriminant validation. Convergent validation involves testing hypotheses of the extent to which the construct of each measure correlated with the other measures. Construct validity was also assessed using discriminative validity. This involves group comparisons where "*a measure is judged in terms of its ability to differentiate between groups thought to differ*" [161]. The process of testing the discriminative validity involved the development of evidence-based hypotheses that were then subjected to rigorous testing. Further detail on the development of hypotheses for this study is included in the section that follows.

In total four separate analyses, using a wide (and purposively selected set of constructs as described in Section 4.7) were conducted. The analyses cover a comprehensive range of associations across measures and conditions and look at both overall measure scores and individual measure items. The four analyses conducted were:

### Analysis 1: Measure score – all conditions

This analysis looked at the association between the overall QoL measure scores for all conditions and contextual variables. The analysis involved splitting contextual variables between those relating to the carer: age, gender, employment status, self-rated life satisfaction; those relating to the care recipient: age, gender, the presence of cognitive difficulties and daily dependencies, health status, direction of health status; and contextual variables relating to the caring situation: co-residence, relationship to the care recipient, duration of caring, hours of care per week, the provision of personal care, main carer, and involvement of others.

### Analysis 2: Measure score – individual conditions

This analysis explored the association between the overall QoL measure scores for the different conditions and contextual variables. As with the first analysis, this analysis involved splitting contextual variables between those relating to the carer, the care recipient, and the caring situation.

**Analysis 3: Measure score – health difficulties**

This analysis looked at the association between the overall QoL measure scores for the different conditions and condition specific health difficulties. To enable this analysis participants were asked in the baseline questionnaire to indicate the presence of any condition specific health difficulties from a list of difficulties collated as part of the survey development process (see Section 4.4).

**Analysis 4: Measure domains – all conditions**

This analysis explored the association between individual items of the QoL measures for all conditions. A subset of constructs was chosen for this analysis. This subset consisted of constructs that were identified from the results of Analysis 1: Measure score – all conditions as being important in impacting on carer QoL. This analysis involved splitting contextual variables between those relating to the carer: self-rated life satisfaction; those relating to the care recipient: the presence of cognitive difficulties, the presence of daily dependencies, health status; and contextual variables relating to the caring situation: hours of care per week, the provision of personal care, main carer, and involvement of others. The presence of a statistically significant association between these contextual variables and the individual items of each outcome measure was then explored.

### *4.5.1. Hypothesis formation*

Data from the review of development of preference-based outcome measures (Chapter 2) and the review on the psychometric properties of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L, and ICECAP-A in studies involving informal carers (Chapter 3) was used to assist hypothesis formation. Information was also collected on specific difficulties that would be associated with dementia, recovery from stroke, mental health conditions and rheumatoid arthritis which may impact on carer QoL (Section 4.4). Information from the broader literature on the caring experience, carer burden and associated characteristics of informal carers (Chapter 1) was also used to develop hypotheses.

Hypotheses were developed about how QoL measure scores and items were expected to associate with survey variables. The hypotheses were reviewed, and the presence and direction of associations were discussed collaboratively with the supervisory team. When it was agreed that an association was expected, this hypothesis was confirmed for testing. In situations where members of the supervisory team and the PhD researcher expected associations in different directions this was discussed collaboratively. The hypothesis formation process is outlined in Figure 4.3.

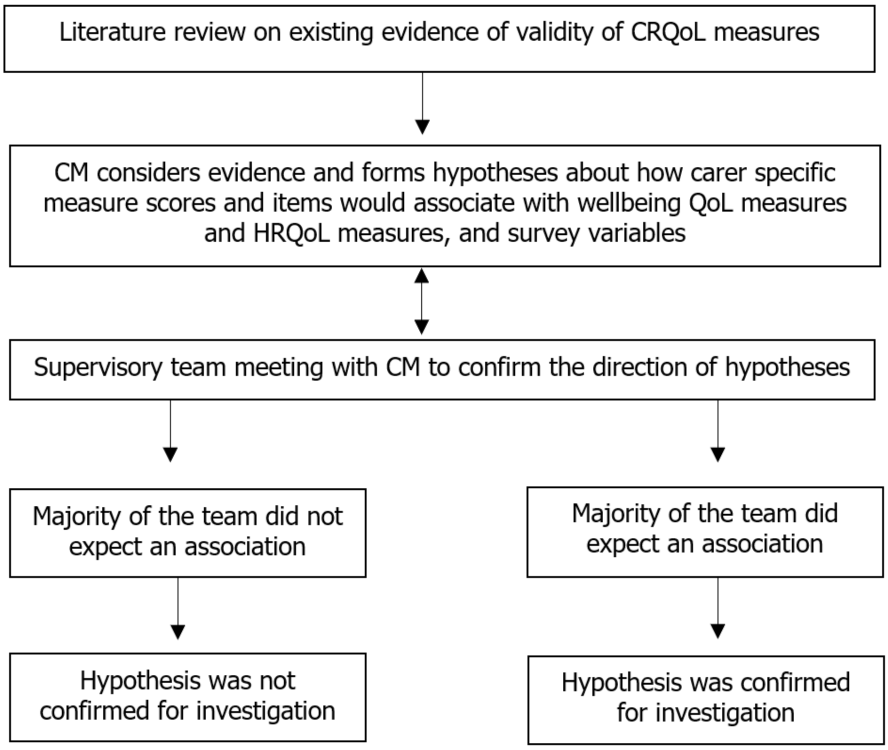

**Figure 4.3.** Process of hypothesis formation

### 4.5.2. Hypotheses

As shown in Table 4.3 of the 21 contextual variables included in the baseline questionnaire, 16 were included for investigation in the first three analyses (Analysis 1: Measure score-all conditions, Analysis 2: Measure score – individual conditions, and Analysis 3: Measure score – health difficulties) based on the process detailed in the previous section (see Figure 4.3). Five variables: ethnicity, educational qualification, impact on occupation, the number of people living with the carer and the effect of health and social care received by the care recipient were not included in the final investigation. The variables 'ethnicity' and 'educational qualification' were excluded based on the sample of carers who responded to the baseline questionnaire. 98% of the sample (n=556) were white and 55% (n=305) had obtained an A-level qualification or higher. It was agreed amongst the supervisory team that this did not qualify as a representative sample of the adult caring population and testing hypotheses related to these variables would not be beneficial to the study. The variable 'number of people living with the carer' was included in the questionnaire as a possible indicator of any additional help the carer may receive in their caring role. However, in developing hypotheses for investigation it was felt that the variable 'involvement of others' better captured this information. Respondents were asked in the questionnaire if there had been any impacts on their (paid) work because of the care they provide. For the validity analysis it was agreed amongst the supervisory team that the variable 'occupation' which asked the carer to tick the activities that describe what they are doing at present was sufficient to enable investigation.

**Table 4.3.** Contextual variables included for investigation in Analysis 1: Measure score - all conditions, Analysis 2: Measure score – individual conditions, and Analysis 3: Measure score – health difficulties

| Contextual variable included in questionnaire | Included for investigation |
|---|---|
| **Carer** | |
| Age | ✓ |
| Gender | ✓ |
| Ethnicity | × |
| Educational qualification | × |
| Self-rated health | ✓ |
| Occupation | ✓ |
| Impacts on occupation because of caring | × |
| Self-rated life satisfaction | ✓ |
| **Care recipient** | |
| Age | ✓ |
| Gender | ✓ |
| Cognitive difficulties & daily dependencies | ✓ |
| Health status | ✓ |
| Direction of health status | ✓ |
| **Caring situation** | |
| Co-residence | ✓ |
| Number of people who live with the carer | × |
| Relationship | ✓ |
| Duration of caring | ✓ |
| Hours of care per week | ✓ |
| Health and social care received by the care recipient | × |
| Personal care | ✓ |
| Main carer | ✓ |
| Involvement of others | ✓ |

For the 16 variables included for investigation in analyses 1-3, hypotheses were formed about the direction of association with QoL measure score, based on existing evidence where available, for all conditions pooled together. Separate hypotheses were also developed for carers of people with dementia, recovery from stroke, a mental health condition, and rheumatoid arthritis. The hypotheses are summarised in Table 4.4 The hypotheses were as follows:

**Carer age:** In the general caring context while some studies put forward that younger carers' experience worse QoL compared with older carers [62], the majority of studies put forward that younger carers' experience better QoL [44, 50, 55, 213].

This hypothesis holds for carers of people with dementia [66], and mental health [59] as older carers struggle with the unpredictable character of these conditions. In contrast, a positive association has been found with carers of people recovering from a stroke [214]. Informal carers of stroke survivors are typically younger than informal carers of people with dementia, and research shows that younger carers have more obligations outside of their caring role, for example full time employment [44]. While there is no evidence of an association for informal carers of people with rheumatoid arthritis it was expected (based on the similar carer/care recipient profile to stroke recovery) that a positive association would be found.

**Carer Gender:** Evidence shows that female carers experience lower QoL compared to male carers in the general field of caring [44, 55, 62, 139] and also for informal carers of people with dementia [66-68, 215], recovery from stroke [69, 214, 216], and mental health conditions [59]. Although no evidence was found that tested this hypothesis amongst informal carers of people with rheumatoid arthritis, it was expected that this association would hold.

**Carer self-rated health:** Given the close relationship between health and overall QoL it was expected that better informal carer health status will be associated with a less negative caring experience in the general context [44, 55, 60, 213] and also for dementia [66, 68], recovery from stroke [69, 214, 217, 218], and mental health conditions [59]. Although no evidence was found that tested this hypothesis amongst informal carers of people with rheumatoid arthritis, it was expected that this association would hold.

**Carer occupation:** Based on general evidence [14, 50, 72] it was expected that informal carers in paid employment (full-time, part-time, and self-employed) would experience better QoL compared to carers who were not in paid employment. However, there is evidence of a negative association between informal carers in paid employment and QoL for recovery from stroke [216], and mental health conditions [59].

**Carer self-rated life satisfaction:** Based on evidence of a positive association with life satisfaction and QoL in informal carers of people recovering from a stroke [219] and in the general caring context [17, 51] it was expected that this association would hold for each condition.

**Care recipient age:** The general field of literature shows associations with care recipient age has contradicting directions of association, but most studies put forward that caring for an older care recipient has a positive impact on informal carer experience [17, 70]. No evidence of an association was found for the individual conditions, and it was therefore expected that no association would be found.

**Care recipient gender:** There is evidence of increased levels of burden for informal carers caring for male compared to female recipients in dementia and mental health conditions [59, 215], and in the general caring context [44, 55]. While no evidence of an association exists for recovery from stroke and rheumatoid arthritis, it was expected that a negative association would be found.

**Cognitive ability & daily dependencies:** Research shows that increased frequency of behavioural difficulties, impaired cognitive ability, and increased daily dependencies are associated with increased informal carer burden [49, 61, 70]. This is true for dementia, recovery from stroke, mental health conditions, rheumatoid arthritis, and caring in general. [59, 215] [219].

**Care recipient health status:** Based on extensive evidence a positive association was expected with overall health status for the pooled conditions [44, 51, 55, 60, 62, 63, 72], dementia [220], recovery from stroke [214, 217, 218], and mental health conditions [59]. Although no evidence was found that tested this hypothesis amongst carers of people with rheumatoid arthritis, it was expected that this association would hold.

**Direction of care recipient health status:** Studies have reported that declining care recipient health status has a negative impact on informal carer QoL in the general caring context [63, 72]. Although no evidence was found in the literature for the individual conditions it was expected that this association would hold for each condition.

**Co-residence:** Informal carers who live with the care recipient report greater involvement in caregiving tasks compared with those who live apart from the care recipient in the general caring context [17, 51, 55, 60-62] and for informal carers of people with dementia [66, 67, 215]. It was therefore expected that this association would hold for each condition.

**Relationship between carer and care recipient:** Based on evidence, it was expected that caring for a spouse would result in a more negative caring experience compared to caring for a parent or child in the general field of caring [44, 51, 55, 60, 62, 63] and for carers of people with dementia [66-68, 215], recovery from stroke [219], and mental health conditions [59]. Although no evidence was found that tested this hypothesis amongst carers of people with rheumatoid arthritis, it was expected that this association would hold.

**Duration of caring:** In general, evidence shows that the longer the carer has been providing care for the recipient will have a negative impact on their caring experience [63]. This has also been found for rheumatoid arthritis, which is a slow, progressive disease that creates long term dependency [221]. It was expected that this association would hold for informal carers of people with dementia and a mental health condition. In contrast, for carers of people recovering from a stroke, over time the level of carer burden has been shown to stabilise and reduce, be that because of the care recipient’s functional capacity improving, or as a result of the carer adjusting to their role as informal carer [219].

**Hours of care per week:** There is evidence that the more hours per week spent on caregiving activities increases informal carer burden in general [55, 63] and specifically in dementia [68], recovery from stroke [58, 216, 217, 222], and mental health conditions [59]. Although no evidence was found that tested this hypothesis amongst informal carers of people with rheumatoid arthritis, it was expected that this association would hold.

**Personal care:** Studies have found that providing personal care results in lower QoL for informal carers in general, irrespective of the amount of time spent on personal care. Although no evidence was found in the literature for the individual conditions it was expected that this association would hold for each condition.

**Respondent identifies as the main carer:** Evidence exists that identifying as the main carer increases informal carer burden in stroke recovery [218]. It was expected that if the carer identifies as the main carer, they have more caring responsibilities and burden and that this would hold for each condition.

**Involvement of others:** Studies have found that having other people involved in sharing the caring responsibilities reduces the burden for informal carers in general [50], and for carers of people with dementia [68, 220], recovery from stroke [222], and mental health conditions [59]. Although no evidence was found that tested this hypothesis amongst carers of people with rheumatoid arthritis, it was expected that this association would hold.

**Table 4.4.** Expected association between contextual variables and carer QoL for Analysis 1: Measure score - all conditions, Analysis 2: Measure score – individual conditions, and Analysis 3: Measure score – health difficulties

| Contextual variable | All conditions | Dementia | Stroke | Mental health condition | Rheumatoid arthritis |
|---|---|---|---|---|---|
| **Carer trait** | | | | | |
| Age | Negative | Negative | Positive | Negative | Positive |
| Gender | Negative | Negative | Negative | Negative | Negative |
| Self-rated health | Positive | Positive | Positive | Positive | Positive |
| Occupation | Positive | Positive | Negative | Negative | Positive |
| Self-rated life satisfaction | Positive | Positive | Positive | Positive | Positive |
| **Care recipient trait** | | | | | |
| Age | Positive | No association | No association | No association | No association |
| Gender | Negative | Negative | Negative | Negative | Negative |
| Cognitive difficulties & daily dependencies | Negative | Negative | Negative | Negative | Negative |
| Health status | Positive | Positive | Positive | Positive | Positive |
| Direction of health status | Negative | Negative | Negative | Negative | Negative |
| **Caring situation** | | | | | |
| Co-residence | Negative | Negative | Negative | Negative | Negative |
| Relationship | Negative | Negative | Negative | Negative | Negative |
| Duration of caring | Negative | Negative | Positive | Negative | Negative |
| Hours of care per week | Negative | Negative | Negative | Negative | Negative |
| Personal care | Negative | Negative | Negative | Negative | Negative |
| Main carer | Negative | Negative | Negative | Negative | Negative |
| Involvement of others | Positive | Positive | Positive | Positive | Positive |

### Analysis 4: Measure domains – all conditions

This analysis explored the association between individual items of the five QoL measures for all conditions. Of the 21 contextual variables included in the questionnaire, 16 were included for investigation in the first three analyses based on the process detailed in the previous section (see Table 4.3). From these 16 contextual variables, a subset of constructs was chosen for Analysis 4: Measure domains – all conditions. This subset consisted of seven constructs that were identified from the results of Analysis 1: Measure score – all conditions, as being important in impacting on carer QoL (Table 4.5).

**Table 4.5.** Contextual variables included for investigation in Analysis 4: Measure domains-all conditions

| Contextual variable included in questionnaire | Included for investigation |
|---|---|
| **Carer** | |
| Age | × |
| Gender | × |
| Ethnicity | × |
| Educational qualification | × |
| Self-rated health | × |
| Occupation | × |
| Impacts on occupation as a result of caring | × |
| Self-rated life satisfaction | ✓ |
| **Care recipient** | |
| Age | × |
| Gender | × |
| Cognitive difficulties & daily dependencies | ✓ |
| Health status | ✓ |
| Direction of health status | × |
| **Caring situation** | |
| Co-residence | × |
| Number of people who live with the carer | × |
| Relationship | × |
| Duration of caring | × |
| Hours of care per week | ✓ |
| Health and social care received by the care recipient | × |
| Personal care | ✓ |
| Main carer | ✓ |
| Involvement of others | ✓ |

For the seven variables included for investigation in this analysis, hypotheses were formed about the direction of association with the QoL measure score, based on existing evidence where available, and the results from Analysis 1: Measure score – all conditions. Further information on the results of Analysis 1 can be found in Chapter 5. The hypotheses were as follows:

**Self-rated life satisfaction:** Based on evidence of a positive association with life satisfaction and QoL in the general caring context [17, 51] and the positive association found for each measure in Analysis 1: Measure score – all conditions, it was anticipated that carer life satisfaction would be linked with each QoL measure domain.

**Cognitive ability & daily dependencies:** Research shows that impaired cognitive ability and increased daily dependencies are associated with increased carer burden [49, 61, 70]. Analysis 1: Measure score – all conditions, reinforced this hypothesis by finding a negative association for each measure. For this analysis it was expected that the presence of cognitive difficulties and daily dependencies would have a negative impact on informal carer occupation, fulfilment, their relationship with the care recipient, and their mental health. In addition, it was hypothesised that impaired cognitive ability would have a negative impact on the carers' sense of control, while increased daily dependencies would have a negative impact on the carers' physical health.

**Health status:** Based on extensive evidence, and the results of Analysis 1: Measure score – all conditions, a positive association was expected with overall health status across all QoL measure domains [44, 51, 62, 63, 72, 217].

**Involvement of others:** Studies have found that having other people involved in sharing the caring responsibilities reduces the burden for informal carers [50]. This hypothesis was tested in Analysis 1: Measure score – all conditions, where a positive association was found for each measure except for the EQ-5D-5L. It was expected that the involvement of others would have a positive impact on the carers' sense of support, control, and safety, along with the domain 'social participation'.

**Hours of care per week:** There is evidence that the more hours per week spent on caregiving activities increases carer burden in general [55, 63]. A negative association was found for each QoL measure in Analysis 1: Measure score – all conditions. It was expected that those who provide more than 20 hours of care per week would have reduced QoL across all QoL measure domains except for the carers' sense of safety and security.

**Personal care:** In Analysis 1: Measure score – all conditions, a statistically significant negative association was found for providing personal care for each QoL measure. Providing personal care was expected to have a negative impact on the carers' sense of fulfilment, and control. It was also anticipated to impact on their relationship with the care recipient and the carers' mental health.

**Respondent identifies as the main carer:** Evidence exists that identifying as the main carer increases carer burden [218] and Analysis 1: Measure score – all conditions, found a negative association for each QoL measure score. It was expected that this would have a negative impact on all measure domains except for the carers' physical and mental health, their relationship with the care recipient, and the carers' sense of safety and security.

## 4.6. Analysis methods for assessing responsiveness

In this part of the study the responsiveness of care-related (CES, CarerQoL-7D, ASCOT-Carer), wellbeing (ICECAP-A) and health-related (EQ-5D-5L) QoL measures were assessed using an anchor-based analysis. As detailed in Chapter 3 there are two distinct methodological approaches available for assessing responsiveness - distribution-based and anchor-based [175]. The distribution-based approach is a set of methods for estimating change based on a statistical parameter of the population or sample [175]. A key criticism of the distribution-based approach is that it is *"anchor free"* with no external reference point [177]. In contrast, anchor-based methods explore the association between the targeted concept of an outcome measure e.g. CRQoL and the same or similar concept measured by an independent and external anchor(s) [175]. The anchor-based approach requires clarity about whether there is an 'important' change in the outcome measure score (either improved or worsened) when compared, or anchored, to changes in the anchoring item [175, 176]. The use of multiple anchors is recommended, and the literature highlights those anchors selected should have a theoretical or proven association with the measure under investigation [175, 178, 179].

### *4.6.1. Anchor selection*

Two concepts were selected as anchors - care recipient HRQoL (as measured by the EQ-5D-5L) and informal care hours - based on their conceptual and empirical relationship with informal carer QoL [12, 44, 72, 214]. The anchors were subdivided into three levels to indicate whether the anchor had increased, decreased, or not changed in an important way between the two time points of the study i.e. at baseline and follow up 12 months later [12, 176].

For this analysis, an 'important' change in care recipient EQ-5D-5L score was determined by the measurement of a minimal clinically important difference (MCID) in scores between the two periods of at least 0.063. This figure was selected based on the results of a study from 2017 which used a simulation-based approach based on instrument-defined single-level transitions to estimate the MCID values of the EQ-5D-5L for various countries, including England [223]. An MCID estimate of 0.074 was also included in a sensitivity analysis based on its use in previous studies [12, 224].

Literature on providing informal care categorises an intensive level of caring as providing more than 20 or 50 hours of informal care per week [54, 73]. An 'important' change in the hours of care provided per week was therefore defined in this study as a movement though a threshold of either 20 or 50 hours of care per week, for example moving from providing 18 hours of care per week to 21 hours or moving from providing 55 hours of care per week to 30.

Hypotheses for responsiveness tests were consistent with the construct validity tests (Section 4.5.2). An improvement in carer QoL was hypothesised in relation to a significant improvement in care recipient HRQoL (and vice versa for a worsening in care recipient HRQoL). An improvement in carer QoL was also hypothesised in relation to a significant reduction in caring hours (and vice versa for an increase in caring hours).

## 4.7. Questionnaire development and data collection

The aim of this study was to test the validity and responsiveness of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures with informal carers across a range of conditions, specifically dementia, recovery from stroke, mental health condition, and rheumatoid arthritis. In this chapter the sections to date have provided information on the QoL measures included for analysis, the conditions included in the study and the process for developing hypotheses to test the validity and responsiveness of these QoL measures.

The section that follows details how two self-completion questionnaires were developed to achieve this objective and subject these hypotheses to rigorous testing. A baseline self-completion postal questionnaire (Appendix 1) was developed to record the QoL of carers and contextual data that could be used to test the validity of the selected QoL measures. A follow-up self-completion postal questionnaire (Appendix 2) was also developed to test the responsiveness of the selected QoL measures.

### *4.7.1. Contextual questions to test validity and responsiveness*

Contextual questions were included in the baseline questionnaire based on the development of hypotheses to test the validity of the QoL measures included in the questionnaire. Further detail on how each hypothesis was developed is included in Section 4.5. The final baseline questionnaire (Appendix 1) contained 25 contextual questions across three sections:

A. Nine questions relating to the care recipient, for example relationship to the carer, demographics, co-morbidities, health status, presence of key stressors

B. Seven questions about the caring situation, for example caring load, caring tasks

C. Nine questions relating to the carer, for example socio-demographics, lifestyle, health status, wellbeing, and perceptions about how healthcare impacts on their QoL

The final follow-up questionnaire (Appendix 2) contained 19 contextual questions across the same three sections. Many of the contextual questions included in the responsiveness questionnaire did not aid the responsiveness analysis per se but they were included to describe the sample of informal carers at this time point compared to at baseline. Other contextual questions (e.g., questions on social capital) were included to aid analysis conducted as part of the aims of the wider project to which this PhD research was attached [225].

In the follow-up questionnaire participants were asked if they are still providing care and support for somebody because of their illness, and whether this was the same person they were caring for when they completed the baseline questionnaire. If they answered no to either of these questions, they were asked to indicate the main reason for the change in circumstance. They were then asked to complete the ICECAP-A, and the EQ-5D-5L, along with a life satisfaction question.

Participants who were still in a caring role were asked to complete the ICECAP-A, the EQ-5D-5L, and thirteen contextual questions relating to the care recipient (living situation, presence of key stressors, health status, and anticipated direction of health status), and the caring situation (caring load, alternative ways they could spend their time, and two social capital questions). They were also asked to complete the CES, CarerQoL-7D and ASCOT-Carer.

### *4.7.2. Questionnaire layout*

Evidence shows that the layout of a questionnaire can impact on the response rate [226, 227]. To ensure the baseline questionnaire would be acceptable to the sample of carers, the questions were divided into three sections:

A. Questions about the person you care for

B. Questions about any help or support you provide
C. Questions about you

This order was chosen to engage the respondent in Section A. Asking respondents to answer questions about the care recipient and the current caring situation before moving on to questions about themselves was based on Williams (2003) noting that it is better to ask personal questions towards the end of the questionnaire when the respondent is more relaxed [226]. Questions were kept *"short, simple, and specific"* [226] to ensure comprehension and completion.

The responsiveness questionnaire contained 19 questions across three sections:

A. Questions about you
B. Questions about the person you care for
C. Questions about any help or support you provide

This order was chosen as all participants, including those who were no longer providing care and support for somebody, were asked to complete Section A. Participants who were still in a caring role were then asked to also complete Section B and Section C.

The baseline questionnaire was laid out over 16 pages (including cover and back page) and the responsiveness questionnaire was laid out over 12 pages. Size 12pt. serif font was used throughout to ensure both questionnaires were easy to read. The questionnaires were both printed on a good quality (100gsm) yellow paper. This colour was chosen to grab the respondent's attention [226] and ensure the questionnaires were easy to find if misplaced.

### *4.7.3. Piloting*

The baseline questionnaire was piloted through meetings with a lived experience advisory panel (LEAP) of five carers [228]. Panel members brought lived experience in providing informal care across dementia, recovery from stroke, and long-term mental health conditions for different family members. Panel members were recruited through lay groups attached to dementia, mental health conditions, and stroke charities as part of the wider project to which this PhD is attached.

This stage saw questions fine-tuned, not only to make them clearer but also to concentrate the focus on carer QoL. Panel members were asked to complete a draft version of the baseline questionnaire and any issues they had with the content and layout of the questionnaire were discussed at a meeting in May 2016. Their comments were recorded, and the feedback was incorporated into the final baseline questionnaire (Appendix 1). Key points raised by the lay panel that were actioned on included the following:

- They suggested revising the lists relating to cognitive impairments, functional ability, and problem behaviour. For example, they suggested an emotional aspect should be included in the list of daily dependencies to cover motivating, encouraging etc. They also advised that the heading 'functional ability' should be revised to 'daily dependencies' and the heading 'problem behaviour' should be changed to 'health difficulties'

- They approved the survey implementation plan detailed in Section 4.7.4 agreeing that giving respondents 28 days to complete the questionnaire was reasonable and that a reminder/thank you postcard should be sent 14 days before the deadline. They also agreed that sending a second questionnaire with cover letter to non-responders when the end date passed would help make it easier for non-responders to reply
- Panel members fed back that the layout of the draft questionnaire could be improved by placing the EQ-5D-5L at the end of Section A, so it was positioned after the condition specific questions.

### *4.7.4. Data collection*

The baseline questionnaire (Appendix 1) along with a pre-paid return envelope, cover letter (Appendix 3), and information leaflet (Appendix 4) was posted to the identified sample of carers (n=1,004) on October 28th, 2016. Evidence shows that providing the respondent with a pre-paid return envelope can help maximise the response rate [226, 227, 229-231]. The response rate can also be improved by including a cover letter and information sheet with the questionnaire [227, 231] and the impact of this strategy can be enhanced by taking a personalised approach [227, 230]. To this end, the cover letter was personalised to read "Dear [name of recipient]" and the letter was signed in blue ink by HA, the principal investigator on the wider project to which this PhD work is linked. Respondents were asked to return the completed questionnaire within three weeks.

Following up on non-respondents is highlighted extensively in the literature as a vital strategy for maximising response rate [226, 227, 229-231]. Following up on non-respondents can be done in a variety of ways, for example postal reminders, telephone calls, emailing the participant, or sending them a reminder text message. For this study, the email addresses and mobile telephone numbers of participants were not known, ruling out the options of text or email. Research shows that there is no difference in the response rate if participants are contacted for follow up by post or telephone [230] and given the large number of non-respondents after the three week return date (n=612) it was decided that a postal strategy would be a more time efficient approach.

A two-stage postal follow-up strategy was developed and implemented. Stage one involved sending a thank you postcard (Appendix 5) to respondents (n=370) and a reminder postcard (Appendix 6) to those in the sample yet to respond (n=612). These were posted on November 21st, 2016, three weeks after the baseline questionnaire had been sent.

The aim of the second stage was to make it as easy as possible for any non-responders who were interested to participate. To do this a second copy of the baseline questionnaire was posted to all non-responders. This approach was consistent with the EAST framework [232]. This framework is based on the principles of nudge theory [233] and was developed by the Behavioural Insights

Team in the UK. The framework outlines four key principles for influencing behaviour – make it Easy, Attractive, Social and Timely (EAST) [232].

To make it 'easy' for remaining non-respondents to complete the survey a second copy of the baseline questionnaire was posted to them along with a pre-paid return envelope. To draw attention to the baseline questionnaire and make it 'attractive' it was printed on good quality (100gsm) yellow paper, and as previously mentioned, the cover letter was signed in blue ink, and it was personalised with the participant's name. A new cover letter to accompany the second copy of the baseline questionnaire was developed (Appendix 7) to make it more 'social', defined in the EAST framework as showing that most people perform the desired behaviour [232]. To this end a line was included in the cover letter indicating the percentage of responses already received. The Behavioural Insights Team recommends that to make it 'timely' people should be prompted when they are likely to be most receptive. The second reminder was posted to remaining non-respondents (n=440) on January 23rd, 2017, nine weeks after the first postal reminder. This date was chosen to avoid contacting the carer in the weeks leading up to Christmas. It was expected that non-respondents were more likely to be receptive to participating in the survey work after the Christmas period had passed.

A direct telephone number and email address for CM were included on the cover letter and information sheet (for both the initial mail out and the second reminder mail out). Participants were encouraged to make contact at any stage if they had questions about filling out the questionnaire. A call response sheet (Appendix 8) and a system for logging queries was developed. 73 queries were received, 22 via email and 51 phone calls. Of the 73 queries recorded, 34 people wished to opt out of the study, 24 participants were querying their eligibility for the study, seven requested stationery that was missing from their pack, six people wished to discuss the research in greater detail, and two participants required assistance in how to answer certain questions.

A data entry protocol was developed (Appendix 9) and data were entered into a secure database, with 5% of questionnaires being double entered to verify the accuracy of data entry. Data entry took place between December 2016 and March 2017. A data cleaning protocol was developed based on issues flagged during the double entry process (Appendix 10) and data cleaning commenced in March 2017. This principally involved flagging completion issues with the QoL measures.

To avoid confusion participants were informed in the information sheet that accompanied the baseline questionnaire (Appendix 4) that this was a two-part study into family care, and they would be receiving a second questionnaire to complete in 12 months. The cover letter and information sheet for the responsiveness questionnaire (Appendix 11 and Appendix 12) reminded carers they had completed the baseline questionnaire, and the responsiveness questionnaire was clearly labelled 'follow-up questionnaire'. A telephone number and email address for CM were included on the cover letter and information sheet and participants were encouraged to make contact at any stage if they had questions about completing the questionnaire.

Participants who responded at baseline in November 2016 (n=468) were sent the responsiveness questionnaire along with pre-paid return envelope, cover letter and information leaflet in October 2017 and those who responded at baseline from December 2016 onwards (n=108) were sent the responsiveness questionnaire in January 2018. This was done to try and get participants to complete the responsiveness questionnaire as close to 12 months after the baseline questionnaire as possible. Participants were asked to return the completed responsiveness questionnaire within 14 days. A thank you postcard (Appendix 13) was sent to participants who responded by this date. A reminder postcard (Appendix 14) was sent to non-responders seven days after this date. Only participants who had a complete set of item responses for the responsiveness tests were included in the responsiveness analysis.

## 4.8. Statistical methods

Table 4.6 summarises the statistical tests used in Analysis 1: Measure score-all conditions, Analysis 2: Measure score–individual conditions, Analysis 3: Measure score–health difficulties, and Analysis 4: Measure domains-all conditions.

To assess the association between measure scores and continuous constructs (age, self-rated life satisfaction, presence of cognitive difficulties and daily dependencies, health status, duration of caring) the Pearson r correlation was used. The Pearson r correlation is the most widely used correlation statistic to measure the degree of the relationship between linearly related variables. For the Pearson *r* correlation, both variables should be normally distributed. Other assumptions include linearity and homoscedasticity [234]. This analysis used the Shapiro-Wilk test on all continuous variables to see if they were normally distributed. Where the Pearson assumption of normal distribution did not hold Spearman's rank-order correlation was used. Spearman's rank correlation coefficients of >0.3 are considered weak, >0.5 moderate, >0.7 strong [234].

To assess associations between individual measure items and continuous constructs one-way analysis of variance (ANOVA) was used to determine whether there are any statistically significant differences [235]. Where the continuous variable was not normally distributed independent t-tests was used. Assessments were made about the magnitude of associations by calculating effect sizes using Cohen's d. For Cohen's d, effect sizes between 0.2 and 0.5 are considered small, between 0.5 and 0.8 moderate, and >0.8 large [175, 236].

To assess the association between measure scores and individual items, and categorical constructs (gender, occupation, relationship, hours of care per week, personal care, main carer, involvement of others) chi-squared tests (for unordered or ordered categorical variables) were used [235]. For smaller sample sizes Fisher's exact test was used. Fisher's exact test produces a p-value indicating the probability that the two variables are independent of one another. Unlike chi-squared, there are no accompanying test statistics. Consequently, the p-values only were reported in the results. Associations significant at the 0.1% level were taken to be strongly suggestive of a relationship between the domain and the variable.

Responsiveness was evaluated using the standardised response mean effect size statistic, calculated as the ratio of the mean change between baseline and follow-up index scores to the standard deviation of the change scores [166]. Assessments were made about the magnitude of response by calculating effect sizes for increases/decreases in QoL in the change group using Cohen’s d. For Cohen’s d, effect sizes between 0.2 and 0.5 are considered small, between 0.5 and 0.8 moderate, and >0.8 large [237]. An assessment was also made of whether there was an expected gradient of effect in the QoL measure change scores [12] that is, whether the measured change in carer QoL over 12 months for the three subgroups of carers (denoted by the anchor categories) was ordered in the expected direction in relation to the change in the construct.

**Table 4.6.** Statistical tests used for investigation in Analysis 1: Measure score - all conditions, Analysis 2: Measure score – individual conditions, Analysis 3: Measure score – health difficulties, and Analysis 4: Measure domains – all conditions

| **Contextual variable included for investigation** | **Analysis 1:** Measure score – all conditions | **Analysis 2:** Measure score – individual conditions | **Analysis 3:** Measure score – health difficulties | **Analysis 4:** Measure domains – all conditions |
|---|---|---|---|---|
| **Carer** | | | | |
| Age | Pearson/Spearman | Pearson/Spearman | Pearson/Spearman | Not investigated |
| Gender | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| Self-rated health | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| Occupation | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| Self-rated life satisfaction | Pearson/Spearman | Pearson/Spearman | Pearson/Spearman | ANOVA |
| **Care recipient** | | | | |
| Age | Pearson/Spearman | Pearson/Spearman | Pearson/Spearman | Not investigated |
| Gender | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| Cognitive difficulties & daily dependencies | Pearson/Spearman | Pearson/Spearman | Pearson/Spearman | ANOVA |
| Health status | Pearson/Spearman | Pearson/Spearman | Pearson/Spearman | ANOVA |
| Direction of health status | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| **Caring situation** | | | | |
| Co-residence | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| Relationship | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Not investigated |
| Duration of caring | Pearson/Spearman | Pearson/Spearman | Pearson/Spearman | Not investigated |
| Hours of care per week | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer |
| Personal care | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer |
| Main carer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer |
| Involvement of others | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer | Chi-squared tests/Fischer |

## 4.9. Ethical issues

The final baseline and follow-up questionnaire (Appendix 1 and Appendix 2) and survey protocol (see Section 4.7.4 for a detailed account) was approved by the University of Birmingham's Ethical Review Committee (ERN_14-1444A). There were several important ethical considerations for the research.

Confidentiality of all information was maintained in line with the University of Birmingham Information Security Policy and the Data Protections Act. The returned questionnaires were stored securely in a locked cabinet at the University of Birmingham. The survey data was anonymised during the data entry process so the names and addresses of participants were not linked to the data obtained.

Participants were reminded of their right to withdraw from the study in the information sheet sent with both questionnaires (Appendix 4 and Appendix 12). If a participant chose to withdraw, they were given the choice as to whether data collected up to that point could continue to be used within the research, or whether they would prefer all data to be destroyed.

## 4.10. Summary

This chapter described the methodology for a quantitative study of the construct validity and responsiveness of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures. Individuals who met the following inclusion criteria were included in the study: they currently had caring responsibilities; they did not receive payment for their caring responsibilities, they were aged 18 or over, the person they cared for was aged 18 or over. Section 4.3 provided information on the QoL measures included in the study, and Section 4.4 provided detail on the conditions included. Section 4.5 and 4.6 described the methods used for analysing the data in relation to construct validity and responsiveness. Section 4.5 provided detail on developing the evidence-based hypotheses which would be subjected to rigorous testing, and Section 4.6 provided detail on the development of an anchor-based approach to test whether there is an 'important' change in the outcome measure score when compared to changes in the anchoring item. Section 4.7 provided information on how two postal questionnaires were developed and how data was collected. Section 4.8 then provided detail on the exact statistical tests used for each analysis. The chapter finished with presenting the ethical issues attached to the research. The chapter that follows will present the results of both the construct validity and responsiveness analyses.

# 5. Quantitative study of the validity and responsiveness of health-related, wellbeing and care-related measures for estimating carer quality of life: Results

## 5.1. Introduction

Chapter 4 described the methods for a quantitative study of the validity and responsiveness of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures. This chapter reports the results of that study. The chapter opens with a description of the characteristics of the participants involved in the study (Section 5.2). Section 5.3 presents the response percentages for each QoL measure at baseline and one year later for the responsiveness analysis. Section 5.4 reports the results of the construct validity analysis. The analysis is structured to look at convergent validity (Section 5.4.1) and discriminative validity (Section 5.4.2) where the results for four separate analyses are reported. The four analyses conducted were: Analysis 1: Measure score – all conditions; Analysis 2: Measure score – individual conditions; Analysis 3: Measure score – health difficulties; Analysis 4: Measure domains – all conditions. Section 5.5 presents the results of the responsiveness analysis. The analysis is structured to look at the responsiveness of each QoL measure using the anchors of care recipient HRQoL (as measured by EQ-5D-5L score) and informal care hours. Finally, Section 5.6 summarises the results from both analyses.

## 5.2. The characteristics of participants

The overall response rate for the baseline questionnaire was 58% (n=579). Figure 5.1 shows the density of geographical coverage of respondents at baseline. The lighter green shade represents a greater concentration of participants, and the dark green represents a lower concentration. The map indicates a wide spread of geographical locations with the main concentration of participants in urban areas. Figure 5.2 displays a flowchart of the response to the baseline survey. Of those who opted out of the study (n=60), 22 were not eligible with the majority (n=18) no longer caring for somebody. 38 people were eligible for the research but chose to opt out. Table 5.1 provides further information on the reasons these people gave for opting out of the research. The main reason given was that they did not feel the questions were relevant to their current caring situation (n=22).

