DETERMinants of quality of life, care and costs, and consequences of INequalities in people with Dementia and their carers (DETERMIND): A Protocol paper

Nicolas Farina[1], Ben Hicks[1], Kate Baxter[2], Yvonne Birks[2], Carol Brayne[3], Margaret Dangoor[4], Josie Dixon[4], Peter R. Harris[5], Bo Hu[4], Martin Knapp[4], Eleanor Miles[5], Rotem Perach[5], Sanna Read[4], Louise Robinson[6], Jennifer Rusted[5], Rob Stewart[78], Alan Thomas[6], Raphael Wittenberg[4], Sube Banerjee[1*]

Author Affiliations:

1. Brighton and Sussex Medical School, University of Sussex, Brighton, UK
2. Social Policy Research Unit, University of York, York, UK
3. Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK
4. Personal Social Services Research Unit, London School of Economics and Political Science, London, UK
5. School of Psychology, University of Sussex, Brighton, UK
6. Institute for Ageing, Newcastle University, Newcastle, UK
7. Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
8. South London and Maudsley NHS Foundation Trust, London, UK

*Corresponding author:

Professor Sube Banerjee, Brighton and Sussex Medical School, University of Sussex, Brighton, BN1 9RY

Email: s.banerjee@bsms.ac.uk

Acknowledgements

The authors would like to thank the people with dementia (and their carers) who have kindly agreed to participate in the DETERMIND project, and we would like to thank in advance those that will go onto participate in the project in the future.

Funding

The DETERMIND study was supported by the Economic and Social Research Council (UK) and the National Institute for Health Research (UK) through grant number ES/S010351/1. RS is part-funded by the National Institute for Health Research (NIHR) Biomedical Research

Centre and Dementia Biomedical Research Unit at South London and Maudsley NHS Foundation Trust and King's College London.

Abstract

Objectives: DETERMIND (DETERMinants of quality of life, care and costs, and consequences of INequalities in people with Dementia and their carers) is designed to address fundamental, and, as yet unanswered, questions about inequalities, outcomes and costs following diagnosis with dementia. These answers are needed to improve the quality of care and equity of access to care, and therefore the quality of life, of people with dementia and their carers.

Method: DETERMIND is a programme of research consisting of seven complementary workstreams (WS) exploring various components that may result in unequal dementia care:
WS1: Recruitment and follow-up of the DETERMIND cohort - 900 people with dementia and their carers from three geographically and socially diverse sites within six months following diagnosis, and follow them up for three years.
WS2: Investigation of the extent of inequalities in access to dementia care
WS3: Relationship between use and costs of services and outcomes
WS4: Experiences of self-funders of care
WS5: Decision-making processes for people with dementia and carers
WS6: Effect of diagnostic stage and services on outcomes
WS7: Theory of Change informed strategy and actions for applying the research findings

Outcomes: During the life of the programme, analysing baseline results and then follow-up of the DETERMIND cohort over 3 years, we will establish evidence on current services and practice. DETERMIND will deliver novel, detailed data on inequalities in dementia care and what drives positive and negative outcomes and costs for people with dementia and carers, and identify factors that help or hinder living well with dementia.

Keywords: Dementia, Alzheimer's disease, inequalities, inequities, ethnicity, gender, deprivation, caregiving, cost of care, services, diagnosis, LGBT+, decision-making, self-funding

Introduction

What is it that enables one family to live well with dementia and another with ostensibly the same illness and challenges to have much poorer experiences? Which groups have better or worse outcomes following diagnosis of dementia and why are there inequalities in care and outcomes? What can we learn from the experiences of people with dementia and their carers to deliver care and support that maximises quality of life for all? Health and social care services play vital roles in sustaining the independence and quality of life of people with dementia and their carers[1]. Services may not, however, reach everyone who needs them due to barriers associated with availability, accessibility and acceptability[1]. Such barriers are likely to affect some groups more than others who, as a result, may experience unmet need, which in turn is known to adversely affect quality of life for people with dementia and carers[2, 3]. Since disadvantaged groups have a higher risk of developing dementia[4], it is especially important to identify the extent of inequities in service access and to understand how best to address these (we use the term inequity to refer to an inequality that is likely to be seen as unfair). Existing evidence is limited in quantity and scope. Studies have found that certain groups of people with dementia and carers experience poorer service access, including those who are non-white or with lower formal education, socio-economic status or income[2, 5-8]. However, existing studies largely focus on healthcare [6, 7, 9] and are cross-sectional[2, 5]. A small number of qualitative studies identify barriers to accessing dementia care, including poor knowledge, poor/inappropriate service provision and impact of cultural beliefs and previous experiences[10-12].This body of evidence is predominantly descriptive, with insufficient attention to understanding causes and processes[13].Public Health England, for example, recently recommended that "qualitative research into the differential access of health services by different ethnic groups mediated by different cultural beliefs is needed" and that "these studies should include the identification of barriers and enablers for those communities"[8, p.26].

In DETERMIND we will seek to go beyond a simple input-output model of dementia care (here is a service, people get it, and here are the outcomes) and instead unpick causal chains and build understanding of contextual factors. We will focus on modifiable mediating factors that generate unequal access and experiences, leading to inequities in outcome. DETERMIND therefore addresses inequalities in care provision and outcomes. DETERMIND focusses on the determinants of quality of life, other outcomes and costs for people with

[1] ***A note on terminology:*** We use "carer" according to the Carers UK definition: "someone of any age providing unpaid support to family or friends". "Family carer" is questioned because not all unpaid care is provided by families and "informal carer" because the term "informal" is seen by some carers to belittle their role. We acknowledge concerns with use of the term "carer" in early dementia but we have not used "supporter", "carer/supporter" or "caregiver" as "carer" was preferred by our PPI group.

dementia and their carers in the three years following diagnosis. It will investigate inequities and inequalities in care provision and outcomes, their causes, and their links to individual circumstances, including health and social care needs and strengths. It is designed to generate unique data that will advance social research theory and health and care practice.

Aims and objectives

Our overall aim is to explore and understand inequalities in dementia care and what drives good and poor quality of life, outcomes and costs for people with dementia and their carers following diagnosis. We will investigate how outcomes and costs vary by content and time of diagnosis, individual circumstances, and with varying support from health and social care services. To do this we have designed a programme of research with seven complementary workstreams (WS). The specific aim of the seven WS are:

WS1: Generate the infrastructure and data needed for DETERMIND by recruiting a new cohort of 900 people from three geographically and socially diverse sites with dementia and their carers in the six months following diagnosis, and following them up annually for three years.

