

Comprehensive modelling of dementia – Protocol v3.0

MODEM: Comprehensive approach to modelling outcome and cost impacts of interventions for dementia

(MODEM WP8 – cohort study)

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Professor Sube Banerjee, Professor of Dementia, Brighton and Sussex Medical School, University of Sussex, Brighton, BN1 9RY. UK.
Tel. 01273 678472

Email s.banerjee@bsms.ac.uk

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Background

Because of its cognitive, functional, behavioural and social consequences, dementia has enormous impacts on the health and quality of life of people with the illness, their families and other people who care for them. Many people with dementia have multiple needs, and receive a lot of support from family and other unpaid carers, as well as treatment and care from health and social care services. Many eventually move into care homes. The costs of supporting people with dementia can therefore be very high. As the UK population continues to age, the number of people with dementia will grow considerably over the coming decades. Continuing with today's treatment, care and support arrangements is widely seen as unsustainable and unaffordable. A major challenge is how to provide high-quality treatment and support to these individuals at a cost seen as affordable. In England, care and support arrangements are guided by the National Dementia Strategy, with similar commitments in Scotland, Wales and Northern Ireland. The Prime Minister's personal 'Challenge' on dementia illustrates the policy priority attached to meeting the needs of people with dementia. Against this background, this project will generate new evidence to help decision-makers in the health and social care systems to develop and implement strategies to meet the needs and improve the wellbeing of people with dementia and their carers in ways that make better use of society's resources over coming decades. This is our first research objective.

Evaluations and audits have identified major quality concerns in provision, highlighting issues around ineffectiveness, coordination, access to care and affordability. They also identify major gaps in the evidence base. Knowledge on the outcomes and costs of interventions has grown considerably in recent years, and the NIHR, RCUK and other current studies will add to the evidence base. But often these are small studies that do not examine how multiple factors interact to influence quality of life, disease progression, survival or costs; or examine inter-personal variations; or follow people with dementia for more than short periods. In turn, this has prevented thorough estimation of current and future economic impacts on individuals and care systems. Models that have been built have generally either simplified the life-course or taken one small element of it and extrapolated to others, without accurately establishing interconnections across dimensions such as cognitive decline and behaviour, dementia and depression, health and social care systems or impacts on carers. Integrative modelling that addresses this complexity is crucial to address key policy and practice questions about outcomes of current and potential future interventions And their economic consequences.

We will develop a comprehensive, integrative, quantitative set of models to estimate current and future needs, and the costs of current and alternative interventions aimed at meeting them. We will draw on the findings of trials and evaluations for evidence on outcomes and costs. (We use the term ‘intervention’ to refer to prevention, treatment, care and support arrangements, and including training of care staff, training and support for carers. By ‘outcome’ we mean improvements in the health and wellbeing of people with dementia and their carers compared to what would have happened without the intervention. By ‘costs’ we mean the full set of resource impacts, across health, social care and other relevant systems, and including the resources of people with dementia, families and local communities.) We will link macro- and micro-simulation models that integrate knowledge from multiple sources, accounting for the complexity that is otherwise impossible to address in studies that focus only on the impact of a specific intervention or treatment. We will explore the impacts of interventions on health and quality of life for people with or at risk of developing dementia and their carers, together with the costs of treatment, care and support. Results from our project will provide important evidence on what types and configurations of interventions have greatest impact on key outcomes, and with what cost and funding consequences. As part of this work, we aim to improve understanding of individual-level variation in the costs and outcomes of interventions. Dementia is a complex mix of diagnoses (Alzheimer’s disease; vascular, mixed and Lewy body dementia), speed and patterns of progression, co-morbidities, unpredictable behavioural and psychological symptoms. There is considerable variability in patterns of social support and formal care, and the effects of care and treatment are uneven. There is also, of course, huge variability in individual characteristics, resilience, coping strategies, circumstances and preferences. This heterogeneity has not previously been adequately incorporated in models. The complexity also leads to considerable variation in the many potential impacts for individuals, families, unpaid and paid carers.