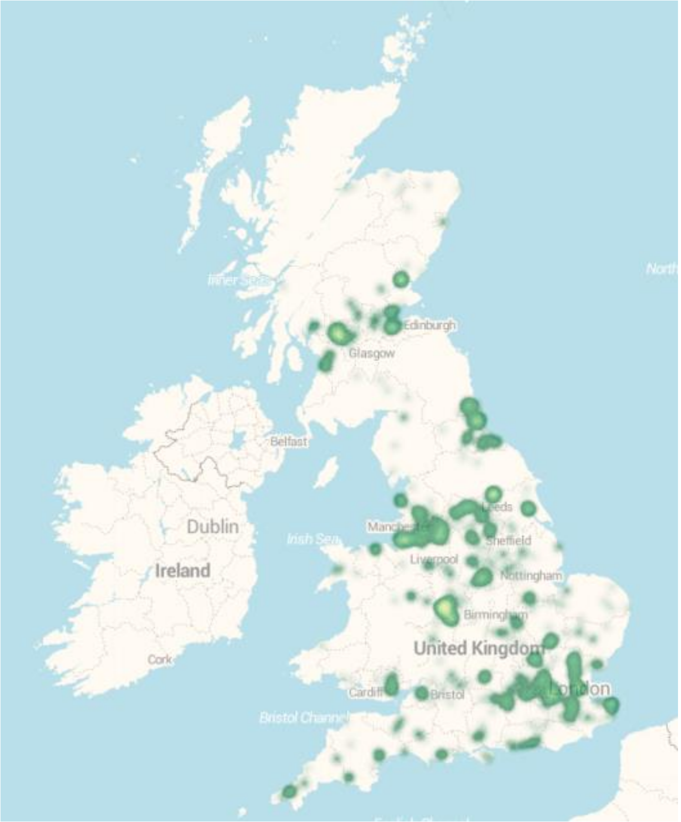

**Figure 5.1.** Geographical coverage of respondents

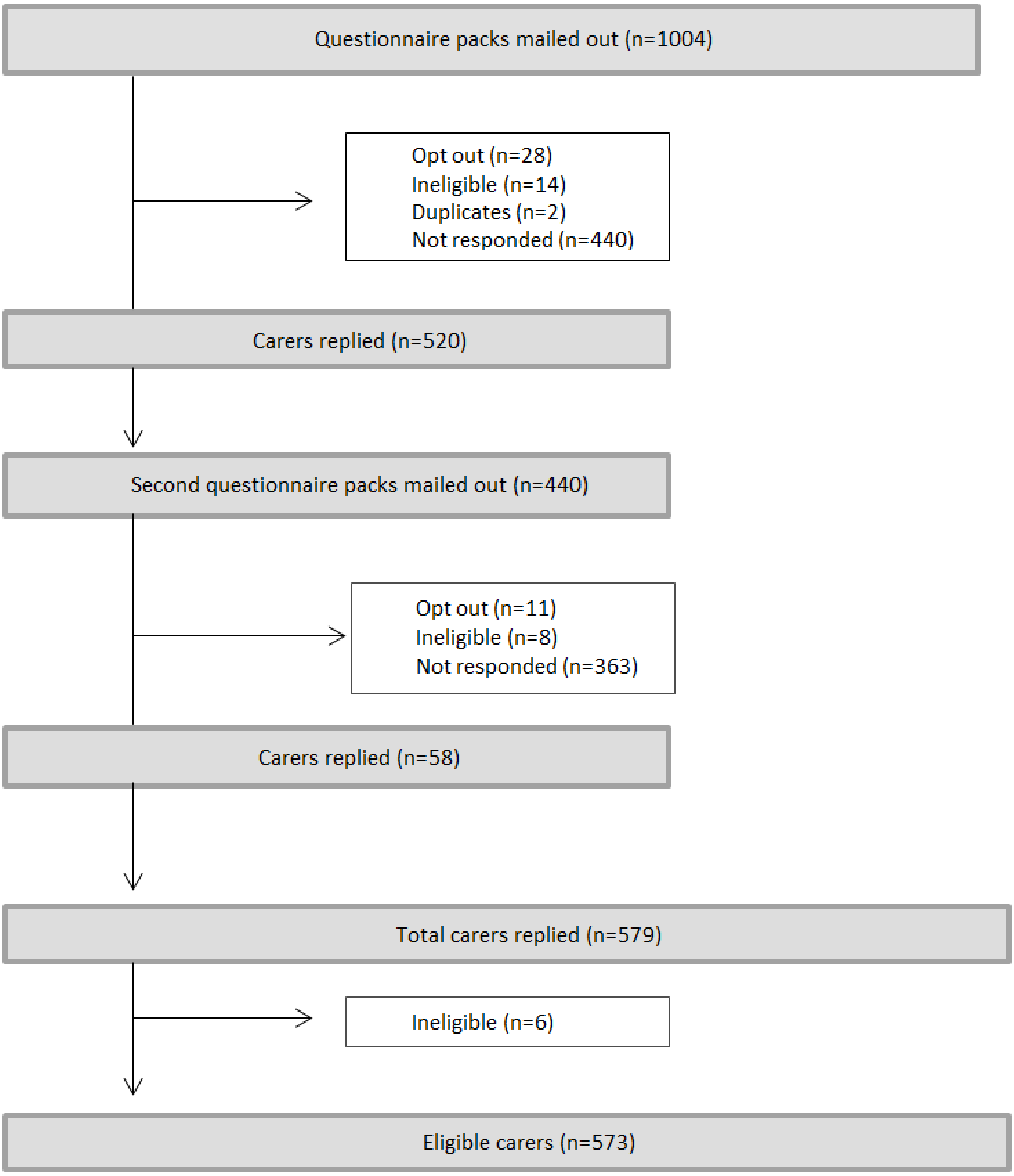

**Figure 5.2.** Response to the baseline questionnaire

**Table 5.1.** Reason for opting out of the study

| Potential participants | n | Further information | n | Further information | n |
|---|---|---|---|---|---|
| Survey mailed out | 1,003 | 1 person was entered twice in the NatCen database | | | |
| No response | (367) | | | | |
| Opt out – not eligible | (22) | No longer caring | 18 | Care recipient is dead | 12 |
| | | | | Care recipient has recovered | 3 |
| | | | | No reason given | 2 |
| | | | | Somebody else has taken over the caring role | 1 |
| | | No caring responsibility | 3 | | |
| | | Carer dead | 1 | | |
| Opt out – eligible | (38) | Does not feel the questions are relevant to their current situation | 22 | No further info given | 12 |
| | | | | Care recipient is in residential care | 10 |
| | | No reason given | 9 | Blank questionnaire returned | 6 |
| | | | | Phone call received | 3 |
| | | Carer ill health | 3 | | |
| | | Does not identify as a carer | 3 | | |
| | | Does not want to upset care recipient | 1 | | |
| Responses received | 579 | | | | |
| Not eligible | (6) | Care recipient <18 | 5 | | |
| | | Carer cares for themselves | 1 | | |
| Eligible responses | 573 | | | | |

The characteristics of respondents at baseline are presented in Table 5.2. Of the 573 eligible respondents, 65% were female. The age of respondents ranged from 24 to 89, with an average age of 62 (SD = 11.10). Most of the sample was white (98%), with four black/black British, three mixed, and two Asian/Asian British respondents. 46% of respondents were caring for a parent and 35% for their spouse/partner. 46% of the sample share a house with the care recipient. 41% of respondents have been providing care for 5-10 years, 32% for less than 5 years, and 27% for more than 10 years. 72% of the sample regard themselves as the main person responsible for the care of the care recipient. 53% of respondents answered that they spend, on average, more than 20 hours per week on caring activities. 66% of the sample were caring for a person with one condition and 34% were caring for somebody with two or more conditions.

The most common caring relationship amongst respondents was that of providing care for a parent, especially amongst those who were providing care for somebody with dementia (61%). The exception was with mental health conditions, where the most common relationship was providing care for a spouse/partner (37%). Respondents providing care for somebody with a mental health condition were also the largest group of people providing care for an adult child (18%) compared to dementia (9%), recovery from stroke (1%), and rheumatoid arthritis (0%).

When asked how long they had been providing care, answers ranged from on average almost seven years (dementia), to 13 years (mental health condition). Of those providing care for somebody with a mental health condition 66% reported spending more than 20 hours per week on caring activities. Amongst the other conditions, 60% of respondents providing care for somebody recovering from stroke, 49% with rheumatoid arthritis, and 44% with dementia reported spending more than 20 hours per week on caring activities.

**Table 5.2.** Characteristics of the carer, care recipient and caring situation for pooled and individual conditions at baseline

| Variable | All conditions (n=576) | Dementia (n=155) | Stroke (n=89) | Mental health condition (n=144) | Rheumatoid arthritis (n=126) |
|---|---|---|---|---|---|
| **Carer** | | | | | |
| Age, years, mean (SD) | 62 (11.10) | 64 (11.32) | 64 (10.70) | 61 (11.53) | 61 (12.27) |
| Gender, female, n (%) | 367 (65) | 107 (69) | 61 (69) | 95 (66) | 71 (57) |
| Health status (EQ-5D-5L), mean (SD) | 0.76 (0.21) | 0.77 (0.22) | 0.74 (0.21) | 0.69 (0.25) | 0.74 (0.21) |
| Occupation, in paid employment, n (%) | 189 (33) | 43 (28) | 30 (34) | 45 (31) | 42 (34) |
| Self-rated life satisfaction, mean (SD) | 6.7 (2.23) | 6.5 (2.12) | 6.7 (2.36) | 6.2 (2.33) | 7.1 (2.34) |
| **Care recipient** | | | | | |
| Age, years, mean (SD) | 74 (18.33) | 84 (7.88) | 77 (13.66) | 65 (20.18) | 80 (13.03) |
| Gender, male, n (%) | 203 (35) | 48 (31) | 237 (42) | 49 (34) | 32 (26) |
| Has cognitive problems, yes, n (%) | 340 (59) | 151 (97) | 66 (74) | 99 (69) | 59 (47) |
| Has daily dependencies, yes, n (%) | 518 (90) | 142 (92) | 82 (92) | 135 (94) | 113 (90) |
| Health status (EQ-5D-5L), mean (SD) | 0.32 (0.31) | 0.31 (0.14) | 0.32 (0.33) | 0.26 (0.32) | 0.24 (0.29) |
| Direction of health status, declining, n (%) | 373 (66) | 127 (83) | 58 (65) | 86 (60) | 97 (78) |
| **Caring situation** | | | | | |
| Co-residence, yes, n (%) | 266 (46) | 55 (36) | 43 (48) | 75 (52) | 50 (40) |
| Relationship to carer, spouse, n (%) | 199 (35) | 43 (27) | 33 (37) | 54 (38) | 39 (31) |
| Duration of caring, years & months, mean (SD) | 122 months (122.1) | 79 months (71.15) | 125 months (122.6) | 160 months (132.4) | 94 months (96.67) |
| Time spent caring >20 hours per week, n (%) | 295 (53) | 66 (44) | 53 (60) | 95 (66) | 60 (49) |
| Provides personal care, n (%) | 343 (68) | 81 (62) | 62 (76) | 100 (75) | 73 (63) |
| Identifies as the main carer, yes, n (%) | 408 (72) | 99 (66) | 61 (70) | 117 (82) | 92 (74) |
| Other people are involved in the caring, yes, n (%) | 367 (65) | 120 (79) | 65 (74) | 83 (58) | 85 (69) |

The follow-up questionnaire was posted to the 576 participants who responded at baseline. A flow chart (Figure 5.3) shows the two different time points at which the follow-up questionnaires were posted (see Section 4.7 for further detail). In total 431 (75%) follow-up questionnaires were returned. Of these, 113 respondents (26%) were not eligible for the responsiveness analysis due to the fact they were no longer providing care (n=85), or they were providing care for a different person (n=28). Further information on why participants were no longer providing care or were caring for a different person is provided in Figure 5.3. Of the 431 respondents, 318 (74%) were eligible for the responsiveness analysis, that is they were still providing informal care to the person they were caring for at baseline.

When broken down by condition the majority (n=160) were providing care for somebody with a condition other than dementia (n=73), recovery from stroke (n=41), a mental health condition (n=48) or rheumatoid arthritis (n=66). Given the relatively small numbers of participants caring for somebody with dementia, recovery from stroke, a mental health condition, or rheumatoid arthritis (at baseline and follow-up) the responsiveness analysis was not broken down by condition. All tables and figures relate to the group as a whole and the baseline figures provided are based on the sample of 318 respondents who also responded at follow-up.

The characteristics of participants included in the responsiveness analysis at baseline and follow-up are presented in Table 5.3. Participants reported similar average levels in their paid employment status and in their residential situation. A small increase in the average self-rated life satisfaction score was recorded from 6.7 at baseline to 7 at follow-up (scale 0-10). At baseline 60% of respondents reported spending more than 20 hours per week on average on caring activities, with this figure rising to 64% at follow-up. Participants reported an increase in the presence of cognitive problems from 58% of care recipients having at least one cognitive problem at baseline to 68% at follow-up. There was also an increase in the presence of any daily dependencies in care recipients from 89% to 93%. Table 5.3 also shows an increase in the percentage of participants providing personal care to the care recipient at baseline (60%) and follow-up (72%). Of note, although these markers indicate a decline in care recipient health status, the mean care recipient EQ-5D-5L score remained the same at baseline (0.30) and follow-up (0.30).

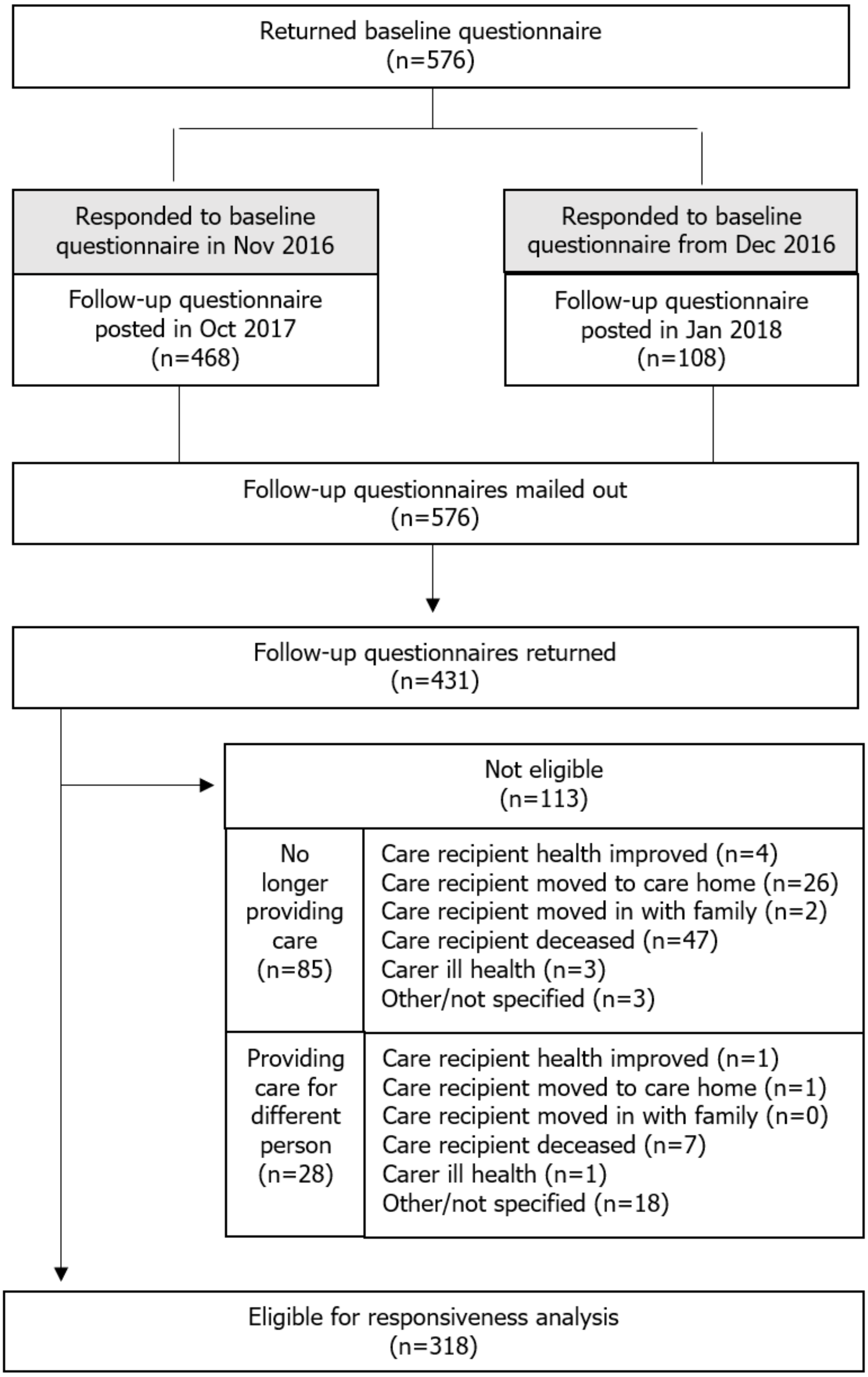

**Figure 5.3.** Response to the follow-up questionnaire

**Table 5.3.** Characteristics of the carer, care recipient and caring situation at baseline and follow-up

| Construct | Responsiveness sample at baseline (n=314) | Responsiveness sample at follow-up (n=314) |
|---|---|---|
| **Carer** | | |
| Age, years, mean (SD) | 63 (10.01) | 64 (10.01) [1] |
| Gender, female, n (%) | 191 (63) | 191 (63) [1] |
| Health status (EQ-5D-5L), mean (SD) | 0.80 (0.21) | 0.74 (0.23) |
| Occupation, in paid employment, n (%) | 84 (14) | 84 (14) |
| Self-rated life satisfaction, scale 0-10, mean (SD) | 6.7 (2.33) | 7 (2.24) |
| **Care recipient** | | |
| Age, years, mean (SD) | 73 (19.11) | 74 (19.11) [1] |
| Gender, male, n (%) | 108 (36) | 108 (36) [1] |
| Has cognitive problems, yes, n (%) | 177 (58) | 205 (68) |
| Has daily dependencies, yes, n (%) | 269 (89) | 279 (93) |
| Health status (EQ-5D-5L), mean (SD) | 0.30 (0.35) | 0.30 (0.35) |
| Direction of health status, declining, n (%) | 191 (63) | 174 (58) |
| **Caring situation** | | |
| Co-residence, yes, n (%) | 153 (49) | 156 (49) |
| Relationship to carer, spouse, n (%) | 111 (37) | 111 (37) [1] |
| Duration of caring, months, mean (SD) | 129 (126.5) | 141 (126.5) [1] |
| Time spent caring >20 hours per week, n (%) | 183 (60) | 193 (64) |
| Provides personal care, n (%) | 183 (60) | 218 (72) |
| Identifies as the main carer, yes, n (%) | 233 (77) | 233 (77) [1] |
| Other people are involved in the caring, yes, n (%) | 182 (61) | 182 (61) [1] |

[1] Question not asked in the follow-up questionnaire

## 5.3. Completion of quality of life measures

The overall and condition specific completion rate and mean score at baseline for the five QoL measures are presented in Table 5.4. Amongst the CRQoL measures, the ASCOT-Carer had the highest completion rate (95% for all conditions) while the CES and CarerQoL-7D both had a completion rate of 88%. The EQ-5D-5L had a 97% completion rate when respondents completed the measure for themselves, and 87% when respondents completed the measure on behalf of the care recipient. The ICECAP-A had an overall completion rate of 94%.

Those caring for somebody with a mental health condition reported the lowest QoL score on average, in each measure. Mean score in the CES ranged from 60.7 for those caring for somebody with a mental health condition, to 65.3 for those caring for somebody with dementia. CarerQoL-7D scores ranged from 64.6 (mental health condition) to 75.1 (rheumatoid arthritis). ASCOT-Carer scores ranged from 0.70 (mental health condition) to 0.79 (rheumatoid arthritis). For the EQ-5D-5L the carer's mean score ranged from 0.69 (mental health condition) to 0.76 (dementia). When reporting on the care recipient HRQoL mean scores in the EQ-5D-5L ranged from 0.24 (rheumatoid arthritis) to 0.32 (recovery from stroke). The carer's mean scores for the ICECAP-A ranged from 0.71 (mental health condition) to 0.80 (rheumatoid arthritis).

The overall completion rate and mean score for the five QoL measures at follow-up for all conditions are presented in Table 5.5. Among the CRQoL measures, the Ascot-Carer had the highest completion rate at baseline (96%) and amongst the subsample of carers included for analysis at follow-up (98%). The CES and CarerQoL-7D increased their completion rates in the follow-up questionnaires from 89% to 96%. Mean score in the CES rose from 62.9 to 65.1 and in the CarerQoL-7D from 72.3 to 73.7. Mean score in the ASCOT-Carer was 0.74 at baseline and remained at 0.74 at follow-up. For the EQ-5D-5L 98% of respondents completed the measure when answering for themselves at both baseline and follow-up. Mean EQ-5D-5L score decreased from 0.79 to 0.74. The ICECAP-A had a completion rate of 94% at baseline and 98% at follow-up with the mean score increasing from 0.76 to

0.81 at follow-up. The overall life satisfaction score saw an increase from 6.69 (98% completion rate) at baseline, to 6.96 (97% completion rate) at follow-up. When completing the EQ-5D-5L for the care recipient, 98% of respondents completed the measure at baseline and 96% completed it at follow-up. Mean EQ-5D-5L score for the care recipient increased from 0.30 at baseline to 0.31 at follow-up.

**Table 5.4.** Quality of life measures completed in full at baseline

| | CES | | CarerQoL-7D | | ASCOT-Carer | | EQ-5D-5L (carer) | | EQ-5D-5L (recipient) | | ICECAP-A | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Complete n (%) | Mean score | Complete n (%) | Mean score | Complete n (%) | Mean score | Complete n (%) | Mean score | Complete n (%) | Mean score | Complete n (%) | Mean score |
| All conditions (n=576) | 506 (88) | 62.9 | 505 (88) | 72.3 | 549 (95) | 0.74 | 560 (97) | 0.79 | 503 (87) | 0.30 | 541 (94) | 0.76 |
| Dementia (n=155) | 139 (90) | 65.3 | 134 (86) | 71.1 | 148 (95) | 0.73 | 151 (97) | 0.76 | 133 (86) | 0.31 | 146 (94) | 0.75 |
| Stroke (n=89) | 80 (90) | 64.7 | 77 (87) | 72.5 | 87 (98) | 0.72 | 87 (98) | 0.74 | 76 (85) | 0.32 | 85 (96) | 0.75 |
| Mental health condition (n=144) | 129 (89) | 60.7 | 128 (89) | 64.6 | 139 (97) | 0.70 | 141 (98) | 0.69 | 129 (89) | 0.26 | 137 (95) | 0.71 |
| Rheumatoid arthritis (n=126) | 110 (87) | 64.6 | 110 (87) | 75.1 | 119 (94) | 0.79 | 123 (98) | 0.74 | 113 (90) | 0.24 | 119 (94) | 0.80 |

**Table 5.5.** Quality of life measures completion rate and mean score at baseline and follow-up for all conditions

| **Measure** | **Sample at baseline (n=318)** | | **Sample at follow-up (n=318)** | |
|---|---|---|---|---|
| | Completion rate % | Mean score | Completion rate % | Mean score |
| CES | 89 | 62.9 | 96 | 65.1 |
| CarerQoL-7D | 89 | 72.3 | 96 | 73.7 |
| ASCOT-Carer | 96 | 0.74 | 98 | 0.74 |
| EQ-5D-5L (carer) | 98 | 0.79 | 98 | 0.74 |
| EQ-5D-5L (care recipient) | 98 | 0.30 | 96 | 0.31 |
| ICECAP-A | 94 | 0.76 | 98 | 0.81 |

## 5.4. Construct validity analysis

### *5.4.1. Convergent validity*

Table 5.6 presents the Spearman's correlation coefficients of the five QoL measures (care recipient EQ-5D-5L is not included). The scores for the CRQoL measures were significantly positively associated with the EQ-5D-5L and ICECAP-A (P<0.001). These relationships are congruent with the hypothesis that better HRQoL and wellbeing would be associated with more positive experiences of caregiving. These effect sizes were weak for the EQ-5D-5L and CES (correlation coefficient 0.25), and moderate for both the ASCOT-Carer and CarerQoL-7D (correlation coefficient 0.44 and 0.51 respectively). The effect sizes were moderate for the ICECAP-A and CES (correlation coefficient 0.57), and strong for both the CarerQoL-7D (correlation coefficient 0.69) and the ASCOT-Carer (correlation coefficient 0.85).

**Table 5.6.** Bivariate correlation analysis of CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L and ICECAP-A

| **QoL measure** | **CES** | **CarerQoL-7D** | **ASCOT-Carer** | **EQ-5D-5L** | **ICECAP-A** |
|---|---|---|---|---|---|
| CES | | | | | |
| CarerQoL-7D | 0.56*** | | | | |
| ASCOT-Carer | 0.60*** | 0.71*** | | | |
| EQ-5D-5L | 0.25*** | 0.51*** | 0.44*** | | |
| ICECAP-A | 0.57*** | 0.69*** | 0.85*** | 0.50*** | |

* $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$

### *5.4.2. Discriminative validity*

#### *5.4.2.1. Analysis 1: Measure score – all conditions*

Table 5.7 presents the results for Analysis 1 split between hypotheses relating to the carer, the care recipient, and the caring situation. In the four constructs related to the carer (age, gender, employment status, self-rated life satisfaction), the CES, CarerQol-7D and EQ-5D-5L detected a statistically significant association 3 out of 4 times, the ICECAP-A in 2 of 4 times, and the ASCOT-Carer in 1 of 4 times. All effect sizes were either small or below the conventional threshold of a small effect size, except for the variable 'life satisfaction'. Statistically significant associations were detected between carer's life satisfaction score and each measure score, and the effect size was moderate (CES and EQ-5D-5L) to strong (CarerQoL-7D, ASCOT-Carer and ICECAP-A).

In the five constructs related to the care recipient (age, gender, the presence of cognitive difficulties and daily dependencies, health status, direction of health status) the CES detected a statistically significant association 4 out of 5 times. All other QoL measures detected a statistically significant association in each test. All associations were small or below the threshold for small except for two variables 'the presence of cognitive difficulties and daily dependencies' and 'health status'. Statistically significant associations were detected using each measure and the effect size was moderate for the CarerQoL-7D, ASCOT-Carer, and ICECAP-A score.

**Table 5.7.** Univariable associations and effect sizes between QoL measure scores (all conditions) and contextual constructs

| Contextual construct | | n= | CES | | CarerQoL-7D | | ASCOT-Carer | | EQ-5D-5L | | ICECAP-A | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CC | Effect size | CC | Effect size | CC | Effect size | CC | Effect size | CC | Effect size |
| **Carer** | Age | 558 | -0.02 | | 0.06 | | -0.01 | | -0.15*** | | 0.01 | |
| | Gender, female | 569 | | -0.18* | | -0.23** | | -0.16 | | -0.01 | | -0.06 |
| | Employment status, paid employment | 567 | | 0.25** | | 0.23** | | 0.17 | | 0.38*** | | 0.22** |
| | Self-rated life satisfaction | 564 | 0.52*** | | 0.64*** | | 0.78*** | | 0.43*** | | 0.82*** | |
| **Care recipient** | Age | 546 | 0.10* | | 0.15** | | 0.17*** | | 0.14** | | 0.23*** | |
| | Gender, male | 574 | | -0.06 | | -0.27** | | -0.22* | | -0.19* | | -0.30*** |
| | Cognitive difficulties & daily dependencies | 576 | -0.14*** | | -0.35*** | | -0.39*** | | -0.18*** | | -0.38*** | |
| | Health status (EQ-5D-5L) | 503 | 0.15*** | | 0.30*** | | 0.32*** | | 0.24*** | | 0.32*** | |
| | Direction of health status, declining | 569 | | -0.34*** | | -0.34*** | | -0.29** | | -0.17* | | -0.24** |
| **Caring situation** | Co-residence | 575 | | -0.49*** | | -0.33*** | | -0.62*** | | -0.40*** | | -0.63*** |
| | Relationship, spouse | 576 | | -0.21* | | -0.16 | | -0.35*** | | -0.37*** | | -0.46*** |
| | Duration of caring (months) | 568 | -0.10* | | -0.14*** | | -0.17*** | | -0.12** | | -0.21*** | |
| | Hours of care per week >20 | 559 | | -0.58*** | | -0.62** | | -0.94*** | | -0.45*** | | -0.86*** |
| | Provides personal care | 508 | | -0.31** | | -0.47*** | | -0.64*** | | -0.42*** | | -0.61** |
| | Main carer | 566 | | -0.59*** | | -0.49*** | | -0.62*** | | -0.34*** | | -0.57*** |
| | Involvement of others | 566 | | 0.44*** | | 0.21* | | 0.22* | | 0.13 | | 0.22** |

Note: CC, correlation coefficient. Spearman's rho reported for continuous variables. Cohen's d effect size reported for all other variables. Spearman's rank correlation coefficients >0.3 considered weak, >0.5 moderate, >0.7 strong. Cohen's d effect sizes >0.2 considered small, >0.5 moderate, >0.8 large. The same interpretations apply for negative CC and effect sizes. *p<0.05; ** p<0.01; *** p<0.001

🟥 Not statistically significant 🟨 Statistically significant, small/weak effect size 🟩 Statistically significant, moderate/high effect size

In the seven constructs related to the caring situation (co-residence, relationship, duration of caring, hours of care per week, provision of personal care, main carer, involvement of others) the CES, ASCOT-Carer and ICECAP-A detected statistically significant associations with all 7 constructs, and the CarerQoL-7D and EQ-5D-5L each detected 6 out of 7 statistically significant associations. The effect sizes were small except for 4 variables. For the variables 'co-residence' and 'personal care' the effect sizes were moderate for ASCOT-Carer and ICECAP-A scores. A moderate effect size was also found between the variable 'main carer' and CES, ASCOT-Carer, and ICECAP-A scores. For the variable 'hours of care per week >20' the effect size was moderate for CES score, and strong for ASCOT-Carer and ICECAP-A scores.

### Carer related variables and QoL measures

There was a statistically significant weak negative association between EQ-5D-5L score and the age of the carer. This result was consistent with the hypothesis that age has a negative impact on carer QoL. However, there was no statistically significant association between the remaining QoL measures and age, and the associations detected by the CarerQoL-7D and ICECAP-A did not fall in the expected direction. Table 5.7 shows a statistically significant association between gender and CES score and CarerQoL-7D score. This supports the hypothesis that female carers experience lower QoL compared to male carers. The effect sizes were small (CarerQoL-7D) and below the conventional threshold of a small effect size (CES). The expected association between gender and the other QoL measures was not found. There was a statistically significant association between paid occupation and the EQ-5D-5L, the CES, CarerQoL-7D, ICECAP-A. These associations were in the expected direction and the effect size was small for each measure. The ASCOT-Carer did not detect a statistically significant association with this variable. In line with hypothesised associations, self-rated life satisfaction showed positive statistically significant correlations with each measure. The effect sizes were moderate for the CES and EQ-5D-5L, and strong for all other measures.

### Care recipient related contextual variables and QoL measures

Age showed a weak positive statistically significant correlation with each QoL measure. Of the five QoL measures, all detected a statistically significant association with gender, except for the CES. These associations were in the expected direction and the effect size was small. There was a statistically significant association between each QoL measure and the presence of cognitive difficulties and daily dependencies. The associations were in the expected direction and the effect size was moderate for the CarerQoL-7D, ASCOT-Carer and ICECAP-A, and weak for the CES and EQ-5D-5L. There was a statistically significant association between each QoL measure score and the health status of the care recipient, as measured by the EQ-5D-5L. The associations were in the expected direction and the effect size was moderate for the CarerQoL-7D, ASCOT-Carer and ICECAP-A, and weak for the CES and EQ-5D-5L. Table 5.7 shows a statistically significant small negative association between the direction of the care recipient health status and each QoL measure.

### Caring situation related contextual variables and QoL measures

There was a statistically significant association between co-residence and each QoL measure score. The effect size was moderate for the CES, ASCOT-Carer, ICECAP-A, and small for the CarerQoL-7D and EQ-5D-5L. Table 5.7 shows there was no statistically significant association between relationship and CarerQoL-7D score. There was a small statistically significant association with the CES, ASCOT-Carer, EQ-5D-5L, and ICECAP-A. There was a statistically significant association between the duration of caring and each QoL measure. The effect size was small for each measure except for the CES for which the effect size was below the conventional threshold of a small effect size. Table 5.7 shows a statistically significant association with hours of care per week and each QoL measure. The effect size is strong for the ASCOT-Carer and ICECAP-A, moderate for the CES and CarerQoL-7D, and weak for the EQ-5D-5L. There was a statistically significant association with providing personal care and each QoL measure score. The effect size was moderate for the ASCOT-Carer and ICECAP-A, and small for the remaining measures. There was a statistically significant association between being the main carer and each QoL measure score. This association was in the expected direction and the effect size was moderate in each measure. A statistically significant association was found between the involvement of others in caring and the CES, CarerQoL-7D, ASCOT-Carer, and ICECAP-A. The effect size was small for each of these measures. There was no association found for the EQ-5D-5L.

#### *5.4.2.2. Analysis 2: Measure score – individual conditions*

Tables provided in Appendix 15 show univariable associations and effect sizes between QoL measures scores for dementia, recovery from stoke, mental health conditions, and rheumatoid arthritis, and contextual variables. The results for these tests of discriminative validity are presented, split between hypotheses relating to the carer, the care recipient, and the caring situation. Given that there are a high number of pairwise associations Table 5.8 shows the number of significant associations between the group of constructs and QoL measure scores for the individual conditions. Table 5.9 shows that for dementia and rheumatoid arthritis, 14 out of 17 hypothesised associations were supported by results. 12 associations in recovery from stroke were confirmed, and in mental health conditions 10 out of 17 hypothesised associations were confirmed by results.

Because of the smaller sample sizes included in this analysis (compared to Analysis 1: Measure score – all conditions) there were fewer significant associations within the individual conditions. However, the results show that overall, of the CRQoL measures more statistically significant associations were found for the CarerQoL-7D for dementia, comparable to the best performing comparator measure, the EQ-5D-5L. For recovery from stroke, mental health conditions and rheumatoid arthritis the ASCOT-Carer performed better than the other CRQoL measures. Of the comparator measures the same number of associations was found for the ICECAP-A as the ASCOT-Carer in recovery from stroke and rheumatoid arthritis, while the same number of associations was found for the EQ-5D-5L as the ASCOT-Carer in mental health conditions.

All effect sizes were either small or below the conventional threshold of a small effect size except for a number of certain constructs. For mental health condition a moderate effect size was found between ‘carer’s health status’ and all QoL measures. This association and effect size was also detected for each QoL measure in dementia, recovery from stroke, and rheumatoid arthritis, except for the CES. A moderate association (CarerQoL-7D, ICECAP-A) was found with the variable ‘care recipient health status’ in dementia. This association and effect size was also found in rheumatoid arthritis with the CES, ASCOT-Carer and ICECAP-A. A moderate association was found with the EQ-5D-5L in dementia, and the CarerQoL-7D in rheumatoid arthritis. A statistically significant association was also detected between ‘carer’s life satisfaction’ score and each measure score for the individual conditions. The effect size in each condition ranged from moderate to strong. The CarerQoL-7D detected a moderate effect size with ‘carer gender’ in dementia and recovery from stroke while for the variable ‘care recipient gender’ a moderate association was found for the ICECAP-A in mental health conditions. In dementia a moderate to strong effect size was found with the variable ‘hours of care per week >20’ for the CES, CarerQoL-7D, EQ-5D-5L (moderate), and ASCOT-Carer, ICECAP-A (strong). The same effect sizes were found in recovery from stroke, and moderate effect sizes were found in mental health conditions and the ASCOT-Carer, ICECAP-A and EQ-5D-

5L. In rheumatoid arthritis strong effect sizes were detected with ASCOT-Carer score and moderate effect sizes were found with CES, CarerQoL-7D, and ICECAP-A scores.

Other constructs where moderate to strong effects sizes were found across the individual conditions and QoL measures were the carer being in paid employment, the carer identifying as the main carer, the relationship between the carer and care recipient, the involvement of others in the caring, the presence of cognitive difficulties and daily dependencies, the provision of personal care, the duration of caring, and if the carer and care recipient share a home.

**Table 5.8.** Associations between QoL measure score and individual conditions

| | **CES** | **CarerQoL-7D** | **ASCOT-Carer** | **EQ-5D-5L** | **ICECAP-A** |
|---|---|---|---|---|---|
| Dementia | 6/17 | 9/17 | 7/17 | 9/17 | 7/17 |
| Stroke | 9/17 | 8/17 | 11/17 | 6/17 | 11/17 |
| Mental health condition | 4/17 | 6/17 | 8/17 | 8/17 | 8/17 |
| Rheumatoid arthritis | 10/17 | 10/17 | 11/17 | 9/17 | 11/17 |

**Table 5.9.** A comparison of hypotheses and results for each condition

| **Contextual variable** | **Dementia** | | **Stroke** | | **Mental health condition** | | **Rheumatoid arthritis** | |
|---|---|---|---|---|---|---|---|---|
| | **Hypothesis** | **Result (strength)** | **Hypothesis** | **Result (strength)** | **Hypothesis** | **Result (strength)** | **Hypothesis** | **Result (strength)** |
| **Carer** | | | | | | | | |
| Age | Negative | Negative (w) | Positive | - | Negative | - | Positive | - |
| Gender | Negative | Negative (m) | Negative | Negative (m) | Negative | - | Negative | Negative (w) |
| Self-rated health | Positive | Positive (w/m) | Positive | Positive (w/m) | Positive | Positive (m) | Positive | Positive (m) |
| Occupation | Positive | - | Negative | - | Negative | Positive (m) | Positive | Positive (w) |
| Life satisfaction | Positive | Positive (m/s) | Positive | Positive (m/s) | Positive | Positive (m/s) | Positive | Positive (m/s) |
| **Care recipient** | | | | | | | | |
| Age | - | - | - | Positive (w) | - | - | - | - |
| Gender | Negative | - | Negative | - | Negative | Negative (w/m) | Negative | - |
| Cognitive difficulties & daily dependencies | Negative | Negative (w/m) | Negative | Negative (w/m) | Negative | Negative (w) | Negative | Negative (w/m) |
| Health status | Positive | Positive (w/m) | Positive | Positive (w) | Positive | Positive (w) | Positive | Positive (w/m) |
| Direction health status | Negative | - | Negative | Negative (w/m) | Negative | Negative (w) | Negative | Negative (w/m) |
| **Caring situation** | | | | | | | | |
| Co-residence | Negative | Negative (w/s) | Negative | Negative (m) | Negative | Negative (w) | Negative | Negative (w/m) |
| Relationship | Negative | Negative (w/m) | Negative | Negative (w/m) | Negative | - | Negative | Negative (w) |
| Duration of caring | Negative | Negative (w) | Positive | Negative (w) | Negative | - | Negative | Negative (w) |
| Hours of care week | Negative | Negative (m/s) | Negative | Negative (m/s) | Negative | Negative (w/m) | Negative | Negative (m/s) |
| Personal care | Negative | Negative (w) | Negative | Negative (m) | Negative | Negative (m) | Negative | Negative (m/s) |
| Main carer | Negative | Negative (w/s) | Negative | Negative (m) | Negative | - | Negative | Negative (m/s) |
| Involvement of others | Positive | Positive (m) | Positive | Positive (m) | Positive | - | Positive | - |

w: weak, m: moderate, s: strong

### *5.4.2.3. Analysis 3: Measure score – health difficulties*

Table 5.10 shows the number of associations between QoL measure scores and condition specific health difficulties. Table 5.11 lists the health difficulties included in the analysis and where no hypothesised association was found, the health difficulty is in italics. The results have been summarised, so the cell entries indicate the number of significant associations between the group of constructs and the measure scores. Overall, of the CRQoL measures more statistically significant associations were found with the CarerQoL-7D and ASCOT-Carer for dementia, recovery from stroke, and mental health conditions than the CES, and of the comparator measures the ICECAP-A performed better than the EQ-5D-5L for each condition except for rheumatoid arthritis. For dementia health difficulties, the CarerQoL-7D detected 3/10 significant associations and it detected more than the EQ-5D-5L and ICECAP-A. For stroke a statistically significant association was found with eight out of ten health difficulties, the largest number from the four conditions included for analysis. Of the care-related measures, the ASCOT-Carer had 7/10 significant associations– one more than the ICECAP-A. For mental health condition the CarerQoL-7D detected 4/10 significant associations , and for rheumatoid arthritis the EQ-5D-5L detected 2/8 significant associations.