WS2: Provide new evidence on the extent of inequalities in access to dementia care, unmet need for care, barriers and facilitators to accessing care and impact of unmet need over time in a longitudinal context.

WS3: Identify relationships between use and costs of services and outcomes for people with dementia and carers.

WS4: Investigate the experience of people with dementia and their carers as self-funders of care and to compare this and their outcomes and costs with non-self-funders.

WS5: Develop a deeper, mechanistic understanding of the processes involved in, and factors influencing, self-regulation and decision-making by people with dementia and carers.

WS6: Investigate the impacts of earlier or later diagnosis and subsequent provision of peridiagnostic and post diagnostic treatment and care on quality of life and other outcomes for people with dementia and their carers.

WS7: Co-ordinate findings from the WSs so the data generated can be translated into strategies and actions capable of bringing about better systems and services for people with dementia and carers.

Figure 1 provides an overview of the DETERMIND research programme.

Methods

Overview DETERMIND will establish a bespoke cohort of people newly diagnosed with dementia from whom longitudinal survey and qualitative data will be gathered. We will use those data in seven complementary WSs designed to test specific hypotheses covering five of the most important information gaps in dementia care: (i) inequalities in access to care [WS2]; (ii) costs and outcomes and the relationship between them [WS3]; (iii) self-funding of social care [WS4]; (iv) decision-making [WS5]; and (v) effect of diagnosis, including differential effect of earlier and later diagnosis [WS6]. We will take these data and formulate actions to address inequalities in care in an inclusive process using Theory of Change (ToC) methodology in collaboration with the Alzheimer's Society.

WS1: Establishment and follow up of the DETERMIND cohort

Research questions: WS1 generates the infrastructure within which WS2-WS6 are conducted. Each WS has its own detailed research questions. WS1 will be judged against process indicators (i.e. recruitment of 300 participants in each centre in one year, follow ups completed each year).

Method: We will recruit, from three sites across England enrolling people from a range of social and economic backgrounds (South East England, South East London, North East England), a large (n=900) cohort of people diagnosed with dementia in the previous six months prior to interview. This baseline sample size will enable a difference over time between two subgroups in measures such as the EQ5D of 0.042 or in DEMQoL of 2.24 to be ascertained with power of 0.8 at 5% confidence level. This is on the basis that the annual attrition rate of the sample is 10% and that the subgroups are of equal size. If the attrition rate is 15%, a difference of 2.44 in DEMQOL could be determined (with 80% power at 5% significance) and if the size of the two groups is in a 3:1 ratio, a difference of 2.59 in DEMQOL could be established. For three groups (three pairwise comparisons), a difference of 3.16 in DEMQOL could be ascertained.

We wish our sample to be representative of all people diagnosed with dementia so we will recruit without exclusion criteria. We will include people in any household situation; they will be primarily defined by having a diagnosis of dementia made in one of the Memory Assessment Services (MAS) or other services where a diagnosis of dementia may be made. We estimate that up to 10% may have no identifiable family or paid carer able to act as an informant for the carer-rated instruments, but we will include them in the cohort, subject to informed or proxy consent being obtained, since not having an identifiable carer may be an important influence on the outcomes we are studying.

We will follow up participants annually for three years embedding qualitative work detailed in WS2-WS6. This allows us to look in detail retrospectively at processes leading up to diagnosis and the diagnostic process itself, and prospectively at outcomes and services used in the three years following diagnosis. Although we estimate two thirds of participants will have dementia of mild severity (sMMSE 20+) and a third moderate (sMMSE 10-20), we will not exclude people with severe dementia. We also envisage that there will be a substantial incidence of events of interest, with 5-15% per year entering care homes, high rates of transition from no-help to home care, and over half with general hospital admissions. Participants will be drawn primarily from MAS in the three sites chosen to enable exploration of key attributes in our WSs. The South East England site draws from MASs serving areas with high self-funding, and areas with a high south Asian older population (e.g. Crawley/Woking) and the oldest LGBTQ+ population in the UK (Brighton). The South East London site includes the inner city and sizeable older black Caribbean and south Asian populations, and North East England white working class and rural-dwelling older adults. There are important limitations to the random or population-based sampling in terms of yielding recruits from black, Asian and minority ethnic (BAME) groups and those from LGBTQ+ populations because of the relatively small numbers we will have, even with an overall sample size of 900. We will therefore oversample black African Caribbean and South Asian populations in South East England and South East London. We will aim for 25% of participants from these areas to be from BAME groups, yielding 150 participants for quantitative analyses. Although the heterogeneity within the group may be a challenge, when possible, we will use the multiple group approach (e.g. available in Mplus). This approach makes it possible to simultaneously analyse relatively small subgroups of unequal sample sizes. For the LGBTQ+ group, even with the concentrated population in Brighton, we will not have the numbers for definitive quantitative analyses; therefore we will also oversample this group and expect to identify 50 participants in our cohort. These numbers in the BAME and LGBTQ+ groups will allow us to sample purposively for the embedded qualitative studies, and we believe that there will be much novel, important and useful data on inequalities and outcomes that will come from these analyses, including areas for further specific investigation.

Complementary recruitment strategies will be used to ensure that we are as inclusive as possible, particularly for those who may have been lost within the healthcare system, and those who were not offered opportunity to participate in the research from a healthcare professional. This includes the use of local ‘opt-in’ case registers at South East London[14] and North East England and ‘opt-out’ case registers in South East England, Join Dementia

Research (https://www.joindementiaresearch.nihr.ac.uk/), and self-referrals via posters or flyers. Following referral and consent, researchers will ask participants to complete a series of questionnaires that will last up to 120 minutes. The person with dementia and their carer (if applicable) will both complete the assessment. One option will be for these assessments to occur in tandem (with two researchers visiting together) and so reduce the length of time testing and respondent burden. Such a strategy has worked well in the MODEM study[15]. Participants will then be contacted annually (for three years) to arrange follow-up visits. The assessments will include quantitative questionnaires to assess patient quality of life, cognitive function, patient neuropsychiatric symptoms, carer quality of life, carer burden, use of services, patient activities of daily living, medication, and physical illnesses (see Table 1 for an overview of all baseline measures). Participants will also provide consent for researchers to access their medical records so that we are able to ascertain further details about their pathways to diagnosis and subsequent health care use. Participants have the option to be contacted about future research studies, and for their details to be shared with NHS Digital so that the research team can be notified upon their death. Qualitative interviews will be offered to a subset of participants, as set out in other WSs, enabling us to elicit a better understanding of complex issues.