MODEM is organised into 12 work packages (WPs): **WP1** Project management and coordination; **WP2** conceptual framework; **WP3** Macro-simulation projection model; **WP4** Micro-simulation epidemiological model; **WP5** Social participation model (Bowling, Grundy); **WP6** Literature review; **WP7** Data extraction from previous studies; **WP8** Cohort study; **WP9** Qualitative study; **WP10** Intervention models; **WP11** Legacy model; **WP12** User engagement; **WP13** Knowledge transfer. This ethical approval covers WP8 which seeks to collect new data from people with dementia and carers.

The MODEM programme will examine existing data to get a clearer understanding of the links between a number of factors: the characteristics of individuals and families, their dementia-related and other needs for care and support, and the services and treatments that could be available to them. We will look at the effects of care, support and treatments on outcomes for individuals and carers - how those interventions can improve their health and wellbeing - and also on the costs of support.

With this information we will first make projections of how many people there will be with dementia over the period to 2040, what family or other unpaid support they are likely to have available, and what it will cost to provide care services. Second, we will examine whether there are better ways to support people with dementia and their carers by introducing new forms of care and treatment. For this part of the research we will rely on previous studies that have examined whether these interventions improve health and wellbeing, and at what cost. We will identify those 'new ways' by reviewing previous studies of dementia care and treatment (and also reviewing ways to prevent or delay dementia). We will look for evidence on, e.g., medications, cognitive stimulation and other therapies, exercise programmes, nutrition advice, telecare, community initiatives, respite and training for carers.

This ethical approval relates to a single element of the MODEM programme where new clinical data will be collected. We will collect new data from 300 people with dementia and their carers, looking at their lives, needs and care at two time points over 12 months. We will not be testing any interventions with these people. Instead we need information to help make the best use of data that we can draw from previous studies.

We will pull all this evidence together to simulate what would be likely to happen if interventions with proven benefits for people with dementia and/or their carers were more widely adopted nationally over the coming decades. We are particularly interested in the economic implications: how the future costs of care might be reduced while health and wellbeing are improved. We will develop a publicly available tool (accessible via the Web) to enable commissioners, providers, charities, individuals and families to use our evidence to make projections of future costs under different assumptions about population needs, services and treatments. We will work with people with dementia, carers and other potential users of our research at all stages of the project.

Aim

We have six project objectives:

1. To generate new evidence to inform policy and practice so as better to meet needs, promote health and wellbeing, and achieve efficiency in the use of society's resources.
2. To build on a comprehensive conceptual and integrative framework that covers impacts of dementia on cognition, functioning and behaviour, responses from unpaid carers, responses from health and social care systems, the effectiveness and cost impacts of these interventions, and the potential long-term funding implications.
3. To develop a suite of linked quantitative models - both micro- and macro-simulation - to project future numbers of people with dementia, unpaid and formal care and associated expenditure, and to estimate typical life-time costs of dementia, under varying assumptions about risk factors, patterns of care and support, and about preferences.
4. To gather new evidence on the lives of people with dementia and their carers, and interventions that could delay onset, slow deterioration in cognition, functioning or behaviour, or reduce their adverse impacts on wellbeing, and on costs. This evidence would be gathered through literature reviews, data from previous/ongoing trials and observational studies, primary data from a new cohort, qualitative interviews and focus groups.
5. To use this new evidence (from literature reviews, previous evaluations, new data collection, interviews/focus groups) in combination with the micro- and macro-simulation models to produce projections to 2040 of the numbers of older people with dementia in England, their needs for care and support, and associated public and private expenditure, together with projected outcomes and costs of a range of interventions to prevent or delay dementia incidence, slow symptom development, provide treatment and care, and support carers.
6. To develop a publicly available web-tool (a 'legacy model' and associated media) to enable service commissioners, providers, advocacy groups, individuals and families to access the findings and outputs of the project, and to make their own projections of expected, needs for care and support, outcomes and costs.

Method

Inclusion and Exclusion Criteria

Inclusion: We will recruit 300 people with a clinical diagnosis of dementia using ICD-10 criteria representative of people with dementia in contact with services, stratified by dementia severity. Of those recruited, 100 people will have mild dementia (scoring 20+ on the standardised Mini-Mental State Examination, 100 that are moderate (score 10-19) and 100 that are severe (score 0-9).

Exclusion: We will exclude those with no identifiable family carer or other informant (e.g. a formal/professional carer).

