UK Data Service Study Number 854293

Improving the experience of Dementia and Enhancing Active Life: The IDEAL Programme

Wave 1 Supporting documents

12/03/2020

University of Exeter, Centre for Research in Ageing and Cognitive Health (REACH)

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This Handbook is for the use of researchers working on the IDEAL study and should not be passed on to anyone outside the study. To ensure you are working with the current version of the handbook, always refer to the Investigators Site File for the latest version.

Version 1. 18/06/2014

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www.IDEALproject.org.uk

The IDEAL study: Quick reference

The IDEAL study is a five-year longitudinal cohort study of the experiences of 1500 people with dementia and their primary carers throughout the UK. This study focuses on understanding what helps people with dementia and carers to live well with dementia and how we can improve the ability of people with dementia and carers to live well with dementia.

Funding and Project Partners

The IDEAL study is funded by the Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR) through grant ES/L001853/1 'Improving the experience of dementia and enhancing active life: living well with dementia' (Investigators: L. Clare, I.R. Jones, C. Victor, J.V. Hindle, R.W. Jones, M. Knapp, M. Kopelman, A. Martyr, R.G. Morris, S.M. Nelis, J. Pickett, C. Quinn, J. Rusted, N. Savitch, J. Thom, & R. Whitaker). The support of the ESRC and NIHR is gratefully acknowledged.

IDEAL started in January 2014 and is led by the Research in Ageing and Cognitive Health (REACH) group at Bangor University. The REACH group and NWORTH at Bangor University will act as the co-ordinating centre for the study.

Project partners are the Alzheimer's Society, Brunel University, Cardiff University, Innovations in Dementia CIC, Kings College London, London School of Economics, NWORTH, Sussex University, and RICE. We will work closely with the UK research networks – NIHR Clinical Research Network (CRN): Dementia and Neurodegenerative Diseases in England, NISCHR CRC in Wales, and SDCRN in Scotland.

Ethics

The IDEAL study was approved for the UK by the North Wales – West NHS Research Ethics Committee (reference 13/WA/0405), and the Ethics Committee of the School of Psychology, Bangor University (reference 2014 – 11684). Scotland A REC informally reviewed the IDEAL application, and it did not require to be ethically reviewed under the requirements of the Adults with Incapacity (Scotland) Act 2000.

Portfolio Registration

The IDEAL study is registered with UKCRN, registration number 16593.
http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=16593

The IDEAL Handbook for Researchers

In this Handbook we have included the key information that you, as a researcher working on the IDEAL study, will need. We acknowledge that researchers working on this study will have a range of expertise and experience. Some sections in this handbook may be more appropriate for researchers who are new to conducting research with people with dementia, while more experienced researchers may find these sections useful as refreshers.

There are three parts to this Handbook: Background information, Instructions and Monitoring and Reporting.

- The first part of this Handbook, Background information, gives an overview of the background and design of the IDEAL study, and describes the roles and responsibilities of the people involved in IDEAL.
- The second part, Instructions, is a practical guide to what exactly is involved in your work, and describes the process for recruitment and assessment of participants.
- The third part, Monitoring and reporting, describes the systems used for monitoring and reporting progress, and managing study data and documents.

This handbook should be used in conjunction with the ***IDEAL Time 1 Case Report Forms Handbook*** which provides instructions on how to complete the Case Report Forms and provides specific instructions for the administration and scoring of the cognitive assessments: MMSE, ACE-III, GDS and FAST. There are also sections providing detailed instructions on the completion of the RADIX and the CSRI.

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List of acronyms

ACE-III	The Addenbrooke's Cognitive Examination-III
AE	Adverse Event
CI	Chief Investigator
CRN	Clinical Research Network
CRF	Case Report Form(s)
CSRI	Client Services Receipt Inventory
DeNDRoN	Dementias and Neurodegenerative Diseases Research Network
ESRC	Economic and Social Research Council
FAST	Functional Assessment Staging
GCP	Good Clinical Practice
GP	General Practitioner
GDS	Global Deterioration Scale
IDEAL	Improving the experience of Dementia and Enhancing Active Life: living well with dementia
ISF	Investigator Site File
MMSE	Mini Mental State Examination
NHS	National Health Service
NIHR	National Institute for Health Research
NIHR CRN	National Institute for Health Research Clinical Research Network
NISCHR CRC	National Institute of Social Care and Health Research Clinical Research Centre
NWORTH	North Wales Organisation for Randomised Trials in Health – the Bangor clinical trials unit
OMG	Operational Management Group
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
POVA	Protection of Vulnerable Adults
PMG	Project Management Group
SAE	Serious Adverse Event
SDCRN	Scottish Dementia Clinical Research Network
T1	Time 1 (baseline)
T2	Time 2: 12 month follow-up
T3	Time 3: 24 month follow-up

I. Background information about the IDEAL study

1. Theoretical background

1.1. Introduction to the IDEAL study

IDEAL is a major, five-year longitudinal cohort study of 1500 people with dementia and their primary carers throughout the UK using mixed methods to examine how social and psychological capitals, assets and resources influence the possibility of living well with dementia and to identify changes that could result in improved well-being, life satisfaction and quality of life. The name 'IDEAL' reflects the full title of the study, which is 'Improving the experience of dementia and enhancing active life: living well with dementia'.