**Table 5.10.** Number of significant associations between measure score and condition specific health conditions

| | CES | CarerQoL-7D | ASCOT-Carer | EQ-5D-5L Carer | ICECAP-A |
|---|---|---|---|---|---|
| Dementia | 2/10 | 3/10 | 2/10 | 1/10 | 2/10 |
| Stroke | 3/10 | 5/10 | 7/10 | 3/10 | 6/10 |
| Mental health condition | 0/10 | 4/10 | 2/10 | 2/10 | 2/10 |
| Rheumatoid arthritis | 1/8 | 1/8 | 0/8 | 2/8 | 1/8 |

**Table 5.11.** Condition specific health difficulties

| Dementia | Stroke | Mental health condition | Rheumatoid arthritis |
|---|---|---|---|
| *Mislaying or hiding items around the house* | Problems with co-ordination and balance | *Delusions, paranoia, or hallucinations* | Sleep disturbance / difficulties |
| *Forgetting recent conversations or events* | Sleep disturbance / difficulties | *Confused or racing thoughts* | *Pain and stiffness of affected joints* |
| Struggle to find the right word or keep track of conversation | *Changes to emotions e.g., feelings of misery or anxiety* | *Diminished emotional expression* | *Loss of appetite or weight loss* |
| Grasping new ideas and unwilling to try out new things | Problems with swallowing | Inappropriate or unpredictable behaviour | Swelling of affected joints, joints become hot and tender to touch |
| *Losing track of the day or date* | *Visual problems e.g., double vision, reduced field of vision* | *Emotional withdrawal* | *Pinched or compressed nerves e.g., carpal tunnel syndrome* |
| Withdrawal from friends and activities | Irritability or rudeness | Changes in sleeping patterns | Skin complications e.g., rash, ulcers, blisters, lumps under the skin |
| Showing confusion about where they are or walking off | Communication problems i.e., difficulty with speech and language | Feelings of helplessness and hopelessness | Changes to emotions e.g., feelings of misery or anxiety |
| Unusual behaviour (e.g., agitation in social situations) | Overdependence | Compulsive behaviour | *Struggle to carry out a familiar task (e.g., make a cup of tea)* |
| Delusions, paranoia, or hallucinations | Muscle weakness or stiffness | Loss of energy | |
| *Struggle to carry out a familiar task (e.g., make a cup of tea)* | Struggle to carry out a familiar task (e.g., make a cup of tea) | *Reckless behaviour (e.g., substance abuse or gambling)* | |

Note: No statistically significant association was found between health difficulties in italics and QoL measure scores for the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L (carer), or ICECAP-A

### *5.4.2.4. Analysis 4: Measure domains – all conditions*

Tables provided in Appendix 16 show the number of associations between QoL measure domains and contextual variables for all conditions pooled together. The results for these tests of discriminative validity are presented, split between hypotheses relating to the carer, the care recipient, and the caring situation. The p-values only are summarised in the tables provided in Appendix 16 and the nature and direction of the associations are reported here in the text.

There was a statistically significant, positive association between carer life satisfaction score and all domains in each QoL measure except for the CES domain 'assistance from organisations and government' and the CES domain 'control' where a statistically significant relationship was not found.

The presence of cognitive difficulties had a significant, positive association across all domains of the ICECAP-A and ASCOT-Carer except for the domain 'support'. No statistically significant relationship was found with any domain of the EQ-5D-5L with the exception of the 'anxiety/depression' domain. A significant association was found in each QoL measure except for the EQ-5D-5L for the domains 'occupation', 'mental health', 'self-care'. A significant association was found in the ICECAP-A for the domain 'support' and in the CES 'support from organisations and government' but not for 'support from friends & family'. No relationship was found for this domain in the CarerQol-7D.

The presence of daily dependencies had a significant, positive association across all domains of the ASCOT-Carer and the ICECAP-A. A significant association was found in each QoL measure for the domains ‘occupation’, ‘social participation’, ‘mental health’, ‘safety & stability’, ‘finances’, ‘achievement’. A significant association was found in each measure for the domain ‘control’ except for the CES. A significant association was found in the CES for the domain ‘support from organisations and government’.

The care recipient’s health status had a significant, positive association across all domains of the EQ-5D-5L and ICECAP-A. A positive association was found across each domain of the CarerQol-7D except for ‘support’ and ‘fulfilment’. Finally, a positive association was found in one domain of the CES, ‘occupation’.

The involvement of others in the caring role had a significant, positive association across the domain ‘support’ for all measures. No relationship was found with the other domains of the ICECAP-A and the CES.

The hours of care per week >20 had a significant, positive association across all domains of the ICECAP-A, the ASCOT-Carer except for the domain ‘safety’, and each domain of the CarerQol-7D except for ‘relationship’ and ‘fulfilment’ where no association was found. It had a significant, positive association with the domains ‘occupation’, ‘control’, ‘social participation’, ‘safety & stability’, ‘finances’, and ‘achievement’ across each measure. It had a significant, positive association with the domain ‘support’ across each measure except for the CES domain ‘assistance from organisations and government’, and ‘physical health’ except for the EQ-5D-5L.

Providing personal care had a significant, positive association across all domains of the ASCOT-Carer and ICECAP-A. It had a significant, positive association with the domains 'occupation', 'control', 'social participation', 'physical health', 'safety & stability', 'finances', and 'achievement' across each measure.

Identifying as the main carer had a significant, positive association across all domains of the ICECAP-A, and each domain of the ASCOT-Carer except for 'safety'. It had a significant, positive association with the domains, 'control', 'social participation', 'finances', and 'achievement' across each measure. A significant association was found with the domain 'support' except for the CarerQoL-7D and CES attribute 'assistance from organisations and government'.

## 5.5. Responsiveness analysis

### *5.5.1. Anchor of change: ±20hrs and ±50hrs of care per week*

For informal care hours the average number of hours per week spent on caring activities (as indicated in Figure 5.4) was used for the analysis. Figure 5.5 provides greater descriptive detail on how the hours of care provided per week are divided between the following activities: assisting with daily living, organisational support, extra household activities, providing emotional support. If the respondent's combined hours per week across all activities exceeded 168 hours, 168 hours were recorded as the total hours, and the allocation between tasks was a percentage based on their reported answer.

Table 5.12 provides detail on the number of eligible respondents for the sensitivity to change analysis. Using the thresholds of 20 hours and 50 hours per week 49 respondents report in the follow-up questionnaire that they are providing less hours of care per week at follow up, 193 report no change, and 61 respondents report that they are providing more hours of care at follow-up. If respondents did not provide a specific estimation of the number of hours of care provided their response to a separate survey question on the average number of hours provided per week was used for the analysis. In this question respondents were asked if they, on average, provided more or less than 20 hours of care per week. If they answered 'less than' they were categorised as providing 1-19 hours of care per week for this analysis. If they answered 'more than' they were categorised as providing 20-49 hours of care per week for this analysis.

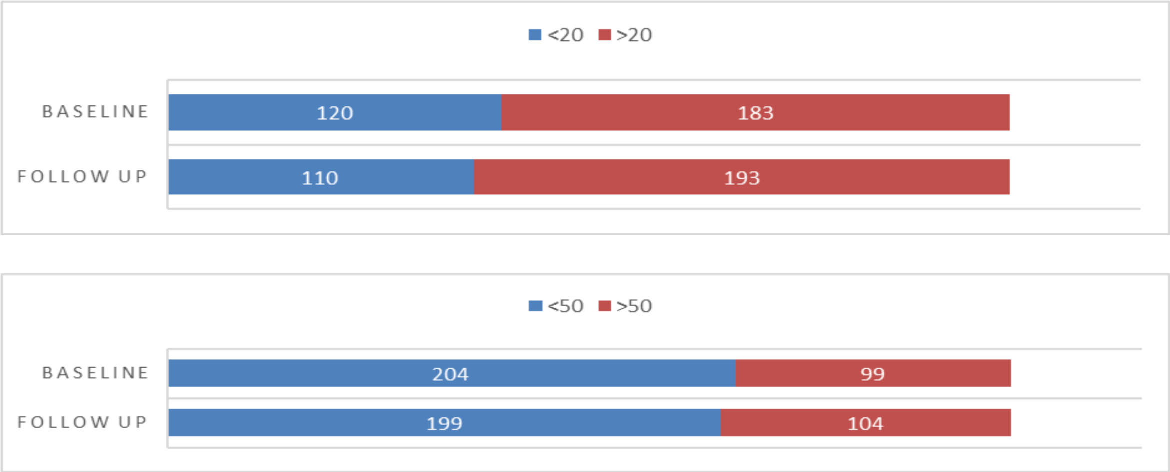

**Figure 5.4.** Number of respondents who gave an average number of hours per week spent on caring activities at baseline and follow-up

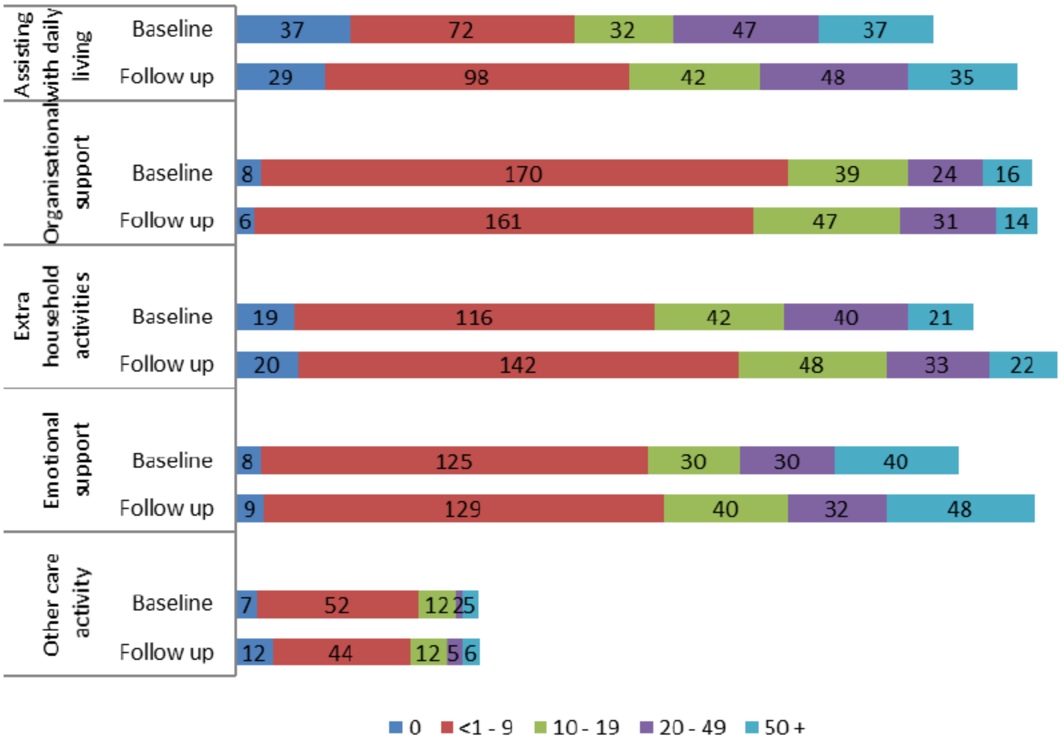

**Figure 5.5.** Number of respondents who gave an average number of hours per week spent on caring activities at baseline and follow-up broken down by activity

**Table 5.12.** Movement of respondents between change categories for hours of care per week i.e., +20 hours and +50 hours of care per week

| **Category** | **Detail** | **n=** |
|---|---|---|
| Less hours | Moved from providing<br>• 20-49hrs to <20hrs<br>• >50hrs to 20-49hrs<br>• >50hrs to <20hrs | 49 |
| No change | Stayed in the same category<br>• <20hrs<br>• 20-49hrs<br>• >50hrs | 193 |
| More hours | Moved from providing<br>• <20hrs to 20-49hrs<br>• <20hrs to >50hrs<br>• 20-49hrs to >50hrs | 61 |

Table 5.13 reports the results of the sensitivity to change analysis using ±20 hours and ±50 hours of care per week as an anchor of change. The text that follows

assesses if there was an expected "*gradient of effect*" in the QoL measure change scores [12] that is, whether the measured change in carer QoL measure score over 12 months for the three subgroups of carers (denoted by the anchor categories) was ordered in the expected direction in relation to the change in the construct [12].

Each of the three care-related measures detected a slight gradient of effect from positive change to negative change in line with the number of hours of care provided per week. The change in QoL score was larger for the ASCOT-Carer compared to the CES and CarerQoL-7D. For the sub-group of carers (n=61) who experienced an increase in hours of care, it was hypothesised that there would be a reduction in carer QoL. The results show that each QoL measure, except for the CES detected an expected gradient of effect. Carer QoL fell when measured by the ASCOT-Carer, CarerQoL-7D, EQ-5D-5L and ICECAP-A. In contrast, when measured by the CES, carer QoL rose by 0.57. For the subgroup of carers (n=193) who did not experience an 'important' change in hours of care, it was hypothesised that there would be no change in carer QoL. However, the results show that carer QoL rose when measured by the CES and CarerQoL-7D, while it fell when measured by the ASCOT-Carer, EQ-5D-5L and ICECAP-A. For the sub-group of carers (n=49) who experienced a decrease in hours of care, it was hypothesised that there would be an increase in carer QoL. The results show that carer QoL rose when measured by each QoL measure except for the EQ-5D-5L where carer QoL fell by 0.04.

**Table 5.13.** Results for ±20hrs and ±50hrs of care per week anchor of change

| | n | Baseline score Mean (SD) | Follow-up score Mean (SD) | Score change Mean (SD) | Effect size |
|---|---|---|---|---|---|
| **CES** | | | | | |
| Less hours | 44 | 59.34 (20.69) | 64.91 (21.05) | 5.38 (22.57) | Small |
| No change | 177 | 62.95(18.49) | 65.02 (19.39) | 1.53 (16.67) | |
| More hours | 45 | 64.95 (18.17) | 65.61 (18.69) | 0.57 (15.70) | |
| **CarerQoL-7D** | | | | | |
| Less hours | 43 | 68.68 (23.28) | 74.06 (18.82) | 6.02 (21.13) | Small |
| No change | 168 | 72.33 (21.56) | 73.44 (21.74) | 1.30 (14.54) | |
| More hours | 48 | 74.69 (20.84) | 74.15 (18.79) | -0.06 (13.50) | |
| **ASCOT-Carer** | | | | | |
| Less hours | 45 | 0.70 (0.21) | 0.75 (0.19) | 0.05 (0.19) | Small |
| No change | 189 | 0.74 (0.23) | 0.74 (0.23) | -0.01 (0.14) | |
| More hours | 56 | 0.78 (0.20) | 0.75 (0.19) | -0.03 (0.13) | Small |
| **EQ-5D-5L** | | | | | |
| Less hours | 48 | 0.77 (0.23) | 0.74 (0.18) | -0.04 (0.20) | Small |
| No change | 190 | 0.80 (0.21) | 0.74 (0.25) | -0.06 (0.17) | Small |
| More hours | 55 | 0.82 (0.19) | 0.73 (0.19) | -0.09 (0.20) | Small |
| **ICECAP-A** | | | | | |
| Less hours | 45 | 0.74 (0.21) | 0.83 (0.14) | 0.08 (0.21) | Small |
| No change | 184 | 0.75 (0.22) | 0.81 (0.19) | 0.06 (0.15) | Small |
| More hours | 57 | 0.80 (0.19) | 0.78 (0.19) | -0.02 (0.19) | |

### *5.5.2. Anchor of change: MCID change in care recipient health status*

For change in care recipient health status, data on the care recipient's health status as measured by the EQ-5D-5L and reported by the carer at baseline and follow-up was used for the analysis. The section that follows reports the results of the analysis measuring an 'important' change in care recipient EQ-5D-5L score between the two periods of at least 0.063. An MCID estimate of 0.074 is also included as a sensitivity analysis.

Table 5.14 provides detail on the number of eligible respondents for the sensitivity to change analysis. Using the threshold of 0.063, 94 respondents report in the follow-up questionnaire (completed as close to 12 months after the baseline questionnaire as possible) that the care recipient's health status has improved, 80 report no change, and 97 respondents report that the care recipient's health status is worse at follow-up. Using the threshold of 0.074, 89 respondents report that the care recipient's health status has improved, 91 report no change, and 91 respondents report that the care recipient's health status has worsened.

**Table 5.14.** Meaningful change in care recipient health status as measured by EQ-5D-5L score at 0.063 and at 0.074

| | Meaningful change at 0.063 (n=) | Meaningful change at 0.074 (n=) |
|---|---|---|
| Improved | 94 | 89 |
| No change | 80 | 91 |
| Worsened | 97 | 91 |

Table 5.15 reports the results of the sensitivity to change analysis using a meaningful change of 0.063 as an anchor of change. For the sub-group of carers (n=94) who experienced an improvement in care recipient health status of at least 0.063 it was hypothesised that there would be an increase in carer QoL. The results show that each QoL measure, except for the EQ-5D-5L detected an expected gradient of effect. For the sub-group of carers (n=80) who experienced no change in care recipient health status it was hypothesised that there would be no change in carer QoL. However, the results show this was only the case when carer QoL was measured by the ASCOT-Carer. When measured by the CES and EQ-5D-5L there was a decrease in carer QoL, and there was an increase when measured by the CarerQoL-7D and ICECAP-A. For the sub-group of carers (n=97) who experienced a

worsening in care recipient health status of at least 0.063, it was hypothesised that there would be a decrease in carer QoL. The results show this to be the true when carer QoL was measured by the EQ-5D-5L. Conversely, carer QoL rose when measured by each of the other QoL measures.

**Table 5.15.** Responsiveness of QoL measures by care recipient health status (meaningful change at 0.063)

| | n | Baseline score Mean (SD) | Follow-up score Mean (SD) | Score change Mean (SD) | Effect size |
|---|---|---|---|---|---|
| **CES** | | | | | |
| Improved | 81 | 62.14 (17.41) | 66.03 (18.97) | 3.88 (17.67) | Small |
| No change | 73 | 65.18 (19.05) | 64.24 (19.51) | -0.94 (13.68) | |
| Worsened | 83 | 61.77 (19.15) | 66.11 (19.06) | 4.34 (20.44) | Small |
| **CarerQoL-7D** | | | | | |
| Improved | 82 | 72.75 (21.03) | 75.68 (18.11) | 2.94 (17.55) | |
| No change | 68 | 72.60 (22.13) | 72.99 (21.27) | 0.39 (13.80) | |
| Worsened | 82 | 70.99 (19.91) | 71.06 (20.90) | 0.07 (15.39) | |
| **ASCOT-carer** | | | | | |
| Improved | 91 | 0.74 (0.21) | 0.76 (0.21) | 0.02 (0.15) | |
| No change | 75 | 0.77 (0.22) | 0.77 (0.21) | 0.00 (0.12) | |
| Worsened | 91 | 0.74 (0.21) | 0.76 (0.18) | 0.02 (0.18) | |
| **EQ-5D-5L** | | | | | |
| Improved | 92 | 0.80 (0.21) | 0.74 (0.20) | -0.05 (0.20) | Small |
| No change | 79 | 0.80 (0.20) | 0.76 (0.22) | -0.04 (0.14) | Small |
| Worsened | 93 | 0.80 (0.22) | 0.72 (0.22) | -0.09 (0.16) | Moderate |
| **ICECAP-A** | | | | | |
| Improved | 91 | 0.75 (0.21) | 0.81 (0.17) | 0.05 (0.16) | Small |
| No change | 76 | 0.76 (0.22) | 0.83 (0.16) | 0.07 (0.17) | Small |
| Worsened | 92 | 0.77 (0.21) | 0.81 (0.18) | 0.04 (0.18) | Small |

Performing a sensitivity analysis using a meaningful change of 0.074 as an anchor of change gives comparable results to when a meaningful change of 0.063 is applied. For the sub-group of carers (n=89) who experienced an improvement in care recipient health status, each QoL measure except for the EQ-5D-5L detected an expected increase in carer QoL. For the sub-group of carers (n=91) who experienced no change in care recipient health status the results show (as with a meaningful change of 0.063) that only when measured by the ASCOT-Carer does carer QoL show no change. When measured by the CES and ICECAP-A there was an increase in carer QoL, and a decrease when measured by the CarerQoL-7D and EQ-5D-5L. Finally, for the sub-group of carers (n=91) who experienced a worsening in care recipient health status of at least 0.074, the results show (as with a meaningful change of 0.063) that carer QoL only decreased when measured by the EQ-5D-5l. Conversely, carer QoL rose when measured by each of the other QoL measures. Further detail on the results from this sensitivity analysis can be found in Table 5.16.

**Table 5.16.** Responsiveness of QoL measures by care recipient health status (meaningful change at 0.074)

| | n | Baseline score Mean (SD) | Follow-up score Mean (SD) | Score change Mean (SD) | Effect size |
|---|---|---|---|---|---|
| **CES** | | | | | |
| Improved | 78 | 62.08 (17.72) | 65.70 (18.63) | 3.62 (17.51) | Small |
| No change | 82 | 65.18 (18.72) | 65.30 (19.58) | 0.12 (14.52) | |
| Worsened | 77 | 61.45 (19.12) | 65.50 (19.32) | 4.08 (20.70) | Small |
| **CarerQoL-7D** | | | | | |
| Improved | 77 | 72.16 (21.48) | 75.29 (18.42) | 3.12 (18.05) | |
| No change | 78 | 73.15 (21.12) | 73.01 (20.58) | -0.14 (13.85) | |
| Worsened | 77 | 70.92 (20.29) | 71.49 (21.21) | 0.57 (15.08) | |
| **ASCOT-carer** | | | | | |
| Improved | 86 | 0.74 (0.21) | 0.75 (0.21) | 0.01 (0.15) | |
| No change | 86 | 0.77 (0.22) | 0.78 (0.20) | 0.00 (0.11) | |
| Worsened | 85 | 0.75 (0.22) | 0.76 (0.18) | 0.01 (0.18) | |
| **EQ-5D-5L** | | | | | |
| Improved | 87 | 0.79 (0.21) | 0.74 (0.21) | -0.05 (0.21) | Small |
| No change | 90 | 0.80 (0.19) | 0.76 (0.21) | -0.04 (0.13) | Small |
| Worsened | 87 | 0.81 (0.22) | 0.72 (0.23) | -0.09 (0.18) | Small |
| **ICECAP-A** | | | | | |
| Improved | 86 | 0.75 (0.21) | 0.81 (0.17) | 0.05 (0.16) | Small |
| No change | 86 | 0.76 (0.22) | 0.83 (0.15) | 0.07 (0.16) | Small |
| Worsened | 87 | 0.77 (0.21) | 0.80 (0.19) | 0.03 (0.18) | |

## 5.6. Summary

This chapter described the results for a quantitative study of the construct validity and responsiveness of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L and ICECAP-

A. The chapter began by describing the characteristics of the participants who responded to the baseline and follow-up questionnaires. Section 5.4 outlined the results of the construct validity analysis beginning with the convergent validity analysis. Section 5.4.2 detailed the results of the four tests of discriminative analysis conducted:

- Analysis 1: Measure score- all conditions
- Analysis 2: Measure score – individual conditions
- Analysis 3: Measure score – health difficulties
- Analysis 4: Measure domains – all conditions

The results show that in terms of construct validity, across the analyses, of the CRQoL measures more statistically significant associations were found in relation to the ASCOT-Carer compared with the CES or CarerQoL-7D. Of the comparator measures the ICECAP-A exhibited greater construct validity than the EQ-5D-5L. The ASCOT-Carer and ICECAP-A were also comparable in the sense that larger effect sizes and stronger associations were detected for these measures relative to the other QoL measures, when the conditions were analysed separately. No measure exhibited clear responsiveness to changes within a year in care recipient health status or hours of care provided per week. Each of the three care-related measures detected a slight gradient of effect in relation to change of hours of care provided per week. The change in QoL score was larger for the ASCOT-Carer, suggesting it may be more responsive than the CES and CarerQoL-7D.

The findings from this quantitative study, how they compare to related research, and how they move this field forward will be discussed in Chapter 8. The next two chapters will detail the methods and results for a qualitative study of the feasibility, content validity and face validity of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L and ICECAP-A.

# 6. Qualitative study of the feasibility, content validity and face validity of health-related, wellbeing and care-related measures for estimating carer quality of life: Methods

## 6.1. Introduction

The first three chapters of this thesis established the need for assessing the validity of care-related, health-related and wellbeing QoL measures with informal carers. The aim of this thesis was to establish the validity of QoL measures amongst informal carers. Chapter 4 and 5 presented the methods and results for a quantitative study of the construct validity and responsiveness of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L and ICECAP-A with informal carers across a range of conditions, specifically dementia, recovery from stroke, mental health condition, and rheumatoid arthritis. The purpose of the next two chapters is to describe the methods and results of a qualitative study of the feasibility, content validity and face validity of these same five measures. To meet this objective two qualitative approaches; a think-aloud interview, and semi-structured interview, were used to identify response process issues and to explore how and why respondents arrive at their answer when completing an outcome measure [167, 238].

The sections that follow will show how rigour was applied at each stage of the interview process including sampling (Section 6.2). A description of the methods for analysing the data is presented in Section 6.3 The methods employed for conducting the cognitive interviews and handling the data is then presented in Section 6.4 and Section 6.5. Finally, how ethical issues were addressed in presented in Section 6.6.

## 6.2. The sample frame for the analysis

The aim of this study was to investigate the feasibility, content validity and face validity of QoL measures with informal carers across a range of conditions. To meet this objective interview participants were purposively sampled to gain a diverse sample in relation to condition i.e., dementia, recovery from stroke, mental health condition, rheumatoid arthritis. As detailed in Chapter 4 these conditions were chosen as high prevalence chronic conditions associated with diverse impacts on informal carer's lives. Participants were also purposively sampled in relation to their relationship to the care recipient (spouse, parent, and adult-child), gender, age, ethnicity, rural/urban area of residence, length of time in the caring role, and level of burden as indicated by the number of hours per week spent caring. Participants were identified through survey work completed for the quantitative study included in this PhD and focus groups conducted as part of the wider programme of work to which this PhD project was linked [239]. Individuals who met the following inclusion criteria were included in the study: (i) they currently had caring responsibilities; (ii) they did not receive payment for their caring responsibilities; (iii) they were aged 18 or over; (iv) the person they cared for was aged 18 or over. These broad inclusion criteria were based on data that is collected by the FRS from which the sample of carers for the quantitative analysis was drawn. Further detail on the FRS is provided in Chapter 4.

As part of the survey work completed for the quantitative study detailed in Chapters 4 and 5, the follow-up questionnaire included a question on the last page where participants were asked to indicate if they would be willing to be contacted by the University of Birmingham about taking part in (i) a face-to-face interview (ii) a focus group (iii) an online survey. Participants for the focus groups and online survey were recruited as part of the wider project to which this PhD is attached. 116 respondents who returned the follow-up questionnaire indicated that they were still in a caring role and were still willing to participate in a face-to-face interview. These respondents were targeted as potential participants in the qualitative research. The recruitment of participants occurred from March to September 2018. An invitation to participate in the face-to-face interview (Appendix 17), along with an information sheet (Appendix 18), and consent form (Appendix 19) was posted to potential participants in March 2018. Participants who had provided an email address on their return questionnaire were also sent the invitation and information via email. Following the return of the consent form, a participant was contacted by CM by telephone and an interview location and date was confirmed.

Additionally, to gain responses from carers not associated with the quantitative analysis, a number of informal carers were approached through focus groups conducted as part of the wider programme of work to which this PhD project was linked [239]. Recruiting informal carers from both the quantitative analysis and the focus groups ensured sampling variation. Including participants from the focus groups also ensured a number of informants were included that were not already familiar with the QoL measures being completed. The inclusion criteria used for the quantitative analysis was also applied for participants of the focus groups. Participants were required to have current caring responsibility for which they did not receive payment for, they were aged 18 or over, and the person they cared for was also aged 18 or over. Carers were recruited to focus groups with the assistance of charitable organisations in the areas of dementia, stroke, and mental health.

The initial recruitment target for the face-to-face interviews was 30 participants. The sample size was chosen after reviewing similar research projects which ranged from 6 participants [240, 241] to 56 [184]. The mean number of participants was 26. Although the recruitment target was set at 30 participants, it was agreed amongst the supervisory team that the final number of participants would be determined by saturation. As discussed in Chapter 3, saturation in qualitative research is the point whereby additional participants are not expected to yield new or valuable information. Unfortunately, there are no clear-cut rules on when "*enough is enough*". [167]. Detailed field notes (Appendix 20), written after each interview, included notes and memos relating to early emerging themes. These field notes were used to support the judgement that saturation had been reached. Also considered were practical time and resource constraints in that the interviews were conducted across the UK by one person (CM).

## 6.3. Analysis methods

### *6.3.1. Think-aloud interview analysis*

As detailed in Chapter 3 there are two main techniques of cognitive interviewing: verbal probing and 'think-aloud' interviewing [182]. The main difficulty with verbal probing is that it may influence and interfere with the respondents thought processes [184]. Therefore, for this study a think-aloud approach was used to explore the feasibility of care-related (CES, CarerQoL-7D, ASCOT-Carer), wellbeing (ICECAP-A) and health-related (EQ-5D-5L) QoL measures. Think-aloud interviews are respondent driven and designed not to alter the interview dynamic in any significant way that might affect comparability with the instrument's "*normal*" usage [184]. In think-aloud interviews, respondents are asked to verbalise their thoughts on the survey questions without interference from the interviewer [182, 183]. Data generated from think-aloud interviews can be analysed to explore if the QoL measure is practically useable in the relevant context.

For this study, data from the think-aloud exercise were coded and analysed using the model developed by Tourangeau [242], adjusted in line with Murphy et al [243] to account for the fact that participants were being asked to consider their current situation when completing the QoL measures. Tourangeau's theory identifies four cognitive tasks required when responding to a questionnaire: comprehension, retrieval, decision, and response. The retrieval process refers to how information is retrieved from memory. This was considered irrelevant for the measure being tested by Murphy et al [243] as it refers to the current time. Given that each of the measures being evaluated in this study ask the participant to consider their current situation, retrieval was replaced with a process Murphy et al [243] called *"temporal comprehension"*. This process addressed if the participant understood that the question was referring to the current period. The classification of errors was therefore based on the following four cognitive processes:

1. General Comprehension: Does the participant understand the question?
2. Temporal Comprehension: Does the participant understand that the question is referring to the current period?
3. Decision process: How does the participant decide on the answer; for example, do they have a hidden agenda, do they give sufficient mental effort to the task, or do they want to give a socially desirable answer?
4. Response process: Does the participant manage to map their desired response onto the scale without introduction of error? For example, do they understand the scale, and are the scale responses available appropriate?

Examples of the different errors identified in the transcripts are presented in Table 6.1. Think-aloud transcripts were segmented by questionnaire and item. Each segment was then classified according to the presence or absence of an error or struggle [19]. If an error or struggle was identified, it was mapped to one or more of the cognitive processes. One member of the supervisory team independently coded 25% of the transcripts. This was done based on the printed transcript of the interview and the adjusted Tourangeau framework, without sight of CM's coding. Each set of codes were compared in STATA and an overall percentage agreement and Cohen's kappa coefficient was calculated. The kappa coefficient (κ) is a measurement of the agreement between raters for a series of items with dichotomous ratings. If the raters agreement is no greater than what would be expected by chance then $\kappa = 0$ [244]. Kappa scores of 0.75 or higher are generally considered to be excellent, 0.6–0.75 substantial/good and 0.4–0.6 moderate/fair [243]. All identified errors were presented to the supervisory team and if there was disagreement amongst the team the relevant transcript(s) and clarifying discussion were considered in greater depth to determine if an error had occurred and where issues with the QoL measures might be leading to errors [245].

**Table 6.1.** Types of errors identified in the think-aloud transcripts

| Type of Error | Error | Not error |
|---|---|---|
| **General comprehension** | | |
| Does the participant understand the question? | Interviewer: When you read 'in control' what does that make you think of?<br>Participant: That I'm coping. That I'm not at the stage where I can't cope. Sometimes I feel I can't cope. | Interviewer: When you read 'in control' what does that make you think of?<br>Participant: I have as much quality control, control over quality. |
| **Temporal comprehension** | | |
| Does the participant understand that the question is referring to the current period? | I bashed my knee, does that count? It's a temporary slight pain. Generally, no. | Pain discomfort, I've got slight pain at the moment. |
| **Decision process** | | |
| How does the participant decide on the answer?<br>- Do they have a hidden agenda<br>- Do they give sufficient mental effort to the task<br>- Do they want to five a socially desirable answer<br>- Do they question the relevance of relevant experiences | I don't particularly find caring fulfilling … so at the moment I'm not finding it fulfilling and I don't think he appreciates any of it at the moment so I would say I sometimes find caring fulfilling but certainly not mostly. | Yeah, I think we mostly find it fulfilling because we're trying to keep her happy all the time. |
| **Response process** | | |
| Does the participant manage to map their desired response on to the scale without introduction of error?<br>- Do they understand the scale<br>- Are the scale responses available appropriate | I would feel that I have adequate social contact with people. Although, at times, I would like to have more but feel that I can't be away from home too often. Again, it varies between 'adequate' and 'I would like more'. [ticked both boxes] | I would say I have as much social contact with the people I like, but to be honest, I don't really see anybody. But that's not because of the carer's role, that's just because I don't tend to see people socially anyway. |
| **Struggle** | | |
| Participant has difficulty answering the question but eventually reached an appropriate answer | Relational problems with the care receiver, he/she is very demanding, he/she behaves differently, we have communication problems. No, we don't have any of that so what do I tick, a lot of, oh no it's a no, no those are all negative, no I don't have any of that. | We occasionally have relational problems, I would say, because sometimes, he can be very demanding and behaves differently. I would say 'some'. That probably sums it up and occasionally, it could be a lot. |

### *6.3.2. Semi-structured interview analysis*

Chapter 3 states that assessment of content and face validity is largely based on the judgements of individuals – patients, public or research professionals and the most appropriate way to collect data to support content and face validity is through direct communication with the participants using qualitative data collection techniques such as individual interviews, focus groups and observations [167, 168]. In this study, a thematic analysis of data from semi-structured interview transcripts was completed to explore verbalisations related to the content validity, face validity and feasibility of the five QoL measures completed by participants.

Themes and codes were developed to refine understanding of the emerging results [195, 246]. Chapter 3 provides detail on the options for qualitative analysis. As outlined in this chapter the methodology employed to assess validity should be documented and transparent, the research should be grounded in the data, and the analysis should be iterative, thematic and constantly comparative [170, 171]. For this study, thematic analysis was used to categorise recurring themes [171]. The data were analysed through close reading of the semi-structured portion of the qualitative interview transcripts. The transcripts were read and re-read for meaning and understanding. Detailed field notes, written after each interview, provided clarity on the intentions or motivations of participants when answering a question if this was not clear from the transcript (Appendix 20). Notes and memos were also made in the field notes relating to early emerging themes.

As stated in Brod et al [167] coding is "*the fundamental analytic process used to develop a theoretical conceptualisation from the data*". Strauss and Corbin [246] distinguish three types of coding processes: open, axial, and selective. In open coding, data is broken down, examined, compared for similarities and differences, and categorised. Axial coding is defined by Strauss and Corbin [246] as "*a set of procedures whereby data are put back together in new ways after open coding, by making connections between categories. This is done by using a coding paradigm involving conditions, context, action/interactional strategies, and consequences*". As such, where open coding breaks down the data into categories, axial coding puts the data back together by making connections between the categories and subcategories [247]. Finally, in selective coding, all categories are unified around an overarching core concept [246].

The analysis process for this study began with the semi-structured interview transcripts being open coded [248]. Initial codes were developed and assigned to segments of data that provided insight into the participants experience of completing the measures. These codes were kept as close to the quoted text as possible. Example codes were: 'context'; 'response options'; and 'length of measure'. When the initial list of codes was established a formal coding framework was developed based on the initial list of codes, field notes, and input from the supervisory team. The aim was to devise an index to tag all the data in a logical, systematic, and comprehensive way [170, 239, 248]. Categories and subcategories were identified from the initial codes based on the list of prepared questions included in the topic guide. At this stage repetitious or very similar codes were eliminated and merged. Five transcripts were independently analysed and categorised by one member of the supervisory team. Categorisation was then discussed in detail and agreement reached. This coding framework was then applied to the full set of transcripts. Data management was undertaken using NVivo 12 qualitative data management software, to facilitate the coding of interviews and retrieval of coded segments for analysis.

Following the coding of all transcripts, a descriptive account was developed. In this account, all coded data was arranged by category and sub-category. This account sought to synthesise the data and map the diversity of opinion amongst the participants [171]. As detailed in Coast, 2017 [248] this stage is not just about reporting results, it allows the researcher to gain further insights and create more ideas about the data while they are writing. This idea is reinforced by Ritchie and Spencer [170] who state that "*the process of actually writing a summarised account begins to trigger the vital insights into, or questions about, the data that will lead to the later interpretative stages of analysis*".

From this descriptive account the connections between categories and subcategories became clearer and an explanatory account was formed [171]. The explanatory stage of the analysis is further removed from the data than the descriptive stage and therefore requires more interpretation by the researcher [170]. In the explanatory account the data was structured by the themes, and "*patterns of association*" were developed to explain how participants felt the measures captured the QoL issues pertinent to how providing informal care affects their lives [171]. These themes were broader and more interpretive than the categories and subcategories, and they were linked with the psychometric concepts under investigation. For example, 'face validity - relevance'; 'content validity – moment in time'; 'feasibility – difficulty answering'. Themes were presented using verbatim quotes to support the findings.

## 6.4. Interview conduct

The face-to-face interviews took place at a location convenient to the participant (such as the participant's home, the University of Birmingham, or a neutral venue of the participants choice). The interview began with a description of what would occur during the interview, i.e., a think-aloud exercise followed by a semi-structured interview, and participants were provided with another copy of the information sheet to read (Appendix 18). To help the participant familiarise themselves with the think-aloud techniques they first completed a warm-up task [249]. The researcher demonstrated thinking out loud as they counted how many windows are in their house [249]. This exercise helped participants to get comfortable with the idea of thinking aloud and has been used in a previous think-aloud study conducted by Al-Janabi et al [191] when conducting think-aloud interviews to investigate the feasibility of individuals self-reporting their capabilities. Next, the participant was asked to do the same task and think out loud while counting windows in their home. Any queries or problems relating to the task were dealt with at this stage by the researcher. Participants were given three QoL measures to complete as part of the think-aloud exercise, one health-related (EQ-5D-5L) or wellbeing (ICECAP-A) and two care-related measures (CES, CarerQoL-7D, or ASCOT-Carer). The order of the three QoL measures was randomised for each interview. This was done so that overall, participants would not show bias towards one measure if they completed it first or last. Where physically possible CM then sat out of the line of sight of the participant while they completed the three QoL measures. Participants were not interrupted while they completed the measures unless they paused for a few seconds at which point CM asked them to keep thinking aloud. Notes were taken on any problems participants had with completing the measures. Following the think-aloud exercise, a focused discussion was conducted to clarify the participants' previous expression of thoughts while completing the exercise. For example, "*When you were thinking aloud, you said … can you explain what you meant?*'

A semi-structured interview was then conducted with participants. A topic guide (Appendix 21) was developed to act as a prompt, and to remind the researcher of necessary topics to cover, questions to ask and areas to probe [167]. As part of the topic guide questions were developed (Table 6.2) based on concepts derived from the reviewed literature (Chapter 2 and Chapter 3). This topic guide was then reviewed by the supervisory team based on the first set of four interview transcripts. The transcripts highlighted the need for set questions to better steer the discussion towards the topics under investigation while also allowing for a more general discussion on the QoL measures between CM and the participant. Questions 1-4 focused on the potential for double counting. This topic is discussed in Chapter 2. Briefly it is a situation where the value of an item has been counted more than once

[83]. It was anticipated that the topic of double counting would add to the validity and responsiveness results. However, the data generated from the questions on feasibility, face and content validity was more than sufficient to support the aims of this thesis, and the potential for double counting, while present, was found to be minimal. As such it is included as a sub-section in the results and not considered in detail in the discussion chapter that follows.