Recruitment

There will be 3 key routes for potential participants to be identified:

1. Patients will be identified from clinical populations served by the Sussex Partnership NHS Foundation Trust, covering Brighton and Hove and East and West Sussex. The trust serves a population of 500,000 older adults, including 30,000 people with dementia. Memory Services in the Trust see over 1,000 new cases per year, 60% of whom would meet entry criteria for this study. Another 3,000 cases are under the care of services, at least 50% of whom would be eligible for this study.
2. Study flyers will be able to be given out by clinical or care staff, or left at relevant health or care settings. Study posters will only be placed in communal areas following the relevant approvals. Potential participants will be able to self-refer to the study by contacting a member of the research team using the contact information on the flyer and poster. Research staff will not approach potential participants directly. If a participant is self-referred, a member of the research team will confirm eligibility prior to enrolment onto the study.
3. We will also be using 'Join dementia research' (JDR) as a recruitment tool. This is an on-line self-registration service that enables volunteers with memory problems or dementia, carers of those with memory problems or dementia and healthy volunteers to register their interest in taking part in research. The purpose of JDR is to allow such volunteers to be identified by researchers as potentially eligible for their studies. Researchers can then contact volunteers, in line with the volunteers preferred method of contact, to further discuss potential inclusion. JDR is funded by Department of Health working in partnership with the charities

Alzheimer's Society and Alzheimer's Research UK and is Health Research Authority (HRA) endorsed. The on-line service and all associated documentation, methods of contacting volunteers and handling of data, were reviewed by a specially convened HRA committee which included experts in research ethics, data protection and information governance. Formal endorsement was issued by the HRA in a letter dated 20 May 2014.

Any potential participant interested to learn more about the research and will be followed up by the research worker (RW) by telephone to arrange a home or clinic visit. Potential participants will be offered the chance to opt out of the telephone contact by means of a return postage-paid letter included with the information sent. At the first meeting the RWs will explain the study; if consent is obtained the person with dementia and their main family carer will be interviewed.

Ethical Issues

We have extensive experience of trial work and other research in dementia. We will recruit people with mild to severe dementia; some may not have the capacity to give informed written consent. In such cases, carers will be asked for their assent for the person with dementia to take part and the person with dementia would only be enrolled if they showed no dissent. We obtain separate consent from the carer for their contribution.

Quantitative Assessment

Patients and their carers will be interviewed by a pair of RWs who will complete the assessment at baseline and at 52 week follow-up, in either the clinic or patient's home according to the preference of the participants. The interviews will be designed to minimise respondent burden while still collecting a comprehensive dataset. Data collection is split between the person with dementia and their carer. They will be interviewed simultaneously each by the one of the RWs. We have used this approach successfully in past RCTs and observational studies in dementia. We estimate, on the basis of past fieldwork using these instruments that the data collection will take no more than 90 minutes. This approach and this length of interview has been well tolerated by participants in other studies that we have conducted. Demographic data will include person with dementia and caregiver date of birth, gender, ethnicity, education, income, living arrangements, etc.

Person with dementia on person with dementia

1. DEMQOL (Smith et al., 2007) – 28 item interviewer-administered questionnaire answered by the individual with dementia, dementia specific health related quality of life measure.
2. EuroQol (EQ5D; EuroQol, 1990) – a 5 item, self-report questionnaire on generic health related quality of life.
3. Standardized Mini-Mental State Examination (sMMSE; Molloy et al., 1997) – a brief, global measure of cognitive function.
4. Alzheimer's Disease Assessment Scale – Cognition (ADAS-COG; Rosen et al., 1984) – an 11 item, global measure of cognitive function.
5. English Longitudinal Study of Aging (ELSA) cognitive functioning module (Banks et al 2014) – assesses a range of cognitive processes including memory, speed and mental flexibility.
6. CASP-19 (Hyde et al., 2003) – a 19 item, self-report measure of quality of life comprising of four domains (control, autonomy, self-realisation and pleasure).
7. Relationship Quality Questionnaire – a two item questionnaire about their perceived relationship with their carer. This measure will only be taken at follow-up.
8. Disease insight scale – a single question on insight into their memory problems, alongside a rater report of insight. This measure will only be taken at follow-up.
9. Social isolation scale (Step toe et al., 2013) – A 14 item questionnaire about the social resources of the individual. This measure will only be taken at follow-up.
10. Physical Activity Stages of Change Questionnaire (Marcus & Forsyth, 2003) - A 4 item measure of current physical activity habits and readiness to change them. This measure will only be taken at follow-up.
11. Personal well-being scale (Step toe et al., 2013) – A 4 item measure of well-being. This measure will only be taken at follow-up.