The project draws together expertise from psychology, sociology, medicine, public health, economics, social policy, physiology and statistics to examine in detail what can be done to ensure that as many people as possible are enabled to live well with dementia. The study is led by researchers at Bangor University in collaboration with colleagues at Cardiff University, Brunel University, the London School of Economics, King's College London, Sussex University, the Research Institute for the Care of Older People (RICE) in Bath, the Alzheimer's Society and Innovations in Dementia CIC. IDEAL is funded by The Economic and Social Research Council and National Institute for Health Research, and will be carried out in conjunction with NIHR CRN DeNDRoN in England, NISCHR CRC in Wales, and SDCRN in Scotland, with research network staff playing a key role.

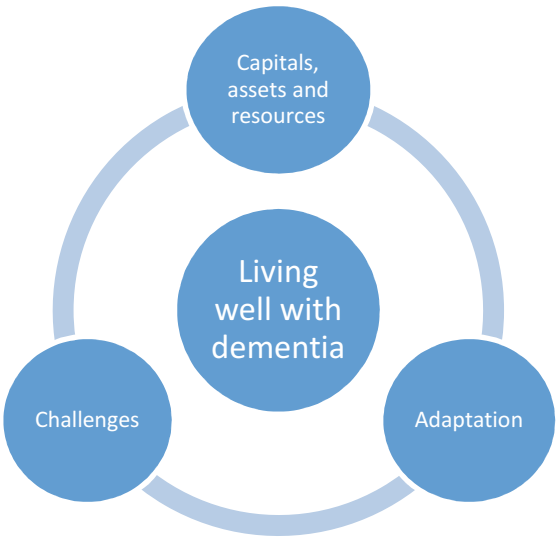
Living well with dementia, whether as a person with dementia or as a carer, can be thought of as experiencing optimal well-being and the best possible quality of life, and feeling satisfied with life. Enabling people with dementia and informal carers to live well with dementia is a key UK policy objective, but we need to know more about what can help people to live well with this type of long-term condition. In this project the research team will find out how social and psychological assets and resources, and the extent to which people are able to engage in activities and participate in the community, affect the way in which people adapt to the effects of the condition and the challenges it presents, and how this changes over time as dementia progresses (see Figure 1 below).

Over a two-year period the research network staff contributing to the study will recruit and assess 1500 people with early-stage dementia, and at least 1000 primary carers, identified through National Health Service (NHS) memory services and other related services

throughout the UK. The study will focus at the start on people living in their own homes with mild or moderate dementia and will follow them over time, observing whether and how their situation changes, in order to identify what influences their ability to live well. This might include their social situation, relationships and social support, what the home and neighbourhood is like, financial situation, physical health and fitness, personal characteristics, psychological resources, and the ways in which individuals cope with challenges in their lives. All participants will be visited on three occasions over three years, and will be asked to respond to questions about things that influence their well-being, quality of life and satisfaction with life. Participants for whom well-being improves or declines markedly over the first year of the study will be interviewed in more depth, as will their carers, to help explain why these changes have occurred.

The findings from the study will help to identify what can be done by individuals, communities, health and social care practitioners, care providers and policy-makers to improve the likelihood of living well with dementia.

Figure 1. Proposed model of factors affecting ability to live well with dementia



1.2. How will IDEAL help?

IDEAL will be the first large-scale study of its kind, and it is important to make the most of this resource by using the findings to make a real difference for people with dementia and carers. The aims of IDEAL are:

- To increase the potential for, and possibility of, living well with dementia for people with dementia and carers of people with dementia.
- To provide evidence that contributes to the development of policy and supports effective targeting of resources.
- To provide evidence that contributes to the development of practice and helps to optimise the information, services and care offered to people with dementia and carers of people with dementia.
- To increase public understanding and awareness of the condition and support the development of dementia-friendly communities.
- To contribute to building research capacity in the dementia field within the social sciences, to stimulate theoretical and methodological developments, and to provide a unique resource for dementia researchers.

The findings will be relevant to a number of different groups:

- People with dementia and their families – the findings from IDEAL will provide knowledge that will empower them to make changes in their lives and manage the condition more effectively.
- Practitioners (including general practitioners, memory services teams, dementia advisors, social services teams, care home managers) – the findings will provide information, knowledge and skills to practitioners that will form the basis for defining new approaches and interventions aimed at maintaining the well-being of people with dementia and their families.
- Service providers – the findings will provide evidence that will help to define new service models and approaches aimed at maintaining well-being.
- Policy makers – the findings will provide an evidence-base for decisions about social policy and appropriate targeting of resources.
- General public – the findings will inform awareness-raising initiatives such as creating dementia-friendly communities.
- Researchers and research networks – the findings will produce major developments in knowledge and understanding in the field of dementia research and create a valuable resource and focal point for dementia researchers that will stimulate further investigation and development of new collaborations.