WS2: Inequalities in use of dementia care

Research questions: Examining the extent and nature of inequalities will be preliminary to studying key questions around why some subgroups experience different access to care and support, what the barriers and facilitators are in the care pathways, and to generate grounded ideas for addressing inequities of access. We will address the following research questions:

(i) How far are there inequalities of access to dementia care, including social care as well as health care?

(ii) How far do these inequalities entail unmet need for care?

(iii) Which subgroups experience unmet need and how do the unmet needs change over time?

(iv) Why do inequities in access to care and consequent unmet need occur, what barriers and facilitators do people experience and how can groups that are disadvantaged in this way be best enabled to access support they need?

(v) What are the consequences of unmet need for people with dementia and their carers?

Method: Use of longitudinal, observational data is a powerful approach to investigate natural processes and what shapes them over time. Although this type of approach lacks

experimental control over the environment, it allows studying the individual in a natural setting surrounded by meaningful contextual factors, which leads to a richer view of the interplay between the individuals and significant others and the systems around them, and leads to better generalizability of the findings to real-world settings. Repeated measures also make it possible to adjust for initial levels of needs and access, identify different patterns of change, and explore the interplay between changes in different processes. Such observational data, can usefully be further explored using qualitative methods, to allow investigation of underlying mechanisms and people's first-hand perceptions and experiences, and to increase theoretical validity. To provide a comprehensive analysis of the causes and impacts of inequity in access to health and care services for people with dementia and their carers, as well as to identify practical and effective solutions, it is therefore important we explore equity of access from various perspectives using both quantitative and qualitative methods.

In WS2, we will use a mixed methods design comprising (i) statistical analyses of existing datasets, (ii) statistical analyses of new DETERMIND cohort longitudinal survey data, and (iii) qualitative interviews of DETERMIND cohort members. We will focus on inequalities by ethnicity, gender, sexual orientation, marital status, socioeconomic status, and area type (urban/rural). In quantitative analyses, we will examine variation between groups in access to unpaid care provided by family and friends, to publicly and privately funded social care (residential and community care), and to different forms of health care. We will examine unmet need in terms of self-reported unmet need and self-reported disability (in particular activities of daily living limitations) among people not receiving care. We will consider quality of life using EQ-5D, DEMQOL and ONS4. There are three stages to this process.

Stage 1 (months 1 to 24): We will complete secondary analyses of data from the MODEM study[15], the English Longitudinal Survey of Ageing (ELSA)[16], and the Cognitive Function and Ageing Study (CFAS)[17]. The MODEM cohort includes 300 people with dementia and their carers quota-sampled to balance mild, moderate and severe dementia, followed up one year later: it allows us to examine differences by gender and socioeconomic group in receipt of care and support among a mixed convenience sample of people with different dementia severities. ELSA analyses of waves 6-8, which contain detailed longitudinal data on needs and characteristics, receipt of unpaid and paid care and cognitive tests and proxy interviews on cognitive change (but not diagnoses of dementia) will enable us to identify, for those at earlier stages of cognitive decline, the level of and change in unmet needs and their socioeconomic correlates, and how these affect access to care and outcomes such as probability of entering a care home and quality of life. CFAS will allow us to explore a limited

number of service use and demographic variables in an epidemiologically generalisable group of well characterised people with dementia. We will run descriptive analyses for the key outcomes (quality of life of people with dementia and their carers), and intermediate factors (unmet needs, social network, care by family and friends, publicly and privately funded social care including residential and community care, health care, and cost of social care) by cognitive functioning (ELSA) and mild, moderate and severe dementia (MODEM) and inequality indicators (gender, marital status, socioeconomic status and type of area (urban/rural). We will also examine changes over time in outcomes, intermediate factors and cognition/dementia. We will then analyse how the patterns of change in cognition, unmet needs, receipt of services and outcomes are shaped by inequality indicators using latent growth curves.

Stage 2 (months 25 to 36): We will conduct quantitative analyses of the first wave of the new DETERMIND cohort data and, on the basis of the findings, develop detailed plans for stage three. We will first carry out descriptive analyses of the first wave on the quality of life, receipt of health and social care, (un)met needs and social networks by severity of dementia and inequality indicators. Our analyses of services received will include sources of funding for care including personal funds to provide key descriptive data for WS4. We will describe differences in receipt of health and social care between sub-groups by ethnicity, gender, marital status, sexuality, socioeconomic status and urban/rural area, controlling for differences in needs and dementia severity. We will examine to what extent identified subgroups receiving less care experience or perceive unmet need for care. We will then compare the quality of life of those experiencing unmet needs with those not experiencing unmet needs controlling for other factors. For these analyses, we will use multivariate modelling suitable for binary, ordinal and continuous outcomes, such as Generalized Linear Models. Latent class analysis will identify subgroups characterised by similar needs, strengths and service access patterns (typologies; cross-sectionally) and investigate potential facilitating factors associated with these patterns.

Stage 3 (months 37 to 60): Through analyses of successive waves of the DETERMIND cohort we will examine whether inequalities in unmet need and receipt of services at baseline persist over time, whether unmet need at baseline and accumulation of unmet needs over time are associated with lower quality of life for people with dementia and their carers, and what processes might facilitate better outcomes over time. We will provide descriptions of trends in key variables from successive waves of the DETERMIND cohort for WS4-WS6. We will analyse how the differences in receipt of care between the different subgroups change over successive waves and how they are associated with differences in

unmet need, costs of care and outcomes including quality of life. At 3-year follow-up we will use Latent Change Score to analyse whether the level or change in one factor affects the subsequent change in another factor. This is a strong method for investigating causality in observational studies (e.g. a facilitator improves access to care which in turn improves quality of life).