Question 5 focused on face validity, asking the participant if there were any aspects of caring that impact on their life that was not covered in the QoL measures. This question was included to ascertain if the dimensions of the QoL measures are comprehensive and if they adequately reflect the perspective of the informal carer. Question 6 asked the participant if there are any aspects of caring that impact on their life that was not covered in the QoL measures they completed. This question was developed to assess if the items of each measure were "*relevant and important*" [168] to the participants and to gauge whether there were additional areas of interest that were not covered in the existing measure [167, 168]. Finally, questions 7-10 focused on the topic of feasibility. These questions involved asking the participant how clear they found the instructions, the phrasing of the questions, if they thought the response options were appropriate, and if they found any questions difficult to answer. These questions were developed to ascertain if the QoL measures were practically useable for informal carers. Chapter 3 provides further detail on the concepts of face validity, content validity, and feasibility. The questions included in the topic guide acted as a prompt for CM during the semi-structured interview.

**Table 6.2.** Topic guide for use in the semi-structured interviews

| Question number | Topic point | Question | Follow-up question |
|---|---|---|---|
| 1 | Potential for double counting | Have you felt any impacts on your free time (i.e., leisure, family time, housework, sleep) because of your caring role? | Did that impact on how you answered the questionnaires? |
| 2 | Potential for double counting | Have you felt any impacts on your working life because of your caring role? | Did that impact on how you answered the questionnaires? |
| 3 | Potential for double counting | Have you felt any financial impacts (e.g., paying for travel, healthcare) because of your caring role? | Did that impact on how you answered the questionnaires? |
| 4 | Potential for double counting | Were you considering the care recipient's health when completing the questionnaire? | Yes – how? |
| 5 | Face validity | Do the questionnaires reflect the way caring impacts on your life? | |
| 6 | Content validity | Are there any aspects of caring that impact on your life that were not covered in the questionnaires? | |
| 7 | Feasibility | How clear did you find the instructions? | |
| 8 | Feasibility | How did you find how the questions were phrased? | |
| 9 | Feasibility | Were the response options available appropriate? | |
| 10 | Feasibility | Were there any questions you found difficult to answer for any reason? | |

### *6.4.1. Piloting*

The cognitive interview process was piloted with three members of the lived experience advisory panel, described in Chapter 4 [228]. Panel members were asked to complete a think-aloud warm-up exercise and three QoL measures, followed by a clarifying discussion and semi-structured interview. Panel members were then asked for their feedback on each aspect of the interview process. The interviews were recorded, and the feedback was incorporated into the final interview process. Panel members fed back that it would be less cumbersome for participants to complete two QoL measures, one health-related or wellbeing and one care-related rather than one health-related or wellbeing and two care-related measures. Following discussion with the supervisory team, it was agreed to use three QoL measures in the interview process, one health-related or wellbeing measure and two care-related measures. This was to ensure there was as even a number of responses across the five measures as possible. A key point raised by the panel members that was actioned on was to provide the interview participant with more details on what was expected of them in the think-aloud warm-up exercise where participants were asked to count the windows in their home.

## 6.5. Data handling

All interviews were digitally recorded. In addition to audiotaping the interviews field notes were taken. The first three interviews were transcribed verbatim by CM to generate familiarity with the data. Remaining interviews were transcribed verbatim using a transcription service. All names and references to locations that would have indicated the participant's identity were removed. Each participant was assigned a code. An electronic index of the codes and the corresponding participant were kept in a password protected document. All electronic transcripts and field notes were stored on a password protected computer. Hard copies of transcripts and field notes were kept in a locked cabinet in a locked office in the University of Birmingham.

## 6.6. Ethical issues

University ethics approval (ERN_14-1444C) was obtained allowing recruitment in the study. There were several important ethical considerations for the research.

Participants were reminded of their right to withdraw from the cognitive interviews verbally at the time of the interview. CM monitored how comfortable participants felt during the interview, and reminded participants, as needed, that they could withdraw from the study. If a participant became upset during the interview, they were asked whether they wished to continue and/or referred to sources of help for example the Carers Trust and The Samaritans. If a participant chose to withdraw, they were given the choice as to whether data collected up to that point could continue to be used in the research, or whether they would prefer all data to be destroyed.

Confidentiality of all information was maintained in line with the University of Birmingham Information Security Policy and the Data Protections Act. Names and addresses of participants were not linked to the data obtained. Audio-recordings of the cognitive interviews were stored as mp3 files and deleted from the recording device. Transcribed interviews were stored as word files. Audio-recordings and transcriptions of interviews were uploaded to secure folders, and only the supervisory team had access to these. All electronic transcripts and field notes were stored on a password protected computer. Hard copies of transcripts and field notes were kept in a locked cabinet in a locked office in the University of Birmingham.

To protect CM when interviewing participants in non-institutional premises, a fieldwork system was used to minimise the risk of harm. A designated person was fully briefed on CM’s schedule and clearly instructed on when and how to act. At the end of each interview a telephone call was placed by CM to this person informing them that the schedule had been completed if no call arrived the designated person was instructed to open an envelope containing the address where the interview was being conducted and raise an alarm.

## 6.7. Summary

This chapter described the methodology for a qualitative study of the feasibility, content validity and face validity of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures. The chapter began by describing how participants were identified through survey work completed for the quantitative study described in Chapter 4 and 5, and focus groups conducted as part of a wider programme of work. Participants were purposively sampled to gain a diverse sample in relation to condition i.e., dementia, recovery from stroke, mental health condition, rheumatoid arthritis. The methods for analysing the data were then presented. Section 6.3 outlined how data from the think-aloud exercise were coded and analysed using a model developed by Tourangeau [242], adjusted in line with Murphy et al [243]. Transcripts were segmented by questionnaire and item. Each segment was then classified according to the presence or absence of error or struggle. If an error or struggle was identified, it was mapped to one or more of the cognitive processes. Section 6.3 also detailed the methods employed for a thematic analysis of the semi-structured interview transcripts. Themes and codes were developed to refine understanding of the emerging results from verbalisations related to the feasibility, content validity and face validity of the QoL measures completed by participants. Section 6.4 provided information on how the cognitive interviews were conducted, from the think-aloud exercise to the semi-structured interview process, and how all aspects of the interview process were piloted with members of a lived experience advisory panel. Section 6.5 then provided detail on how the data was handled, and the chapter finished with presenting the ethical issues attached to the research. The chapter that follows will present the results of both the think-aloud and semi-structured interview analyses.

# 7. Qualitative study of the feasibility, content validity and face validity of health-related, wellbeing and care-related measures for estimating carer quality of life: Results

## 7.1. Introduction

The previous chapter described the methodology for a qualitative study of the feasibility, content validity and face validity of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L and ICECAP-A. This chapter reports the results of that study. The chapter opens with a description of the characteristics of the participants involved in this study (Section 7.2). Section 7.3 reports the results of the think-aloud interview. This qualitative analysis is used to demonstrate the key issues that were encountered when completing the measures. The analysis is structured to look at the key issues by cognitive process, by QoL measure, by theoretical domain, and by care recipient condition. Section 7.4 presents the results of the semi-structured interview where verbatim quotations have been used to illustrate the issues that emerged. Finally, Section 7.5 summarises the results from both analyses.

## 7.2. The characteristics of participants

The characteristics of the interview sample are shown in Table 7.1. Interviews were conducted over a 6-month period between May and October 2018. In total 24 informal carers consented to being interviewed, 15 female and 9 male. While this falls short of the recruitment target of 30 participants detailed in Chapter 6, it was agreed amongst the supervisory team – based on detailed field notes - that saturation had been achieved at this point. Eight participants (33%) were recruited through the focus groups conducted as part of the wider programme of work to which this PhD project was linked. The remaining 16 participants (66%) were recruited through the questionnaire sample. The 24 participants were aged between 47 and 84. Half the sample shared a home with the care recipient. Most participants (n=10; 42%) were caring for a parent, 8 (33%) were providing care for their adult child, and 6 (25%) were caring for a spouse. Participants were providing care for somebody with dementia (n=7; 29%), a mental health condition (n=6; 25%), recovery from stroke (n=2; 8%) and eight (33%) participants were providing care for somebody with another condition for example, a heart condition or learning difficulty. Of note, no participants were providing care for somebody with rheumatoid arthritis. In 63% of interviews (n=15) participants were providing care for a female care recipient. The sample of carers were predominately of white ethnicity with only one participant identifying as Black/British. The length of time participants were providing care ranged from 2 years to 45 years, and the average time providing care was 15 years. Participants were educated to GCSE (n=6; 25%), or A-level (n=4; 17%) and 11 participants (46%) were educated to at least degree level. The education level for the remaining 3 participants (12%) is not known. Interviews were conducted in locations throughout the UK (see Figure 7.1). The length of the interviews varied between 15 and 64 minutes and the average length of interview was 35 minutes.

**Figure 7.1.** Location of cognitive interviews

**Table 7.1.** Participant characteristics

| Participant ID | Carer (M/F) | Recruited through | Cares for somebody with | Cares for their | CR (M/F) | CR age | Co-residence | Years caring | Carer age | Carer ethnicity | Carer education | Location of interview |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 001 | M | FG | MHC | Child | F | >49 | No | 33 | Not known | White | Not known | West Midlands |
| 002 | M | FG | MHC | Child | M | Not known | No | Not known | Not known | Black British | Not known | West Midlands |
| 003 | M | FG | MHC | Spouse | F | Not known | Yes | Not known | Not known | White | Not known | West Midlands |
| 004 | F | Q | Dementia | Spouse | M | >80 | Yes | 6 | >80 | White | GCSE | London |
| 005 | F | Q | Stroke | Parent | M | >80 | No | 3 | 50-59 | White | A-level | London |
| 006 | M | FG | Dementia | Parent | F | Not known | Yes | Not known | 50-59 | White | Degree | East Midlands |
| 007 | F | FG | Dementia | Spouse | M | 60-69 | Yes | Not known | 60-69 | White | A-level | East Midlands |
| 008 | F | FG | Dementia | Parent | F | Not known | No | Not known | <49 | White | GCSE | East Midlands |
| 009 | F | Q | MHC | Child | M | <49 | Yes | 16 | 70-79 | White | Degree | Scotland |
| 010 | F | Q | Lung disease | Parent | F | >80 | No | 6 | 60-69 | White | Degree | Scotland |
| 011 | M | FG | MHC | Child | M | <49 | No | 13 | 70-79 | White | Degree | West Midlands |
| 012 | F | FG | MHC | Child | M | 50-59 | No | 25 | >80 | White | Degree | West Midlands |
| 013 | F | Q | Bone disease | Child | F | <49 | No | 45 | 70-79 | White | GCSE | Southeast England |
| 014 | M | Q | Bone disease | Child | F | <49 | No | 45 | 70-79 | White | Degree | Southeast England |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 015 | F | Q | Dementia | Parent | F | >80 | Yes | 11 | 60-69 | White | Degree | Northwest England |
| 016 | F | Q | Stroke | Parent | F | >80 | No | 2 | 60-69 | White | A-level | Northwest England |
| 017 | F | Q | Learning difficulties | Child | M | <49 | Yes | 32 | 50-59 | White | GCSE | Northwest England |
| 018 | F | Q | Dementia | Parent | F | >80 | Yes | 6 | 50-59 | White | GCSE | East Midlands |
| 019 | F | Q | Heart disease | Spouse | M | 70-79 | Yes | 7 | 70-79 | White | A-level | Northern England |
| 020 | F | Q | Bone disease | Parent | F | >80 | Yes | 8 | 60-69 | White | Degree | Northeast England |
| 021 | F | Q | Dementia | Parent | F | >80 | Yes | 4 | 50-59 | White | Degree | Northeast England |
| 022 | M | Q | Not specified | Spouse | F | >80 | No | 3 | >80 | White | Degree | Northeast England |
| 023 | M | Q | Heart disease | Parent | F | 70-79 | No | 9 | 50-59 | White | Degree | Northeast England |
| 024 | M | Q | Brain disease | Spouse | F | 60-69 | Yes | 7 | 60-69 | White | GCSE | Northeast England |

Notes: M: Male, F: Female, CR: Care Recipient, FG: Focus Group, Q: Questionnaire, MHC: Mental Health Condition

## 7.3. Think-aloud interview

Following independent coding of six think-aloud interviews by CM and the supervisory team inter-rater agreement of 77% was reached and a kappa score of 0.28 was calculated. CM chose the six transcripts to represent a spread across disease areas and measures completed. CM and the supervisory team identified a total of 26 potential errors. CM and the lead supervisor had a face-to-face meeting to consider the transcripts and clarifying conversations in greater detail. For 21 of the potential errors, it was agreed in the meeting to go with the majority decision of the three raters (CM and the supervisory team). Of the five situations where the majority decision was not chosen, in three instances upon reading the transcript a second time CM and the lead supervisor arrived at a consensus decision. In another instance it was confirmed that an error occurred based on the clarifying conversation that followed the think-aloud exercise. Finally, where a general comprehension query arose it was clarified by CM that the participant was reading the instructions out loud, and no error had occurred.

The qualitative analysis below is used to demonstrate the key issues that were encountered when completing the measures. The verbal contributions made during the think-aloud task provide an insight into the type and nature of problems participants experienced when completing the measures. The analysis is structured to look at the key issues by cognitive process, by QoL measure, by theoretical domain, and by care recipient disease. Verbatim quotations have been used to illustrate the issues that emerged from the analysis. Verbatim quotes are included in italics with ellipses to denote missing text.

### *7.3.1. Distribution of judged problems: By cognitive process*

As Table 7.2 illustrates, using the four classifications of errors i.e., general comprehension, temporal comprehension, decision process, response process, 14 participants (58%) were judged as having one or more errors with one or more of the measures completed. A further two participants 'struggled' but were judged to answer the measure appropriately and eight participants had no judged errors completing the measures. Participants completed the CES (n=16), CarerQoL-7D (n=16), and ASCOT-Carer (n=16) measures along with the EQ-5D-5L (n=12) and ICECAP-A (n=12). As the CES contains 6 items, the CarerQoL-7D and ASCOT-Carer both contain 7 items, and the EQ-5D-5L and ICECAP-A both contain 5 items this resulted in 440 measure items to be included in the analysis (i.e. ((16*6)+(16*7)+(16*7)+(12*5)+(12*5))=440). From the 440 measure items that were analysed, judged errors occurred in 5% (n=22). Most errors that occurred were response process errors (n=11, 50%), followed by decision process (n=5, 23%) or temporal comprehension errors (n=4, 18%), and general comprehension problems (n=2, 9%).

**Table 7.2.** Number of measure items with problems for each participant

| Participant ID | Struggled but answered correctly | Cognitive Process | | | | Total Problems |
|---|---|---|---|---|---|---|
| | | General Comprehension | Temporal Comprehension | Decision Process | Response Process | |
| 001 | | - | - | - | 1 | 1 |
| 002 | | - | - | - | - | - |
| 003 | | - | 1 | - | - | 1 |
| 004 | | 1 | - | 2 | - | 3 |
| 005 | | - | 1 | - | - | 1 |
| 006 | | - | - | - | - | - |
| 007 | | - | - | 1 | 1 | 2 |
| 008 | | - | - | - | - | - |
| 009 | | - | - | - | 3 | 3 |
| 010 | | - | - | - | 1 | 1 |
| 011 | | - | - | - | - | - |
| 012 | | 1 | - | - | - | 1 |
| 013 | | - | - | - | 2 | 2 |
| 014 | | - | - | 1 | - | 1 |
| 015 | | - | - | - | - | - |
| 016 | 1 | - | - | - | - | - |
| 017 | | - | 1 | 1 | - | 2 |
| 018 | | - | 1 | - | 1 | 2 |
| 019 | | - | - | - | - | - |
| 020 | | - | - | - | 1 | 1 |
| 021 | 1 | - | - | - | - | - |
| 022 | | - | - | - | 1 | 1 |
| 023 | | - | - | - | - | - |
| 024 | | - | - | - | - | - |
| **Total Problems** | 2 | 2 | 4 | 5 | 11 | 22 |

### *7.3.1.1. General comprehension*

General comprehension issues were judged as any misunderstanding relating to the measure instructions, the question being asked, the response options available, and whether the participant understood the item in the way intended by the developers. There were very few problems coded to general comprehension. From the 22 judged errors, two participants (9%) misinterpreted two separate items. This resulted in them answering a different question to the one intended. One participant interpreted an item enquiring about their ability to influence the overall care of the person they look after, as their ability to cope with the caring role:

> From clarifying conversation: *When you read 'in control' what does that make you think of? "That I'm coping. That I'm not at the stage where I can't cope. Sometimes I feel I can't cope".* [Wife >80, cares for husband with dementia, speaking about the CES 'in control' item]

The second participant interpreted an item asking how safe they felt from fear of physical harm, which are a result of their caring role, as asking them about their general safety:

> *Well, I did have a break in in the house last year which shook me a bit, no I feel as safe as I want, I mean it was just a one off.* [Mother 50-59, cares for adult son, speaking about the ASCOT-Carer 'safety' item]

#### *7.3.1.2. Temporal comprehension*

Errors relating to temporal comprehension were based on the participants understanding that the question being asked was referring to the current period. In the analysis, from the 22 judged errors there were four (18%) judged temporal comprehension errors. One participant based their response on past rather than current status:

> *I was hospitalised last year you know.* [Daughter 50-59, cares for mother with dementia, speaking about ASCOT-Carer 'self-care' item]

Three participants based their response on a general timeframe, or the ‘bigger picture’. For example:

> From clarifying conversation: *Were you thinking about the big picture or were you thinking of today? "Oh, I see, no the big picture. Sometimes it's ok, and sometimes it's not ok".* [Father, cares for adult daughter with mental health condition, speaking about CarerQol-7D ‘relational problems with the care recipient’ item]

### *7.3.1.3. Decision process*

Decision process issues were judged on how the participant decided on their answer. In the analysis, from the 22 judged errors there were five (23%) judged decision process errors. Each participant gave a socially desirable answer when asked about the fulfilment they derive from the caring role, for example:

> *I suppose I’ve got to say that mostly I do. But there are some things which I find far from fulfilling.* [Father 70-79 cares for their adult daughter with bone disease, speaking about the CES ‘fulfilment’ item]

### *7.3.1.4. Response process*

In the analysis, from the 22 judged errors most problems were identified with the response process (n=11, 50%). For this category of error, the judgement was based on whether the participant managed to map their desired response onto the scale without introduction of error. In most problems, the participant struggled to select one item response over the other. This resulted in some participants selecting two answers or leaving the answer blank. The following example is from a participant who felt they could not answer the question asked based on the response options given:

> *The government help, yes, but the council help absolutely no. how do I mark that? They're really very different, those three. I can't really … I can't really because I would have to break those down. Okay, I'm going to leave that because I really can't answer.* [Mother 70-79 cares for their adult child with bone disease, speaking about the CES 'assistance from organisations and government' item]

Participants also verbalised their frustration with the limited number of response options available, and these participants selected 'neutral' or middle ground answers. For example:

> *I wish there was 'a little' here instead of just 'no' and 'some' 'a lot'.* [Mother 70-79 cares for their adult son with mental health condition, speaking about the CarerQoL-7D 'support with carrying out care tasks, as needed' item (selected 'some')]

> *Quite a lot of people who I would regard as close friends have just not visited or been involved at all; whereas my family, who don't live locally, have been very involved. I don't know how to answer this one … I'll go for the second one a neutral point.* [Father cares for their adult son with mental health condition, speaking about the ICECAP-A 'love, friendship and support' item (selected 'quite a lot')]

Finally, based on the participants verbalised thought process and their selected response, it was evident that some participants struggled to map their desired response onto the scale without the introduction of error:

> *I can do few of the other things I want to do. The demands of the cared for are quite high.* [Father cares for adult daughter with mental health condition, speaking about the CES 'activities outside caring' item (selected 'some')]

### *7.3.2. Distribution of judged problems: By measure*

The frequency of problematic items by QoL measure is shown in Table 7.3. This table illustrates that no measure was completely without error and some items were more problematic than others. The three CRQoL measures were completed by 16 participants. From the 96 CES items that were analysed (i.e., 16*6=96), judged errors occurred in 6% (n=6). From the 112 CarerQoL-7D items (i.e., 16*7=112), judged errors occurred in 5% (n=6) and from the 112 ASCOT-Carer items (i.e., 16*7=112) that were analysed, judged errors occurred in 4% (n=5). The EQ-5D-5L and ICECAP-A were both completed by 12 participants. From the 60 EQ-5D-5L items (i.e., 16*5=60) that were analysed, judged errors occurred in 3% (n=2), and from the 60 ICECAP-A items (i.e., 16*5=60) analysed, judged errors occurred in 6% (n=4).

With the six items of the CES no problems were identified for the 'support from family and friends' item and the 'getting on with the person you care for' item. Most problems (n=3, 50%) were identified for the 'fulfilment from caring' item. All problems with this item were judged to be decision process errors, where the participant gave a socially desirable answer, for example:

> *Obviously, I suppose I have to say I do because he is my son.* [Father 50-59 cares for their adult son with learning difficulties, speaking about the CES 'fulfilment' item]

With the seven items of the CarerQoL-7D no problems were identified with the 'problems with physical health' and 'financial problems due to care tasks' items. Most problems (n=2, 33%) were identified for the 'support with carrying out care tasks, as needed' item. Both problems were judged to be response process errors, where the participant did not manage to map their desired response onto the scale without introduction of error, for example:

> *I know that my brother and my sister would help out with caring duties when I can't do it.* [Daughter 60-69 cares for their mother with lung disease, speaking about the CarerQoL-7D 'support with carrying out care tasks, as needed' item (selected 'no support')]

With the seven items of the ASCOT-Carer no problems were identified with the 'occupation in valuable or enjoyable activities' item or the 'space and time to be yourself' item. One error was judged in each of the remaining five items, with most problems judged to be response process errors (n=3, 60%), for example:

> *I think I have adequate control over my daily life. It alternates between having 'not enough' and 'adequate' so I could probably tick both of these*

> *boxes.* [Mother 70-79 cares for their adult son with mental health condition, speaking about the ASCOT-Carer 'control over daily life' item (selected 'some' and 'adequate')]

The only item of the EQ-5D-5L that had identified problems was the 'pain/discomfort' item where two problems were identified, both of which were judged to be temporal comprehension errors, where the participant did not understand that the question was referring to the current period, for example:

> *I'm going to go with moderate, just depends.* [Mother 50-59, cares for adult son with learning difficulties, speaking about the EQ-5D-5L 'pain/discomfort' item]

With the five items of the ICECAP-A no problems were identified with the 'achievement and progress' item. All other items had one problem each with most problems (n=3, 75%) judged to be response process errors, for example:

> *I think that's most on this one.* [Daughter 50-59 cares for their mother with dementia, speaking about the ICECAP-A 'feeling settled and secure' item (selected 'none')

**Table 7.3.** Problems and struggles on each measure

| QoL measure | Theoretical domain | Item | Number of people with no identified problems | Judged problems | | | | Total problems n (%) | Struggled but answered correctly n (%) | Insufficient information n (%) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | G | T | D | R | | | |
| **CES** (n=16) | Occupation | Activities outside caring | 15 | 0 | 0 | 0 | 1 | 1 (6) | 0 | 0 |
| | Support | Support from friends & family | 16 | 0 | 0 | 0 | 0 | 0 | 1 (6) | 0 |
| | | Assistance from orgs & government | 15 | 0 | 0 | 0 | 1 | 1 (6) | 2 (13) | 0 |
| | Fulfilment | Fulfilment from caring | 13 | 0 | 0 | 3 | 0 | 3 (19) | 0 | 0 |
| | Control | Control over caring | 15 | 1 | 0 | 0 | 0 | 1 (6) | 0 | 0 |
| | Relationship | Getting on with the person you care for | 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **CarerQoL-7D** (n=16) | Occupation | Problems with combining care tasks with daily activities | 15 | 0 | 0 | 0 | 1 | 1 (6) | 0 | 1 (6) |
| | Support | Support with carrying out care tasks, as needed | 14 | 0 | 0 | 0 | 2 | 2 (13) | 1 (6) | 0 |
| | Fulfilment | Fulfilment from carrying out care tasks | 15 | 0 | 0 | 1 | 0 | 1 (6) | 0 | 0 |
| | Relationship | Relational problems with the care receiver | 15 | 0 | 1 | 0 | 0 | 1 (6) | 0 | 0 |
| | Physical health | Problems with physical health | 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | Mental health | Problems with mental health | 15 | 0 | 0 | 0 | 1 | 1 (6) | 0 | 1 (6) |
| | Finances | Financial problems due to care tasks | 16 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **ASCOT-Carer** (n=16) | Occupation | Occupation in valuable or enjoyable activities | 16 | 0 | 0 | 0 | 0 | 0 | 1 (6) | 0 |
| | | Space and time to be yourself | 16 | 0 | 0 | 0 | 0 | 0 | 1 (6) | 1 (6) |
| | Support | Feeling supported and encouraged | 15 | 0 | 0 | 0 | 1 | 1 (6) | 1 (6) | 1 (6) |
| | Control | Control over daily life | 15 | 0 | 0 | 0 | 1 | 1 (6) | 0 | 0 |
| | Social participation | Social contact with people you like | 15 | 0 | 0 | 0 | 1 | 1 (6) | 0 | 0 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Self-care | How well you look after yourself | 15 | 0 | 1 | 0 | 0 | 1 (6) | 0 | 0 |
| | Safety & stability | How safe you feel | 15 | 1 | 0 | 0 | 0 | 1 (6) | 0 | 1 (6) |
| **EQ-5D-5L** (n=12) | Occupation | Usual activities | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 2 (17) |
| | Physical health | Pain/discomfort | 10 | 0 | 2 | 0 | 0 | 2 (17) | 0 | 2 (17) |
| | | Mobility | 12 | 0 | 0 | 0 | 0 | 0 | 1 (8) | 0 |
| | Mental health | Anxiety/depression | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (8) |
| | Self-care | Self-care | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 1 (8) |
| **ICECAP-A** (n=12) | Support | Love, friendship, and support | 11 | 0 | 0 | 0 | 1 | 1 (8) | 1 (8) | 0 |
| | Fulfilment | Enjoyment and pleasure | 11 | 0 | 0 | 0 | 1 | 1 (8) | 0 | 0 |
| | Control | Being independent | 11 | 0 | 0 | 1 | 0 | 1 (8) | 0 | 1 (8) |
| | Safety & stability | Feeling settled and secure | 11 | 0 | 0 | 0 | 1 | 1 (8) | 0 | 0 |
| | Achievement | Achievement and progress | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

Notes: G: general comprehension, T: temporal comprehension, D: decision process, R: response process

### *7.3.3. Distribution of judged problems: By theoretical domain*

As discussed in Chapter 4, the items of the five QoL measures can be categorised under 12 theoretical domains (see Table 4.2 in Chapter 4). For this section of the think-aloud analysis, these theoretical domains have been used to frame the results. Table 7.4 provides further detail on the frequency and type of problems that occurred when participants answered items in these domains.

**Table 7.4.** Problems identified for theoretical domains

| Theoretical domain | Number of items analysed | No error n (%) | Error n (%) |
|---|---|---|---|
| Occupation | 76 | 74 (97) | 2 (3) |
| Support | 76 | 71 (93) | 5 (7) |
| Fulfilment | 44 | 39 (89) | 5 (11) |
| Control | 44 | 41 (93) | 3 (7) |
| Relationship | 32 | 31 (97) | 1 (3) |
| Social participation | 16 | 15 (94) | 1 (6) |
| Physical health | 40 | 38 (95) | 2 (5) |
| Mental health | 28 | 27 (96) | 1 (4) |
| Self-care | 28 | 27 (96) | 1 (4) |
| Safety & stability | 28 | 26 (93) | 2 (7) |
| Finances | 16 | 16 (100) | 0 |
| Achievement | 12 | 12 (100) | 0 |

Two domains were judged to have no errors, 'finances' and 'achievement'. Both these domains are represented by one item each on the CarerQoL-7D and ICECAP-A respectively. For the 'relationship' domain, from the 32 measure items that were analysed, judged errors occurred in 3% (n=1), and the same number of errors were judged to occur for the 'self-care', 'mental health', and 'social participation' domains.

Under the 'occupation' domain, from the 76 measure items that were analysed, judged errors occurred in 3% (n=2). The CES, CarerQol-7D, ASCOT-Carer and EQ-5D-5L all have at least one item within this domain. In the analysis the errors were judged to occur in the items of the CES and CarerQoL-7D, and both errors were judged to be a response process error. For example:

> *I have problems combining my care tasks with my daily activities, well some I can't do because I have got COPD as well.* [Daughter 50-59 cares for their mother with dementia, speaking about the CarerQoL-7D 'combining care tasks with daily activities' item (selected 'a lot of problems')]

Under the 'physical health' domain, from the 40 measure items that were analysed, judged errors occurred in 5% (n=2). The CarerQoL-7D and EQ-5D-5L both have at least one item within this domain. In the analysis the errors were both judged to occur in the 'pain/discomfort' item of the EQ-5D-5L, and both errors were judged to be a temporal comprehension error. For example:

> *I bashed my knee, does that count? It's a temporary slight pain. Generally, no.* [Daughter 50-59, cares for father recovering from stroke, speaking about EQ-5D-5L 'pain/discomfort' item]

Under the 'support' domain, from the 76 measure items that were analysed, judged errors occurred in 7% (n=5). The CES, CarerQoL-7D, ASCOT-Carer and ICECAP-A all have at least one item within this domain. In the analysis, errors were judged to occur in each of these items, and each error was judged to be a response process error, i.e., the judgement was based on whether the participant managed to map their desired response onto the scale without introduction of error. For example:

> *Most of the time I feel I have adequate encouragement and support but when things flare, I tend to be the lead of it … so I don't know if you want me to tick both boxes there or … I'll put when caring flares up.* [Daughter 60-69 cares for their mother with bone disease, speaking about the ASCOT-Carer 'encouragement and support' item (selected 'some' and 'adequate')]

Under the 'safety and stability' domain, from the 28 measure items that were analysed, judged errors occurred in 7% (n=2). The ASCOT-Carer and ICECAP-A both have an item under this domain. In the analysis an error was judged to occur in both these items, one general comprehension and one response process error. Under the 'control' domain, from the 44 measure items that were analysed, judged errors occurred in 7% (n=3). The CES, ASCOT-Carer and ICECAP-A all have one item within this domain. In the analysis, an error was judged to occur in each of these items. These problems were judged to be a general comprehension error, a decision process error, and a response process error. For example, the following quote is an example of the judged response process error:

> *I'm able to be independent in many things. Yes, I can run the car, I can go shopping, this sort of thing. I am able to be independent in a few things. Yes, quite a few things. So, I'm able to be independent in a few things.* [Wife >80 caring for their husband with dementia, speaking about the ICECAP-A 'being independent' item, they selected 'I am able to be independent in a few things' rather than 'I am able to be independent in many things']

The most problematic domain was the 'fulfilment' domain. From the 44 measure items that were analysed, judged errors occurred in 11% (n=5). The CES, CarerQoL-7D and ICECAP-A all have one item within this domain. In the analysis an error was judged to occur in each of these items, and four of the five errors were judged to be a decision process error, with participants all giving a socially desirable answer. For example:

> *I don't find caring fulfilling … so at the moment I'm not finding it fulfilling and I don't think he appreciates any of it at the moment so I would say I sometimes find caring fulfilling but certainly not mostly.* [Wife 60-69 caring for their husband with dementia, speaking about the CES 'fulfilment' item]

### *7.3.4. Distribution of judged problems: By condition*

The five QoL measures were completed by seven participants caring for somebody with dementia. Participants completed the CES (n=4), CarerQoL-7D (n=5), ASCOT-Carer (n=5), EQ-5D-5L (n=4), and ICECAP-A (n=3). From the 129 measure items that were analysed (i.e. ((4*6)+(5*7)+(5*7)+(4*5)+(3*5))=129), judged errors occurred in each measure except for the EQ-5D-5L. The ICECAP-A was the most problematic measure with 20% of items analysed (n=3) judged to have an error. Table 7.5 and Table 7.6 provide further detail on the frequency and type of problems that occurred. Table 7.5 shows that judged errors occurred in five theoretical domains, with most occurring in the 'fulfilment' domain. Here, judged errors occurred in 33% (n=3) of the measure items that were analysed. As Table

7.6 illustrates, using the four classifications of errors, problems occurred under each cognitive process, with most being classified as decision process (n=3, 38%) and response process (n=3, 38) errors. The following is an example of a decision process error where the participant gave a socially desirable answer:

> *I wouldn't not do it for the world, but I couldn't say it's fulfilling.* [Wife >80 caring for their husband with dementia. Speaking about the CES 'fulfilment' item, they selected 'sometimes find caring fulfilling']

Two participants in the analysis were caring for somebody recovering from a stroke. Here, participants completed the CES (n=1), the CarerQoL-7D (n=1), the ASCOT-Carer (n=2), the EQ-5D-5L (n=1), and the ICECAP-A (n=1). From the 37 measure items that were analysed (i.e. ((1*6)+(1*7)+(2*7)+(1*5)+(1*5))=37), the EQ-5D-5L was the only measure where judged errors occurred. In the analysis a single error was judged to occur in the 'physical health' domain of the EQ-5D-5L, and this was judged to be a temporal comprehension error based on the participants understanding that the question being asked was referring to the current period. For example:

> *I bashed my knee, does that count? It's a temporary slight pain. Generally, no.* [Daughter 50-59, cares for father recovering from stroke, speaking about EQ-5D-5L 'pain/discomfort' item]

The five QoL measures were completed by six participants caring for somebody with a mental health condition. Participants completed the CES (n=3), the CarerQoL-7D (n=4), the ASCOT-Carer (n=5), the EQ-5D-5L (n=3), and the ICECAP-A (n=3). From the 111 measure items that were analysed (i.e. ((3*6)+(4*7)+(5*7)+(3*5)+(3*5))=111), judged errors occurred in the three CRQoL measures. No errors were judged to occur in the EQ-5D-5L and ICECAP-A. Judged errors occurred in six theoretical domains, with most occurring in the 'social participation' domain, where judged errors occurred in 20% (n=22) of the measure items that were analysed.

The ASCOT-Carer was the most problematic measure with 9% of items analysed (n=3) judged to have an error. Most of these errors (n=2, 66%) were judged to be response process errors, for example:

> *I feel that I have adequate social contact with people. It varies between 'adequate' and 'I would like more'.* [Mother 70-79 cares for their adult son with mental health condition, speaking about the ASCOT-Carer 'social contact' item (selected 'some' and 'adequate')]

Nine participants in the analysis were caring for somebody with a health condition other than dementia, recovery from stroke, or mental health conditions. Participants completed the CES (n=8), the CarerQoL-7D (n=6), the ASCOT-Carer (n=4), the EQ-5D-5L (n=4), and the ICECAP-A (n=5). Here, from the 163 measure items that were analysed (i.e. ((8*6)+(6*7)+(4*7)+(4*5)+(5*5))=163), judged errors occurred in each of the five QoL measures. The CarerQoL-7D was the most problematic measure with 7% of items analysed (n=3) judged to have an error. Judged errors occurred in four theoretical domains, with most occurring in the 'fulfilment' domain. Here, judged errors occurred in 16% (n=3) of the measure items that were analysed. Using the four classifications of errors, problems occurred under each cognitive process except for general comprehension. Most errors were judged to be response process errors where the participant did not manage to map their desired response onto the scale without introduction of error. For example:

> *No to most of it, just the stress caused by this everlasting trying to cut back. So, do I put in there no and ring stress? I think I will because I don't really have a mental health problem, but stress can get bad.* [Mother 70-79 cares for their adult daughter with bone disease, speaking about the CarerQoL-7D 'carer mental health' item (selected 'no')]

**Table 7.5.** Problems identified for theoretical domains for each condition

| Theoretical domain | Dementia | | Stroke | | Mental health condition | | Other condition | |
|---|---|---|---|---|---|---|---|---|
| | Items analysed (n) | Problems n (%) | Items analysed (n) | Problems n (%) | Items analysed (n) | Problems n (%) | Items analysed (n) | Problems n (%) |
| Occupation | 23 | 1 (4) | 7 | - | 20 | 1 (5) | 26 | - |
| Support | 21 | - | 6 | - | 18 | 1 (6) | 33 | 4 (12) |
| Fulfilment | 9 | 3 (33) | 3 | - | 10 | - | 19 | 3 (16) |
| Control | 10 | 2 (20) | 4 | - | 11 | 1 (9) | 17 | - |
| Relationship | 9 | - | 2 | - | 7 | 1 (14) | 14 | - |
| Social participation | 5 | - | 2 | - | 5 | 1 (20) | 4 | - |
| Physical health | 13 | - | 3 | 1 (33) | 10 | - | 14 | 1 (7) |
| Mental health | 9 | - | 2 | - | 7 | - | 10 | 1 (10) |
| Self-care | 8 | 1 (13) | 3 | - | 8 | - | 8 | - |
| Safety & stability | 7 | 1 (14) | 3 | - | 8 | 1 (13) | 9 | - |
| Finances | 5 | - | 1 | - | 4 | - | 6 | - |
| Achievement | 3 | - | 1 | - | 3 | - | 5 | - |

**Table 7.6.** Problems on each measure for each condition

| Condition | Measure | Number of participants | Number of items analysed | Judged problems | | | | Total problems | % Problems |
|---|---|---|---|---|---|---|---|---|---|
| | | | | G | T | D | R | | |
| Dementia (n=7) | CES | 4 | 24 | 1 | - | 2 | - | 3 | 13 |
| | CarerQoL-7D | 5 | 35 | - | - | - | 1 | 1 | 3 |
| | ASCOT-C | 5 | 35 | - | 1 | - | - | 1 | 3 |
| | EQ-5D-5L | 4 | 20 | - | - | - | - | - | - |
| | ICECAP-A | 3 | 15 | - | - | 1 | 2 | 3 | 20 |
| Stroke (n=2) | CES | 1 | 6 | - | - | - | - | - | - |
| | CarerQoL-7D | 1 | 7 | - | - | - | - | - | - |
| | ASCOT-C | 2 | 14 | - | - | - | - | - | - |
| | EQ-5D-5L | 1 | 5 | - | 1 | - | - | 1 | 20 |
| | ICECAP-A | 1 | 5 | - | - | - | - | - | - |
| Mental health condition (n=6) | CES | 3 | 18 | - | - | - | 1 | 1 | 5 |
| | CarerQoL-7D | 4 | 28 | - | 1 | - | 1 | 2 | 7 |
| | ASCOT-C | 5 | 35 | 1 | - | - | 2 | 3 | 9 |
| | EQ-5D-5L | 3 | 15 | - | - | - | - | - | - |
| | ICECAP-A | 3 | 15 | - | - | - | - | - | - |
| Other health condition (n=9) | CES | 8 | 48 | - | - | 1 | 1 | 2 | 4 |
| | CarerQoL-7D | 6 | 42 | - | - | 1 | 2 | 3 | 7 |
| | ASCOT-C | 4 | 28 | - | - | - | 1 | 1 | 4 |
| | EQ-5D-5L | 4 | 20 | - | 1 | - | - | 1 | 5 |
| | ICECAP-A | 5 | 25 | - | - | - | 1 | 1 | 4 |

Notes: G: General Comprehension T: Temporal Comprehension D: Decision Process R: Response Process

## 7.4. Semi-structured interview

The results of the thematic analysis of the face validity, content validity and feasibility of the five QoL measures are presented below. The thematic results cover the main issues discussed by participants during the semi-structured interview. As discussed in Chapter 6 each participant was asked the same ten questions during the semi-structured interview. These questions are provided in the topic guide included in Table 6.1 from Chapter 6. The main issues that arose from these questions covered topics not directly asked about in the interview. This included the desire of most participants to be able to provide context to their responses when completing a measure, and their difficulty with the grouping together of certain words and organisations in questions. The issues raised by participants are presented in Table 7.7 as themes. These themes are used to frame the analysis that follows. Verbatim quotes are included in this section in italics with ellipses to denote missing text.