Ways in which we will engage with these different groups of people will include:

- Using the project website and social media
- Preparing printed and online materials based on our findings
- Contributing to training programmes for practitioners and researchers
- Running regional workshops
- Presenting at events and conferences
- Writing articles and papers for practitioner and academic journals.

Helping to make sure that the results have maximum impact will be our advisory network of people with dementia and carers, the Action on Living Well: Asking You (ALWAYS) group, and our Project Advisory Group, chaired by Dr Nori Graham.

The study findings will be used to develop an action plan that will be presented at an end-of-study conference. This will outline recommendations about what can be done by individuals, communities, health and social care practitioners, care providers and policy-makers to make it possible for everyone to live better, and for more people to live well, with dementia.

1.3. Overview of methods

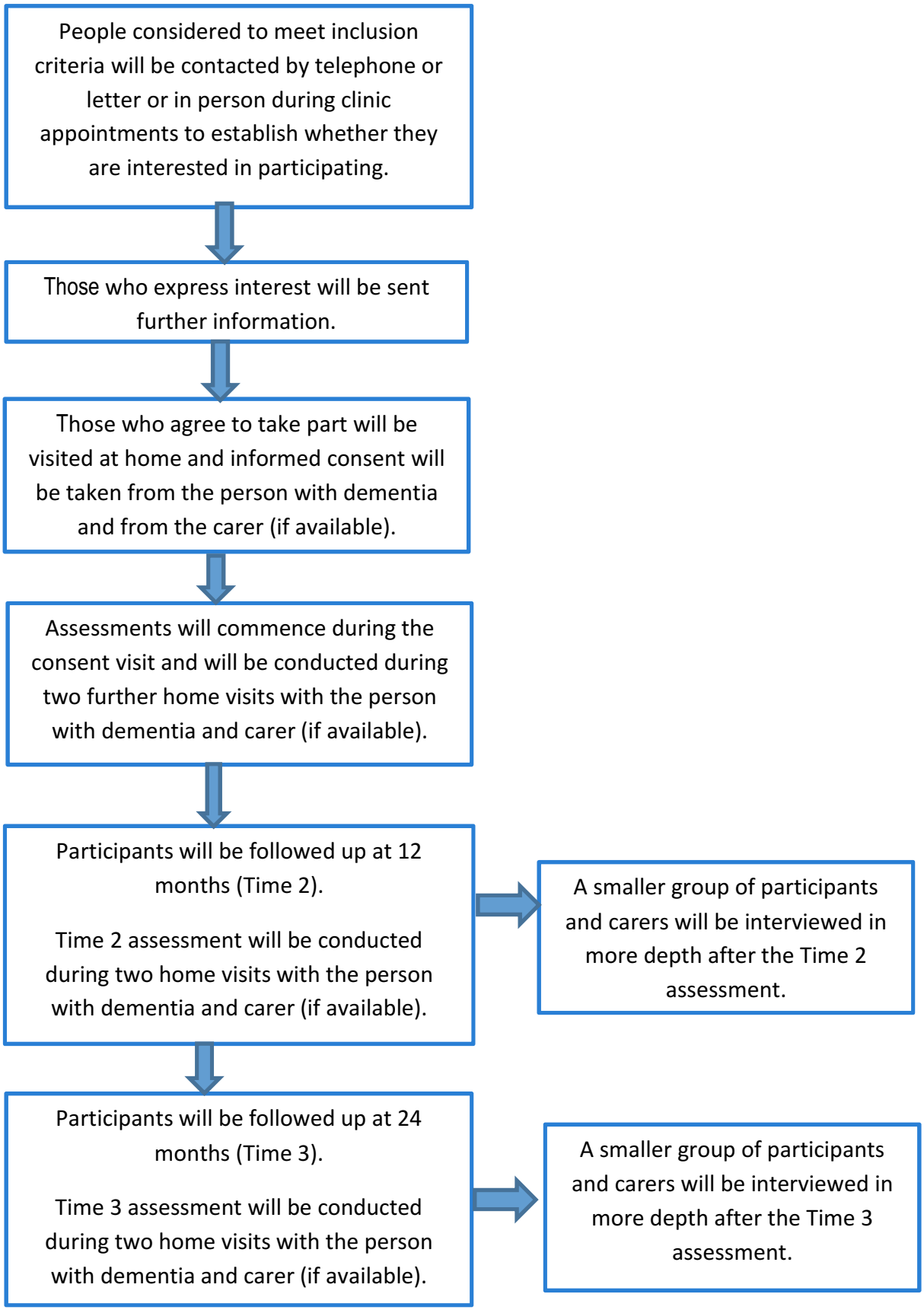
1.3.1. Aims

- To investigate how social and psychological circumstances and resources affect the possibility of living well with dementia.
- To identify what can be done by individuals, communities, health and social care practitioners, care providers and policy makers to improve the likelihood of living well with dementia.