Qualitative work: In-depth, face-to-face qualitative interviews with people with dementia and their carers (N=40-60) will be undertaken to examine experiences and underlying mechanisms, focusing on the most compelling and potentially productive questions emerging from quantitative analyses. These questions will be identified and refined through the Theory of Change workshops (WS7), with a focus on key subgroups identified in the quantitative research as disadvantaged in terms of their access to dementia care and support. To address these questions, in-depth interviews will be conducted with a purposively (theoretically) selected sub-sample of people with dementia and their carers. Our strategy, for each sub-group, will be to compare those experiencing poor access and unmet need and those who, despite being part of this disadvantaged sub-group, do not experience poor access and unmet need. This will allow us to explore not just barriers but also what facilitates access and protective factors. Within this, we will explore people's perceptions and experiences: for example, how they perceive their need for support, alternative and informal sources of support, experiences of 'help-seeking,' and the impacts of unmet need. We will aim to include 'less heard' groups in dementia research who, even in our cohort, may be low in frequency, such as those who identify as LGBTQ+ and those with young-onset dementia.

WS3: Relationship between use and cost of services and outcomes for people with dementia and carers

Research questions:

(i) How much do increases in service use lead to improvements in outcomes?
(ii) What are the relationships between costs of care and outcomes?
(iii) Do unmet needs have negative consequences on outcomes?
(iv) Do the relationships between service use and outcomes vary according to characteristics of the person with dementia and carer?

Method: Detailed data on receipt of unpaid care and use of services will be collected in WS1 using the CSRI. Services will include primary and secondary health care, residential and community-based social care, special housing, aids and adaptations, technology and support for carers. We will estimate costs of services by applying unit costs from the latest

PSSRU unit cost report[18] and the opportunity costs of unpaid care by applying wage rates for hours of personal care and national living wage for hours of other care and supervision. Many people in the first three years after diagnosis will have mild dementia with relatively little functional disability, but are likely to go from independence to service use within the life of the cohort. Others will develop moderate or in some cases severe dementia within three years of diagnosis. All will receive at least some services and most will receive unpaid care. It is important that services promote continued independence, offer choice, are well co-ordinated and provide sufficient care and support to maintain good quality of life for the person with dementia and carers. Detailed data on outcomes for people with dementia will also be collected in WS1. Our main outcomes in analyses of these data will be quality of life for the person with dementia (DEMQOL, DEMQOL-Proxy, EQ5D, ONS4) and for carers (C-DEMQOL, EQ5D, ONS4). For some analyses DEMQOL-Proxy, DEMQOL and EQ5D will be converted into QALYs using societal weights. We will also examine intermediate outcomes: for people with dementia these will include functional disability, social participation, remaining in the community (not entering residential care), and not experiencing avoidable hospital admission or delayed discharge from hospital; and for carers these will include carer stress, social participation and health.

Stage 1 (months 1 to 24): We will analyse data from the MODEM study cohort of 300 people with dementia and their carers, in parallel with our analyses of these data in WS2. We will examine in particular the association between service use and costs of care in wave 1 of the MODEM cohort with outcomes at wave 2 and changes in outcomes between waves 1 and 2 controlling for the needs and characteristics of the person with dementia. Findings from these analyses will not only provide some initial evidence and insight to answer the research questions but importantly will test the strategy to be used for analysing data from the new DETERMIND cohort.

Stage 2 (months 25 to 36): We will conduct quantitative analyses of the first wave of the new DETERMIND cohort data and, on the basis of the findings, refine our plans for stage 3. We will conduct regression analyses to examine (i) the relationships at baseline between outcomes and service inputs and their costs; (ii) variations in this relationship by social determinants such as gender, marital status and socio-economic status; and (iii) the variation in use of services and costs between people with differing levels of cognition and functional disability, controlling for individual characteristics.

Stage 3 (months 37 to 60): We will examine how care packages and their costs at successive waves of the cohort are associated with outcomes at different points in time

(RQs 1 and 2) and how this relationship varies with the personal characteristics of the person with dementia and carer (RQ4). We will study how unmet needs in earlier waves affect outcomes in later waves (RQ3) and how this relationship varies with the characteristics of the person with dementia and carer (RQ4). Longitudinal analyses will examine influences on outcomes at different time-points.

Statistical methods: In all stages, we will first conduct descriptive analyses to investigate the characteristics of people in the sample and understand how different variables are correlated. To understand the relationships between outcome and costs, in stages 1 and 2, we plan to build linear regression models. The dependent variables will be the quality of life of older people living with dementia and the immediate outcomes outlined above. The key independent variables are the use of care services, unmet needs and costs of care.

Drawing on the rich information in the MODEM (see WS2) and DETERMIND datasets, we will control for demographic characteristics (age, gender, ethnicity), social support network (marital status, living arrangements, number of children), care needs and strengths (severity of dementia, self-reported health, and number of chronic diseases), and socioeconomic status (income, education, and housing tenure). We will calculate robust standard errors to take account of the heteroskedastic data and make valid statistical inferences. We will conduct post-estimation diagnostics to make sure that our models are correctly specified and to minimise any bias in our estimates. In stage 3, we will build multi-level linear regression models and latent growth curve models. Drawing on a longitudinal dataset, a multilevel design has two further advantages. First, it accounts for the unobserved individual-level heterogeneity which may lead to biased regression results. Second, by including a time variable, random intercept and random slope (coefficient) in the models allows us to examine trajectories of quality of life and immediate outcomes over time and so understand better the important factors that alter these trajectories.

WS4: Experience of self-funders of care

Research questions:

(i) What are self-funders' experiences of navigating care systems and arranging care post-dementia diagnosis?

(ii) What are the patterns of self-funders' journeys over time, and how do these differ from those of people funded by councils?

(iii) How do interactions with key people and services affect self-funders' choices and decision-making over time?

(iv) What are the socio-demographic characteristics of self-funders, and what role do particular characteristics such as age, sexuality and ethnicity play in decision-making and experiences of care and support?
(v) What social science theories facilitate understanding of self-funders' experiences?

Method: WS4 will investigate the experiences of people with dementia and carers who are presented with the challenges and opportunities of self-funding. We will initially identify, using economic characteristics, those in our DETERMIND cohort who are likely to become self- or council-funded (WS1), and follow them up to explore differences in costs and outcomes quantitatively, the decisions that they make, when they make them and the relationship with subsequent transitions in care. We will examine difference in patterns between self- and council-funded individuals (e.g. falling back on council funding when personal resources are depleted). We will identify those starting home care and making transitions into care homes, exploring these processes in detail through in-depth qualitative interviews with people with dementia and their carers. Interviews will also explore interactions with service providers, councils, family, friends and carers, and sources of information such as the internet, plus experiences of choice and control, especially at key transitions between services or sectors. WS4 will yield valuable data via complementary quantitative and qualitative approaches interfacing with WS5 developments on individual characteristics that determine choice and effective use of that choice and WS6 in the effects of services over time.