**Table 7.7.** Summary of themes derived from semi-structured interviews

| | **Theme** | **Sample quote from participant** |
|---|---|---|
| Face and content validity | Relevance | It's very difficult because every situation is different, and these are all facts and figures |
| | Context | I think I would've liked to have given context…but I can do that because it's a one-to-one interview…the context would…enrich the tapestry |
| | Moment in time | What actually fits on this week might not fit next week. There's quite a variation. |
| | Missing items | The only thing it didn't ask about which I'd say is there is guilt |
| Feasibility | Length of measure | Oh, it was fine because I've had to do so many; we've had them like 30 pages long. |
| | Difficulty answering | I think if some of these questions were split down a bit more it would be a lot easier to actually get a truer picture |
| | Instructions | Certainly, your expansions with italics are useful because it is helping someone think about what it really means |
| | Language | The government, does that mean the NHS? Define your terms |
| | Response options | Some of them were quite difficult to select as to what fits |
| Double counting | Financial losses | Our grandchildren are now coming to the stage where we would...we've given them a little bit of money but nothing like we'd have liked to have done |
| | Time losses | Well, yes, I mean problems combining care tasks with daily activities |
| | Care recipient health | My health, is it my health or his health, I don't know, is it mine? |

### *7.4.1. Face and content validity*

The participants' reaction to what measure they felt best captured the QoL issues pertinent to how caring affects their lives at the present moment in time is described below, along with the participants' reaction to individual items of the measures, under the sub-headings of relevance, context, capturing a moment in time, and missing items.

#### *7.4.1.1. Relevance*

When discussing 'relevance' with participants, the goal was to establish how relevant they considered what the QoL measures were asking them for capturing their QoL. Most participants did not raise any concerns. A strong theme running through the interviews with participants who did question the relevance of the measures was the issue of the limitations of using *any* QoL measure to capture the way caring impacts on their QoL with some participants believing a QoL measure to be inherently limited and lacking in nuance.

> *It's always very stark, isn't it, when you're doing that?* [Mother 70-79, cares for adult son with mental health condition]

> *It's very difficult because every situation is different, and these are all facts and figures.* [Daughter <49, cares for mother with dementia]

Participants also spoke of the importance of what the QoL measure focused on. This heavily influenced how the participant responded when they were asked to select their preferred measure of the three that they completed. Table 7.8 provides information on the measures each participant completed, and which measure they felt best captured their QoL. Some participants favoured a measure they felt engaged them as a carer, looked at the real issues for carers, and focused on their role as a carer.

> *Well, it was looking at the carer, so…it's looking more to me* [Wife 60-69, cares for husband with dementia, speaking about the CES]

Meanwhile, other participants struggled with the focus of the questionnaire being on them, or with how they felt the measures focused on the caring role, their place within that role, and how they have adapted to their role as an informal carer.

> *It's more geared to someone who's the primary carer whereas I realise that the situation I'm in, I mean I queried that specifically when I was approached in the first place.* [Daughter 50-59, cares for mother with dementia, speaking about the research study in general]

When discussing the relevance of individual items of the QoL measures the goal was to ascertain what items the participants considered to be relevant in capturing their QoL. Participants focused on how their experience of providing care has an impact on the relevance of items to them, such as the 'fulfilment' item of the CES,

> *…well see on that one really, I think because he's my son it doesn't sound right fulfilment. If he was like I don't know if he was a three-year-old and you had a little toddler and you'd seen him learning to read a book, first word or do that first little jigsaw and you'd done it with him and you've taught him, really you think, yeah you would get some fulfilment from that wouldn't you. But at 32 and 33 years of age I suppose part of me is thinking it's not the same and you've had this all your life, we've had this all our life, if anything it's only gone worse not easier. And I'm not sure fulfilment is the right word.* [Father 50-59, cares for adult daughter with learning difficulties, speaking about the CES 'fulfilment' item]

the ‘usual activities’ item of the EQ-5D-5L,

> *…see usual activities, I find that one quite difficult too. Because I’ve never had usual activities in the way most people would who have a normal child and whose child has grown that’s 45. For some people their normal activities are they’re out and about and are doing things and are visiting children, grandchildren, but we don’t have a normal, the same as everybody else…it’s not really relevant.* [Mother 70-79, cares for adult daughter with bone disease]

and the ‘achievement and progress’ item of the ICECAP-A.

> *I never envisaged my lifestyle would be picking someone off the floor, feeding them, trying to keep them clean and all the rest of it, it goes with caring, it’s just not something you plan for, or expect. So, as I say, as far as that goes, achievement and progress well, it’s sort of fairly irrelevant I think, it’s just a case of struggling by from day to day.* [Husband 60-69, cares for wife with brain disease].

Other participants commented on how issues beyond the caring role, such as having a family or retiring, had an impact on their answer in relation to the ‘independent’ item of the ICECAP-A,

> *When you look at being independent. I mean I’m not independent and I haven’t been independent since the day I got married because there’s now two of you. And I’ve been even less independent the day we started, the*

> *children started coming along…* [Father 70-79, cares for adult daughter with learning difficulties]

and the 'achievement and progress' item of the ICECAP-A.

> *…when you're retired your achievements are limited really…* [Husband 60-69, cares for wife with brain disease]

### *7.4.1.2. Context*

When discussing the topic of using a QoL measure to capture carer QoL, and the limitations attached to this, several participants expressed their desire to provide context to the answer they gave when completing the measures. Participants felt this would allow them to elaborate on their answers, give background information, and provide personal experiences to "*enrich the tapestry*" as one participant commented. This participant felt that the face-to-face interview allowed them to provide that context.

> *I think I would've liked to have given context…but I can do that because it's a one-to-one interview…the context would…enrich the tapestry.* [Son 50-59, cares for mother with heart disease]

> *I've been through so much and you can't put it in one question, do you know what I mean?* [Daughter <49, cares for mother with dementia]

> *I suppose the only thing none of them have is really the tale of where we've come from.* [Father 70-79, cares for adult son with mental health condition].

Another participant discussed the importance of providing context to their answers in relation to the CES 'support from family & friends' item.

> *Yeah, I think I would've liked to have given context if I can, but I can do that because it's a one-to-one interview. But at home, see if you hadn't have come, I'd have just tick, tick, tick, tick, tick, and you wouldn't know why I've had no support from family and friends.* [Son 50-59, cares for mother with heart disease]

### *7.4.1.3. Moment in time*

The aim of the five QoL measures included in this study is to capture the respondents' QoL at a given moment in time. Each of the measures completed by participants asked them to think of their current situation when selecting their answer. In the semi-structured interview, when asked if they were thinking of their current situation or the overall picture when completing the measures, most participants were thinking of their current situation. However, some participants struggled with this instruction. They commented on the variability inherent in providing care and how it is difficult to measure the fluctuations.

> *What actually fits on this week might not fit next week. There's quite a variation.* [Father, cares for adult daughter with mental health condition]

Some participants also commented that answering the measures based on the current situation did not allow them to provide an answer that covered their overall experience of caring.

> *It's very difficult to give an overall picture of what being a carer for something like 30 years is like because like life it's a changing pattern.* [Mother >80, cares for adult son with mental health condition]

While most participants did answer the questions thinking of their current situation, some participants selected their answer based on a particular moment in time,

> *This is a moment in time now, effectively. I've sort of embellished it and talked about what it used to be like.* [Father 70-79, cares for adult son with mental health condition]

> *In the end I thought about it when he's really bad.* [Father 50-59, cares for adult daughter with learning difficulties].

or they selected an answer that fit with their historical experience of caring.

> *No, the big picture. Sometimes it's ok, and sometimes it's not ok.* [Husband, cares for wife with mental health condition]

Some participants commented on how they might answer some individual questions differently in the future, such as the 'self-care' and 'mobility' items of the EQ-5D-5L,

> *I mean there might come a time when some of these things are relevant, self-care and mobility.* [Mother 70-79, cares for adult daughter with bone disease]

and the 'finances' item of the CarerQoL-7D.

> *I have financial problems because of my care tasks, now what do I put here, you know what opportunity cost is don't you? And that's high but I don't have financial problems yet and this is supposed to be a current.* [Daughter 50-59, cares for mother with dementia]

### *7.4.1.4. Missing items*

When asked if there were any aspects that impact on their QoL that they thought were missing from the measures most participants felt nothing was missing while others spoke about how they as a carer engage with care recipient services,

> *I wish there's an element in these questionnaires…that the integration between your role as a carer and the professional services that the person is receiving, how do you feel about that. Because then I would have had something to add whereas now if we're just looking at me only and all the way through one of the worst aspects is the lack of communication.* [Son 50-59, cares for mother with dementia]

and the dual benefit attached to some of these services.

> *…I have very little contact socially with people other than my mother's friends…when I'm taking mum out to socialise, I'll do some socialising myself. Is that for her benefit or for my benefit?* [Son 50-59, cares for mother with dementia]

Other participants spoke about the caring role, the guilt that can be attached to this, and how none of the questions focused on what the participant has done to improve the care recipient’s situation, instead focusing on the assumption that the care recipient’s condition was worsening.

> *Only I think the fact that it wasn’t, it was all about assuming the patient was going to get worse. There wasn’t anything there to say, what have you done to help if that makes sense.* [Wife 70-79, cares for husband with heart disease]

> *The only thing it didn’t ask about which I’d say is there is guilt.* [Daughter 60-69, cares for mother with bone disease]

Two participants who had noted the importance of financial impacts on their QoL commented on the lack of items relating to finance in the measures.

> *No, I didn’t notice any questions that mentioned that.* [Husband 60-69, cares for wife with brain disease]

> *There was one question, wasn’t there, about assistance? I suppose that’s the only one that relates to finance.* [Husband >80, cares for wife, speaking about the CES]

Finally, one participant commented on the CarerQoL-7D ‘support with carrying out care tasks’ item and how it did not ask about the support they might receive from statutory bodies.

> *Well, I don't know. Were you particularly interested in where the support was from? You asked about friends, families, neighbours, and acquaintances but you didn't ask about the authorities. You haven't asked about the statutory bodies.* [Mother 70-79, cares for adult son with mental health condition]

#### *7.4.1.5. Participants thoughts on each measure*

The face and content validity analysis shows that overall, no measure stood out as performing better than another measure. Participants discussed, in general terms, the difficulty of answering each measure thinking of the current moment in time. They also discussed what they felt was lacking in each measure, such as the ability to provide context to responses. However, asking participants to select their preferred measure of the three they completed, provides insight into how each measure performed. Table 7.8 provides information on the measures each participant completed, and which measure they felt best captured their QoL.

Seven participants could not choose between the three measures they completed, or they had no preference. Of the 19 participants who indicated a preference for one measure, no participant chose the EQ-5D-5L and one participant chose the ICECAP-A. This participant was providing care for his wife who had died in the days preceding the interview. The participant found it difficult to answer questions directly related to their caring role.

Seven participants indicated that they felt the ASCOT-Carer measure best captured their QoL as a carer, six indicated the CES, and three indicated a preference for the

CarerQoL-7D. The three participants who chose the CarerQoL-7D measure chose it because they found it to be more comprehensive, and that it got to the core of that impacts on their QoL.

> *…it's getting down to the nitty gritty realism* [Daughter 50-59, cares for mother with dementia]

Participants who favoured the CES measure, chose it because they felt the questions were easier to answer, and it was more comprehensive. Participants indicated that the CES included items that impacted on their QoL. These items were fulfilment, and control over caring.

> *…rather than like social contact and having support or leisure time, it's actually having control over what I do* [Husband, 60-69, cares for wife with brain disease]

Of the six participants who indicated a preference for the CES, there was an even spread amongst who they were providing care for: spouse, parent, or adult child. All participants were aged 50-79, and they were providing care across a wide range of diseases including lung disease, heart disease, and learning difficulties.

Reasons participants chose the ASCOT-Carer as their preferred measures were that it was the most in-depth measure, it gave them more response options to choose from, and it encouraged them to express their emotions.

> *…it encourages me to express what’s going on in my head* [Daughter 60-69, cares for mother with dementia]

The seven participants who favoured the ASCOT-Carer measure were providing care for either their parent or their adult child. For those providing care for a parent, most were aged 50-69 and the parent had dementia. For those providing care for their adult child, the child typically had mental health problems and the carer was over 70 years of age.

**Table 7.8.** Measures completed by participants

| Participant ID | Participant profile | QoL measures completed and order* | | |
|---|---|---|---|---|
| | | **First** | **Second** | **Third** |
| 001 | Father, cares for adult daughter with mental health condition | ASCOT-C | CES | ICECAP-A |
| 002 | Father, cares for adult son with mental health condition | CarerQoL-7D | CES | EQ-5D-5L |
| 003 | Husband, cares for wife with mental health condition | CarerQoL-7D | ASCOT-C | ICECAP-A |
| 004 | Wife >80, cares for husband with dementia | ICECAP-A | CES | **CarerQoL-7D** |
| 005 | Daughter 50-59, cares for father recovering from stroke | CarerQoL-7D | EQ-5D-5L | **ASCOT-C** |
| 006 | Son 50-59, cares for mother with dementia | EQ-5D-5L | **ASCOT-C** | CES |
| 007 | Wife 60-69, cares for husband with dementia | **CES** | ICECAP-A | CarerQoL-7D |
| 008 | Daughter <49, cares for mother with dementia | ASCOT-C | CES | EQ-5D-5L |
| 009 | Mother 70-79, cares for adult son with mental health condition | EQ-5D-5L | CarerQoL-7D | **ASCOT-C** |
| 010 | Daughter 60-69, cares for mother with lung disease | ICECAP-A | CarerQoL-7D | **CES** |
| 011 | Father 70-79, cares for adult son with mental health condition | CES | EQ-5D-5L | ASCOT-C |
| 012 | Mother >80, cares for adult son with mental health condition | **ASCOT-C** | ICECAP-A | CarerQoL-7D |
| 013 | Mother 70-79, cares for adult daughter with bone disease | **CES** | CarerQoL-7D | EQ-5D-5L |
| 014 | Father 70-79, cares for adult daughter with bone disease | ICECAP-A | **ASCOT-C** | CES |
| 015 | Daughter 60-69, cares for mother with dementia | EQ-5D-5L | **ASCOT-C** | CarerQoL-7D |
| 016 | Daughter 60-69, cares for mother recovering from stroke | CES | ICECAP-A | ASCOT-C |
| 017 | Father 50-59, cares for adult daughter with learning difficulties | CarerQoL-7D | EQ-5D-5L | **CES** |
| 018 | Daughter 50-59, cares for mother with dementia | ASCOT-C | **CarerQoL-7D** | ICECAP-A |
| 019 | Wife 70-79, cares for husband with heart disease | CES | ASCOT-C | EQ-5D-5L |
| 020 | Daughter 60-69, cares for mother with bone disease | ICECAP-A | **CarerQoL-7D** | ASCOT-C |
| 021 | Daughter 50-59, cares for mother with dementia | **ASCOT-C** | EQ-5D-5L | CarerQoL-7D |
| 022 | Husband >80, cares for wife | CarerQoL-7D | CES | **ICECAP-A** |
| 023 | Son 50-59, cares for mother with heart disease | EQ-5D-5L | ASCOT-C | **CES** |
| 024 | Husband 60-69, cares for wife with brain disease | **CES** | ICECAP-A | CarerQoL-7D |

*Preferred measure in bold

### *7.4.2. Feasibility*

The participants reaction to the practicality of each measure is described below under the sub-headings of length of measure, difficulty answering, instructions, language, and response options.

#### *7.4.2.1. Length of measure*

The topic of the length of the measures arose in the context of the limitations of using any QoL measure to capture the way caring impacts on QoL. Participants did not have any issues with the length of the measures and indeed one participant compared them favourable with other forms they complete,

> *Oh, it was fine because I've had to do so many; we've had them like 30 pages long. You know, where they're looking at - have things changed…and you sit there talking it through, trying to work it out and you'd pencil out your answers and then you'd go back to it two, three, four, five times. A huge amount of form filling, which is the last thing you need. If you're caring and they call these meeting and they want you filling forms and things, you can spend hours when you should be able to be doing something more pleasurable…* [Mother 70-79, cares for adult daughter with bone disease].

#### *7.4.2.2. Difficulty answering*

When asked if they encountered any difficulty answering the questions, most participants experienced no difficulty. Others spoke about the desire to split some of the items, with one participant commenting that by splitting the items the measure might get to the real issues that impact on carer QoL.

> *So, I think if some of these questions were split down a bit more it would be a lot easier to actually get a truer picture.* [Mother 70-79, cares for adult daughter with bone disease]

Again, this was discussed in the context of the limitation of using any QoL measure to capture the impacts on carer QoL. Participants focused on individual items such as the ICECAP-A 'love, friendship and support' item,

> *I would not have linked those three together personally because very often support does not come with friendship or love. I mean I think I can have quite a lot of love, but not necessarily so much of the other. So, I'm not quite sure where to put my tick.* [Father 70-79, cares for adult daughter with bone disease]

the CES 'support from organisations & government' item,

> *Assistance from organisations and the government, oh that's a nasty one. Organisations like where she goes now, we get lots of support. Lots and lots of support. The government help, yes, but the council help absolutely no. How do I mark that? It doesn't really answer it all because they're really very different, those three you know. How can I answer that when some are excellent, and some are rubbish?* [Mother 70-79, cares for adult daughter with bone disease]

and the ASCOT-Care ‘encouragement and support’ item.

> *What I’m hesitating over with the feeling supported and encouraged is I’m not sure where that might come from. So, if it comes from within the family, definitely not enough, my brothers useless. I am quite well supported by the care home although that kind of varies depending on management turnover but in steady state at the care home I do get some encouragement and support. And from the health service or whoever is supposed to be supporting us in these things, almost none, the family doctor’s fantastic when you can get hold of them, but you almost never can. So, I have some but probably not enough but that’s what I’m hesitating over with that one.* [Daughter 50-59, cares for mother with dementia]

#### *7.4.2.3. Instructions*

Most participants found the instructions given for each measure to be clear.

> *Yeah, clear enough. There wasn’t a problem.* [Mother 70-79, cares for adult son with mental health condition]

However, other participants spoke about both the need for, and the importance of, clarity.

> *Certainly, your expansions with italics are useful because it is helping someone think about what does it really mean.* [Daughter 60-69, cares for mother with dementia, speaking about the CarerQoL-7D]

> *When it says he/she behaves differently…I don't quite know what that means.* [Wife >80, cares for husband with dementia, speaking about the CarerQoL-7D 'relational problems' item]

Another participant focused on the importance of engaging the carer from the start with clear instructions.

> *…describing first of all within the last two weeks would be current. You could also ask people to list, to make them think about what they actually do, tell them to list the things they do without the person they're caring for. So, go to bingo, watch the television or whatever, yeah then break it down into socialising as well. Because it also jogs your mind a bit*. [Son 50-59, cares for mother with dementia, speaking about the CarerQoL-7D].

#### *7.4.2.4. Language*

Most participants found the language used in the measures to be clear and easy to understand.

> *I like the fact that they're very ordinary words and they're not laden with technicality, you know, which is good. So, it could have a general appeal and there aren't any language barriers in that respect.* [Daughter 60-69, cares for mother with dementia].

One participant commented on the vagueness of the term 'government' used in the CES 'assistance from organisations & government' item,

> *Okay, the government, does that mean the NHS? Define your terms, organisations, Age UK, Alzheimer's? Government, social services?* [Son 50-59, cares for mother with dementia]

while another participant struggled with the term 'love' used in the 'love, friendship and support' item of the ICECAP-A.

> *I also found the word quite a lot of love, you can have love from all sorts of different people, so I find that a bit…it's not exactly off putting but I just find, friendship and support, don't know, I found it easier to answer that one.* [Wife 60-69, cares for husband with dementia]

Connected to the language used in the measures, two participants took issue with how the questions were phrased negatively in the CarerQoL-7D measure.

> *…that's all negative isn't it. Relational problems with the care receiver, he/she is very demanding, he/she behaves differently, we have communication problems.* [Mother >80, cares for adult son with mental health condition]
>
> *So, it's like when you're marking students and it's got a double negative in, to check whether you're actually reading it, the same sort of feeling as here, and I found that less comfortable to do and I suspect other people might.* [Daughter 60-69, cares for mother with dementia]

### *7.4.2.5. Response options*

Many participants found the response options available in the measures appropriate while others struggled to select an answer from the given options,

> *I can understand that to analyse, and you've got to tick one box, it doesn't always cover your circumstance.* [Son 50-59, cares for mother with heart disease]

> *Some of them were quite difficult to select as to what actually fits.* [Father, cares for adult daughter with mental health condition]

some felt there was not enough choice,

> *…I mean they can't do an answer for everybody you know but sometimes you just think, well I'm not really that and I'm not really that.* [Father 50-59, cares for adult daughter with learning difficulties]

> *I wanted five boxes rather than four for a lot of them because I felt like I was between two* (enough) *and three* (some)*.* [Daughter 50-59, cares for mother with dementia, speaking about the ASCOT-Carer measure]

and others thought the response options were too similar to choose between them. These issues can be linked to the wider theme of the limitations of using any QoL measure to capture carer QoL.

> *I tended to go for the 'some' but sometimes, I would have put 'a little', I think. On some, I've ticked a couple of them* [laughter] *because they were kind of equal.* [Mother 70-79, cares for adult son with mental health condition, speaking about the CarerQoL-7D measure]

When asked if they found the response options appropriate, participants discussed the importance of providing context to their answers.

> *Not always, there was a lot of in between things that perhaps if you got just a line that you could put something in just to explain it because they are quite bland aren't they really.* [Wife 60-69, cares for husband with dementia]

> *There's nowhere to put if you want to answer differently. There's nothing there to put anything. So, if there was something that came up you might want to put it.* [Mother 70-79, cares for adult daughter with bone disease]

The theme of using a QoL measure to capture a moment in time was also discussed in the context of response options with one participant commenting that they would pick different options at different moments in time.

> *Most of the time I feel I have adequate encouragement and support but when things flare, I tend to be the lead of it and… then I would say I have some encouragement and support but not enough...* [Daughter 60-69, cares for mother with bone disease, speaking about the ASCOT-Care 'feeling supported & encouraged' item]

Another participant felt the questions asked and the response options given, encouraged them to engage with the task.

> …*it wasn't the case of just ticking one, one, one, one, one. It did make you think.* [Father 70-79, cares for adult son with mental health condition]

#### *7.4.2.6. Participants thoughts on each measure*

No measure obviously performed better than another in terms of practicality. When discussing the length of each measure, participants were happy with all five QoL measures. When discussing response options, participants discussed the difficulty of selecting just one box. This was discussed in relation to the measures in general, not as a critique of one measure. The issue of language and grouping of terms was discussed by participants in relation to the ICECAP-A 'love, friendship and support' item, and the CES 'support from organisations & government' item. Participants also indicated that the instructions provided in the CarerQoL-7D measure could be clearer, and the questions could be phrased more positively.

### ***7.4.3. Double counting***

This section presents evidence of an analysis of the potential for double counting when measuring carer QoL using the CES, CarerQoL-7D, ASCOT-Carer, ICECAP-A, and EQ-5D-5L. Double counting refers to a situation where the value of an item has been counted more than once. The issue of double counting is discussed in detail in Chapter 2. The participants' consideration of outcomes is described below under the sub-headings of financial losses, time losses, and care-recipient health or QoL.

#### *7.4.3.1. Financial losses*

When discussing financial losses with participants the goal was to establish if they had felt any financial impacts resulting from the caring role, and how they took this into consideration when answering the QoL measures. Most participants had not noticed any financial impacts. Amongst the participants who did feel a financial impact, many spoke about the impact financing the caring role had on other areas of their life, such as selling their house,

> *We had to sell the house, and then that's basically what's paying for it* [Daughter 50-59, cares for mother with dementia]

reducing their savings,

> *It would have been better if I'd been able to save more money when I was working.* [Mother >80, cares for adult son with mental health condition]

or using savings that were earmarked for other purposes.

> *…our grandchildren are now coming to the stage where we would...we've given them a little bit of money but nothing like we'd have liked to have done.* [Son 50-59, cares for mother with heart disease]

Other participants, when asked about the financial impact of caring, spoke about how they adapted their working hours to facilitate their caring responsibilities,

> *…I've had to change the pattern because I've gone part time it's meant that I've had more time to kind of fit everything in, so I have to do everything now.* [Daughter 50-59, cares for mother with dementia]

> *I was able to flex my hours around.* [Daughter 60-69, cares for mother with dementia].

However, when asked in a follow up question if they had considered these financial impacts when answering the QoL measures, each participant replied that they had not.

> *No. No, not at all.* [Father 70-79, cares for adult daughter with bone disease]

> *They're historical, it said currently, and I was trying to do as currently rather than looking backwards.* [Daughter 50-59, cares for mother with dementia]

#### *7.4.3.2. Time losses*

When discussing time losses with participants the goal was to establish if there had been an impact on their leisure activities or free time resulting from caring, and how this affected their answer when completing the QoL measures. Most participants had not noticed any time loss impacts. For the participants who did notice an impact on their leisure time, some spoke about how they had adapted their lives to the caring role,

> *… it's pretty much what drives everything that I do, because I don't do anything else…* [Son 50-59, cares for mother with heart disease]

while others spoke of the impact caring can directly have on their leisure time.

> *The bit that's the caring would be used, you know for something else if not…with the flare ups, then you perhaps don't go to your craft group or don't go to the choir or whatever you know.* [Daughter 60-69, cares for mother with bone disease]

Of the three participants who reported time losses, when asked if they considered these impacts when answering the measures, all replied that they had,

> *Oh yes.* [Husband >80, cares for wife]

with one participant highlighting the 'combining care tasks with daily activities' item of the CarerQoL-7D as a particular item they answered thinking about the impacts on their leisure activities:

> *Well, yes, I mean problems combining care tasks with daily activities.* [Husband >80, cares for wife]

#### *7.4.3.3. Care-recipient health or quality of life*

Each of the measures completed by participants asks them to consider their own QoL when selecting their answer. The potential for double counting could occur if participants considered the care recipient's QoL instead of their own. No participants in this study completed the QoL measures from the point of view of the care recipients QoL. However, one participant was initially confused over who they should be thinking about when answering the measures,

> *…so, my health, is it my health or his health, I don't know, is it mine?* [Father 50-59, cares for adult daughter with learning difficulties]

and another participant had to stop and remind themselves not to answer on behalf of the care-recipient.

> *it's just you're used to answering the questions about them, you're just in that mode, I think.* [Daughter 60-69, cares for mother with bone disease]

## 7.5. Summary

This chapter described the results for a qualitive study of the feasibility, content validity and face validity of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L and ICECAP-A. The chapter began by describing the characteristics of the 24 participants who consented to being interviewed. Section 7.3 outlined the results of the think-aloud analysis. The results are structured to look at the key issues by cognitive process, by QoL measure, by theoretical domain, and by care recipient condition. When considered by cognitive process, 58% of participants were judged as having one or more errors with one or more of the QoL outcome measures completed. The think-aloud analysis showed that no measure was completely without error. Of the care-related measures the CES was judged to be slightly more problematic with errors occurring in 6% of the measure items completed. This is compared to 5% of the CarerQoL-7D items and 4% of the ASCOT-Carer items. The results also show that participants struggled most with the 'fulfilment' domain. The CES, CarerQoL-7D and ICECAP-A all have one item within this domain and the results show that from the 44 measure items that were analysed, judged errors occurred in 11% (n=5).

The results from the semi-structured interview show that all five QoL measures were considered simple and feasible for use by participants. When asked to select their preferred measure from the three they completed most participants selected a CRQoL measure. They found these to be more comprehensive and that they got to the point of how caring impacts on their QoL in a way the EQ-5D-5L or ICECAP-A did not. The findings from this qualitative study, how they compare to related research, and how they move this field forward will be discussed in the next chapter.

# 8. Discussion

## 8.1. Introduction

This chapter discusses the empirical work on assessing the construct validity and responsiveness (Chapter 4 and 5) and the feasibility, content validity and face validity (Chapter 6 and 7) of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures. The psychometric performance of each QoL measure was investigated in a UK sample of informal carers of adults with dementia, recovery from stroke, mental health conditions, or rheumatoid arthritis. The findings from this empirical research are then placed in the context of the broader literature presented in Chapters 1-3.

This discussion chapter contains six sections. Section 8.2 summarises and synthesises the results of the quantitative and qualitative research conducted to assess the psychometric properties of the five QoL measures. Section 8.3 places these findings in the context of published research and Section 8.4 discusses the findings in greater detail using broad themes that emerged during the analyses. Section 8.5 reflects upon the strengths and weaknesses of the work, and in Section 8.6 the practical implications of this research, and areas for future research are discussed. The conclusion in Section 8.7 reiterates the rationale for this research, the key findings from the empirical work, and how this work adds to the field of research on including informal carers in economic evaluation.

## 8.2. Summary of findings

This study investigated, for the first time, the psychometric performance, in terms of validity and responsiveness, of different preference-based measures of carer QoL for different groups of informal carers. The study focused on the performance of one health-related (EQ-5D-5L), one wellbeing (ICECAP-A) and three care-related (CES, CarerQoL-7D, and ASCOT-Carer) QoL measures for capturing and measuring carer QoL for use in economic evaluation. The construct validity, responsiveness, feasibility, content validity, and face validity of each measure were investigated in informal carers of adults with dementia, recovery from stroke, mental health conditions, or rheumatoid arthritis. The results of this research are summarised in Table 8.1. This table highlights the implications of the results, and these will be discussed in later sub-sections of the discussion chapter. Taken together, the results of the quantitative and qualitative analyses indicate that each of the five QoL measures can, in general, be considered valid and feasible for use with informal carers in economic evaluation.

In tests of construct validity, the ASCOT-Carer was the least problematic of the three CRQoL measures. Of note, the results for the ICECAP-A were comparable to the ASCOT-Carer in tests assessing construct validity. No measure exhibited clear responsiveness to changes within a year in care recipient health status or hours of care provided per week. Each of the three care-related measures detected a slight gradient of effect in relation to change of hours of care provided per week. The change in QoL score was larger for the ASCOT-Carer, suggesting it is more responsive than the CES and CarerQoL-7D, although effect sizes were small.

In terms of feasibility, relatively few judged errors occurred in the think-aloud analysis and these errors were spread across the five QoL measures. Most judged errors that occurred were response process errors where the participant was unable to map their desired response onto the scale without introduction of error. Of note, when asked to select their preferred measure from the three they completed during the cognitive interview process, all participants, except for one, indicated a preference for a CRQoL measure. The majority (41%) selected the ASCOT-Carer, 35% chose the CES, and 18% of participants indicated a preference for the CarerQoL-7D. Finally, the results showed no major challenges with each measure in terms of content or face validity. The results from the content and face validity analysis provide rich, detailed data based on the participants perspectives and interpretations of the QoL measures and how effective they are at capturing the impact caring has on their QoL.

**Table 8.1.** Summary of validity and responsiveness analyses results for each QoL measure amongst informal carers of adults with dementia, recovery from stroke, mental health conditions, or rheumatoid arthritis

| | Measure | Key results | | Implications |
|---|---|---|---|---|
| **CRQoL measures** | **CES** | Convergent validity | Strongly correlated with CarerQoL-7D and ASCOT-Carer. | • In tests of construct validity the ASCOT-Carer was the least problematic measure and would be suitable for use across all conditions, and in particular with informal carers of stroke, mental health conditions, and rheumatoid arthritis. For informal carers of dementia, the highest number of significant associations was found with the CarerQoL-7D.<br>• In tests of feasibility and acceptability, for the CES, judged errors occurred in 6% (n=6) of items analysed. Majority (n=3) were for the 'fulfilment' item.<br>• The ASCOT-Carer was relatively more responsive to changes in QoL score than the CES and CarerQoL-7D for changes in hours of care provided per week.<br>• When asked to select their preferred measure, all participants, except for one, selected a CRQoL measure and majority of participants selected the ASCOT-Carer (41%) followed by the CES (35%). 18% of participants selected the CarerQoL-7D |
| | | Responsiveness | Slight gradient of effect detected for both change in hours of care per week and change in care recipient health status. | |
| | | Feasibility & acceptability | Judged errors occurred in 6% (n=6) of items analysed. Majority (n=3) were for the 'fulfilment' item. Judged errors for the individual conditions except for stroke. | |
| | | Preferred measure, n (%) | 6 (35) | |
| | **CarerQoL-7D** | Convergent validity | Strongly correlated with CES, ASCOT-Carer, and ICECAP-A. | |
| | | Construct validity | Large effect size and associations for constructs related to the care recipient. | |
| | | Responsiveness | Slight gradient of effect detected for both change in hours of care per week and change in care recipient health status. | |
| | | Feasibility & acceptability | Judged errors occurred in 5% (n=6) of items analysed. Majority (n=2) were for the 'support' item. Judged errors for each individual condition except for stroke. | |
| | | Preferred measure, n (%) | 3 (18) | |
| | **ASCOT-Carer** | Convergent validity | Strongly correlated with CES, CarerQoL-7D, and ICECAP-A. | |
| | | Construct validity | Larger effect size and stronger associations found compared with CES and CarerQoL-7D.<br>Most significant associations for each individual condition except for dementia. | |

| | | | | |
|---|---|---|---|---|
| | | Responsiveness | Larger gradient of effect compared with CES and CarerQoL-7D for change in hours of care per week.<br>Only measure to detect expected gradient of effect when health status did not change. | |
| | | Feasibility & acceptability | Judged errors occurred in 4% (n=5) of items analysed. Judged errors for each individual condition except for stroke. | |
| | | Preferred measure, n (%) | 7 (41) | |
| **HRQoL measure** | **EQ-5D-5L** | Convergent validity | Not strongly correlated with any of the other QoL measures. | • Tests of construct validity showed the EQ-5D-5L may be the suitable to use for informal carers of people with dementia. It also performed comparably with the ASCOT-Carer and ICECAP-A for mental health conditions.<br>• No participants selected it as their preferred measure indicating that HRQoL is a limiting measurement for informal carers. |
| | | Construct validity | Most significant associations (9 of 16) compared with the other measures for dementia. Comparable number of significant associations with the ASCOT-Carer and ICECAP-A for mental health conditions. | |
| | | Responsiveness | Only measure to not detect expected gradient of effect when hours of care decreased and when health status improved.<br>Only measure to detect expected gradient of effect when health status worsened. | |
| | | Feasibility & acceptability | Judged errors occurred in 3% (n=2) of items analysed. Both were for the 'pain/discomfort' item. | |
| | | Preferred measure, n (%) | 0 (0) | |
| **Wellbeing measure** | **ICECAP-A** | Convergent validity | Strongly correlated with CES, CarerQoL-7D and ASCOT-Carer. | • The scores for the CRQoL measures were significantly positively associated with the ICECAP-A indicating that better wellbeing is associated with more positive experiences of caregiving.<br>• The results for the ICECAP-A are comparable to the ASCOT-Carer in many tests of validity. |
| | | Construct validity | Most significant associations (11 of 16), same number as the ASCOT-Carer for stroke.<br>Comparable number of significant associations with the ASCOT-Carer and EQ-5D-5L for mental health conditions.<br>Comparable number of significant associations with the ASCOT-Carer for rheumatoid arthritis | |

| | | | |
|---|---|---|---|
| | Responsiveness | Slight gradient of effect detected for both change in hours of care per week and change in care recipient health status. | • Only one participants selected it as their preferred measure indicating it doesn’t capture carers QoL as comprehensively as a CRQoL measure. |
| | Feasibility & acceptability | Judged errors occurred in 6% (n=4) of items analysed. | |
| | Preferred measure, n (%) | 1 (6) | |

## 8.3. Findings compared to existing literature

### Care related QoL measures

When assessing the construct validity of the three CRQoL measures included for analysis the findings for each measure were consistent with the available literature in the field. McCaffrey [8] assessed the construct validity of the ASCOT-Carer, CES and CarerQoL-7D amongst a general population of informal carers and found that each measure performed reasonably well, with the ASCOT-Carer exhibiting the best psychometric properties overall. This is in keeping with the results from the quantitative analysis conducted in this thesis, which showed that in tests of construct validity the ASCOT-Carer was less problematic than the CES and CarerQol-7D, though each measure performed well. McCaffrey [8] also found that higher care-related scores were associated with lower hours of care provided per week for the ASCOT-Carer, CarerQoL-7D and CES. This aligns with the results from this thesis, where a statistically significant association with hours of care per week >20 was found for all measures.

The results from the responsiveness analysis conducted as part of this thesis show a slight gradient of effect in the CES, CarerQoL-7D, and ASCOT-Carer change score in terms of change in hours of care per week and change in care recipient health status, indicating some limited evidence of responsiveness. These results, although they provide limited evidence, help to address the dearth of information that currently exists of the responsiveness of these, or any CRQoL measures in the literature.

McCaffrey [8] and Hoefman [16] assessed the feasibility of the ASCOT-Carer, CES [8], and CarerQoL-7D [8, 16] amongst a general population of informal carers by assessing the percentages of respondents with missing values. McCaffrey [8] found that virtually all respondents completed each item on the instruments (ASCOT-Carer, 99.5 %; CarerQol-7D, 98.1%; CES, 98.9%), while Hoefman [16] found that approximately 3% did not answer at least one of the CarerQoL-7D dimensions. These findings differ slightly with the completion rates recorded in this thesis for the CRQoL measures. Taking the completion rate for all conditions pooled together from the baseline questionnaire, the ASCOT-Carer had the highest completion rate (95%) but the CES and CarerQoL had a lower completion rate of 88%.

Goranitis [18] listed as a potential limitation to their study, the fact that around 25% of individuals who reported being informal carers did not fully complete the CES measure. The authors questioned if some groups of informal carers feel certain questions on the CES do not apply to them [18]. While the completion rate for this thesis (88%) was not as low as that recorded by Goranitis, we can look at the breakdown of completion rate by condition and identify that for carers of people with dementia or recovery from stroke the completion rate was 90%, for carers of people with a mental health condition the completion rate was 89% and for carers of people with rheumatoid arthritis the completion rate was 87%. This would indicate that across the four conditions included in this analysis there was not a significant difference in completion rates.

In terms of content validity, a 2020 study which assessed these same psychometric properties in six preference-based measures within the context of dementia, amongst patients and their informal carers, found that informal carers discussed the importance of a sense of control [9]. This was also the case with the participants of the qualitative analysis in this thesis where participants who favoured the CES measure, chose it because it included items that impacted on their QoL, specifically fulfilment and control over caring. The findings from the face and content validity analyses in this thesis were in line with some more of the findings from Engel [9]. This study included the EQ-5D-5L, ASCOT, ICECAP-O and three dementia specific QoL measures (AQoL-8D, DEMQOL-U, AD-5D). There was no clear preference for one of the six measures explored and participants identified advantages and disadvantages across all measures [9]. This was also found to be the case in the qualitative analysis conducted for this thesis where participants did not always display a preference for any one outcome measure. Seven participants (29%) could not choose between the three measures they completed, or they had no preference. However, the results from Engel [9] showed that although particularly designed for individuals with dementia, dementia-specific QoL measures were not always favoured over non-specific measures. This is in slight contrast to the findings from this thesis. The results of the face and content validity analyses showed no major challenges for each of the five QoL measures indicating that participants did not favour one measure over another. However, when asked to indicate which measure they preferred, of the 17 participants who indicated a preference for one measure, 16 indicated a preference for a CRQoL measure.