1.3.2. Design

This is a mixed-method, longitudinal cohort study of people with dementia and their primary carers. Quantitative assessments, questionnaires, will be conducted at **baseline** (T1), **12 months** (T2) and **24 months** (T3). Qualitative interviews will be conducted at the 12 and 24 month time points with a sample of participants showing evidence of change in indicators of living well and will enrich the quantitative findings by illuminating the reasons and subjective experiences underlying these changes. Figure 2 shows the participant pathway through the study.

Figure 2. Participant pathway through the study



1.3.3. Participants

We will recruit a sample of 1500 people with mild and moderate dementia over a 24-month period. We will also seek to recruit the carer in each case, if there is one, but we will still include people with dementia who do not have a carer. Participants and carers will need to have sufficient proficiency in English to understand and complete the questionnaires.

The person with dementia may have any sub-type of dementia. We anticipate that most participants will have one of the following sub-types:

- Alzheimer's disease
- Vascular dementia
- Mixed dementia
- Fronto-temporal dementia
- Dementia with Lewy bodies or Parkinson's disease dementia

These are the types of dementia we are **actively seeking to cover**, and we expect that most participants with these types will be identified from generic memory assessment and movement disorder clinics. We expect to have sufficient numbers in each category to be able to carry out meaningful sub-group analyses. We are keen to include a range of ages, and to identify enough people with early onset dementia (diagnosed before age 65) to be able to look at the specific needs and experiences of this group in our analyses.

We anticipate that a very small proportion of our sample will have other forms of dementia, for example dementia resulting from rare neurological conditions (e.g. Huntington's disease), and in some cases the type of dementia may not be known. We are not proposing to actively sample specialist services to access people falling into the 'other' category, but it is acceptable to include such people if they come to your attention.

Some people with lifelong intellectual (learning) disability may develop dementia, although assessment in these cases can be challenging. Our measures are not designed to be suitable for people with intellectual disability and we are not proposing to actively sample specialist services for this group. However, it is acceptable to include people with (mild or borderline) intellectual disability if they come to your attention and it is clear that they are able to fully understand the questions asked.

Specific information on inclusion/exclusion criteria is provided in *Chapter 5: Identification of study participants*. To ensure that the study successfully recruits participants across the whole range of mild to moderate dementia we will perform a check on the distribution of T1 Mini Mental State Examination (MMSE) or equivalent scores 6, 12 and 18 months into the recruitment period, and will adjust recruitment targets accordingly if necessary.

1.3.4. Procedure

People with dementia considered to meet the inclusion criteria, with their carer where applicable, will be contacted by telephone or letter or in person during clinic appointments to establish whether they are interested in participating.

Those who express interest will be sent further information and then, if they are willing, will be visited at home; where appropriate, consent will be taken from the person with dementia and from the carer (if available) during this visit. The T1 assessments will be conducted over **three** home visits.

Participants will be followed up **12** (T2) and **24** (T3) months later, completing the assessment in two home visits at each time point. The first follow-up should be scheduled 12 months after the first T1 visit and the second follow-up should be scheduled 24 months after the first T1 visit.

An acceptable window for follow-up will be **no earlier** than one month prior to the scheduled follow-up date and **no later** than two months post the scheduled follow-up date at each time point.

Visits to participants (whether a person with dementia and carer together, or a person with dementia alone) are expected to last up to 2 hours each. Participants will be offered a small shopping voucher as a token of appreciation for taking part in the study upon the completion of the assessments at each time point.

Timelines for recruitment and follow up are provided below.

Milestone	Target date
Time 1 Recruitment and assessment commences	01/07/14
Time 1 Recruitment and assessment completed	30/06/16
Time 2 Follow up assessment commences	01/07/15
Time 2 Follow up assessment completed	30/06/17
Time 3 Follow up assessment commences	01/07/16
T3 Follow up assessment completed	30/09/18

1.3.5. Ethical approval

The IDEAL study was approved for the UK by the North Wales – West NHS Research Ethics Committee (reference 13/WA/0405), and the Ethics Committee of the School of Psychology, Bangor University (reference 2014 – 11684). Scotland A REC informally reviewed the IDEAL application, and it did not require to be ethically reviewed under the requirements of the Adults with Incapacity (Scotland) Act 2000. Sites will be notified of any ethical amendments, and relevant documentation will be circulated to add to the Investigator Site File (ISF).

2. The IDEAL team

This section provides information about the people involved in IDEAL. This includes the project team, local Principal Investigators (PIs) and research network staff. An initial list of sites participating in the study is provided.

2.1. Project team

The project co-ordinating centre is at Bangor University, where the Chief Investigator (**Professor Linda Clare**), Project Manager (**Dr Sharon Nelis),** Research Fellow (**Dr Catherine Quinn**), Research Officer (**Dr Anthony Martyr**), Research Project Support Officer (**Ms Rachel Clarke**) and Project Administrator (**Ms Lester Bath**) are all based. The sections below provide information about the co-investigators and other team members.