Through semi-structured interviews we will explore experiences and issues of information-need and seeking, reassurance and confidence in decision-making as well as the dynamic journey through the condition in relation to care and funding for self-funders living with dementia. The topic guide will ensure consistency, but the format will be flexible to allow participants to generate naturalistic data on what they constitute as important and/or successful in terms of outcomes. It is anticipated that an initial sample of 30 people with dementia and/or their carers will be selected from baseline data, with 10 followed up at two time points (12m and 24m). A further 20 selected from discussions with other work streams to target arising points for further exploration will be selected from 12 month follow up data and followed up (at 24m and 36m). Sampling will be driven from two perspectives: (i) purposive sampling to achieve maximum variation addressing gender, ethnicity, living circumstances, funding, levels of care need, impact of dementia; and (ii) to further explore questions informed by interim analyses emerging from the cohort data.

WS5: Understanding decision-making by people with dementia and carers

The principal research question addressed by WS5 is:

Do individual differences in self-regulation predict differences in outcomes (e.g., decision-making, quality of life, well-being) over time?

Method: The basic assumption underlying analyses in WS5 is that individuals' self-regulatory and decision-making competencies following a diagnosis of dementia vary, and thus different people will show different response trajectories, and benefit from different support. Consistent with the notion of precision medicine, the ultimate goal is to understand how best to support decision-making for the best personal outcome, optimally using the resources available. We will first explore how differences in key elements related to decision-making competencies (understood through core aspects of self-regulation: emotion regulation, cognitive control, self-reflection) impact upon various outcomes such as well-being and quality of life and how this changes with disease progression. We will examine how standardized measures of the core aspects of self-regulation (e.g., emotion regulation: mDES, ERQ; cognitive control: Brief COPE; self-reflection: SSAM, LOT, BPNSF) individually and jointly determine indicators of decision making (e.g., CFQ, BADL, DMI, responses to specific decision-making questions embedded in Brief COPE, SOC, and BPNSF) and how this can help us to understand individual differences in outcomes (linking with WS3). Disease progression, indexed by sMMSE, NPI, and IES will be included in the model.

Quantitative analyses will include examining cross-sectional and longitudinal associations between variables. These will be supplemented by the use of purposively sampled qualitative interviews with individuals whose trajectories diverged at key decisions to enhance our understanding of decision making processes and their impact on outcomes. For WS5, a key focus will be on the role of emotion regulation, an important but poorly understood predictor of outcomes in both people with dementia and carers[19, 20]. The combined insights from qualitative and quantitative data will allow us to develop grounded hypotheses to inform the development of mechanistic models of decision making and to move towards the development of empirically grounded behavioural interventions.

WS6: Effect of diagnostic stage and services on outcomes

Research questions:

(i) How do outcomes for people with dementia and their carers vary by diagnosis at earlier/later stages of the disorder?

(ii) What diagnostic service characteristics predict better and worse outcomes?

(iii) How do outcomes for people with dementia and carers vary by differing peridiagnostic and post-diagnostic care?

Method: The interviews will include at baseline a direct assessment of severity of dementia at diagnosis from MAS notes, MMSE score and Clinical Dementia Rating (CDR), a four-point global staging of dementia (0.5=minimal, 1=mild, 2=moderate, 3=severe). We will define 'earlier' as CDR=0.5&1 and 'later' as CDR=2&3 at diagnosis. We will also at baseline ascertain the date of onset (6m period) of first symptoms of dementia and date and pathway to diagnosis including a retrospective assessment of service receipt up to diagnosis, so allowing an assessment of time to diagnosis from emergence of the dementia. Illness trajectory to diagnosis will be ascertained by time from first symptoms to diagnosis and CDR stage at diagnosis. We will prospectively record the offers and use of post diagnostic health and social care services over the three year follow up period.

Quantitative analyses will focus on assessing the impact of earlier/later diagnosis of dementia, service characteristics, and subsequent care on outcomes, identifying predictors of good/bad outcomes. For example, in the earlier/later stage diagnosis analyses, adjusting for patient characteristics, the specific hypotheses to be tested will include whether there are clinically significant differences between those diagnosed earlier compared with later at 12/24/36m in: (i) person with dementia HRQL (DEMQOL/DEMQOL-Proxy) higher by 4 points; (ii) comprehensive costs (CSRI) lower; (iii) emotional impact of diagnosis (IES) lower; (iv) carer burden (CBI) lower; (v) carer quality of life (EQ-5D and C-DEMQOL) higher. In the first stage of the analyses, descriptive statistics will characterise the samples at baseline. Our primary analysis will be a multiple linear regression model with DEMQOL-Proxy as outcome, baseline DEMQOL-Proxy as covariate, and stage at diagnosis as our main covariate. We will adjust for other possible confounders at baseline. We will use similar models for secondary outcomes. Stage will be defined primarily as a binary variable (CDR earlier=0.5&1, later=2&3) in secondary analyses this will be examined as an ordered categorical variable (0.5/1/2/3). The final analysis will model all outcomes (12/24/36m) in a mixed effects model using the same covariates. DEMQOL-Proxy is our primary outcome, dementia is progressive and DEMQOL-Proxy has good psychometric properties across the range of dementia severity.

To complement and contextualise the quantitative data we will complete in-depth interviews with people with dementia and carers from the cohort to capture different narratives of 'how' and 'why' things happen at diagnosis and after, and how these affect quality of life and other outcomes. These interviews will provide an understanding of the impacts and outcomes of diagnosis on patients and carers over time. Specifically, they enable us to explore how variation by earlier or later diagnosis and post-diagnostic care, including how services and

the diagnostic process are perceived, enhance or impair quality of life. These interviews will explore post-diagnosis expectations and experiences that endure, what changes and what, over time, ceases to be an issue. A maximum variation sample will be drawn to ensure inclusion of key characteristics (e.g. ethnicity, living alone) to aid generalisability. Interview guides will be developed with the research team from the literature[21, 22] and our PPI panel. The framework for interviews and analysis will draw on stress, appraisal and coping theory[23]. Based on earlier work we anticipate three broad areas that are likely to be affected by when and how they received their dementia diagnosis: (i) how it affects individuals' sense of self, relationships and ability to maintain activities that are important to them as active citizens; (ii) how it enables them (or not) to adapt and use technologies and existing networks of support; and (iii) how it links to the use of information and the ability to connect with and navigate professional systems of support. We will triangulate the complementary quantitative and qualitative data to generate an evidenced framework to help professionals understand better the positive/negative impacts of making a diagnosis in dementia at differing stages.