Carer on person with dementia

1. DEMQOL-Proxy (Smith et al., 2007) – 31 item interviewer-administered questionnaire answered by the caregiver on the individual with dementia, dementia specific health related quality of life measure.

2. EuroQol (EQ5D; EuroQol, 1990) – a 5 item, proxy-report questionnaire on generic health related quality of life.
3. Neuropsychiatric Inventory (NPI; Cummings., 1997) - Brief rating scale to record presence of behavioural and psychiatric symptoms in dementia.
4. Bristol Activities of Daily Living (BADL; Bucks et al., 1996) - Brief questionnaire to assess independence in activities of daily living which is validated in older adults.
5. Client Service Receipt Inventory (CSRI; Beecham & Knapp, 1992) - a well-established instrument for the assessment of direct and indirect costs of illness.
6. Charlson Comorbidity Index (CCI; Charlson et al., 1987) – a weighted index measure of comorbidity.
7. Adult Social Care Outcomes Toolkit (ASCOT; Netten et al., 2009) – a measure designed to capture information about individual’s social care-related quality of life. This measure will only be taken at follow-up.
8. Cornell Scale for Depression in Dementia (CSDD; Alexopoulos et al., 1988) – Scale used to rate symptoms of depression which is validated in older adults with dementia. This measure will only be taken at follow-up.

Carer on carer

1. General Health Questionnaire 12 (GHQ-12; Goldberg, 1992) – a 12 item measure of nonpsychotic psychiatric disorders in a general setting.
2. EuroQol (EQ5D; EuroQol, 1990) – a 5 item, self-report questionnaire on generic health related quality of life.
3. Short Form Health Survey (SF-12; Ware et al., 1998) – a 12 item measure to measure generic health related quality of life.
4. Zarit Carer Burden Inventory (ZCBI; Zarit et al., 1985) – 22 item scale to measure carer burden.
5. Older Americans Resources and Services (OARS) social resources scale (Fillenbaum, 1988) – a 10 item questionnaire that assess the social resources available to older adults.
6. Social isolation scale (Steptoe et al., 2013) – A 14 item questionnaire about the social resources of the individual. This measure will only be taken at follow-up.
7. Personal well-being scale (Steptoe et al., 2013) - A 4-item measure of well-being. This measure will only be taken at follow-up.

Sample size

A sample size of 300 at baseline will have sufficient power to generate parameter estimates for the measures that can be used alongside existing datasets. Using baseline data from the HTA-SADD study, we calculate that $n=300$ would enable the following 95% confidence intervals for key variables: MMSE ± 0.84 (out of 30); DEMQOL ± 1.95 (out of 112); NPI ± 1.99 (out of 144). In terms of change (e.g. to test hypotheses that people with mild dementia have different quality of life outcomes than those with severe dementia) our sample size ($n=100$ in each group) is sufficient to show a standardized difference (effect size) ≥ 0.4 at $p < 0.05$ and 80% power allowing for 10% attrition at follow-up. For paired data (e.g. to test hypotheses that quality of life will deteriorate over time in the mild dementia group) our subsample size ($n=100$ at baseline and $n=90$ at follow-up) is sufficient to show a standardised difference ≥ 0.3 at $p < 0.05$ and $> 80\%$ power, assuming pre-post correlation of 0.5. The trials from which we will derive comparative data (e.g. SADD, DOMINO, CALM and pivotal) are all roughly the same size. We judge that 300 at baseline will deliver sufficient precision in terms of the parameter estimates of the clinical and cost variables generated. By balancing numbers across severity groups, we will maximise efficiency while delivering comparable precision.

Timetable

Fieldwork to start 1 April 2015

1. Months 1 to 12: Obtain ethical approvals, preparation of materials, staff recruitment and training
2. Months 13 to 24: Recruit cohort of 300 patients and conduct baseline interviews
3. Months 25 to 36: 12 month follow up interviews

Funding and Resources

The study is funded by the Economic and Social Research Council (ESRC). For WP8 two full-time and two part-time RWs will be employed in the recruitment of participants and administer quantitative measures.

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