## The ICECAP-A and EQ-5D-5L

Bhadhuri et al [12] was the only study identified that looked at the responsiveness of the EQ-5D-5L amongst informal carers. As with the results from this thesis, the authors found no clear evidence of responsiveness of the EQ-5D-5L. Engel et al [9] explored the content and face validity of the EQ-5D, along with the ASCOT, ICECAP-O and three dementia specific QoL measures (AQoL-8D, DEMQOL-U, AD-5D) in a population of informal carers. This study found that there was no clear preference for one of the six measures explored, and participants identified advantages and disadvantages across all measures. This is in keeping with the results from this thesis where participants did not always display a preference for any one outcome measure. Seven participants (29%) could not choose between the three measures they completed, or they had no preference. However, of those who did select a preferred measure, no participant chose the EQ-5D-5L.

Of the existing evidence identified only one study exploring feasibility did so using qualitative methods. Bailey et al [19] explored the feasibility of the EQ-5D-5L, ICECAP-A and ICECAP-SCM among close persons of people receiving palliative care. The error rates across the think-aloud study conducted by Bailey et al [19], and the results of this thesis are not dissimilar. Bailey [19] reported an error rate of 5.5% for the EQ-5D-5L, 4.5% for the ICECAP-SCM, and 5.5% for the ICECAP-A. In this thesis, an error rate of 3% for the EQ-5D-5L, and 7% for the ICECAP-A were recorded. Also, in terms of feasibility the ICECAP-A had a completion rate of 94%, comparable to the best performing CRQoL measure, the ASCOT-Carer with a completion rate of

95%. However, the EQ-5D-5L had the highest completion rate amongst the five QoL measures included for analysis (97%).

## 8.4. Explanation of findings

Chapters 1-3 explored the need for the evaluative space in economic evaluation to be broadened to include informal carers and set out associated challenges. Presently, in terms of resource allocation decision making, the evaluative scope is typically focused on the patient (or care recipient) as an isolated individual [56]. However, interventions designed to improve the health and wellbeing of the patient do not impact on the patient alone. This field of research is constantly advancing, and authors have argued for the need to include informal carer health, and other impacts, in economic analyses to consider "*the full spectrum of effects of disease on society*" [93]. Not taking informal care into consideration in economic evaluation might undervalue the economic value of informal care [23, 38, 80]. In turn it may also underestimate the costs and impacts of an intervention intended for the care recipient [93, 94]. The presentation of the conceptual, and methodological challenges associated with broadening the evaluative space explored in the first three chapters of this thesis allowed for the identification of areas that require specific attention. Specifically, to be included in economic evaluation in a way that is meaningful to decision makers we must strengthen our confidence in the ability of outcome measures used with informal carers, to be used in economic evaluation. This provided the rationale for the empirical research conducted in Chapters 4-7. In this section the principal findings of that empirical research will be described using broad themes that emerged during both the quantitative and qualitative analyses.

### *8.4.1. All QoL measures analysed are valid and feasible for use*

The question of whether the five QoL measures included in this analysis are valid and feasible for use in economic evaluations with informal carers is central to the research presented in this thesis.

The qualitative analysis provided an insight into how participants approached the QoL measures, and the type and nature of problems participants experienced when completing each measure. Overall, the results showed that participants found the five QoL measures to be easy to complete and relatively short compared to other forms they regularly complete. This may be because the analysis was conducted using five well established QoL measures. Each measure was developed using qualitative and quantitative methodology. They were developed specifically for use in economic evaluation and designed for use alongside the QALY in economic evaluation with the intention of providing additional information to standard methods.

The analysis found challenges existed in relation to face and content validity, but these were general issues related to the concept of QoL measurement rather than challenges specific to the QoL measures. The main issue participants discussed in relation to the QoL measures were based on what they perceived to be the limitations of using *any* QoL measure to capture the way caring impacts on their

QoL. Some participants believed the QoL measures were inherently limited and lacking in nuance. This theme emerged when participants discussed the relevance of individual items of the QoL measures, the response options available in the measures, and when they were discussing if they had any difficulty answering the questions thinking of the current moment in time.

None of the participants struggled to complete the measures and the content of the measures was considered acceptable in general to most participants. However, when asked to select their preferred measure from the three they completed most participants selected a care-related measure. They found these measures to be more comprehensive and that they got to the care of how caring impacts on their QoL in a way the EQ-5D-5L or ICECAP-A did not. This topic will be discussed in the section that follows, but from a practical point of view this may be because while each of the five QoL measures has qualitive testing built into its development the CES, CarerQoL-7D, and ASCOT-Carer specifically were developed using findings from qualitative research with informal carers [41] [127] [11].

### 8.4.2. Sensitivity of care-related QoL measures to carer QoL

As discussed in Chapter 2 HRQoL may be a limiting measurement as it does not capture the full impacts of providing informal care. Instead, focusing on care-related outcomes for informal carers may be appropriate as they map onto the issues important to them better than HRQoL. The key benefit of using the EQ-5D to measure carer QoL is that it can easily be combined with care recipient QoL.

However, as noted by Al-Janabi [125] "*there is nothing inherent in the QALY approach that requires life-years to be adjusted by a health-related QoL measure*".

The qualitative findings and quantitative results show that focusing on outcomes broader than health for informal carers is more appropriate and provides an endorsement for using CRQoL and wellbeing outcomes in economic evaluation. The face and content validity analysis shows that overall, no measure stood out as performing better than another measure. However, a strong theme running through the qualitative data was that participants viewed the CRQoL measures as capturing different information to that captured by the EQ-5D-5L and ICECAP-A. When the participants were asked to select their preferred measure of the three that they completed most participants favoured a CRQoL measure. Participants felt these measures engaged them as a carer, looked at the real issues for carers, and focused on their role as a carer. Of note, no participants selected the EQ-5D-5L and one participant selected the ICECAP-A. This participant was providing care for his wife who had died in the days preceding our interview and they found it difficult to answer questions directly related to their caring role. These results show the importance to participants of what the QoL measure focuses on. The QoL measures that were developed for use with carers, were each developed using findings from qualitative research with carers. Their focus is on outcomes specifically related to the carer and the caring role, and how this impacts on the carers' QoL. These results show that if the aim is to include carers in economic evaluation in a way that is meaningful and relevant to both carers and decision makers it is vital to focus on outcomes wider than health and wellbeing. This can be achieved by using a CRQoL measure.

The quantitative results support the opinions of participants. In terms of construct validity, across all conditions, of the three CRQoL measures, more statistically significant associations were found in relation to the ASCOT-Carer compared with the CES or the CarerQoL-7D. Of the other measures, the ICECAP-A exhibited greater construct validity than the EQ-5D-5L. The ASCOT-Carer and ICECAP-A were also comparable in the sense that larger effect sizes and stronger associations were detected for these measures, relative to the other measures, when the conditions were analysed separately. This result reinforces the idea that focusing on outcomes broader than health for carers is more appropriate. What was perhaps unexpected was that the results show that CRQoL measures were not always more sensitive to constructs hypothesised to be associated with QoL of carers. The ICECAP-A attributes are predominately psychosocial [250], and this could explain its comparative sensitivity to constructs associated with carer QoL.

Taken together, the results from the quantitative and qualitative analyses show that when including informal carers in economic evaluation the focus should ideally be on outcomes broader than health. This can be achieved by using a CRQoL measure (in particular, the ASCOT-Carer). However, of note, the ICECAP-A performed comparably to the ASCOT-Carer in many tests of validity and it may be considered as a ‘middle ground’ general wellbeing/QoL option that performs well with both patients and informal carers.

## 8.5. Strengths and limitations

This thesis reports the first assessment of the validity and responsiveness of the CES, CarerQoL-7D, ASCOT-Carer, EQ-5D-5L, and ICECAP-A for informal carers of adults with dementia, recovery from stroke, mental health conditions, or rheumatoid arthritis. In evaluating the strengths and weaknesses a number of aspects of the research are considered, related to the characteristics of participants, the methodology used, and the impacts of the researcher upon the research.

### *8.5.1. The characteristics of participants*

Participants were recruited to this research as they identified as providing informal care to an adult. To my knowledge none of the participants had extensive knowledge on the field of QoL measurement or in completing QoL outcome measures.

The FRS survey estimated that in 2020/21 informal carers aged 55-64 were most likely to care for others, with younger age groups generally less likely to provide care, and in most age groups, women were more likely to provide informal care than men. The characteristics of the participants involved in the quantitative and qualitative analyses conducted for this thesis support this data. Of the 573 eligible respondents for the quantitative analysis, 65% were female, and the average age of respondents was 62. Therefore, the opinions of participants in this research can be considered those of a typical population of adult informal carers in the UK.

Effort was made at the start of the cognitive interviews to ensure participants were comfortable sharing their views, that there were no 'wrong' answers and that their input and opinions were of great value to the research [139]. However, at times it was apparent that some participants sometimes stopped themselves from divulging too much private information. Of note with the qualitative analysis, participants who completed the cognitive interviews had already completed the five QoL measures twice, once for the baseline questionnaire and again for the responsiveness questionnaire. This means that each participant had some level of familiarity with the outcome measures, and this might have impacted on how they approached the think-aloud task and how they answered the questions asked in the semi-structured interview. To counter this effect participants were recruited from focus groups conducted as part of the wider programme of work to which this PhD project was linked [239].

Participants were recruited to this research as part of a wider programme of work conducted by the lead supervisor and funded through a NIHR career development fellowship. Although all aspects reported in the PhD were conducted by CM, identification, and recruitment of eligible informal carers for the PhD work was conducted as part of this wider project. Informal carers were initially identified by NatCen from the FRS as informal carers are difficult to identify in the community and recruit to research studies without bias in response [202, 203]. The sample of carers for this study was drawn across the (then) three most recent waves (2013/14, 2014/15 or 2015/16). Participants were sent the first questionnaire in October 2016 and the quantitative interviews were conducted between May and October 2018. As such, the sample does not include carers who are relatively new to the role. This may have had an impact on the overall results. For example, relative to a 'new' carer, the sample of carers included in this research may experience a frustration and exhaustion with their role over time that impacts negatively on their QoL. Conversely, because the sample of carer included in this research are established in their role, they may have made adaptations to their lifestyle over time that result in a positive impact on their QoL. As discussed in Chapter 2, the impact of providing care is considerable and multidimensional and can have both negative and positive impacts on the carers.

The quantitative analysis included 4 separate analyses. Two of the analyses included all informal carers who responded to the questionnaire. The remaining two analyses involved studying how the QoL measures performed for the individual conditions i.e., dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis. When divided into these conditions, the result was relatively small sub samples of carers for the individual conditions analysed. This reduced the power to detect associations between the overall measure scores and contextual constructs. With the responsiveness analysis, again the number of participants who responded to the responsiveness questionnaire is relatively small compared to the number who responded to the baseline questionnaire. This resulted in a relatively small sample size for the responsiveness analysis. This requires us to be relatively cautious in how the results of these analyses are interpreted and reported.

### *8.5.2. The methodology used*

The recruitment target for the cognitive interviews conducted as part of the qualitative analyses was 30 participants. The sample size was chosen after reviewing similar research projects which ranged from 6 participants [240, 241] to 56 [184]. The number of participants recruited for this thesis was 24, which fell just short of the recruitment target. As detailed in Chapter 6, 116 eligible respondents to the quantitative analysis indicated their willingness to take part in an interview. While extensive effort was made to recruit these respondents to the cognitive interview process, with potential participants being contacted by email and telephone, only 16 participants completed the interview. This is perhaps a limitation of the methodology chosen to recruit participants. However, it was decided to not pursue questionnaire participants further due to practical time and resource constraints in that the interviews were conducted across the UK by one person. Instead, additional participants were recruited from focus groups conducted as part of the wider programme of work to which this PhD project was linked [239]. This had the added advantage of gaining responses from carers who were not associated with the quantitative analysis and had not completed the QoL measures previously.

Data from the think-aloud exercise were coded and analysed using Tourangeau's model [242], adjusted in line with Murphy et al [243]. Tourangeau's theory identifies four cognitive tasks required when responding to a questionnaire: Comprehension, Retrieval, Decision, and Response. The retrieval process refers to how information is retrieved from memory. This was considered irrelevant for the measure being tested by Murphy et al as it refers to the current time [243]. Given that each of the measures being evaluated in this study ask the participant to consider their current situation, retrieval was replaced with a process Murphy et al called *"temporal comprehension"* [243]. This process addressed if the participant understood that the question was referring to the current period. Adjusting Tourangeau's model to ensured robustness in the analysis. In turn, this produced more meaningful results regarding the feasibility of the outcome measures.

The baseline questionnaire was piloted extensively through meetings with a lived experience advisory panel of five carers [228]. Panel members brought lived experience in providing informal care across dementia, recovery from stroke, and long-term mental health conditions for different family members. Panel members completed a draft version of the baseline questionnaire, and their feedback was discussed at a face-to-face meeting before being incorporated into the final version of the questionnaire. Members of the lay panel also provided feedback on the materials that were posted to participants such as information sheets, cover letters etc. This process was hugely beneficial in ensuring the material carers were receiving would be considered acceptable and user friendly. The cognitive interview process was also piloted with the lay panel, though only with three members, and only one time. Although feedback from panel members was incorporated into the final cognitive interview it may have proved beneficial to pilot the interview process with all five members of the panel, and to pilot it a second time once feedback had been incorporated. This would have the added advantage of gaining practice for CM and improving confidence.

The analysis included five preference-based QoL measures that can be used with informal carers. The selection of these measures was based on a review of the literature. The QoL measures chosen for analysis included a HRQoL measure (the EQ-5D-5L) along with three CRQoL measures (the CES, CarerQoL-7D, ASCOT-Carer) and one measure of wellbeing (ICECAP-A). Including five outcome measures ensured the results of this research provide, not only the first, but also an unarguably comprehensive, assessment of the validity and responsiveness of relevant outcome measures that can be used with informal carers.

The methodology and statistical analysis detailed in Chapter 4 and Chapter 6 used to test the validity and responsiveness of the QoL outcome measures was appropriate and has been used to test the psychometric properties of QoL measures in previous research [5-19]. This has the benefit of allowing the results to be easily interpreted in the context of past and future research. The methodology used for this analysis has a number of strengths. It has utilised best practice from established research techniques in the field of QoL measure validation [212]. First, it used a rigorous process of hypothesis formation to arrive at a comprehensive range of constructs through which the validity of the QoL measures could be assessed. These constructs focused on the carer, the care recipient, and the caring situation. These hypotheses were formed based on a thorough review of the relevant literature and they were confirmed for final testing by the supervisory team.

Establishing the validity and responsiveness of an outcome measure for a particular purpose is an ongoing process, requiring both qualitative and quantitative approaches. It is not possible to arrive at the level of 100% certainty, but it is possible to estimate the probability of having a valid and responsive instrument [168]. The use of a combination of qualitative and quantitative data in this thesis improves the evaluation of the five outcome measures by ensuring that the limitations of one type of data are balanced by the strengths of another [180]. The strengths of the quantitative methods used in this analysis are that they produce factual, reliable outcome data [180]. In contrast, the strengths of the qualitative methods employed in this analysis are that they generate rich, detailed data based on the participants perspectives and interpretations [180]. The main point of difference in quantitative and qualitative approaches can be said to be that qualitative studies try to answer questions about the 'what', 'how' or 'why' of a phenomenon, rather that questions about 'how many' or 'how much' [181]. This is evidenced in the results from the analyses conducted in this thesis where the construct validity and responsiveness analyses provide us with concrete data on the number of statistically significant associations, and gradients of effect. This data was analysed to indicate that the ASCOT-Carer and ICECAP-A were broadly comparable in terms of their psychometric performance. The qualitative methods in this thesis are then used to add depth and nuance to the overall evaluation. The data generated from this analysis indicated that participants favoured a CRQoL measure (in particular the ASCOT-Carer) as they found these to be more comprehensive and that they got to the care of how caring impacts on their QoL in a way the EQ-5D-5L or ICECAP-A did not. From this, we see how the use of both qualitative and quantitative data in this thesis improves the evaluation of the five outcome measures.

### *8.5.3. The impact of the researcher on the analysis*

The issue of the researcher's objectivity and if they are seen by participants as a neutral figure with no opinion on the research is a keenly debated topic in qualitative research [170]. In this situation it is likely that CM, as a researcher, had some unquantifiable effect on the information shared by participants and how that data was interpreted. Two influences that may have had some effect, CM's gender may have influenced how comfortable participants felt sharing the full extent of how their role as an informal carer has influenced their QoL, and CM's relative lack of experience of qualitative interviewing and data analysis may have influenced the quality of the data generated, and how it was interpreted. To limit this, CM completed a week long qualitative research course at the University of Birmingham, which provided a practical grounding for the interview conduct and analysis. The analysis was also conducted in close consultation with the supervisory team to ensure that no bias was present, and that the analysis was comprehensive. The transcripts of the first four interviews were reviewed by the supervisory team to check the interview style and ensure relevant data was being generated from participants. From this CM further developed a topic guide to better structure the discussion towards the topics under investigation while also allowing for a more general discussion on the QoL measures between CM and the participant.

As discussed in Section 8.3 many participants queried the relevance of using *any* QoL measure to capture the way caring impacts on their QoL. While some of the limitations are relevant to the outcome measures themselves, in the context of both the quantitative and qualitative research conducted, another limitation is how the point of the research is communicated to participants. To this end, an information sheet was created which was sent to participants along with both the baseline and follow-up questionnaire. This information sheet included details on what the research was about, outlining that we are trying to understand the best way of measuring the QoL of family carers. The information sheet explained that various questionnaires provide a snapshot of QoL by asking about different aspects of life and caring, and how in this study we are trying to understand which questionnaires work best. Before the qualitative interviews CM spoke with participants about the point of the research and answered any questions they had about the QoL measures in general and how they are used in research.

## 8.6. Practical implications of the findings and future research

This study investigated, for the first time, the psychometric performance of five preference-based measures of carer QoL in informal carers of adults across a range of chronic diseases. By not only exploring how the measures perform in ech disease area, but also how they perform relative to other QoL measures the results from this study can be considered robust and unbiased. The results therefore represent a comprehensive exploration of how carer QoL can be estimated and included in economic evaluation in a meaningful way in studies related to chronic conditions, but particularly dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis.

The findings from this thesis have several practical implications for economic evaluation and future research. Carer QoL is increasingly considered alongside patient (or care recipient) QoL in economic evaluation and research in this field is advancing on how we can value carer and patient QoL effects alongside one another [138]. As discussed in Chapter 2, the inclusion of informal care in economic evaluation is strongly conditioned by the rules that each country adapts or recommends, and the range of guidance reviewed showed a lack of uniformity in the methods recommended for including informal care in economic evaluation. Current guidelines for the UK [158] and France state that carer health effects should be considered where relevant. This perspective would allow for the use of a HRQoL measure such as the EQ-5D-5L with informal carers and care recipients. The guidelines for Canada [118] specifically recommend the inclusion of carer effects when relevant, and although informal carers are not specifically mentioned in the guidelines for America [149] [150], Australia [151], France [159], Germany [152], Ireland [153] and Italy [154], each country recommends a supplementary analysis can be conducted using a societal perspective. Likewise, the guidelines for the Netherlands [155], Sweden [156], and Denmark [157] recommend a societal perspective in the reference case analysis which would allow for the inclusion of carer impacts. This perspective would allow for the inclusion of the effects of informal care where relevant, be they measured using a HRQoL instrument, or supplementing/replacing this with a wider outcome measure that focuses on carer wellbeing or CRQoL. The findings from this thesis add to this field of widening the evaluative space by highlighting valid instruments to do this. It does not provide a perfect solution to this issue but rather drives the debate forward in such a way as to show that focusing on outcomes wider than health would mean that informal care can be included in economic evaluation in a more meaningful way for decision makers. If the focus is on health maximisation, the results suggest that the EQ-5D-5L has relatively encouraging validity as an outcome measure with informal carers. However, where there is more flexibility in the economic evaluation, the findings show that the ICECAP-A and measures of CRQoL (in particular, the ASCOT-Carer) could be included in addition or instead of a HRQoL measure, in view of their performance. The results of this thesis can also be built upon to judge how carer outcomes can be analytically considered alongside patient outcomes where the same outcome of interest is being measured (e.g. HRQoL) and also, where different units are being measured, for example HRQoL of the patient, and CRQoL of the carer. The results could be applied to future research by using both a HRQoL measure along with a wellbeing or CRQoL measure in studies involving informal carers and then comparing how the results impact on the overall cost-effectiveness. Aside from the issue of what outcome measure to use, and how best to aggregate care recipient and carer outcomes in economic evaluation, greater consideration needs to be given in future research to how to avoid double counting when incorporating information care in economic evaluation.

As detailed in Chapter 3, establishing the validity and responsiveness of an outcome measure is an ongoing process and no study can claim to arrive at the level of 100%

certainty [168]. There is, therefore, a general need for further study into the validity and responsiveness of each of the five QoL measures included in this thesis. The results from the responsiveness analysis highlight the need for further studies of the responsiveness of these five QoL measures amongst informal carers. The results show that no measure exhibited clear responsiveness to changes within a year in care recipient health status or hours of care provided per week. The mixed evidence on responsiveness may in part be due to the nature of the sample, and this is an area for further research. Only 57% of participants completed the 12-month follow-up questionnaire. Although this reflects the frequent transitions in and out of caring role, it does mean the sample for the responsiveness analysis is smaller and has a different composition from the construct validity sample. In addition to this, assessment of the responsiveness of these measures at different time points other than 12 months may yield more definitive results and would add greater context to the results of this thesis. Assessment of responsiveness amongst larger samples of informal carers, both in the UK and internationally would also enhance the findings from this thesis.

There are many options for future work in terms of both responsiveness and construct validity. The methodology detailed in Chapters 4 and 6 represents a rigorous and researched process that could be adapted and applied to any number of different disease areas and caring contexts, and it would be interesting to see if the findings from this thesis are broadly replicated in other contexts. Studies using different QoL measures and in different populations of informal carers will also add weight to the validity results presented in this thesis. For example, studies on the psychometric performance of these QoL measures in other disease contexts (for example, non-chronic conditions, a different section of chronic conditions, ageing in general), or amongst carers of different subgroups of the population (parents caring for children with chronic conditions for example), or in different countries.

The results from the qualitative analysis highlight the perceptions of participants when completing these five QoL measures. These results can be used to enhance future research. For example, the desire to provide context to their answers was raised in the semi-structured interviews as was the limitations of using any QoL measure to capture the impact caring has on QoL. These points could be considered in future semi-structured interviews with informal carers and adequate time and space should be provided for participants to discuss their attitudes and perceptions of the QoL measures they are completing, along with the more general task of completing QoL measures.

## 8.7. Conclusion

There is a growing interest in including in the evaluative scope in economic evaluation the wider, or spillover, effects of a given intervention on a patient’s informal carer(s). To include informal care in economic evaluation in a way that is meaningful to decision makers, we must be able to demonstrate confidence in the tools we use to measure and value carer impacts.

While the literature on the validity and responsiveness of outcome measures with informal carers is initially promising, there is still ambiguity over which outcome measure to use in economic evaluations that involve informal carers, and little is known about the relative performance of different QoL measures at measuring carer QoL across a range of common conditions. Similarly, evidence on the psychometric properties of preference-based health or wellbeing QoL measures with informal carers is limited.

The aim of this thesis was to address these gaps in our knowledge, through a comprehensive multi-instrument, multi-disease study of different psychometric properties. This was achieved through two distinct studies. They were:

- a quantitative study of the construct validity and responsiveness of the CES, CarerQoL-7D, ASCOT-Carer, ICECAP-A, and EQ-5D-5L amongst informal carers for adults with dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis
- a qualitative study of the feasibility, content validity and face validity of the CES, CarerQoL-7D, ASCOT-Carer, ICECAP-A, and EQ-5D-5L amongst informal carers for adults with dementia, recovery from stroke, mental health conditions, and rheumatoid arthritis.

Taken together, the results of the quantitative and qualitative analyses indicate that each of the five QoL measures can be considered valid and feasible for use with informal carers in economic evaluation. Where the focus is on health-related outcomes, this research supports the psychometric performance of the EQ-5D-5L with informal carers. However, the results show that when including informal carers in economic evaluation the focus should ideally be on outcomes broader than health. Focusing on care-related or wellbeing outcomes for informal carers were shown to be more appropriate as they map onto the issues important to carers better than HRQoL. The results from this research show that, when there is more flexibility in the economic evaluation, the ICECAP-A, and measures of CRQoL (in particular, the ASCOT-Carer) can be used in addition or instead of a HRQoL measure, in view of their performance.

# Appendices

## Appendix 1. Baseline questionnaire

UNIVERSITY OF
BIRMINGHAM

NHS
National Institute for
Health Research

# Family carers' quality of life

This questionnaire is part of a NHS-funded research study into family carers. We are interested in developing ways of including the carer perspective in healthcare decisions.

This research will test ways of measuring the quality of life of family carers of people with health problems. The findings from the research will help medical researchers and policy-makers to better consider carers' needs alongside those of patients in their work.

More information about the study can be found in the enclosed letter and information sheet.

**The questionnaire should take about 20 minutes to complete.**

**PLEASE RETURN THIS QUESTIONNAIRE IN THE ENCLOSED PRE-PAID ENVELOPE BY NOVEMBER 21st**

**For office use only:**

Study ID

Date returned

# SECTION A. Questions about the person you care for

**In this questionnaire we are interested in the care and support you provide for someone because of their illness or disability.**

**1. Who is the <u>main</u> person you currently care for?**

| | |
|---|---|
| Your parent (or parent-in-law) | 1 |
| Your husband, wife or partner | 2 |
| Your child | 3 |
| Your grandparent | 4 |
| Your brother or sister | 5 |
| Other (please state below) | 6 |

______________________________

**2. Is the person you care for female or male?**

| | |
|---|---|
| Female | 0 |
| Male | 1 |

**3. How old is this person** …… years

**4. Do you share a house with this person?**

| | |
|---|---|
| Yes | 0 |
| No | 1 |

**5. How many people share your house? (including you and, if relevant, the person you care for)**

_____ adults (18 or over)

_____ children (17 or under)

**6. Approximately how long have you been providing additional care and support for this person as a result of their illness or disability?**

_____ years and _____ months

**7. Please put a tick next to any specific difficulties that the person you care for has. (Please tick all that are applicable)**

| | | |
|---|---|---|
| **Cognitive Problems** | Orientation to time or place | 1 |
| | Remembering words | 2 |
| | Understanding simple instructions | 3 |
| | Attention or calculation | 4 |
| | Speaking sentences | 5 |
| | Recognition of familiar faces | 6 |
| **Daily Dependencies** | Feeding | 1 |
| | Bathing | 2 |
| | Grooming or dressing | 3 |
| | Toilet use or incontinence | 4 |
| | Transferring (moving in and out of bed or a chair) | 5 |
| | Mobility (on level surfaces) | 6 |
| | Using stairs | 7 |
| | Needs additional reassurance and motivation | 8 |

**8. What conditions does the person you care for live with?**

| | | |
|---|---|---|
| Dementia | (Please tick and move to question 8a) | 1 |
| After-effects of a stroke | (Please tick and move to question 8b) | 2 |
| A mental health condition | (Please tick and move to question 8c) | 3 |
| Rheumatoid arthritis | (Please tick and move to question 8d) | 4 |

Other: Please specify the condition and move to question 8e ____________________

**8a. Dementia**

**Has the person you care for been diagnosed with:**

| | |
|---|---|
| Alzheimer’s Disease | 1 |
| Vascular or Multi-Infarct Dementia | 2 |
| Dementia with Lewy Bodies | 3 |
| Frontotemporal Dementia | 4 |
| No clinical diagnosis received | 5 |

**Please put a tick next to any specific health difficulties that the person you care for has. (tick all that are applicable)**

| | |
|---|---|
| Mislaying or hiding items around the house | 1 |
| Forgetting recent conversations or events | 2 |
| Struggle to find the right word or keep track of conversation | 3 |
| Grasping new ideas and unwilling to try out new things | 4 |
| Losing track of the day or date | 5 |

| | |
|---|---|
| Withdrawal from friends and activities | 6 |
| Showing confusion about where they are or walking off | 7 |
| Unusual behaviour (e.g. agitation in social situations) | 8 |
| Delusions, paranoia or hallucinations | 9 |
| Struggle to carry out a familiar task (e.g. make a cup of tea) | 10 |

Other (please specify)

____________________________________________________________

**8b. Stroke**

**Did the person you care for experience a:**

| | |
|---|---|
| Ischaemic stroke (caused by a blockage) | 0 |
| Haemorrhagic stroke (caused by a bleed) | 1 |

**Please put a tick next to any specific health difficulties that the person you care for has. (tick all that are applicable)**

| | |
|---|---|
| Problems with co-ordination and balance | 1 |
| Sleep disturbance / difficulties | 2 |
| Changes to emotions e.g. feelings of misery or anxiety | 3 |
| Problems with swallowing | 4 |
| Visual problems e.g. double vision, reduced field of vision | 5 |
| Irritability or rudeness | 6 |
| Communication problems i.e. difficulty with speech and language | 7 |
| Overdependence | 8 |
| Muscle weakness or stiffness | 9 |
| Struggle to carry out a familiar task (e.g. make a cup of tea) | 10 |

Other (please specify)

____________________________________________________________

**8c. Mental health condition**

**Has the person you care for been diagnosed with:**

| | |
|---|---|
| Psychosis or Schizophrenia | 1 |
| Anxiety Disorder | 2 |
| Bipolar Disorder | 3 |
| Depression | 4 |

Other (please specify) ________________________________

If no clinical diagnosis has been received please specify the condition you think the person you care for is suffering from: ________________________________

**Please put a tick next to any specific health difficulties that the person you care for has. (tick all that are applicable)**

| | |
|---|---|
| Delusions, paranoia or hallucinations | 1 |
| Confused or racing thoughts | 2 |
| Diminished emotional expression | 3 |
| Inappropriate or unpredictable behaviour | 4 |
| Emotional withdrawal | 5 |
| Changes in sleeping patterns | 6 |
| Feelings of helplessness and hopelessness | 7 |
| Compulsive behaviour | 8 |
| Loss of energy | 9 |
| Reckless behaviour (e.g. substance abuse or gambling) | 10 |

Other (please specify)

________________________________________________________

### 8d. Rheumatoid arthritis

**Please put a tick next to any specific health difficulties that the person you care for has. (tick all that are applicable)**

| | |
|---|---|
| Sleep disturbance / difficulties | 1 |
| Pain and stiffness of affected joints | 2 |
| Loss of appetite or weight loss | 3 |
| Swelling of affected joints, joints become hot and tender to touch | 4 |
| Pinched or compressed nerves e.g. carpal tunnel syndrome | 5 |
| Skin complications e.g. rash, ulcers, blisters, lumps under the skin | 6 |
| Changes to emotions e.g. feelings of misery or anxiety | 7 |
| Struggle to carry out a familiar task (e.g. make a cup of tea) | 8 |

Other (please specify)

________________________________________________________

### 8e. Other conditions

**Please use text box below to list any specific health difficulties (e.g. sleep difficulties, changes to emotions, problems with coordination/ balance) that the person you care for has that were not included in question 7.**

**9. Under each heading please tick one box that you think best describes the health of the person you care for <u>today</u>.**

**MOBILITY**

They have no problems in walking about 1
They have slight problems in walking about 2
They have moderate problems in walking about 3
They have severe problems in walking about 4
They are unable to walk about 5

**SELF CARE**

They have no problems in washing and dressing themselves 1
They have slight problems in washing and dressing themselves 2
They have moderate problems in washing and dressing themselves 3
They have severe problems in washing and dressing themselves 4
They are unable to wash and dress themselves 5

**USUAL ACTIVITIES (e.g. work, study, housework, family or leisure)**

They have no problems in doing their usual activities 1
They have slight problems in doing their usual activities 2
They have moderate problems in doing their usual activities 3
They have severe problems in doing their usual activities 4
They are unable to do their usual activities 5

**PAIN/DISCOMFORT**

They have no pain or discomfort 1
They have slight pain or discomfort 2
They have moderate pain or discomfort 3
They have severe pain or discomfort 4
They have extreme pain or discomfort 5

**ANXIETY/DEPRESSION**

They have no anxiety or depression 1
They have slight anxiety or depression 2
They have moderate anxiety or depression 3
They have severe anxiety or depression 4
They have extreme anxiety or depression 5

**10. Compared to 12 months ago, how would you rate their health <u>today</u>?**

Much better than 12 months ago 1
Somewhat better than 12 months ago 2
About the same 3
Somewhat worse than 12 months ago 4
Much worse than 12 months ago 5

# Section B. Questions about any help or support you provide

**The questions in section B are about any <u>care</u> you provide for the person, <u>because of their illness or disability</u>.**

**1. In a typical week, please state roughly how many hours, on average, you spend on the activities below as a result of their illness or disability.**

Assisting the person with daily living ........................................... _____hours/week
*(e.g. helping with personal care, going to the toilet, eating, communication, moving around, therapy)*

Organisational support for the person affected............................ _____hours/week
*(e.g. help with outings, visits to health and care professionals, organising assistance, taking care of finances)*

Extra household activity............................................................... _____hours/week
*(e.g. additional work on food preparation, cleaning, laundry, home maintenance)*

Emotional support for the person affected.................................... ______hours/week
*(e.g. providing reassurance, motivation, encouragement, boosting morale)*

Other care activity (please state what the activities are below)..... _____hours/week

______________________________________________

______________________________________________

______________________________________________

<u>If the time spent on the above activities varies</u>, would you say it was, on average:

More than 20 hours per week 0
Less than 20 hours per week 1

**2. In this question, we are interested in the health and social care services this person receives from the NHS and other organisations and how this affects your life. Have any aspects of health and social care this person has received had a positive or negative effect on your own life?** (In answering this question, we understand that people are in different caring roles and will have different experiences of health and social care services. Please feel free to answer any questions that are relevant).

| Impact on your life: | Positive<br>↓ | Negative<br>↓ | Positive and negative<br>↓ |
|---|---|---|---|
| Changes in their medication | 1 | 2 | 3 |
| Physiotherapy, occupational therapy or other therapy | 1 | 2 | 3 |
| Co-ordination of their care | 1 | 2 | 3 |
| Social care in the person’s home (e.g. paid carer, equipment) | 1 | 2 | 3 |
| Social care outside the home (e.g. day centres) | 1 | 2 | 3 |
| Personal budgets (money paid to you to arrange care) | 1 | 2 | 3 |
| Admission as an inpatient to hospital care | 1 | 2 | 3 |
| Admission as an inpatient to respite care | 1 | 2 | 3 |
| Other (please specify below) | 1 | 2 | 3 |

_________________________________

*Please use text box below to tell us in more detail about how this person’s health or social care has had a positive or negative effect on your life (please feel free to use as many examples as you would like).*

**3. Do you regard yourself as the main person responsible for the care of this person?**

No 0
Yes 1

**4. Are any other people, other than you, involved in caring for this person?**

No 0
Yes 1

*(if yes, please indicate roughly how many hours below)*

Relatives or friends of the person affected _____hours per week
Paid carers _____hours per week

**5. Thinking about your <u>current</u> experience of caring for this person, please tick one box for each group to indicate which statement best describes your current caring situation.**

| | **No** | **Some** | **A lot of** | |
|---|---|---|---|---|
| I have | 1 | 2 | 3 | fulfillment with carrying out my care tasks |
| I have | 1 | 2 | 3 | relational problems with the care receiver *(e.g., he/she is very demanding; he/she behaves differently, we have communication problems)* |
| I have | 1 | 2 | 3 | problems with my own mental health *(e.g., stress, fear, gloominess, depression, concern about the future).* |
| I have | 1 | 2 | 3 | problems combining my care tasks with my daily activities *(e.g., household activities, work, study, family, and leisure activities).* |
| I have | 1 | 2 | 3 | financial problems because of my care tasks. |
| I have | 1 | 2 | 3 | support with carrying out my care tasks, when I need it *(e.g., from family, friends, neighbors, acquaintances)* |
| I have | 1 | 2 | 3 | problems with my own physical health *(e.g., more often sick, tiredness, physical stress).* |

**6. Again, thinking about your current experience of caring for this person, please tick one box for each group to indicate which statement best describes your current caring situation.**

**ACTIVITIES OUTSIDE CARING** *(Socialising, physical activity and spending time on hobbies, leisure or study)*

| | |
|---|---|
| You can do most of the other things you want to do outside caring | 1 |
| You can do some of the other things you want to do outside caring | 2 |
| You can do few of the other things you want to do outside caring | 3 |

**SUPPORT FROM FAMILY AND FRIENDS** *(Personal help in caring and/or emotional support from family, friends, neighbours or work colleagues)*

| | |
|---|---|
| You get a lot of support from family and friends | 1 |
| You get some support from family and friends | 2 |
| You get little support from family and friends | 3 |

**ASSISTANCE FROM ORGANISATIONS AND THE GOVERNMENT** *(Help from public, private or voluntary groups in terms of benefits, respite and practical information)*

| | |
|---|---|
| You get a lot of assistance from organisations and the government | 1 |
| You get some assistance from organisations and the government | 2 |
| You get little assistance from organisations and the government | 3 |

**FULFILMENT FROM CARING** *(Positive feelings from providing care, which may come from: making the person you care for happy, maintaining their dignity, being appreciated, fulfilling your responsibility, gaining new skills or contributing to the care of the person you look after)*

| | |
|---|---|
| You mostly find caring fulfilling | 1 |
| You sometimes find caring fulfilling | 2 |
| You rarely find caring fulfilling | 3 |

**CONTROL OVER THE CARING** *(Your ability to influence the overall care of the person you look after)*

| | |
|---|---|
| You are in control of most aspects of the caring | 1 |
| You are in control of some aspects of the caring | 2 |
| You are in control of few aspects of the caring | 3 |

***GETTING ON WITH THE PERSON YOU CARE FOR*** (Being able to talk with the person you look after, and discuss things without arguing)

| | |
|---|---|
| You mostly get on with the person you care for | 1 |

You sometimes get on with the person you care for 2
You rarely get on with the person you care for 3

**7. Finally, thinking about your <u>current</u> experience of caring for this person, please tick one box for each group to indicate which statement best describes your current situation.**

**Which of the following statements best describes how you spend your time?**
*When you are thinking about how you spend your time, please include anything you value or enjoy, including leisure activities, formal employment, voluntary or unpaid work, and caring for others.*
I’m able to spend my time as I want, doing things I value or enjoy 1
I’m able to do enough of the things I value or enjoy with my time 2
I do some of the things I value or enjoy with my time 3
I don’t do anything I value or enjoy with my time 4

**Which of the following statements best describes how much control you have over your daily life?**
I have as much control over my daily life as I want 1
I have adequate control over my daily life 2
I have some control over my daily life, but not enough 3
I have no control over my daily life 4

**Thinking about how well you look after yourself – such as, getting enough sleep or eating well – which statement best describes your present situation?**
I look after myself as well as I want 1
I look after myself well enough 2
Sometimes I can’t look after myself well enough 3
I feel I am neglecting myself 4

**Which of the following statements best describes how safe you feel?**
*By ‘feeling safe’ we mean feeling safe from fear of abuse, being attacked or other physical harm, such as accidents, which are a result of your caring role.*
I feel as safe as I want 1
Generally I feel adequately safe, but not as safe as I would like 2
I feel less than adequately safe 3
I don’t feel at all safe 4

**Thinking about how much contact you have with people you like, which of the following statements best describes your social situation?**

| | |
|---|---|
| I have as much social contact as I want with people I like | 1 |
| I have adequate social contact with people | 2 |
| I have some social contact with people, but not enough | 3 |
| I have little social contact with people and feel socially isolated | 4 |

**Thinking about the space and time you have to be yourself in your daily life, which of the following statements best describes your present situation?**

| | |
|---|---|
| I have all the space and time I need to be myself | 1 |
| I have adequate space and time to be myself | 2 |
| I have some of the space and time I need to be myself, but not enough | 3 |
| I don't have any space or time to be myself | 4 |

**Thinking about feeling supported and encouraged in your caring role, which of the following statement best describes your present situation?**

*This question is asking about* ***feeling*** *supported and encouraged, rather than how you are supported and encouraged by particular people or organisations.*

| | |
|---|---|
| I feel I have the encouragement and support I want | 1 |
| I feel I have adequate encouragement and support | 2 |
| I feel I have some encouragement and support, but not enough | 3 |
| I feel I have no encouragement and support | 4 |

# Section C. Questions about you

**The questions on this page are about you. All personal details will be treated in confidence.**

| | | |
|---|---|---|
| **1. Are you female or male?** | Female | 0 |
| | Male | 1 |
| **2. How old are you?** | _____ years old | |

**3. How would you describe your ethnicity?**

| | |
|---|---|
| White | 1 |
| Black or Black British | 2 |
| Asian or Asian British | 3 |
| Mixed (please specify below)<br>____________________ | 4 |
| Other (please specify below)<br>____________________ | 5 |

**4. What is your highest level of educational or technical qualification?**

| | |
|---|---|
| None | 1 |
| GSCE, O-level, NVQ level 1 or equivalent | 2 |
| AS-level, A-level, NVQ level 2 or equivalent | 3 |
| Degree level or equivalent | 4 |

**5. Which of these activities describes what you are doing at present? (Please tick all boxes that apply)**

| | |
|---|---|
| Paid employment (>30hrs per week ) | 1 |
| Paid employment (<30hrs per week) | 2 |
| Voluntary work | 3 |
| Looking after home & family | 4 |
| Full-time carer | 5 |
| Wholly retired from work | 6 |
| Unemployed and available for work | 7 |
| Self-employed | 8 |
| Permanently sick or disabled | 9 |
| In full-time education or training scheme | 10 |

**6. Have there been any impacts on your work or other activities, as a result of the illness, disability or care requirements of the person you care for?** (Please tick any that are applicable).

| | In the last 12 months<br>↓ | Prior to 12 months ago<br>↓ |
|---|---|---|
| I gave up work | 1 | 1 |
| I took time off work | 2 | 2 |
| I reduced my working hours | 3 | 3 |
| I missed promotion or job opportunities | 4 | 4 |
| I took a more flexible job | 5 | 5 |

**7. Please indicate which statements best describe your overall quality of life at the moment by placing a tick in ONE box for each of the five aspects of quality of life below.**

**Feeling settled and secure**

| | |
|---|---|
| I am able to feel settled and secure in **all** areas of my life | 4 |
| I am able to feel settled and secure in **many** areas of my life | 3 |
| I am able to feel settled and secure in **a few** areas of my life | 2 |
| I am **unable** to feel settled and secure in **any** areas of my life | 1 |

**Love, friendship and support**

| | |
|---|---|
| I can have **a lot** of love, friendship and support | 4 |
| I can have **quite a lot** of love, friendship and support | 3 |
| I can have **a little** love, friendship and support | 2 |
| I **cannot** have **any** love, friendship and support | 1 |

**Being independent**

| | |
|---|---|
| I am able to be **completely** independent | 4 |
| I am able to be independent in **many** things | 3 |
| I am able to be independent in **a few** things | 2 |
| I am **unable** to be at all independent | 1 |

**Achievement and progress**

| | |
|---|---|
| I can achieve and progress in **all** aspects of my life | 4 |
| I can achieve and progress in **many** aspects of my life | 3 |
| I can achieve and progress in **a few** aspects of my life | 2 |
| I **cannot** achieve and progress in **any** aspects of my life | 1 |

**Enjoyment and pleasure**

| | |
|---|---|
| I can have **a lot** of enjoyment and pleasure | 4 |
| I can have **quite a lot** of enjoyment and pleasure | 3 |
| I can have **a little** enjoyment and pleasure | 2 |
| I **cannot** have **any** enjoyment and pleasure | 1 |

**8. All things considered, how satisfied or dissatisfied are you with your life overall?**

**Completely dissatisfied** — **Completely satisfied**

0 1 2 3 4 5 6 7 8 9 10

**9. Under each heading, please tick the ONE box that best describes YOUR health today.**

**MOBILITY**

I have no problems in walking about 1
I have slight problems in walking about 2
I have moderate problems in walking about 3
I have severe problems in walking about 4
I am unable to walk about 5

**SELF CARE**

I have no problems in washing and dressing myself 1
I have slight problems in washing and dressing myself 2
I have moderate problems in washing and dressing myself 3
I have severe problems in washing and dressing myself 4
I am unable to wash and dress myself 5

**USUAL ACTIVITIES (e.g. work, study, housework, family or leisure)**

I have no problems doing my usual activities 1
I have slight problems doing my usual activities 2
I have moderate problems doing my usual activities 3
I have severe problems doing my usual activities 4
I am unable to do my usual activities 5

**PAIN/DISCOMFORT**

I have no pain or discomfort 1
I have slight pain or discomfort 2
I have moderate pain or discomfort 3
I have severe pain or discomfort 4
I have extreme pain or discomfort 5

**ANXIETY/DEPRESSION**

I have no anxiety or depression 1
I have slight anxiety or depression 2
I have moderate anxiety or depression 3
I have severe anxiety or depression 4
I have extreme anxiety or depression 5

# What happens next?

**Thank you for your answers. Before returning this survey please read the text below and complete the question about the follow-up study.**

As explained in the initial telephone interview, this is a two-part study. There is a follow-up questionnaire to find out how people's answers about their quality of life change over time. We are also conducting some interviews and focus groups to better understand specific issues relating to carers' quality of life.