WS7: Programme management and Theory of Change guided research development, coordination and promotion of impact

We will use Theory of Change to coordinate and co-develop research findings from each of the WSs in order to generate a theoretically integrated and holistic model of inequities in dementia care. This model will, in turn, help guide our outputs and proposed actions for impact. The development of the theory of change model will be both iterative and collaborative, extending over the course of the project and undertaken in close collaboration with stakeholders, including people with dementia, carers, practitioners, commissioners and policy makers. Theory of change is particularly well suited to guiding investigations into mediating factors in complex systems. The theory of change model will also provide a visual conceptual map of the journey undertaken by people with dementia and carers, covering initial diagnosis, post-diagnostic care and outcomes of interest, and will clarify how mediating factors explored in WS2-WS6 shape people's experiences, access to support and the outcomes they achieve. Led as a separate WS, we will use this theory-driven framework in four key ways:

(i) To coordinate and integrate research processes
(ii) To facilitate the conceptually-grounded integration of findings
(iii) To facilitate and capture practice insights from stakeholders
(iv) To guide and support stakeholder engagement approaches, communication, influencing and co-production strategies

Method:

Phase 1 (months 3 to 9): We will organise two initial theory of change workshops; each will introduce, develop and refine an initial theory of change model to establish a clear, shared starting point. One of these workshops, for the research teams, will be used to clarify relevant theoretical and conceptual frameworks (relevant to the overall model and/or specific aspects of it) and to represent these appropriately (as, if necessary, provisionally) in the model, making clear how they inform research questions, hypotheses, assumptions and/or interpretive frameworks. Research questions and approaches will be honed in light of these discussions and clear objectives for each WS will be established. For our second workshop, we will identify key national stakeholders, with the help of our academic partners, Alzheimer's Society and other health and care partners. We will share the evolving theory of change model and seek input and insights to inform it as a whole and to help develop ideas within specific WSs. We will also use these discussions to begin to identify contextually feasible goals, outputs and pathways to effect necessary changes in practice. In addition to the workshops, we will conduct six face-to-face qualitative interviews with senior staff from local service providers in the areas that our cohort is drawn from to provide the project team with further relevant context; the content of these interviews will be determined during the workshops.

Phase 2 (months 18, 30 & 42): We will reconvene our researcher and stakeholder groups annually over the next 3 years to develop the overall theory of change model. In these workshops, we will review data and findings to date, clarify how these shape the model and, as needed, further refine and focus the investigations in each WS. We will also use the workshops to review progress using indicators developed as part of the theory of change process, for each WS and the programme as a whole. In the workshop held 18 months into the project, for example, we will review the recruitment of the cohort to target and its characteristics (WS1); and review emerging data from analyses of ELSA, MODEM and CFAS to inform the next stage analyses of the DETERMIND cohort (WS2, WS3).

Phase 3 (months 54 to 60): In two further sets of workshops, we will intensively refine and finalise the overall theory of change model so that it adequately reflects findings from each WS, provides an overall conceptual map of ways in which mediating factors influence access, experiences, outcomes and costs and, within this, develop and refine practical proposals for addressing inequities. These proposals will be grounded in empirical, conceptual and theoretical developments and be located clearly within causal pathways. In addition to working with experts, advisors, people with dementia and carers in workshops we

will also conduct nine interviews with senior staff from service providers in the areas from which the cohort is drawn to gain additional insights into the model and to 'road-test' ideas and proposals generated through the theory of change workshop process. Through these activities we will agree the final set of conclusions, recommendations and actions.

DETERMIND PPI and ethical processes

PPI process: Margaret Dangoor (MD), an expert by experience of being a family carer for two people with dementia over a 20-year period and is active in the dementia and carer community, is a full applicant on this proposal and has been involved in all stages of the research. The Alzheimer's Society supports this programme and has agreed to work with us as an integral element of our PPI strategy and in WS7 throughout the programme. Pre-study PPI consultation identified sensitivities for carers, reflecting on different experiences of diagnosis and post-diagnostic support. Group members identified the need for interviewers to be aware of and trained for the emotional impact of interviews. The group reinforced the need to ensure that recruitment represents a diverse population.

Our PPI lead MD has set up a Reference Group of Users and Carers (RGUC) of about ten people, and as noted above, has been involved in all stages of the preparation of our proposal. The RGUC, which will be an evolving group and aim to reflect the diversity of people with dementia and their carers, will meet at least twice in the first year, and then at key points in the project when we are facing key decisions about next steps or about the interpretation of findings. Some members will be asked to join project subgroups. The RGUC will be represented on the project's Advisory Group. The RGUC will meet throughout the study: prior to ethics submission they will consult on consent and information sheets; they will represent the patient/carer view in recruitment preparation; troubleshoot recruitment issues; collaborate in the development of frameworks for interviews in the qualitative elements of the study; and support the interpretation of results and dissemination to patient and carer groups. Deliberative workshops will inform interpretation and dissemination of findings.

Ethical considerations: Ethical approval for the study has been obtained from The London: Brighton and Sussex Research Ethics Committee (REC 19/LO/0528). Where possible, fully informed written consent will be obtained from people with dementia at entry, carers will give their consent for their own participation. Some people with dementia may lack the mental capacity to give this. The study aims are incompatible with only entering people with mild dementia and capacity. Also we must allow for increasing severity of dementia over time with possible loss of capacity. After the study has been explained and information given, all

people with dementia will have capacity assessed by a trained researcher. Agreement to participate will be obtained to their best level of understanding and recruitment will not proceed if they refuse or show signs of distress. Each participant with dementia, will have a consultee (personal or professional) identified. Where capacity is lacking, their opinion will be sought about whether the person with dementia would have chosen to participate if they still had capacity to express a view. They will be asked to sign a consultee declaration. Those assessed as not having the capacity to consent will be enrolled if they show no objection to participation. If the participant loses capacity (assessed each visit) their consultee will be asked to make decisions on their behalf.

Conclusion

This is a mixed methods study with integrated and complementary quantitative and qualitative enquiry that seeks to examine and address inequalities in dementia care. The new DETERMIND cohort will facilitate regularly collected quantitative data across the pathway of the journey through dementia from diagnosis. This will be combined with qualitative methods to allow in-depth enquiry at regular points, providing the opportunity to systematically interrogate trends from the quantitative data and to generate new hypotheses and insights. We will use 'triangulation protocols' at a thematic level and 'mixed methods matrices' at the level of individual cases for data integration.