IDEAL Co-investigators:

- Professor Linda Clare (Chief Investigator), Bangor University
- Dr John Hindle, Bangor University
- Professor Ian Rees Jones, Cardiff University
- Professor Roy Jones, RICE Centre, Bath
- Professor Martin Knapp, London School of Economics
- Professor Michael Kopelman, King's College London
- Dr Anthony Martyr, Bangor University
- Professor Robin Morris, King's College London
- Dr Sharon Nelis, Bangor University
- Dr James Pickett, Alzheimer's Society
- Dr Catherine Quinn, Bangor University
- Professor Jennifer Rusted, Sussex University
- Ms Nada Savitch, Innovations in Dementia
- Dr Jeanette Thom, Bangor University
- Professor Christina Victor, Brunel University

2.1.1. Other team members

NWORTH

The North Wales Organisation for Randomised Trials in Health (NWORTH) is a Bangor-based Clinical Trials Unit that provides research support for IDEAL. NWORTH provides guidance on all aspects of quality management and regulatory issues. NWORTH will oversee the data entry and manage the MACRO system for monitoring and electronic data capture. The team at NWORTH includes:

NWORTH Unit Manager	**Jean Ryan**
IT Support	**David Hunnisett**
Quality Assurance and Compliance Officer	**Debbie Skelhorn**
Data Manager	**Cathy Blakey**
NWORTH Statistician	**Andrew Brand**

We will also have a number of data entry clerks based at NWORTH who will be responsible for entering the data from the Case Report Forms (CRFs) into the MACRO database.

Health economist: **Cate Henderson** works at the London School of Economics with **Professor Martin Knapp**, and contributes expertise in health economic evaluation.

Network Representative: **Helen Collins** is the network representative on the Project Management Group.

Future members of the team

As the study progresses other members of staff will join this project. These include:

- An Epidemiologist/Statistician based at Bangor University who will play a leading role in analysing the quantitative data.
- A Research Officer based at Cardiff University who will be responsible for conducting and analysing the qualitative interviews.
- A Knowledge Transfer Fellow based at Brunel University.
- A Communications Officer based at the Alzheimer's Society.