We would like to know whether you would be willing to take part in an interview, focus group, or online survey. (There is no obligation if you tick a box below – it just means that we will contact you with further details about this research).

**I would be willing to be contacted by the University of Birmingham about taking part in (tick all that apply):**

| | |
|---|---|
| A face-to-face interview | 1 |
| A focus group | 2 |
| An online survey | 3 |

I understand that the information will be used only for the purposes set out in the statements above, and my consent is conditional upon the University complying with its obligations under the Data Protection Act. I understand that I am able to withdraw from the study at any time, without giving a reason.

Signature…………………………………… Date……………..

Name (please print)……………………………………………………………

Please put your contact email below if you would prefer us to get in touch via email about the interview, focus group, or online survey.

*Email address* ……………………………………………………………

**Please could you check that you have answered all the relevant questions and then return the questionnaire to us in the enclosed FREEPOST envelope.**

**Thank you very much for your valuable help in this research study.**

## Appendix 2. Follow-up questionnaire

UNIVERSITY OF BIRMINGHAM

NHS
National Institute for Health Research

# Family carers' quality of life

# Follow-up questionnaire

Last year, you completed a questionnaire as part of a two-part study into family carers. This follow-up questionnaire will help us see how people's answers about their quality of life change over time. This is important in assessing whether measures perform appropriately. More information about the study can be found in the enclosed letter and information sheet.

Please return the questionnaire even if you are no longer in a caring role or there have been no changes in your circumstances in the last year.

**The questionnaire should take about 10 minutes to complete.**

**PLEASE RETURN THIS QUESTIONNAIRE IN THE ENCLOSED PRE-PAID ENVELOPE BY NOVEMBER 16th**

**Thank you very much for your valuable help in this research study.**

**For office use only:**

Study ID

Date returned

# SECTION A. Questions about you

**1. Are you still providing care and support for someone because of their illness or disability?**

| | |
|---|---|
| Yes | 0 |
| No (please go to question 3) | 1 |

**2. If you answered yes to question 1, is the person you currently provide care for the same <u>main</u> person you were caring for when you completed the first questionnaire?**

(If you are unsure who you considered to be the main person you provided care for in the first questionnaire please contact us and we can check. Contact details are on the information sheet enclosed)

| | |
|---|---|
| Yes (please go to question 4) | 0 |
| No | 1 |

**3. If you answered no to question 1 or 2, please indicate the main reason for the change in circumstance**

| | |
|---|---|
| Care recipient's health has improved | 1 |
| Care recipient has moved into a care home | 2 |
| Care recipient has moved in with family | 3 |
| Care recipient is deceased | 4 |
| You are unable to provide care as a result of ill health | 5 |
| Other (please state below) | 6 |

**4. Under each heading, please tick the ONE box that best describes YOUR health today.**

**MOBILITY**

I have no problems in walking about 1
I have slight problems in walking about 2
I have moderate problems in walking about 3
I have severe problems in walking about 4
I am unable to walk about 5

**SELF CARE**

I have no problems in washing and dressing myself 1
I have slight problems in washing and dressing myself 2
I have moderate problems in washing and dressing myself 3
I have severe problems in washing and dressing myself 4
I am unable to wash and dress myself 5

**USUAL ACTIVITIES (e.g. work, study, housework, family or leisure)**

I have no problems doing my usual activities 1
I have slight problems doing my usual activities 2
I have moderate problems doing my usual activities 3
I have severe problems doing my usual activities 4
I am unable to do my usual activities 5

**PAIN/DISCOMFORT**

I have no pain or discomfort 1
I have slight pain or discomfort 2
I have moderate pain or discomfort 3
I have severe pain or discomfort 4
I have extreme pain or discomfort 5

**ANXIETY/DEPRESSION**

I have no anxiety or depression 1
I have slight anxiety or depression 2
I have moderate anxiety or depression 3
I have severe anxiety or depression 4
I have extreme anxiety or depression 5

**5. All things considered, how satisfied or dissatisfied are you with your life overall?**

| **Completely dissatisfied** | | | | | | | | | | **Completely satisfied** |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**6. Please indicate which statements best describe your overall quality of life at the moment by placing a tick in ONE box for each of the five aspects of quality of life below.**

**Feeling settled and secure**

| | |
|---|---|
| I am able to feel settled and secure in **all** areas of my life | 4 |
| I am able to feel settled and secure in **many** areas of my life | 3 |
| I am able to feel settled and secure in **a few** areas of my life | 2 |
| I am **unable** to feel settled and secure in **any** areas of my life | 1 |

**Love, friendship and support**

| | |
|---|---|
| I can have **a lot** of love, friendship and support | 4 |
| I can have **quite a lot** of love, friendship and support | 3 |
| I can have **a little** love, friendship and support | 2 |
| I **cannot** have **any** love, friendship and support | 1 |

**Being independent**

| | |
|---|---|
| I am able to be **completely** independent | 4 |
| I am able to be independent in **many** things | 3 |
| I am able to be independent in **a few** things | 2 |
| I am **unable** to be at all independent | 1 |

**Achievement and progress**

| | |
|---|---|
| I can achieve and progress in **all** aspects of my life | 4 |
| I can achieve and progress in **many** aspects of my life | 3 |
| I can achieve and progress in **a few** aspects of my life | 2 |
| I **cannot** achieve and progress in **any** aspects of my life | 1 |

**Enjoyment and pleasure**

| | |
|---|---|
| I can have **a lot** of enjoyment and pleasure | 4 |
| I can have **quite a lot** of enjoyment and pleasure | 3 |
| I can have **a little** enjoyment and pleasure | 2 |
| I **cannot** have **any** enjoyment and pleasure | 1 |

**Thank you for your answers. If you are no longer providing care and support for someone please return the questionnaire (having completed this section) to us in the enclosed FREEPOST envelope.**

**If you are still providing care and support for someone please complete the rest of the questionnaire.**

# Section B. Questions about the person you care for

**Please focus on the person you cared for last year or, if you are no longer providing care for this person, please focus on the main person you now provide care for.**

**1. Do you share a house with this person?**

| | |
|---|---|
| Yes | 0 |
| No | 1 |

**2. How many people share your house? (Including you and, if relevant, the person you care for)**

_____ adults (18 or over)
_____ children (17 or under)

**3. Please put a tick next to any specific difficulties that the person you care for has. (Please tick all that are applicable)**

| | | |
|---|---|---|
| **Cognitive Problems** | Orientation to time or place | 1 |
| | Remembering words | 2 |
| | Understanding simple instructions | 3 |
| | Attention or calculation | 4 |
| | Speaking sentences | 5 |
| | Recognition of familiar faces | 6 |
| **Daily Dependencies** | Feeding | 1 |
| | Bathing | 2 |
| | Grooming or dressing | 3 |
| | Toilet use or incontinence | 4 |
| | Transferring (moving in and out of bed or a chair) | 5 |
| | Mobility (on level surfaces) | 6 |
| | Using stairs | 7 |
| | Needs additional reassurance and motivation | 8 |

**4. Compared to 12 months ago, how would you rate their health today?**

| | |
|---|---|
| Much better | 1 |
| Somewhat better | 2 |
| About the same | 3 |
| Somewhat worse | 4 |
| Much worse | 5 |

**5. Under each heading please tick one box that you think best describes the health of the person you care for <u>today</u>.**

**MOBILITY**

| | |
|---|---|
| They have no problems in walking about | 1 |
| They have slight problems in walking about | 2 |
| They have moderate problems in walking about | 3 |
| They have severe problems in walking about | 4 |
| They are unable to walk about | 5 |

**SELF CARE**

| | |
|---|---|
| They have no problems in washing and dressing themselves | 1 |
| They have slight problems in washing and dressing themselves | 2 |
| They have moderate problems in washing and dressing themselves | 3 |
| They have severe problems in washing and dressing themselves | 4 |
| They are unable to wash and dress themselves | 5 |

**USUAL ACTIVITIES (e.g. work, study, housework, family or leisure)**

| | |
|---|---|
| They have no problems in doing their usual activities | 1 |
| They have slight problems in doing their usual activities | 2 |
| They have moderate problems in doing their usual activities | 3 |
| They have severe problems in doing their usual activities | 4 |
| They are unable to do their usual activities | 5 |

**PAIN/DISCOMFORT**

| | |
|---|---|
| They have no pain or discomfort | 1 |
| They have slight pain or discomfort | 2 |
| They have moderate pain or discomfort | 3 |
| They have severe pain or discomfort | 4 |
| They have extreme pain or discomfort | 5 |

**ANXIETY/DEPRESSION**

| | |
|---|---|
| They have no anxiety or depression | 1 |
| They have slight anxiety or depression | 2 |
| They have moderate anxiety or depression | 3 |
| They have severe anxiety or depression | 4 |
| They have extreme anxiety or depression | 5 |

**6. In the <u>next</u> 12 months, how do you anticipate their health changing?**

| | | |
|---|---|---|
| I expect them to get… | Much better | 1 |
| | Somewhat better | 2 |
| | About the same | 3 |
| | Somewhat worse | 4 |
| | Much worse | |

# Section C. Questions about any help or support you provide

**1. In a typical week, please state roughly how many hours, on average, you spend on the activities below as a result of their illness or disability.**

Assisting the person with daily living ............................................ _____hours/week
*(e.g. helping with personal care, going to the toilet, eating, communication, moving around, therapy)*

Organisational support for the person affected............................ _____hours/week
*(e.g. help with outings, visits to health and care professionals, organising assistance, taking care of finances)*

Extra household activity.............................................................. _____hours/week
*(e.g. additional work on food preparation, cleaning, laundry, home maintenance)*

Emotional support for the person affected................................... ______hours/week
*(e.g. providing reassurance, motivation, encouragement, boosting morale)*

Other care activity (please state what the activities are below)..... _____hours/week

_______________________________________________

If the time spent on the above activities varies, would you say it was, on average:

| | |
|---|---|
| More than 20 hours per week | 0 |
| Less than 20 hours per week | 1 |

**2. If you were not caring for this person, which of these activities would you spend your time doing? (Please tick all boxes that apply)**

| | |
|---|---|
| Paid employment (>30hrs per week) | 1 |
| Paid employment (<30hrs per week) | 2 |
| Voluntary work | 3 |
| Leisure activities | 4 |
| Caring for others | 5 |

**3. Thinking about your current experience of caring for this person, please tick one box for each group to indicate which statement best describes your current caring situation.**

|  | **No** | **Some** | **A lot of** |  |
|---|---|---|---|---|
| I have | 1 | 2 | 3 | fulfillment with carrying out my care tasks |
| I have | 1 | 2 | 3 | relational problems with the care receiver *(e.g., he/she is very demanding; he/she behaves differently, we have communication problems)* |
| I have | 1 | 2 | 3 | problems with my own mental health *(e.g., stress, fear, gloominess, depression, concern about the future)*. |
| I have | 1 | 2 | 3 | problems combining my care tasks with my daily activities *(e.g., household activities, work, study, family and leisure activities).* |
| I have | 1 | 2 | 3 | financial problems because of my care tasks. |
| I have | 1 | 2 | 3 | support with carrying out my care tasks, when I need it *(e.g., from family, friends, neighbors, acquaintances)* |
| I have | 1 | 2 | 3 | problems with my own physical health *(e.g., more often sick, tiredness, physical stress)*. |

**4. Again, thinking about your current experience of caring for this person, please tick one box for each group to indicate which statement best describes your current caring situation.**

**ACTIVITIES OUTSIDE CARING** *(Socialising, physical activity and spending time on hobbies, leisure or study)*

You can do most of the other things you want to do outside caring 1
You can do some of the other things you want to do outside caring 2
You can do few of the other things you want to do outside caring 3

**SUPPORT FROM FAMILY AND FRIENDS** *(Personal help in caring and/or emotional support from family, friends, neighbours or work colleagues)*

You get a lot of support from family and friends 1
You get some support from family and friends 2
You get little support from family and friends 3

**ASSISTANCE FROM ORGANISATIONS AND THE GOVERNMENT** *(Help from public, private or voluntary groups in terms of benefits, respite and practical information)*

You get a lot of assistance from organisations and the government 1
You get some assistance from organisations and the government 2
You get little assistance from organisations and the government 3

**FULFILMENT FROM CARING** *(Positive feelings from providing care, which may come from: making the person you care for happy, maintaining their dignity, being appreciated, fulfilling your responsibility, gaining new skills or contributing to the care of the person you look after)*

You mostly find caring fulfilling 1
You sometimes find caring fulfilling 2
You rarely find caring fulfilling 3

**CONTROL OVER THE CARING** *(Your ability to influence the overall care of the person you look after)*

You are in control of most aspects of the caring 1
You are in control of some aspects of the caring 2
You are in control of few aspects of the caring 3

***GETTING ON WITH THE PERSON YOU CARE FOR*** (Being able to talk with the person you look after, and discuss things without arguing)

You mostly get on with the person you care for 1
You sometimes get on with the person you care for 2
You rarely get on with the person you care for 3

**5. Finally, thinking about your current experience of caring for this person, please tick one box for each group to indicate which statement best describes your current situation.**

**Which of the following statements best describes how you spend your time?**
*When you are thinking about how you spend your time, please include anything you value or enjoy, including leisure activities, formal employment, voluntary or unpaid work, and caring for others.*

| | |
|---|---|
| I'm able to spend my time as I want, doing things I value or enjoy | 1 |
| I'm able to do enough of the things I value or enjoy with my time | 2 |
| I do some of the things I value or enjoy with my time | 3 |
| I don't do anything I value or enjoy with my time | 4 |

**Which of the following statements best describes how much control you have over your daily life?**

| | |
|---|---|
| I have as much control over my daily life as I want | 1 |
| I have adequate control over my daily life | 2 |
| I have some control over my daily life, but not enough | 3 |
| I have no control over my daily life | 4 |

**Thinking about how well you look after yourself – such as, getting enough sleep or eating well – which statement best describes your present situation?**

| | |
|---|---|
| I look after myself as well as I want | 1 |
| I look after myself well enough | 2 |
| Sometimes I can't look after myself well enough | 3 |
| I feel I am neglecting myself | 4 |

**Which of the following statements best describes how safe you feel?**
*By 'feeling safe' we mean feeling safe from fear of abuse, being attacked or other physical harm, such as accidents, which are a result of your caring role.*

| | |
|---|---|
| I feel as safe as I want | 1 |
| Generally I feel adequately safe, but not as safe as I would like | 2 |
| I feel less than adequately safe | 3 |
| I don't feel at all safe | 4 |

**Thinking about how much contact you have with people you like, which of the following statements best describes your social situation?**

| | |
|---|---|
| I have as much social contact as I want with people I like | 1 |
| I have adequate social contact with people | 2 |
| I have some social contact with people, but not enough | 3 |
| I have little social contact with people and feel socially isolated | 4 |

**Thinking about the space and time you have to be yourself in your daily life, which of the following statements best describes your present situation?**

| | |
|---|---|
| I have all the space and time I need to be myself | 1 |
| I have adequate space and time to be myself | 2 |
| I have some of the space and time I need to be myself, but not enough | 3 |
| I don’t have any space or time to be myself | 4 |

**Thinking about feeling supported and encouraged in your caring role, which of the following statement best describes your present situation?**
*This question is asking about **feeling** supported and encouraged, rather than how you are supported and encouraged by particular people or organisations.*

| | |
|---|---|
| I feel I have the encouragement and support I want | 1 |
| I feel I have adequate encouragement and support | 2 |
| I feel I have some encouragement and support, but not enough | 3 |
| I feel I have no encouragement and support | 4 |

**6. Have you given any unpaid help or worked as a volunteer for any type of local, national or international organisation or charity more than once in the last 12 months?** (This can include things like running events, participation in recreational groups and help with children’s schools)

| | |
|---|---|
| Yes | 0 |
| No | 1 |

**7. Generally speaking, would you say that most people can be trusted or that you need to be very careful in dealing with people?**

| | |
|---|---|
| Most people can be trusted | 0 |
| You can never be too careful when dealing with others | 1 |

# What happens next?

**Thank you for your answers.**

If you indicated in the first questionnaire that you would be willing to be contacted by the University of Birmingham about taking part in an interview, focus group, or online-survey we are very grateful and may be in touch with you in the future.

If you no longer wish to take part in any future research please contact the researcher, Carol McLoughlin, by telephone on [redacted] or by email at [redacted]

If your contact information have changed in the last 12 months please fill in the new information below.

**New postal address:** ____________________________________________

____________________________________________

____________________________________________

**New contact number:** ___________________________________________

**New email address:** ___________________________________________

**Please check that you have answered all the relevant questions and then return the questionnaire to us in the enclosed FREEPOST envelope.**

**Thank you very much for your valuable help in this research study.**

## Appendix 3. Baseline cover letter

UNIVERSITY OF
BIRMINGHAM

Institute of Applied Health Research

Public Health Building

University of Birmingham

Birmingham   B15 2TT

Dear

Family carers' quality of life

I am writing to invite you to take part in the first stage of our research on family carers – a postal survey about your caring role and 'quality of life'. Further details of the study can be found in the enclosed information sheet. We are very grateful for the interest you have shown in this research.

The findings from this research will help us to develop better ways of measuring family carers' quality of life. In turn, this will enable researchers and decision-makers to better understand what treatment and care would most improve carers' lives, in addition to patients' lives. We are working closely with a range of family carers as part of this project.

To take part we would like you to fill in the questionnaire and return it by November 21st in the enclosed pre-paid envelope. Please read the information sheet first, as it has important information about the study.

If you have any questions about the survey please contact Carol McLoughlin (the researcher), who will be happy to help, on [redacted] or email her at [redacted].

Thank you very much for your help.

Yours sincerely

Hareth Al-Janabi, Project Lead

University of Birmingham

## Appendix 4. Baseline information sheet

UNIVERSITY OF BIRMINGHAM

NHS
National Institute for Health Research

# Measuring family carers' quality of life

## *Information about the survey*

This information sheet provides answers to some questions you may have about the research. If you have any more questions please feel free to use the 'sources of help' listed in this information sheet.

### *What is this research about?*

We are trying to understand the best way of measuring the 'quality of life' of family carers. Various questionnaires provide a snapshot of quality of life by asking about different aspects of life and caring. In this study we are trying to understand which questionnaires work best. Specifically, we are surveying 1,000 carers to investigate how well some potential measures of 'care-related' quality of life work with family carers of people with health problems.

### *Why is this research important?*

Good measures of quality of life will mean that the impact of new treatments on carers' lives can be accurately recorded. This will help health researchers understand whether treatments bring additional benefit to carers' lives (in addition to patients' lives). This is useful for agencies like NICE who evaluate whether treatments can be funded on the NHS.

### *Why have I been chosen?*

You spoke to a researcher at NatCen and indicated you would be willing to take part in a survey about your quality of life. **We would like you to take part as long as you are currently providing any care or support for someone with health problems.**

### *What do I have to do?*

We would like you to complete a short questionnaire about your current caring circumstances. We expect that this survey will take about 20 minutes to complete. In one year we will post a follow-up questionnaire to you. If you have indicated an interest in an interview, focus group, or online survey we will contact you about this so please let us know if your contact details change.

Who is carrying out the research?

The University of Birmingham is carrying out the research. We are working in partnership with a panel of family carers. The National Institute for Health Research (NIHR), a major government body that pays for health research, has approved and funded the research.

## *Is the survey confidential?*

Yes. We take great care of the information we are given. Files containing identifiable information will be stored securely, with only the two researchers attached to this project having access to this file. When we write up the findings, we will not include any personal details. Your name and address will only be used to contact you about the follow-up study. The questionnaires will be stored in a locked filing cabinet at the University of Birmingham. In very rare instances researchers may encounter a situation during a field visit where something they see or hear gives them particular cause for concern. Such concerns may relate to immediate risk of harm or to illegal activity or behaviour which could harm the public. In such cases we may need to notify an appropriate third-party. Anonymised survey data may be made available to other researchers, but we will always check these are genuine research requests and we will never share any personal details.

## *What will be done with the information you collect?*

The answers from the surveys will be studied in detail at the University of Birmingham to determine whether the different quality of life questionnaires work well and are 'valid'. We will publish the findings for other scientists and researchers to use, present the findings at research events and to government bodies involved in making decisions about new treatments. A summary of the findings will be available on the University of Birmingham webpage: http://www.birmingham.ac.uk/research/activity/applied-health/research/healtheconomics/research/HEU-led-research-highlights.aspx

## *Is the survey compulsory?*

No, this is a voluntary survey, but we are contacting you because you indicated in the screening survey that you would be willing to help. The success of the research project depends on the goodwill of people like you. You are free to withdraw, and decide whether we can use the information you have provided to date. To withdraw please contact the study researcher (please see 'sources of help') by June 30th 2017. Taking part in this survey will not affect the care that you receive or your legal rights.

## *Sources of help*

If you have any questions about filling in the survey, please feel free to contact the researcher, Carol McLoughlin, by telephone on [redacted] or by email at [redacted] at the University of Birmingham.

If there is anything more generally that upsets you or you would like to know about sources of support, you may find the contacts below useful:

Carers Trust: support@carers.org The Samaritans: 08457 909090

## Just to recap…

1. *Please complete the questionnaire and indicate on the last page whether you are willing to be contacted about a follow-up interview, focus group, or online survey;*
2. *Please return the questionnaire in the pre-paid envelope;*
3. *We will then be in touch about the interview, focus group, online survey or the follow-up questionnaire.*

This study has been reviewed by the Science, Technology, Engineering & Mathematics Ethical Review Committee at the University of Birmingham Research.

## Appendix 5. Baseline thank you card

UNIVERSITY OF
BIRMINGHAM

Thank you for taking the time to complete and return the questionnaire on family care, Your contribution to this research is much appreciated.

In one year we will post a follow-up questionnaire to you. If you have indicated an interest in an interview, focus group, or online survey we will contact you about this so please call Carol on 0121 414 8319 if your contact details change.

With best wishes,

[redacted]

Hareth Al-Janabi      Carol McLoughlin

## Appendix 6. Baseline reminder card

UNIVERSITY OF
BIRMINGHAM

Recently a questionnaire was sent to you about family care.

If you have already completed and returned the questionnaire, please accept our sincere thanks. If not, we would be grateful if you could return the questionnaire by **XXX**.

If you did not receive a questionnaire, or it was misplaced, please call us on 0121 4148319 and we will send you a replacement pack.

With best wishes,

[redacted]

Hareth Al-Janabi Carol McLoughlin

## Appendix 7. Baseline 2nd stage cover letter

Informant's Name
Informant's Address

Institute of Applied Health Research
Public Health Building
University of Birmingham
Birmingham   B15 2TT

Date

Dear

**Family carers' quality of life**

Last Autumn we sent you a research questionnaire about family care. We have not heard back from you, and just in case the questionnaire was misplaced or forgotten, we have enclosed a replacement. We would be very grateful if you could return the questionnaire, or let us know if you are unable to take part.

To date we have received responses from over 60% of those we approached, but every response is important in helping us gain a deeper understanding of family care and quality of life. We would really value hearing from you, whether you provide round-the-clock care or occasional support from a distance.

To take part, please fill in the questionnaire and return it in the next couple of weeks, or as soon as you can, in the enclosed pre-paid envelope. Please read the information sheet first, as it has important information about the study.

If you have any questions about completing the survey or whether it is relevant to you, please call me on [redacted] or email me at [redacted]. I will be happy to help.

Yours sincerely

Carol McLoughlin
Research Associate
University of Birmingham

## Appendix 8. Call response sheet

### Measuring family carers' quality of life: survey calls

- Thank them for their response and record their name and study ID number (6 digit number on bottom right of questionnaire)

- If anyone is upset by the survey, they are directed (on the info sheet) to call Carers Trust (support@carers.org). If anyone is upset and needs general sources of support they are given a free call number for the Samaritans on the information sheet (08457 909090). If anyone has any questions about completing the survey they are asked to contact Carol.

- We want to encourage people, if at all possible, to complete what they can on the questionnaire and return it on the prepaid envelope.

- Even if people cannot answer some of the questions it is better that they complete what they can and return it, rather than do not return it. They can always write comments on the questionnaire to explain their answers/problems

- Some possible questions and answers are listed below. Some of this is covered by the information about the study in the enclosed information sheet. If in doubt please take a phone number and Carol will call them back as soon as possible. Please log all calls (whether resolved or otherwise) on the call sheet.

### QUESTION AND ANSWER

1. **AM I ELIGIBLE TO TAKE PART?** As long as you are over 18, you currently provide any care or support for someone aged 18 or over with health problems and you don't receive payment for your caring responsibilities.

2. **DON'T UNDERSTAND QUESTION.** If you are able to, please have a go at answering it (noting in the margin what the problem is). However, if you are still stick our researcher (Carol) would be happy to call you back and try and help. Or if you really do not want to answer one of the questions please leave it and answer what you can and return the questionnaire to us.

3. **DON’T WANT TO TAKE PART.** That’s fine. Please give us your name and/or ID number so we can make sure you will not be contacted about it again. Would you mind giving us the reason?

4. **DON’T HAVE TIME TO TAKE PART.** That’s fine. If you would like more time, feel free to return the survey when it is convenient to you. We will start studying them properly in January so ideally we need the response back by then. If you don’t want to take part, please let us have your name and/or ID number so we can make sure you will not be contacted about it again.

5. **WHAT IS THE STUDY ABOUT? WHAT IS THE INFORMATION USED FOR?** We’re looking at the impact your caring responsibilities have on your quality of life. We are going to study all the answers together to investigate how well some potential measures of ‘care-related’ quality of life work with family carers of people with health problems. We will write the findings up and present them to other researchers and policy-makers and. The findings will provide additional information that would support including the quality of life of carers in economic evaluation.

6. **A LOT OF THE QUESTIONS SEEM TO BE ASKING THE SAME THING.** The survey includes a number of slightly different measures so it may be that you’re asked the same thing in a slightly different manner. We’re trying to find out which measure works best so we’d appreciate you filling in all the questions on the survey.

7. **WHY IS THE NHS INSTERESTED IN THE QUALITY OF LIFE OF CARERS?** Good measures of quality of life will mean that the impact of new treatments on carers’ lives can be accurately recorded. This will help researchers understand whether treatment bring additional benefit to carers’ lives (in addition to patients’ lives). This is useful for agencies like NICE who evaluate whether treatments can be funded on the NHS.

8. **CARE RECIPIENT NO LONGER LIVES WITH ME.** We would still like to hear from you. We are interested in all types of support and care. Fill in what you feel is applicable to your situation at present.

9. **CARE RECIPIENT DIED.** We are very sorry to hear this and apologise for sending you this questionnaire. You can complete it if you feel comfortable doing so but are under no obligation.

10. **I SHARE CARING RESPONSIBILITIES WITH ANOTHER PERSON (SPOUSE/SIBLING/NEIGHBOUR) AND THEY WOULD LIKE TO COMPLETE THE SURVEY TOO.** We appreciate that X would like to complete the survey too but you have been identified through the NatCen screening process and we would like you to complete the survey on your own, thinking about your own role as a carer. (if they insist, get a name and address for the other carer and send them a survey)

11. **CAN WE JOINTLY FILL IN A QUESTIONNAIRE?** No. The questionnaire is designed to be filled in by one person only.

12. **I CARE FOR MORE THAN ONE PERSON. HOW SHOULD I COMPLETE THE QUESTIONNAIRE?** We can only include each carer once in this research. Please complete the questionnaire focusing on the care you provide for one person.

13. **SHOULD I FILL IT IN WITH THE CARE RECIPIENT?** No. Please try to complete the questionnaire on your own.

14. **IMMINENT CHANGE OF ADDRESS.** Please tell us so we can send next year's follow- up questionnaire to the right address.

15. **SOMETHING MISSING IN THE PACK.** Pack should contain 1 questionnaire, 1 pre-paid envelope, 1 information sheet and 1 cover letter. If anything is missing and you need it, please give us your ID number and we will send it to you.

# Appendix 9. Data entry protocol

## General

- Use the subscript numbers by the tick boxes
- Enter data as the respondent has written it. Keep the answers as they are on the survey, even if you don't think they make sense. If there is a word that is illegible, indicate using [999]
- If there are blank answers type '.'
- If the answer is illegible type '999'
- Use the notes fields at the end to record any issues, problems for discussion, or extra text
    - Use A NOTES to record problems on Section A
    - Use B NOTES to record problems on Section B
    - Use C NOTES to record problems on Section C
    - Use G NOTES to record any general issues or problems for discussion
- Tick off questionnaire (bottom right) and sort into ID number order
- Double check your work
- Save the spreadsheet

## Section A

5) If 'adults' or 'children' is left blank type '0'

6) Ditto (5) for 'years' or 'months'

8) Check multiple responses. If data is included under 'other' enter it as it is written. If no box is ticked and/or nothing is included in the 'other' text box, write 'NS' i.e. none specified.

8a) Some people have entered data here even if they didn't tick the dementia box in (8). Enter the data as it appears on the survey and flag it up in A notes

8b) – 8e) Ditto 8a

8a) – 8e) If the condition hasn't been ticked in (8) and no data has been entered in the subsequent section type '.'

## Section B

1) Enter number of hours per week as they list it. If they give a range enter the midpoint. If they say 'up to X' enter X and make a note. Convert to hours per week if

recorded in another way (e.g. 1hr per month, list as (1*12/52) = 0.23. Record '999' if hours are marked with no number (e.g. a 'yes', a tick, an 'x', or we are unable to compute the hours based on their text response e.g. "as and when needed"). If they leave any box blank enter it as a '.' If they write '0' enter as '0'. Enter details of completion issues in B notes.

2) If they leave any text option blank enter it as a '.' If data is included under 'other' and/or in the free text box enter it as it is written.

4) If they answered 'no' enter '.' for the next two boxes (hours per week). If they answered 'yes' enter '0' if they leave either of the next two boxes blank (hours per week)

### Section C

6) If they leave any box blank enter it as a '0' Enter details of completion issues in C notes.

8) Enter value marked to the nearest 0.5 (e.g. if respondent has ticked midway between 7 and 8 enter value as 7.5)

### Back page

- Record willingness to participate in future research
- Enter respondents name and email address if provided
- Enter date consent was given if provided

### Exclusion

Individual may be excluded for the following reasons:

- The care recipient is <18 years old
- The respondent is <18 years old
- The respondent is not currently providing care (e.g. care recipient is now deceased or has moved into residential care)

Make a note in G NOTES if you think the respondent should be excluded and explain why.

## Appendix 10. Data cleaning protocol

### General

- Anonymise the database
- Flag if we received responses from carers living together and/or caring for the same person (general notes)
- Flag if the respondent is caring for somebody who lives in residential care (create new variable)
- Flag if the respondent is caring for more than one person (create new variable)
- If the respondent answered for more than one care recipient, go with what makes the most sense from the questionnaire i.e. who did they focus their answers on
- Exclude if: the care recipient is under 18, the respondent is under 18, the respondent is caring for themselves only, the care recipient is deceased
- Double check your work
- Save the spreadsheet as 'data entry_clean'

### Section A

1) If 'other' has been ticked and in the free text they wrote a relation indicated in one of the given options (parent, husband etc.) enter it as the box they should have ticked

4) Turn yes into 1 and no into 0

5) If 'yes' has been ticked in Q4 but they wrote "1" for number of adults in Q5, enter as "2"

8) If they have ticked more than one condition or answered for more than one condition, check the NatCen data, see what they entered here and amend the spreadsheet accordingly e.g. they ticked dementia, but answered for dementia and stroke. The NatCen data file shows they said they care for somebody with dementia and stroke. For the clean spreadsheet tick dementia and stroke.

8a) – 8e) If they have entered data here without ticking the condition in (8) and they didn't indicate the condition to NatCen look at what the difficulties they have ticked:

- If they have ticked the same/a similar difficulty under the main condition, ignore
- If they have ticked a difficulty that could feasibly relate to the main condition, include under the main condition 'other difficulties'
- If they have entered free text in 8e) that relates to the main condition, enter under the main condition 'other difficulties'

- If they have ticked difficulties for a condition they haven't ticked in (8), hasn't been indicated to NatCen, or the difficulty ticked cannot feasibly be related to their main condition, tick the condition in (8)

**Section B**

1) If the sum of hours spent on daily living, organisational support, extra household activity, and other care activities is greater than 168 hours use ratios. Treat emotional support as a separate activity per week i.e. if the respondent entered 168 hours keep it as this. For 'other care activity' if the respondent indicated a care activity that is included in the other options remove it from the free text. If they leave any option blank enter as '0'
2) Create new variable: relevant yes/no. If they leave any option blank enter as '.'
4) If they answered 'no' but wrote how many hours in the subsequent question enter as 'yes'. If they answered 'yes' enter '0' if they leave one of the next two boxes blank. If they answered 'yes' but left the next two boxes blank enter as '.'
5) If they didn't answer any part enter as '.'. If they ticked a box but changed the corresponding text or included text beside the ticked box (e.g. "none") enter the box as ticked. If they wrote text (e.g. "none") and didn't tick a box, or they created their own box and ticked it, enter as '999'. Create new variable flagging completion issues
6) Ditto (5)
7) Ditto (5)

**Section C**

3) If they answered 'other' and wrote in the free text one of the given options, enter it as the option they should have ticked
4) If they ticked more than one box enter the highest qualification. If they didn't tick a box but gave a text answer enter as '.'
6) For 'I gave up work', if they ticked yes under 'in the last 12 months' and 'prior to 12 months ago', enter as 'prior to 12 months ago' only
7) Ditto Section B (5)

## Appendix 11. Follow-up cover letter

UNIVERSITY OF
BIRMINGHAM

Institute of Applied Health
Research
Public Health Building
University of Birmingham
Birmingham   B15 2TT

Dear

**Family care and quality of life**

Last year we sent you a research questionnaire about family care. Thank you for taking the time to complete it, your contribution to this research is much appreciated. **For the second stage of our research on family carers we would like you to complete the enclosed follow-up questionnaire and return by X.**

This second questionnaire will help us understand how and when carers' lives change in response in certain events and study the best way of measuring these changes. As we produce findings you can follow these at www.birmingham.ac.uk/care-econ.

Please complete the questionnaire even if the circumstances of your caring role have not changed. If you are no longer providing care for someone complete section A and return the questionnaire.

The information sheet has important information about the study, please read it first. If you have any questions about completing the survey please call me on [redacted] or email me at [redacted].

Yours sincerely

Carol McLoughlin
Research Associate
University of Birmingham

## Appendix 12. Follow-up information sheet

UNIVERSITY OF BIRMINGHAM

NHS
National Institute for Health Research

# Measuring family carers' quality of life

## *Information about the follow up survey*

This information sheet provides answers to some questions you may have about the research. If you have any more questions please feel free to use the 'sources of help' listed in this information sheet.
What is this research about?