Next steps: It is a major strength of DETERMIND that we can look in detail at the first three years following diagnosis. It is a weakness that much will happen in the next five years after this study has finished its follow-up. Once we have recruited our cohort we will seek further funding to complete five additional waves of follow-up from four to eight years following diagnosis. This would be a very valuable extension

Data availability

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations. All research data will be archived and securely stored for 10 years after the end point of the study. Following the end of the study, anonymised data will also be uploaded to the UK Data Archive online repository. Access to data will be limited to authorised researchers who will agree to the End User License (http://dataarchive.ac.uk/conditions).

References

1. Wallace SP. The no-care zone: Availability, accessibility, and acceptability in community-based long-term care. *The Gerontologist.* 1990;30(2):254-261.
2. Miranda-Castillo C, Woods B, Galboda K, Oomman S, Olojugba C, Orrell M. Unmet needs, quality of life and support networks of people with dementia living at home. *Health and quality of life outcomes.* 2010;8(1):132.
3. Hoe J, Hancock G, Livingston G, Orrell M. Quality of life of people with dementia in residential care homes. *The British Journal of Psychiatry.* 2006;188(5):460-464.
4. Daly S, Allen J. Inequalities in Mental Health, Cognitive Impairement and Dementia Among Older People. *University College London Institute of Health Equity, London.* 2016.
5. Black BS, Johnston D, Rabins PV, Morrison A, Lyketsos C, Samus QM. Unmet needs of community-residing persons with dementia and their informal caregivers: Findings from the maximizing independence at home study. *Journal of the American Geriatrics Society.* 2013;61(12):2087-2095.
6. Cooper C, Lodwick R, Walters K, et al. Observational cohort study: deprivation and access to anti-dementia drugs in the UK. *Age and ageing.* 2015;45(1):148-154.
7. Leist A. Social inequalities in dementia care, cure, and research. *Journal of the American Geriatrics Society.* 2017;65(5):1100-1101.
8. Public Health England. *Prevalence of dementia in population groups by protected characteristics: A systematic review of the literature.* 2015.
9. Ilinca S, Rodrigues R, Schmidt A. Fairness and eligibility to long-term care: an analysis of the factors driving inequality and inequity in the use of home care for older Europeans. *International Journal of Environmental Research and Public Health.* 2017;14(10):1224.
10. Kenning C, Daker-White G, Blakemore A, Panagioti M, Waheed W. Barriers and facilitators in accessing dementia care by ethnic minority groups: a meta-synthesis of qualitative studies. *BMC psychiatry.* 2017;17(1):316.
11. Parveen S, Peltier C, Oyebode JR. Perceptions of dementia and use of services in minority ethnic communities: a scoping exercise. *Health & social care in the community.* 2017;25(2):734-742.
12. Ferguson-Coleman E, Keady J, Young A. Dementia and the Deaf community: knowledge and service access. *Aging & mental health.* 2014;18(6):674-682.
13. Dilworth-Anderson P, Pierre G, Hilliard TS. Social justice, health disparities, and culture in the care of the elderly. *The Journal of Law, Medicine & Ethics.* 2012;40(1):26-32.
14. Callard F, Broadbent M, Denis M, et al. Developing a new model for patient recruitment in mental health services: a cohort study using Electronic Health Records. *BMJ open.* 2014;4(12):e005654.
15. Comas-Herrera A, Knapp M, Wittenberg R, et al. MODEM: A comprehensive approach to modelling outcome and costs impacts of interventions for dementia. Protocol paper. *BMC health services research.* 2017;17(1):25.
16. The Institute for Fiscal Studies. *ELSA English Longitudinal Study of Ageing.* 2011.
17. Matthews FE, Arthur A, Barnes LE, et al. A two-decade comparison of prevalence of dementia in individuals aged 65 years and older from three geographical areas of England: results of the Cognitive Function and Ageing Study I and II. *The Lancet.* 2013;382(9902):1405-1412.
18. Curtis L, and Burns, A. *Unit Costs of Health and Social Care 2017.* University of Kent: PSSRU;2017.

19. Bassal C, Czellar J, Kaiser S, Dan-Glauser ES. Relationship between emotions, emotion regulation, and well-being of professional caregivers of people with dementia. *Research on aging.* 2016;38(4):477-503.
20. Monin JK, Schulz R, Kershaw TS. Caregiving spouses' attachment orientations and the physical and psychological health of individuals with Alzheimer's disease. *Aging & mental health.* 2013;17(4):508-516.
21. Bunn F, Goodman C, Sworn K, et al. Psychosocial factors that shape patient and carer experiences of dementia diagnosis and treatment: a systematic review of qualitative studies. *PLoS medicine.* 2012;9(10):e1001331.
22. Brooker D, Fontaine JL, Evans S, Bray J, Saad K. Public health guidance to facilitate timely diagnosis of dementia: ALzheimer's COoperative Valuation in Europe recommendations. *International Journal of Geriatric Psychiatry.* 2014;29(7):682-693.
23. Brossard B, Carpentier N. To what extent does diagnosis matter? Dementia diagnosis, trouble interpretation and caregiving network dynamics. *Sociology of health & illness.* 2017;39(4):566-580.
24. Thomas AJ, Taylor JP, McKeith I, et al. Development of assessment toolkits for improving the diagnosis of the Lewy body dementias: feasibility study within the DIAMOND Lewy study. *International journal of geriatric psychiatry.* 2017;32(12):1280-1304.
25. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. *American psychologist.* 2000;55(1):68.
26. Carver CS. You want to measure coping but your protocol'too long: Consider the brief cope. *International journal of behavioral medicine.* 1997;4(1):92.
27. Bucks RS, Ashworth D, Wilcock G, Siegfried K. Assessment of activities of daily living in dementia: development of the Bristol Activities of Daily Living Scale. *Age and ageing.* 1996;25(2):113-120.
28. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *Journal of chronic diseases.* 1987;40(5):373-383.
29. Broadbent DE, Cooper PF, FitzGerald P, Parkes KR. The cognitive failures questionnaire (CFQ) and its correlates. *British journal of clinical psychology.* 1982;21(1):1-16.
30. Morris JC. The Clinical Dementia Rating (CDR): current version and scoring rules. *Neurology.* 1993;43:2412–2414.
31. Beecham J, Knapp M. Client Service Receipt Inventory (CSRI). *Database of Instruments for Resource Use Management.* 1992.
32. Menne HL, Tucke SS, Whitlatch CJ, Feinberg LF. Decision-making involvement scale for individuals with dementia and family caregivers. *American Journal of Alzheimer's Disease & Other Dementias®.* 2008;23(1):23-29.
33. Brown A, Page TE, Daley S, et al. Measuring the quality of life of family carers of people with dementia: development and validation of C-DEMQOL. *Quality of Life Research.* 2019:1-12.
34. Smith S, Lamping D, Banerjee S, et al. Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology. *Health Technology Assessment (Winchester, England).* 2005;9(10):1-93.
35. Niven K, Totterdell P, Stride CB, Holman D. Emotion Regulation of Others and Self (EROS): The development and validation of a new individual difference measure. *Current Psychology.* 2011;30(1):53-73.
36. The EuroQoL Group. EuroQol-a new facility for the measurement of health-related quality of life. *Health policy.* 1990;16(3):199-208.
37. Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: A measure of subjective stress. *Psychosomatic medicine.* 1979;41(3):209-218.

38. Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the Life Orientation Test. *Journal of personality and social psychology.* 1994;67(6):1063.
39. Lubben J, Blozik E, Gillmann G, et al. Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations. *The Gerontologist.* 2006;46(4):503-513.
40. Fredrickson BL, Tugade MM, Waugh CE, Larkin GR. What good are positive emotions in crisis? A prospective study of resilience and emotions following the terrorist attacks on the United States on September 11th, 2001. *Journal of personality and social psychology.* 2003;84(2):365.
41. Haslam C, Holme A, Haslam SA, Iyer A, Jetten J, Williams WH. Maintaining group memberships: Social identity continuity predicts well-being after stroke. *Neuropsychological rehabilitation.* 2008;18(5-6):671-691.
42. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. *Neurology.* 1994;44(12):2308-2308.
43. The Office for National Statistics. Personal Well-being user Guidance. 2006; https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/methodologies/personalwellbeingsurveyuserguide
44. Baltes P, Baltes M, Freund A, Lang F. Measurement of selective optimization with compensation by questionnaire. *Berlin: Max Planck Institute for Human Development.* 1995.
45. Robins RW, Hendin HM, Trzesniewski KH. Measuring global self-esteem: Construct validation of a single-item measure and the Rosenberg Self-Esteem Scale. *Personality and social psychology bulletin.* 2001;27(2):151-161.
46. Harris PR, Griffin DW, Napper LE, et al. Individual differences in self-affirmation: Distinguishing self-affirmation from positive self-regard. *Self and Identity.* 2018:1-42.
47. Molloy DW, Standish TI. A guide to the standardized Mini-Mental State Examination. *International Psychogeriatrics.* 1997;9(S1):87-94.
48. Army U. Army individual test battery. *Manual of directions and scoring.* Washington, DC: War Department, Adjutant General's Office, 1944.
49. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *The gerontologist.* 1980;20(6):649-655.

Table 1: Baseline Measures for DETERMIND

Measure	Description	Ref
Assessment Toolkit for Dementia with Lewy Bodies	A 15 item toolkit that aims to facilitate a diagnosis of dementia with Lewy bodies	[24]
Basic Psychological Need Satisfaction and Frustration Scale (BPNSF)	A 24 item questionnaire to measure addresses both need satisfaction and frustration in general in one's life	[25]
Brief COPE	A 28-item measure of coping with life stressors.	[26]
Bristol Activities of Daily Living (BADL)	A 20-item question of activities of daily living	[27]
Charlson Comorbidity Index (CCI)	A 16-item checklist of common comorbidities	[28]
Cognitive Failures Questionnaire (CFQ)	25 items to assess the frequency people experience cognitive failures	[29]
Clinical Dementia Rating Scale (CDR)	A brief measure of dementia severity	[30]
Client Service Receipt Inventory (CSRI)	A well-established instrument for the assessment of direct and indirect costs of illness. The measure includes participant demographics, support provided and care planning	[31]
Decision-Making Involvement Scale (DMI)	15 item scale providing a direct measure of a person with dementia's reported engagement in the decision-making process	[32]
C-DEMQOL	A 30-item questionnaire to assess quality of life in family carers of people with dementia	[33]
DEMQOL	28 item interviewer-administered questionnaire answered by the individual with dementia, dementia specific health related quality of life measure	[34]
DEMQOL-Proxy	31 item interviewer-administered questionnaire answered by the caregiver on the individual with dementia, dementia specific health related quality of life measure	[34]
Emotion Regulation of Others and Self extrinsic subscale (EROS)	A 9-item questionnaire individual differences in the use of strategies to improve and to worsen one's own and other people's affect	[35]

EuroQol (EQ5D-5L)	A 5 item, self-report questionnaire on generic health related quality of life	[36]
IDEAL study questionnaire	A self-created questionnaire on planning for the future and the relationship between the person with dementia and carer	
Impact of Event Scale-Revised (IES-R)	22-item questionnaire that quantified the frequency of intrusive thoughts and avoidance behaviors associated with stressful events. The scale has been adapted to specifically relate to the diagnosis of dementia.	[37]
Life Orientation Test-Revised (LOTR)	A 10- item measure of optimism vs pessimism	[38]
Lubben Social Networks Scale	A 6-item version to assess social engagement.	[39]
Modified Differential Emotions Scale (mDES)	A 20-item measure of discrete emotions, both positive and negative	[40]
Multiple Group Memberships Scale (MGM)	A 4-item scale measuring subjective multiple group memberships.	[41]
Neuropsychiatric Inventory (NPI)	Brief rating scale to record presence of behavioural and psychiatric symptoms in dementia	[42]
ONS4	A four item questionnaire of personal well-being	[43]
Selection, Optimization and Compensation scale (SOC)	A 12-item questionnaire to assess selection, optimization and compensation	[44]
Single Item Self-esteem Scale	A single item measure of self-esteem	[45]
Spontaneous self-affirmation measure (SSAM)	A 10-item measure of self-affirmation	[46]
Standardized Mini-Mental State Examination (sMMSE)	A brief, global measure of cognitive function	[47]
Trail Making Task (TMT)	A neuropsychological test to measure executive function, visual attention, task switching and inhibition.	[48]
Zarit Carer Burden Inventory – Short Form (ZCBI)	A 12 item scale to measure carer burden	[49]