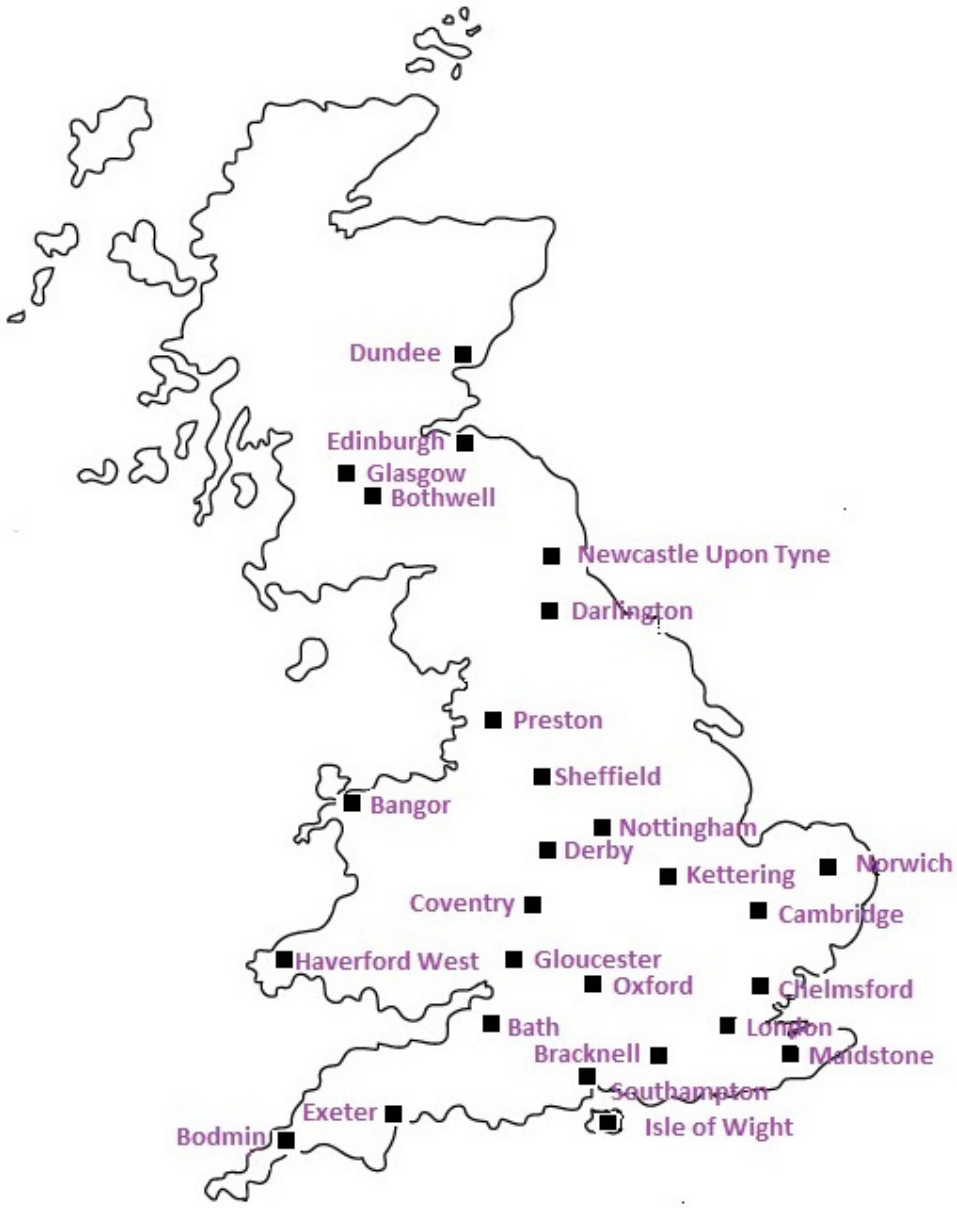
2.2. Research sites

Participants will be recruited from 28 sites, and a list of sites currently participating in provided in Table 1. Additional sites may be added as required. Each site will have a local PI who is responsible for the running of the study in that site.

Table 1. List of participating sites

Clinical Research Network		Trust
Eastern	1	Cambridgeshire & Peterborough NHS Foundation Trust (CPFT)
	2	Norfolk and Suffolk NHS Foundation Trust
	3	North Essex Partnership University NHS Foundation Trust
North East & North Cumbria	4	Northumberland, Tyne and Wear NHS Foundation Trust
	5	Tees, Esk and Wear Valleys NHS Foundation Trust
North West Coast	6	Lancashire Care NHS Foundation Trust (3 areas) Preston; East Lancashire; Morecambe
Wessex	7	Isle of Wight NHS Trust
	8	Southern Health NHS Foundation Trust
South London	9	St. George's NHSTrust
	10	Guy's and St. Thomas's NHS Trust
Kent, Surrey & Essex	11	Kent and Medway NHS and Social Care Partnership Trust (KMPT)
West of England	12	2gether Trust Cheltenham & Gloucester Avon & Wiltshire
	13	The Research Institute for the Care of Older People (RICE), Bath
South West Peninsula	14	Royal Devon and Exeter NHS Foundation Trust
	15	Cornwall Partnership NHS Foundation Trust
Thames Valley & South Midlands	16	Oxford Health NHS Foundation Trust
	17	Berkshire Healthcare NHS Foundation Trust
East Midlands	18	Northamptonshire Healthcare NHS Foundation Trust
	19	Nottinghamshire Healthcare NHS Trust
	20	Derbyshire Healthcare NHS Foundation Trust
West Midlands	21	Coventry & Warwickshire Partnership NHS Trust
Yorkshire & Humber	22	Sheffield Teaching Hospitals NHS Foundation Trust
Scotland	23	NHS Tayside
	24	NHS Lothian
	25	NHS Greater Glasgow and Clyde
	26	NHS Lanarkshire
Wales	27	Betsi Cadwaladr University Health Board
	28	Hywel Dda University Health Board

Figure 3. Map of sites currently participating in the IDEAL study



2.3. Responsibilities associated with the roles of local PIs and research network staff

2.3.1. Local PIs

1. Participation and contribution

(a) Take overall responsibility for the conduct of the research at the site.
(b) Respond promptly to study-related communications from the Chief Investigator (CI), Project Manager, and other staff of the coordinating centre at Bangor University.
(c) Complete project-related tasks according to target timescales and within deadlines.
(d) Notify the CI promptly of any changes or issues that may affect the local conduct of the study.
(e) Provide regular progress information to the study co-ordinating centre.
(f) Attend study-related training events as appropriate.
(g) Contribute to dissemination of findings to NHS professionals and people living with dementia and carers as required, and where appropriate to the development of materials and training manuals to support the implementation of study findings within NHS settings.

2. Conduct of the study

(a) Ensure that the dignity, rights, safety and well-being of participants in the study are protected.
(b) Ensure that appropriate local NHS permissions and approvals are in place for the site and all participant identification centres, and that appropriate insurance cover is in place.
(c) Complete the study accurately, efficiently and expeditiously in accordance to the currently approved protocol and the resources and support available.
(d) Implement quality assurance procedures designed to ensure and record that, inter alia, study participants give informed consent to participate and accurate administration of the study measures (in accordance with the currently approved protocol), and that all study data are as accurate, complete and verifiable as the study resources permit.
(e) Ensure that the study staff receive copies of all relevant study documents.
(f) Ensure that they and their study staff conduct the study in accordance with the currently approved protocol, study procedures and assessment measures; the principles of Good Clinical Practice in clinical studies (GCP); relevant legislation, including the Data Protection Act 1998; the research funder's terms and conditions; and Standard Operating Procedures (SOPs).

3. Management and supervision of local research network staff

(a) Meet regularly with the local research network staff to review study progress and resolve any barriers to study completion.
(b) Manage the local research network staff, providing support and guidance as necessary and ensuring that local policies and procedures (e.g. lone working policy) are followed.