We are trying to understand the best way of measuring the 'quality of life' of family carers. Various measures provide a snapshot of quality of life by asking about different aspects of life and caring. This follow up questionnaire will help us understand how and when carers' lives change and study the best way of measuring these changes.

### *Why is this research important?*

Good measures of quality of life will mean that the impact of new treatments on carers' lives can be accurately recorded. This will help health researchers understand whether treatments bring additional benefit to carers' lives (in addition to patients' lives). This is useful for agencies like the National Institute for Health and Care Excellence (NICE) who evaluate whether treatments can be funded on the NHS.

### *Why have I been chosen?*

You completed the first questionnaire 12 months ago about your quality of life and returned it to us.

### *What do I have to do?*

We would like you to complete a short questionnaire about your current caring circumstances. We expect that this survey will take about 10 minutes to complete. At the end there is a question about taking part in future research, this is voluntary and you are free to withdraw at any stage.
Who is carrying out the research?

The University of Birmingham is carrying out the research. We are working in partnership with a panel of family carers. The National Institute for Health Research (NIHR), a major government body that pays for health research, has approved and funded the research.

### *Is the survey confidential?*

Yes. We take great care of the information we are given. Files containing identifiable information will be stored securely, with only the two researchers attached to this project having access to this file. When we write up the findings, we will not include any personal details. Your name and address will only be used to contact you about the follow-up study. The questionnaires will be stored in a locked filing cabinet at the University of Birmingham. In very rare instances researchers may encounter a situation during a field visit where something they see or hear gives them particular cause for concern. Such concerns may relate to immediate risk of harm or to illegal activity or behaviour which could harm the public. In such cases we may need to notify an appropriate third-party. Anonymised survey data may be made available to other researchers, but we will always check these are genuine research requests and we will never share any personal details.

***What will be done with the information you collect?***

The answers from the surveys will be studied in detail at the University of Birmingham to determine whether the different quality of life questionnaires work well and are ‘valid’. We will publish the findings for other scientists and researchers to use, present the findings at research events and to government bodies involved in making decisions about new treatments. A summary of the findings will be available on the University of Birmingham webpage www.birmingham.ac.uk/care-econ.

***Is the survey compulsory?***

No, this is a voluntary survey, but we are contacting you because you indicated in the screening survey that you would be willing to help and you completed the first questionnaire. The success of the research project depends on the goodwill of people like you. You are free to withdraw, and decide whether we can use the information you have provided to date. You can withdraw until March 1st 2018 by contacting the study researcher (please see ‘sources of help’). Taking part in this survey will not affect the care that you receive or your legal rights.

## *Sources of help*

If you have any questions about filling in the survey, please feel free to contact the researcher, Carol McLoughlin, by telephone on [redacted] [redacted] [redacted] or by email at [redacted] at the University of Birmingham. If there is anything more generally that upsets you or you would like to know about sources of support, you may find the contact below useful:

Carers Trust: support@carers.org

The Samaritans: 08457 909090

## Just to recap…

Please complete the questionnaire even if the circumstances of your caring role have not changed. If you are no longer providing care for someone complete section A;

Please return the questionnaire in the pre-paid envelope;

*We will then be in touch about the interview, focus group or the online survey.*

This study has been reviewed by the Science, Technology, Engineering & Mathematics Ethical Review Committee at the University of Birmingham Research.

**Thank you for reading this. This information sheet is for you to keep.**

## Appendix 13. Follow-up thank you postcard

UNIVERSITY OF
BIRMINGHAM

Thank you for taking the time to complete and return the questionnaire on family care. Your contribution to this research is much appreciated.

If you have indicated an interest in an interview, or online survey we will contact you about this so please call Carol on 0121 414 8319 if your contact details change.

With best wishes,

[redacted]

## Appendix 14. Follow-up reminder postcard

UNIVERSITY OF
BIRMINGHAM

Recently a questionnaire was sent to you about family care.

If you have already completed and returned the questionnaire, please accept our sincere thanks. If not, we would be grateful if you could return the questionnaire by **XXX**.

If you did not receive a questionnaire, or it was misplaced, please call us on 0121 4148319 and we will send you a replacement pack.

With best wishes,

[redacted]

Hareth Al-Janabi     Carol McLoughlin

# Appendix 15. Quantitative analysis 2 results: Measure score – individual conditions

**Table 15.1.** Univariable associations and effect sizes between QoL measure scores (Dementia) and contextual variables

|  |  |  | CES |  | CarerQoL-7D |  | ASCOT-Carer |  | EQ-5D-5L (carer) |  | ICECAP-A |  |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
|  | **Contextual variable** | **n=** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** |
| **Carer** | Age | 151 | -0.04 |  | -0.01 |  | -0.04 |  | -0.19* |  | -0.04 |  |
|  | Gender, female | 154 | -1.26 | -0.24 | -2.71** | -0.51 | -1.72 | -0.31 | -0.75 | -0.13 | -1.56 | -0.28 |
|  | Self-rated health status (EQ-5D-5L) | 151 | 0.18* |  | 0.51*** |  | 0.42*** |  | n/a |  | 0.55*** |  |
|  | Employment status, paid employment | 152 | 0.94 | 0.18 | 0.47 | 0.09 | 0.15 | 0.03 | 1.67 | 0.30 | 0.28 | 0.05 |
|  | Self-rated life satisfaction | 151 | 0.60*** |  | 0.67*** |  | 0.84*** |  | 0.46*** |  | 0.83*** |  |
| **Care recipient** | Age | 147 | 0.05 |  | 0.05 |  | 0.06 |  | 0.05 |  | 0.10 |  |
|  | Gender, male | 155 | 0.38 | 0.07 | -1.32 | -0.25 | -1.29 | -0.23 | -0.78 | -0.14 | -1.69 | -0.31 |
|  | Cognitive difficulties & daily dependencies | 155 | -0.06 |  | -0.45*** |  | -0.36*** |  | -0.26** |  | -0.39*** |  |
|  | Health status (EQ-5D-5L) | 133 | 0.03 |  | 0.35*** |  | 0.28** |  | 0.34*** |  | 0.33*** |  |
|  | Direction of health status, declining | 153 | -1.91 | -0.43 | -1.05 | -0.24 | -1.52 | -0.35 | -0.19 | -0.04 | -0.60 | -0.14 |
| **Caring situation** | Co-residence | 154 | -4.15*** | -0.73 | -2.74** | -0.50 | -5.02*** | -0.87 | -2.85** | -0.49 | -3.95*** | -0.70 |
|  | Relationship, spouse | 155 | -1.36 | -0.26 | -1.83 | -0.36 | -2.09* | -0.39 | -2.28* | -0.42 | -2.70** | -0.51 |
|  | Duration of caring (months) | 154 | -0.10 |  | -0.26** |  | -0.20* |  | -0.15 |  | -0.21** |  |
|  | Hours of care per week >20 | 151 | -4.23*** | -0.73 | -3.82*** | -0.67 | -6.76*** | -1.13 | -4.43*** | -0.73 | -5.23*** | -0.88 |
|  | Provides personal care | 130 | -0.97 | -0.18 | -1.62 | -0.31 | -2.65** | -0.49 | -2.64** | -0.48 | -1.69 | -0.31 |
|  | Main carer | 149 | -3.94*** | -0.72 | -2.87** | -0.53 | -5.26*** | -0.93 | -2.35* | -0.41 | -5.06*** | -0.89 |
|  | Involvement of others | 152 | 2.51* | 0.52 | 1.44 | 0.31 | 1.80 | 0.36 | 0.96 | 0.19 | 2.02* | 0.42 |

CC: Correlation Coefficient *significant (in the expected direction) at the 0.05 significance level; ** significant (in the expected direction) at the 0.01significance level; *** significant (in the expected direction) at the 0.001 level

**Table 15.2.** Univariable associations and effect sizes between QoL measure scores (Stroke) and contextual variables

| | | | CES | | CarerQoL-7D | | ASCOT-Carer | | EQ-5D-5L (carer) | | ICECAP-A | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Contextual variable** | **n=** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** |
| **Carer** | Age | 88 | 0.01 | | 0.22 | | -0.08 | | -0.04 | | -0.01 | |
| | Gender, female | 89 | -0.95 | -0.30 | -2.19* | -0.54 | -1.17 | -0.27 | -0.75 | -0.17 | -1.01 | -0.23 |
| | Self-rated health status (EQ-5D-5L) | 87 | 0.25* | | 0.49*** | | 0.48*** | | n/a | | 0.50*** | |
| | Employment status, paid employment | 89 | 0.09 | 0.20 | -0.78 | -0.18 | -1.06 | -0.24 | 0.71 | 0.16 | -0.74 | -0.17 |
| | Self-rated life satisfaction | 86 | 0.64*** | | 0.66*** | | 0.88*** | | 0.49*** | | 0.87*** | |
| **Care recipient** | Age | 83 | 0.04 | | 0.01 | | 0.12 | | 0.27* | | 0.20 | |
| | Gender, male | 88 | -1.15 | -0.26 | -1.61 | -0.37 | -1.62 | -0.35 | -0.28 | -0.06 | -1.50 | -0.33 |
| | Cognitive difficulties & daily dependencies | 89 | -0.31** | | -0.41*** | | -0.48*** | | -0.26** | | -0.44*** | |
| | Health status (EQ-5D-5L) | 76 | 0.03 | | 0.20 | | 0.25* | | 0.22 | | 0.25* | |
| | Direction of health status, declining | 89 | -0.95 | -0.22 | -1.95* | -0.47 | -2.98** | -0.67 | -1.55 | -0.35 | -2.61** | -0.59 |
| **Caring situation** | Co-residence | 89 | -3.11** | -0.70 | -1.76 | -0.40 | -3.38** | -0.73 | -1.30 | -0.28 | -2.75** | -0.60 |
| | Relationship, spouse | 89 | -1.98* | -0.48 | -1.66 | -0.39 | -2.47* | -0.55 | -1.82 | -0.41 | -2.85** | -0.64 |
| | Duration of caring (months) | 87 | -0.23* | | -0.18 | | -0.23* | | -0.25* | | -0.23* | |
| | Hours of care per week >20 | 89 | -3.38** | -0.76 | -3.09** | -0.71 | -5.21*** | -1.14 | -3.38** | -0.73 | -4.65** | -1.02 |
| | Provides personal care | 82 | -1.07 | -0.29 | -0.24 | -0.06 | -2.06* | -0.53 | -0.78 | -0.20 | -1.40 | -0.36 |
| | Main carer | 87 | -2.70** | -0.66 | -2.65** | -0.65 | -2.92** | -0.69 | -0.89 | -0.21 | -2.45* | -0.58 |
| | Involvement of others | 88 | 2.67** | 0.70 | 2.80** | 0.73 | 1.54 | 0.38 | 1.25 | 0.31 | 2.09* | 0.51 |

CC: Correlation Coefficient *significant (in the expected direction) at the 0.05 significance level; ** significant (in the expected direction) at the 0.01significance level; *** significant (in the expected direction) at the 0.001 level

**Table 15.3.** Univariable associations and effect sizes between QoL measure scores (Mental health condition) and contextual variables

| **Contextual variable** | | | **CES** | | **CarerQoL-7D** | | **ASCOT-Carer** | | **EQ-5D-5L (carer)** | | **ICECAP-A** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **n=** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** |
| **Carer** | Age | 139 | -0.04 | | 0.09 | | -0.06 | | -0.12 | | 0.01 | |
| | Gender, female | 144 | -1.79 | -0.33 | -1.46 | -0.27 | 0.18 | 0.03 | 0.68 | 0.12 | -0.45 | -0.08 |
| | Self-rated health status (EQ-5D-5L) | 141 | 0.31*** | | 0.59*** | | 0.53*** | | n/a | | 0.57*** | |
| | Employment status, paid employment | 144 | 0.69 | 0.13 | 0.28 | 0.05 | 0.87 | 0.16 | 2.81** | 0.51 | 0.98 | 0.18 |
| | Self-rated life satisfaction | 137 | 0.44*** | | 0.64*** | | 0.71*** | | 0.54*** | | 0.73*** | |
| **Care recipient** | Age | 137 | -0.04 | | 0.08 | | 0.04 | | 0.07 | | 0.16 | |
| | Gender, male | 144 | -1.09 | -0.20 | -2.42* | -0.46 | -1.20 | -0.21 | -1.98* | -0.35 | -3.09** | -0.56 |
| | Cognitive difficulties & daily dependencies | 144 | -0.01 | | -0.21* | | -0.27** | | -0.13 | | -0.23** | |
| | Health status (EQ-5D-5L) | 129 | 0.16 | | 0.27** | | 0.25** | | 0.28*** | | 0.27** | |
| | Direction of health status, declining | 143 | -2.34* | -0.42 | -2.15* | -0.39 | -2.08* | -0.36 | -2.53** | -0.44 | -2.13* | -0.37 |
| **Caring situation** | Co-residence | 144 | -1.30 | -0.23 | 0.12 | 0.02 | -2.05* | -0.35 | -2.71** | -0.46 | -2.68** | -0.46 |
| | Relationship, spouse | 144 | -0.21 | -0.04 | 0.92 | 0.17 | -1.18 | -0.21 | -1.34 | -0.23 | -1.41 | -0.25 |
| | Duration of caring (months) | 141 | 0.02 | | -0.02 | | -0.11 | | 0.02 | | -0.11 | |
| | Hours of care per week >20 | 144 | -2.30* | -0.42 | -1.06 | -0.20 | -3.88*** | -0.69 | -3.44*** | -0.62 | -3.60*** | -0.64 |
| | Provides personal care | 133 | -0.66 | -0.14 | -0.54 | -0.12 | -2.03* | -0.41 | -2.64** | -0.54 | -1.69 | -0.35 |
| | Main carer | 143 | -1.29 | -0.29 | -0.24 | -0.06 | -0.59 | -0.13 | -1.77 | -0.39 | -0.46 | -0.10 |
| | Involvement of others | 143 | 1.54 | 0.27 | 0.27 | 0.05 | 0.67 | 0.12 | 0.22 | 0.04 | 0.38 | 0.07 |

CC: Correlation Coefficient *significant (in the expected direction) at the 0.05 significance level; ** significant (in the expected direction) at the 0.01significance level; *** significant (in the expected direction) at the 0.001 level

**Table 15.4.** Univariable associations and effect sizes between QoL measure scores (Rheumatoid Arthritis) and contextual variables

| | | | **CES** | | **CarerQoL-7D** | | **ASCOT-Carer** | | **EQ-5D-5L (carer)** | | **ICECAP-A** | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Contextual variable** | **n=** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** | **CC** | **Effect size** |
| **Carer** | Age | 123 | 0.06 | | 0.13 | | 0.11 | | -0.16 | | 0.06 | |
| | Gender, female | 125 | -2.12* | -0.41 | -1.63 | -0.31 | -1.84 | -0.34 | 1.91 | 0.35 | -1.57 | -0.29 |
| | Self-rated health status (EQ-5D-5L) | 123 | 0.30** | | 0.52*** | | 0.34*** | | n/a | | 0.53*** | |
| | Employment status, paid employment | 125 | -0.17 | -0.03 | 0.44 | 0.29 | -1.12 | -0.22 | 2.58** | 0.49 | -0.15 | -0.03 |
| | Self-rated life satisfaction | 123 | 0.54*** | | 0.72*** | | 0.74*** | | 0.45*** | | 0.79*** | |
| **Care recipient** | Age | 115 | -0.02 | | 0.12 | | 0.05 | | 0.14 | | 0.11 | |
| | Gender, male | 124 | -0.25 | -0.05 | -0.61 | -0.14 | 0.37 | 0.08 | 0.75 | 0.16 | -0.01 | -0.01 |
| | Cognitive difficulties & daily dependencies | 126 | -0.39*** | | -0.50*** | | -0.52*** | | -0.27** | | -0.50*** | |
| | Health status (EQ-5D-5L) | 113 | 0.47*** | | 0.47** | | 0.43*** | | 0.28** | | 0.48*** | |
| | Direction of health status, declining | 125 | -1.73 | -0.40 | -2.71** | -0.63 | -2.16* | -0.49 | -1.31 | -0.29 | -2.51* | -0.56 |
| **Caring situation** | Co-residence | 126 | -2.43* | -0.48 | -1.89 | -0.37 | -2.06* | -0.39 | -3.11** | -0.58 | -2.77** | -0.53 |
| | Relationship, spouse | 126 | -0.30 | -0.06 | -0.45 | -0.94 | -0.65 | -0.13 | -2.01* | -0.40 | -1.63 | -0.33 |
| | Duration of caring (months) | 126 | -0.20* | | -0.20** | | -0.23* | | -0.18* | | -0.24** | |
| | Hours of care per week >20 | 123 | -2.58** | -0.50 | -3.77*** | -0.73 | -4.40*** | -0.81 | -1.84 | -0.34 | -4.37*** | -0.81 |
| | Provides personal care | 115 | -1.72 | -0.36 | -2.74** | -0.56 | -3.47*** | -0.69 | -2.78** | -0.54 | -3.31** | -0.65 |
| | Main carer | 125 | -3.35** | -0.72 | -3.27** | -0.70 | -3.29** | -0.68 | -1.55 | -0.32 | -3.25** | -0.67 |
| | Involvement of others | 124 | 1.56 | 0.33 | 1.81 | 0.37 | 1..62 | 0.32 | 0.82 | 0.16 | 1.81 | 0.37 |

CC: Correlation Coefficient *significant (in the expected direction) at the 0.05 significance level; ** significant (in the expected direction) at the 0.01significance level; *** significant (in the expected direction) at the 0.001 level

# Appendix 16. Quantitative analysis 4 results: Measure domains - all conditions

**Table 16.1.** Significance of relationship between CES attributes and contextual constructs (p-values)

| **Theoretical Domain** | **Occupation** | **Support** | | **Fulfilment** | **Control** | **Relationship** |
|---|---|---|---|---|---|---|
| **Measure item** | Activities outside caring | Support from friends & family | Assistance from organisations & government | Fulfilment from caring | Control over caring | Getting on with the person you care for |
| **Carer** | | | | | | |
| Self-rated life satisfaction[a] | <0.001*** | <0.001*** | 0.007** | <0.001*** | 0.804 | <0.001*** |
| **Care recipient** | | | | | | |
| Cognitive difficulties[a] | <0.001*** | 0.714 | <0.001*** | <0.001*** | 0.133 | 0.080 |
| Daily dependencies[a] | <0.001*** | 0.030* | <0.001*** | 0.003** | 0.008** | 0.955 |
| Health status (EQ-5D-5L) [a] | <0.001*** | 0.006** | 0.089 | 0.019* | 0.753 | 0.803 |
| **Caring situation** | | | | | | |
| Involvement of others[b] | 0.017* | <0.001*** | <0.001*** | 0.394 | <0.001*** | 0.675 |
| Hours of care per week >20[b] | <0.001*** | <0.001*** | 0.027* | 0.785 | <0.001*** | 0.359 |
| Provides personal care[b] | <0.001*** | 0.465 | 1.00 | 0.576 | <0.001*** | 0.701 |
| Main carer[b] | <0.001*** | <0.001*** | <0.007** | 0.592 | <0.001*** | 0.830 |

***significant at 0.1% level, ** significant at 1% level, * significant at 5% level

[a] Using one-way analysis of variance

[b] Using exact test

**Table 16.2.** Significance of relationship between CarerQoL-7D attributes and contextual constructs (p-values)

| **Theoretical domain** | **Occupation** | **Support** | **Fulfilment** | **Relationship** | **Physical health** | **Mental health** | **Finances** |
|---|---|---|---|---|---|---|---|
| **Attribute** | Problems with combining care tasks with daily activities | Support with carrying out care tasks, as needed | Fulfilment from carrying out care tasks | Relational problems with the care receiver | Problems with physical health | Problems with mental health | Financial problems due to care tasks |
| **Carer** | | | | | | | |
| Self-rated life satisfaction[a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Care recipient** | | | | | | | |
| Cognitive difficulties[a] | <0.001*** | 0.080 | 0.028* | <0.001*** | 0.096 | <0.001*** | 0.039* |
| Daily dependencies[a] | <0.001*** | 0.570 | 0.041* | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Health status (EQ-5D-5L) [a] | <0.001*** | 0.725 | 0.821 | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Caring situation** | | | | | | | |
| Involvement of others[b] | 0.332 | <0.001*** | 0.471 | 0.175 | 0.179 | 0.368 | 0.041* |
| Hours of care per week >20[b] | <0.001*** | <0.001*** | 0.184 | 0.003** | <0.001*** | <0.001*** | <0.001*** |
| Provides personal care[b] | <0.001*** | 0.418 | 0.761 | 0.007** | <0.001*** | <0.001*** | <0.001*** |
| Main carer[b] | 0.012* | 0.006** | 0.968 | 0.245 | <0.001*** | <0.001*** | <0.001*** |

***significant at 0.1% level, ** significant at 1% level, * significant at 5% level

[a] Using one-way analysis of variance

[b] Using exact test

**Table 16.3.** Univariable associations and effect sizes between ASCOT-Carer attributes (all conditions) and contextual constructs

| **Theoretical domain** | **Occupation** | **Support** | **Control** | **Social participation** | **Self-care** | **Safety** | **Occupation** |
|---|---|---|---|---|---|---|---|
| **Attribute** | Occupation in valuable or enjoyable activities | Feeling supported and encouraged | Control over daily life | Social contact with people you like | How well you look after yourself | How safe you feel | Space and time to be yourself |
| **Carer** | | | | | | | |
| Self-rated life satisfaction[a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Care recipient** | | | | | | | |
| Cognitive difficulties[a] | <0.001*** | 0.015* | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Daily dependencies[a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Health status (EQ-5D-5L) [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | 0.008** | <0.001*** |
| **Caring situation** | | | | | | | |
| Involvement of others[b] | 0.012* | 0.008** | 0.435 | 0.022* | 0.630 | 0.692 | 0.106 |
| Hours of care per week >20[b] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | 0.002** | <0.001*** |
| Provides personal care[b] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Main carer[b] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** | 0.024* | <0.001*** |

***significant at 0.1% level, ** significant at 1% level, * significant at 5% level

[a] Using one-way analysis of variance

[b] Using exact test

**Table 16.4.** Univariable associations and effect sizes between EQ-5D-5L (carer) attributes (all conditions) and contextual constructs

| **Theoretical domain** | **Occupation** | **Physical health** | | **Mental health** | **Self-care** |
|---|---|---|---|---|---|
| **Attribute** | Usual activities | Pain/discomfort | Mobility | Anxiety / depression | Self-care |
| **Carer** | | | | | |
| Self-rated life satisfaction [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Care recipient** | | | | | |
| Cognitive difficulties [a] | 0.862 | 0.304 | 0.483 | 0.016* | 0.748 |
| Daily dependencies [a] | <0.001*** | 0.044* | 0.005** | <0.001*** | 0.121 |
| Health status (EQ-5D-5L) [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Caring situation** | | | | | |
| Involvement of others [b] | 0.334 | 0.167 | 0.275 | 0.006** | 0.666 |
| Hours of care per week >20 [b] | <0.001*** | 0.007** | 0.003** | 0.037* | 0.031* |
| Provides personal care [b] | <0.001*** | 0.019* | 0.006** | 0.380 | 0.024* |
| Main carer [b] | 0.015* | 0.070 | 0.230 | 0.002** | 0.494 |

***significant at 0.1% level, ** significant at 1% level, * significant at 5% level

[a] Using one-way analysis of variance

[b] Using exact test

**Table 16.5.** Univariable associations and effect sizes between ICECAP-A attributes (all conditions) and contextual constructs

| **Theoretical domain**<br>**Attribute** | **Support**<br>Love, friendship and support | **Fulfilment**<br>Enjoyment and pleasure | **Safety**<br>Feeling settled and secure | **Independence**<br>Being independent | **Achievement**<br>Achievement and progress |
|---|---|---|---|---|---|
| **Carer** | | | | | |
| Self-rated life satisfaction [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Care recipient** | | | | | |
| Cognitive difficulties [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Daily dependencies [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Health status (EQ-5D-5L) [a] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| **Caring situation** | | | | | |
| Involvement of others [b] | 0.009** | 0.225 | 0.325 | 0.073 | 0.225 |
| Hours of care per week >20 [b] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Provides personal care [b] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |
| Main carer [b] | <0.001*** | <0.001*** | <0.001*** | <0.001*** | <0.001*** |

***significant at 0.1% level, ** significant at 1% level, * significant at 5% level

[a] Using one-way analysis of variance

[b] Using exact test

## Appendix 17. Invitation to participate in the cognitive interview

UNIVERSITY OF
BIRMINGHAM

Institute of Applied Health Research
Public Health Building
University of Birmingham
Birmingham B15 2TT

Dear

**Family care and quality of life**

Thank you for taking the time to complete the two postal questionnaires about family care and for expressing interest in a face-to-face interview.
These interviews are part of the second stage of our research on family carers. During the interview we will ask you to complete short questionnaires about your quality of life, thinking out loud as you go. We will then ask you some follow up questions. This process will help us explore how well different questionnaires are working at measuring carer quality of life.

Enclosed please find a study information sheet and a consent form with a reply-paid envelope. Please read through the study information sheet carefully. This explains in more detail what taking part will involve.

We can arrange the interview so that it is at your home, at a time that is convenient for you, or if you would prefer, we can arrange a convenient place to meet. Your travel expenses for this meeting will be paid and to thank you for your time we will give you a £15 shopping voucher if you complete the interview. We expect that the interview will take around 40 minutes.

**If you are willing to take part in an interview, please read the enclosed information sheet, complete the consent form and return it to us.** I will then contact you to arrange a convenient location and date for the interview.

If you have any questions or if you would like more information you can call me on [redacted] or email me at [redacted].

Yours sincerely

Carol McLoughlin
University of Birmingham

## Appendix 18. Cognitive interview information sheet

UNIVERSITY OF
BIRMINGHAM

NHS
National Institute for
Health Research

# Completing ‘quality of life’ questionnaires

## *Information about the interviews*

This information sheet provides answers to some questions you may have about the research. If you have any more questions please feel free to use the ‘sources of help’ listed in this information sheet.

***What is this research about?***
We are trying to understand the best way of measuring the quality of life of family carers. Various measures provide a snapshot of quality of life by asking about different aspects of life and caring. The face-to-face interview will help us understand the extent to which these measures capture the quality of life of family carers.

***Why is this research important?***
Researchers might think certain measures are appropriate. However, a real insight into the meaning and understanding of the questions asked can only be generated through examining the completion with different individuals. Having good measures of quality of life to use with carers is important because it means that these measures can be used in studies of new treatments to better understand whether the treatment improves (or worsens) the lives of carers, as well as patients.

***Why have I been chosen?***
You have been chosen because you are a family carer.

***What do I have to do?***
If you are willing to take part in an interview, you need to complete and return the enclosed consent form. The researcher (Carol) will contact you to arrange an interview location and date convenient for you. In the interview will ask you to ‘think-aloud’ as you complete some measures of quality of life. By thinking aloud we mean talking us through your thought process as you answer some simple survey questions. You may find this a bit tricky, but we will explain the task fully beforehand and use a couple of warm up exercises. After the think aloud exercise we will ask you some follow up questions. We expect that the interview will last around 45 minutes.

***Who is carrying out the research?***

Researchers from the University of Birmingham are carrying out the research and we are working in partnership with a panel of family carers. The National Institute for Health Research (NIHR), a major government body that pays for health research, has approved and funded the research.

### *Is the information confidential?*

Yes. We take great care of the information we are given. When we type up the recordings made during the interview and about the results of the research, all personal details will be removed. All recordings will be destroyed once the interview has been typed up. In very rare instances researchers may encounter a situation during a field visit where something they see or hear gives them particular cause for concern. Such concerns may relate to immediate risk of harm or to illegal activity or behaviour which could harm the public. In such cases we may need to notify an appropriate third-party. Anonymised data may be made available to other researchers, but we will always check these are genuine research requests and we will never share any personal details.

### *What will be done with the information you collect?*

The results will show us what people understanding by the questions, and whether they answer questions in the intended manner. Essentially it is another way of understanding whether the questionnaires are ‘fit-for-purpose’. We will publish the findings for other scientists and researchers to use, present the findings at research events and to government bodies involved in making decisions about new treatments. A summary of the findings will be available in on the University of Birmingham webpage www.birmingham.ac.uk/care-econ.

### *Is the interview compulsory?*

No, it’s a voluntary interview, but we are contacting you because your organisation has been involved in this research project. The success of the research project depends on the goodwill of people like you. You are free to withdraw, and decide whether we can use the information you have provided to date. You can withdraw by contacting the study researcher (please see ‘sources of help’) by December 31st 2019. Taking part in the interview will not affect the care that you receive or your legal rights.

### *Sources of help*

If you have any questions about the interview, please feel free to contact the lead researcher, Carol McLoughlin, by telephone on [redacted] or by email at [redacted] at the University of Birmingham.
If there is anything more generally that upsets you or you would like to know about sources of support, you may find the contacts below useful:
Carers Trust: support@carers.org The Samaritans: 08457 909090

## *Just to recap…*

- *Please complete the consent form or email or phone us to let us know you are willing to be interviewed.*
- *We will then be in touch to confirm a suitable time and date.*

This study has been reviewed by the Science, Technology, Engineering & Mathematics Ethical Review Committee at the University of Birmingham Research.

**Thank you for reading this. This information sheet is for you to keep.**

# Appendix 19. Cognitive interview consent form

UNIVERSITY OF BIRMINGHAM

NHS
National Institute for Health Research

## Completing ’quality of life’ questionnaires: Consent form for participants

*Please read through the following checklist, then, if you feel happy to do so, initial the boxes and sign below to give your agreement to take part in the study on quality of life. Please send the form back to us in the envelope provided. The information sheet is for you to keep.*

*Please initial box*

| | |
|---|---|
| *I confirm that I have read and understood the information sheet dated 29/03/18 for the above study.* | |
| *I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.* | |
| *I agree to take part in the above study.* | |
| *I am happy for the interview to be audiotaped.* | |

Please sign below and print your name and indicate which timeslots and location you would prefer

**Signed:** ……………………………………………… **Date:** ……………………

**Name**: …………………………………………………………………………........

**Telephone:** ……………………………………………………………………..

**Email:** …………………………………………………………………………

I am free to be interviewed at:

………………………………………………………………………………………

………………………………………………………………………………………

# Appendix 20. Cognitive interview field note forms

## THINK ALOUD SCORING SHEET CARER EXPERIENCE SCALE

| | Item | (a) General Comp | (b) Temporal Comp | (c) Decision | (d) Response | Comments |
|---|---|---|---|---|---|---|
| A1 | Activities outside caring | | | | | |
| A2 | Support from Family and Friends | | | | | |
| A3 | Assistance from organisations and Government | | | | | |
| A4 | Fulfilment from caring | | | | | |
| A5 | Control over Caring | | | | | |
| A6 | Getting on with the person you care for | | | | | |
| Did the respondent struggle to be focus on care-related QoL | | | | | | |

**General Comprehension**

- Does the respondent understand the question

**Temporal Comprehension**

- Does the respondent understand that the question is referring to the current period

**Decision Process**

- How does the respondent decide on the answer
    - Do they have a hidden agenda
    - Do they give sufficient mental effort to the task
    - Do they want to five a socially desirable answer
    - Do they question the relevance of relevant experiences

**Response Process**

- Does the respondent manage to map their desired response onto the scale without introduction of error?
    - Do they understand the scale
    - Are the scale responses available appropriate

## THINK ALOUD SCORING SHEET CARERQOL-7D

|  | **Item** | **(a) General Comp** | **(b) Temporal Comp** | **(c) Decision** | **(d) Response** | **Comments** |
|---|---|---|---|---|---|---|
| A1 | Fulfilment from caring |  |  |  |  |  |
| A2 | Relational problems with the care recipient |  |  |  |  |  |
| A3 | Carer mental health |  |  |  |  |  |
| A4 | Combining care tasks with daily activities |  |  |  |  |  |
| A5 | Financial problems |  |  |  |  |  |
| A6 | Support from family & friends |  |  |  |  |  |
| A7 | Carer physical health |  |  |  |  |  |
| Did the respondent struggle to be focus on care-related QoL |  |  |  |  |  |  |

a) **Comprehension**
  - Does the respondent understand the question

b) **Temporal Comprehension**
  - Does the respondent understand that the question is referring to the current period

c) **Decision Process**
  - How does the respondent decide on the answer
    - Do they have a hidden agenda
    - Do they give sufficient mental effort to the task
    - Do they want to five a socially desirable answer
    - Do they question the relevance of relevant experiences

d) **Response Process**
  - Does the respondent manage to map their desired response onto the scale without introduction of error?
    - Do they understand the scale
    - Are the scale responses available appropriate

## THINK ALOUD SCORING SHEET

## ASCOT-CARER

|  | Item | (a) General Comp | (b) Temporal Comp | (c) Decision | (d) Response | Comments |
|---|---|---|---|---|---|---|
| A1 | How you spend your time |  |  |  |  |  |
| A2 | Control over daily life |  |  |  |  |  |
| A3 | Self-care |  |  |  |  |  |
| A4 | Safety |  |  |  |  |  |
| A5 | Social contact |  |  |  |  |  |
| A6 | Space & time to be yourself |  |  |  |  |  |
| A7 | Encouragement & support |  |  |  |  |  |
| Did the respondent struggle to be focus on care-related QoL |  |  |  |  |  |  |

**Comprehension**
- Does the respondent understand the question

**Temporal Comprehension**
- Does the respondent understand that the question is referring to the current period

**Decision Process**
- How does the respondent decide on the answer
    - Do they have a hidden agenda
    - Do they give sufficient mental effort to the task
    - Do they want to five a socially desirable answer
    - Do they question the relevance of relevant experiences

**Response Process**
- Does the respondent manage to map their desired response onto the scale without introduction of error?
    - Do they understand the scale
    - Are the scale responses available appropriate

## THINK ALOUD SCORING SHEET EQ-5D-5L

| | Item | (a) General Comp | (b) Temporal Comp | (c) Decision | (d) Response | Comments |
|---|---|---|---|---|---|---|
| A1 | Mobility | | | | | |
| A2 | Self care | | | | | |
| A3 | Usual activities | | | | | |
| A4 | Pain/discomfort | | | | | |
| A5 | Anxiety/depression | | | | | |

| | |
|---|---|
| Did the respondent struggle to be focus on care-related QoL | |

**Comprehension**
- Does the respondent understand the question

**Temporal Comprehension**
- Does the respondent understand that the question is referring to the current period

**Decision Process**
- How does the respondent decide on the answer
    - Do they have a hidden agenda
    - Do they give sufficient mental effort to the task
    - Do they want to five a socially desirable answer
    - Do they question the relevance of relevant experiences

**Response Process**
- Does the respondent manage to map their desired response onto the scale without introduction of error?
    - Do they understand the scale
    - Are the scale responses available appropriate

**THINK ALOUD SCORING SHEET** **ICECAP-A**

| | Item | (a) General Comp | (b) Temporal Comp | (c) Decision | (d) Response | Comments |
|---|---|---|---|---|---|---|
| A1 | Feeling settled & secure | | | | | |
| A2 | Love, friendship & support | | | | | |
| A3 | Being independent | | | | | |
| A4 | Achievement & progress | | | | | |
| A5 | Enjoyment & pleasure | | | | | |

| | |
|---|---|
| Did the respondent struggle to be focus on care-related QoL | |

**Comprehension**
- Does the respondent understand the question

**Temporal Comprehension**
- Does the respondent understand that the question is referring to the current period

**Decision Process**
- How does the respondent decide on the answer
    - Do they have a hidden agenda
    - Do they give sufficient mental effort to the task
    - Do they want to five a socially desirable answer
    - Do they question the relevance of relevant experiences

**Response Process**
- Does the respondent manage to map their desired response onto the scale without introduction of error?
    - Do they understand the scale
    - Are the scale responses available appropriate

## Appendix 21. Cognitive interview topic guide

### 1. INTRODUCTION

- Explain the aims of study
- Explain what is going to be asked about in this interview
- Check ok to have interview recorded
- Reminder about anonymity and withdrawing from study

### 2. WARM-UP

- 1st warm-up task - window counting:

*"The process of thinking aloud can be unfamiliar, so we would like to start you off with a couple of warm-up practice tasks. For the first task we will do something called window counting. This has been used before to get people familiar with the process of thinking aloud. I would like you to count up how many windows there are in your house. Please think aloud as you try and count up your windows. Only tell me what comes into your mind. I won't interrupt you unless you are silent for more than ten seconds. Ok, now please count up your windows thinking aloud as you go."*

~FEEDBACK/ EXAMPLE/ENCOURAGE~

### 3. CARER QUALITY OF LIFE QUESTIONNAIRE 1

*"Good! Now onto the main task. In a moment I will give you a copy of the xxxxx questionnaire. As explained at the beginning I would like you to complete the questionnaire, thinking aloud while you complete it. I will sit outside your line of sight while you do this so as not to distract you. Just to recap, what we mean by 'Think Aloud' is that we want you to tell us everything you are thinking from the time you read out each question until you have given your final answer. We don't want you to plan what you are going to say, just act as though you are alone in the room speaking to yourself. I would like you to think aloud constantly. If you are silent for any long period of time I will prompt you to keep talking. Please try and speak as clearly as possible, as we shall be recording what you say. Don't worry about hurting our feelings if you want to criticize any of the questions. My job is to find out if there are any problems with the questions. There are no right or wrong answers. I will now give you the questionnaire and would like you to start completing, in your own time, thinking aloud as you go."*

~HAND 1ST QUESTIONNAIRE TO PARTICIPANT~

### 4. CARER QUALITY OF LIFE QUESTIONNAIRE 2

*"Thank you. For the second task I would like you to do the do the same with the quality of life questionnaire I am about to give you."*

~HAND 2nd QUESTIONNAIRE TO PARTICIPANT~

### 5. CARER QUALITY OF LIFE QUESTIONNAIRE 3

*"Thank you. For the final task I would like you to do the do the same with the quality of life questionnaire I am about to give you."*

~HAND 3rd QUESTIONNAIRE TO PARTICIPANT~

Remind if necessary about:

- Thinking aloud from beginning to end.
- Speaking as clearly as possible.
- The fact that there are no right or wrong answers.
- Need not to plan, rush, or go any slower than normal.

## 5. CLARIFYING DISCUSSION

*"That is the end of the think-aloud exercise. For the final section of the interview I would, just briefly, like to discuss with you how you found completing the questionnaires."*

Possible prompts:

**General Prompts**

- How did you go about answering that question?
- How did you arrive at that answer?
- Can you tell me what you were thinking when you were looking at this?

**Comprehension**

- You seemed a bit unclear about the instructions
- You seemed a bit unsure by what was meant by the term [term]
- What does X mean to you?

**Temporal Comprehension**

- What time period were you thinking of?

**Decision/Response Process**

- You seemed a bit unsure about which box to tick on [question] Can you say why that was?
- What brought that to mind?
- What did you think of as you tried to remember X?

## 6. SEMI-STRUCTURED INTERVIEW

*"Thank you. I would like to ask you generally how you found answering the questionnaires"*

1. Have you felt any impacts on your free time (i.e., leisure, family time, housework, sleep) as a result of your caring role?
    - Did that impact on how you answered the questionnaires?
2. Have you felt any impacts on your working life as a result of your caring role?
    - Did that impact on how you answered the questionnaires?
3. Have you felt any financial impacts (e.g., paying for travel, healthcare) as a result of your caring role?
    - Did that impact on how you answered the questionnaires?
4. Were you considering the care recipient's health when completing the questionnaire?
    a. Yes – how? (aim to work out whether it is impact of health on carer's life or proxy reporting)
5. Do the questionnaires reflect the way caring impacts on your life?
6. Are there any aspects of caring that impact on your life that weren't covered in the questionnaires?
7. How clear did you find the instructions?
8. How did you find how the questions were phrased?
9. Were the response options available appropriate?
10. Were there any questions you found difficult to answer for any reason?

## 7. INTERVIEW END

- Thank the participant, give them the voucher, highlight where they can see the findings and leave.

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