4. Participant recruitment

(a) Ensure recruitment of participants into the study at levels corresponding to recruitment targets for the site.
(b) Inform and enthuse local clinical services (memory clinics, movement disorder clinics, working age dementia services, old age psychiatry services, GP practices, as appropriate), and local voluntary groups (e.g. Alzheimer's Society branches) to support effective identification and recruitment of participants.
(c) Ensure the process of obtaining informed consent from participants is completed in line with the protocol.
(d) Ensure that participants recruited into the study meet the stated inclusion criteria and do not fall within the exclusion criteria.
(e) Act as a point of contact for patients and carers in the catchment area who request information about the research.
(f) Ensure that all participants are assessed in accordance with the currently approved protocol and that all required data are collected from participants and accurately recorded.
(g) Inform participants' GPs and/or hospital consultants of their participation in the study.
(h) Ensure that study assessment measures are stored in a safe and secure fashion.
(i) Ensure monthly progress reports are provided to the study co-ordinating centre (including recruitment data, staff training, staff changes, GCP updates etc.).

5. Data management and safety reporting

(a) Ensure that participants' personal data are managed with regard to requirements for confidentiality and local data protection policies.
(b) Ensure that adverse events occurring locally are documented and reported promptly to the CI.

6. Training

(a) Ensure that they and their study staff are qualified and trained to fulfil the duties assigned to them.
(b) Ensure that all local research network staff participate in all project-related training events organised for them (whether organised by the co-ordinating centre or cascaded at a local level).

7. Delegation

(a) Delegate study-related tasks only to appropriately qualified study staff.
(b) Maintain the Investigator's Site File to include an auditable record of the duties assigned to study staff, qualifications they hold, and the training they receive, including training in the currently approved protocol, GCP and relevant legislation.

2.3.2. Research network staff

1. General

(a) Manage the daily running of the research centre.
(b) Be responsible for and undertake all the research duties within the centre in accordance with the currently approved protocol, GCP and trial regulations.
(c) Organise and plan all local study appointments and travel as required to carry out study-related duties.
(d) Regularly report progress to the study co-ordinating centre (including recruitment data, staff training, staff changes, GCP updates etc.).
(e) Ensure that study resources are monitored and used appropriately under the direction of the local PI.

2. Recruitment of study participants

(a) Ensure timely recruitment of participants into the study.
(b) Work closely with and engage with local clinical services (memory clinics, movement disorder clinics, working age dementia services, old age psychiatry services, GP practices, as appropriate), and with local voluntary groups (e.g. Alzheimer's Society branches) to support effective identification and recruitment of participants.
(c) Organise, arrange and assist local professionals in conducting the initial screening interview with potential participants (where applicable).
(d) Check prior to consent that participants recruited into the study meet the stated inclusion criteria and do not fall within the exclusion criteria.
(e) At research sites with a specialist focus on specific subgroups (e.g. fronto-temporal dementia, Lewy body dementia, young onset dementia) staff may be asked to recruit additional participants from within these subgroups.
(f) Act as a point of contact for participants and carers in the catchment area who request information about the research.

(g) Ensure the process of obtaining informed consent from study participants is completed in line with the protocol.
(h) Ensure that participants identify a personal consultee at the initial time point and record their contact details for use at follow up.
(i) Inform participants' GPs and/or hospital consultants of their participation in the study.
(j) Ensure that each participant receives the participation payment at the end of the assessment time point and document the payment process.
(k) Comply with study instructions in administering and recording study measures.
(l) Ensure follow-up assessments are conducted in line with the timescales and windows outlined in the study protocol.
(m) Keep a log of screened and recruited participants.
(n) Try to obtain and record a reason in any case where a participant decides to withdraw from the study.

3. Data and record keeping

(a) Maintain accurate and up-to-date records relating to the study participants.
(b) Ensure that participants' personal data are managed with regard to requirements for confidentiality and local data protection policies.
(c) Report any Adverse Events to the PI immediately in accordance with the currently approved protocol.
(d) Maintain and appropriately file all local study documents.
(e) Collect, record, and maintain local study data accurately, completely and expeditiously in participants' Case Report Forms.
(f) Ensure timely return of the participants' Case Report Forms to the co-ordinating centre.
(g) Respond to co-ordinating centre queries about data and Case Report Forms.
(h) Carry out the assigned duties in accordance with available resources and manage the centre's activities within the agreed budget.

4. Training and supervision

(a) Complete training in Good Clinical Practice with regard to the conduct of the study.
(b) Actively participate in study-related meetings and training events.
(c) Actively engage in professional supervision and develop skills and competencies that assist in study delivery.

3. Training

As a researcher involved in the recruitment and assessment of participants for IDEAL, you will need appropriate training. This involves completing Good Clinical Practice (GCP) training and refresher courses (as appropriate) and attending study-specific training events organised by the Bangor co-ordinating centre. During initial training for IDEAL, you will have the opportunity to familiarise yourself with the background to the study, understand the content of the CRFs and practise administering some of the measures. You will learn best practice with regard to consenting participants and assessing capacity, and how to score the cognitive assessments. Some of you will already be familiar with these practices but the IDEAL training will serve as a useful refresher.

3.1. Training requirements

For research staff involved in the IDEAL study we would like to ensure you have received the appropriate training in our study-specific procedures. This allows us to standardise the research process across our many sites which has important implications for the quality of the data we collect.

IDEAL Initial Training

1. We will be organising an initial training session to provide detailed information on the study. We would like all research staff who will be conducting the assessments to receive this training. Local PIs and networks managers will also be invited. For those who are unable to attend one of the scheduled sessions then we require that a nominated member of your team who has attended the training session cascades the training information provided at the training session to you. We will seek confirmation of this training process for our records.
2. All researchers involved in the study are expected to read and become familiar with the IDEAL study protocol, IDEAL Researcher's Handbook and IDEAL Time 1 Case Report Forms Handbook.
3. The scheduled training sessions will provide practice in administration of the CRFs. Researchers are encouraged to become familiar with the type of questions and response keys for all items within the CRFs.
4. During the training sessions, attendees with learn or be reminded of how to score the cognitive assessments accurately. Researchers are encouraged to practise these assessments.

Training Verification: Feedback on first assessment

As part of our quality assurances procedures, and as verification of training, we would like to look at each researcher's first assessment CRFs in detail. For each researcher we will need to see the following CRFs for his/her **first** participant:

Participant CRF Part 1

Participant CRF Part 2

Each researcher will need to **photocopy** these CRFs and return them to the Bangor co-ordinating centre using the envelope provided.

Project staff at the Bangor co-ordinating centre will check each researcher's completed CRFs for his/her **first** participant for verification of accuracy. These documents will be checked for accurate completion and, where relevant, accurate scoring. If you have completed these CRFs accurately you will receive an email to confirm this. If there are errors in the completion of your CRFs you will be provided with feedback on how to improve your completion of the CRFs.

This process will help resolve any potential issues at the early stage of the study and will help with further assessments to ensure quality data is collected. We would appreciate your co-operation with this process.

3.2. Follow-up training events

Training events will be organised annually throughout the course of the project. We will keep you updated on potential dates and venues for these events. These events will provide specific training sessions on study developments and on the assessments for T2 and T3 including new CRFs, and introduce other elements of the study (e.g. interviews to be conducted by the Cardiff researcher).

4. Materials

There are various materials that you will need when working on the IDEAL study, and we will frequently refer to them when explaining your role as a researcher. In this chapter we provide a quick overview of the documents. These documents will be made available to you in electronic form through the R&D process, and copies will be available in the Investigator Site File (ISF). We explain in *Chapter 16: Study monitoring and reporting* how you can access these materials.

4.1. Information for potential participants

We have developed a range of materials to support the process of identifying and recruiting potential participants. See also *Chapter 5: Identification of study participants* and *Chapter 6: Recruitment of study participants.*

Memory assessment services and other participant identification centres (PICs)

1. The ***factsheet for memory clinic staff*** provides brief information about IDEAL for staff at Memory Assessment Services and **any other** participant identification centres (PICs) to help the consider whether anyone they are in contact with may be suitable for inclusion in the study.
2. Please display the ***information poster*** at PICs and other places where potential participants may see it. Your local details should be added to enable potential participants to contact you.
3. The ***pre-screening and referral information*** form should be used to identify potential participants for IDEAL by going through the inclusion criteria and recording contact details for approach about participation.

Potential participants

1. The ***invitation letter and reply slip*** should be used to approach potential participants where this needs to be done by letter (a copy of this document is given in Appendix 1).
2. The ***information pamphlet*** and ***introduction to the study for participant, family members, friends, and personal consultees*** provide a brief introduction to the study for potential participants.
3. The ***participant information sheets (PIS)*** are longer documents providing detailed information about participating in IDEAL. This document needs to be discussed with potential participants in the process of taking informed consent to ensure the participants understand what is involved in the study.

4.2. Assessment materials

All the materials needed for the assessment visits are listed below. This includes the CRFs. We have also provided a series of showcards that researchers may use to show the response options to the participants to facilitate their responding. Showcards are also recommended for use when asking participants about potentially sensitive information (e.g. income). We have highlighted in the CRFs when you need to use showcards. Information about how to access these documents is provided in *Chapter 15: Data and document management*.

The documents you will need are:

Visit 1

1. ***Consent forms*** for both the person with dementia and carer
2. ***Copy of information sheet*** in case the participant needs clarification of any information.
3. ***Demonstration of capacity checklist*** to be used to record the evidence that shows the person with dementia has capacity to consent to take part in the study.
4. ***Contact details form*** to be used to record the general practitioner (GP) details and personal consultee contact information.
5. ***Participant CRF Part 1***
6. ***Relative/Friend CRF Part 1***
7. ***Showcards visit 1***
8. ***Participant CRF Part 2***
9. ***Relative/Friend CRF Part 2***
10. ***Showcards visit 2***

Visit 2

1. ***Participant CRF Part 2***
2. ***Relative/Friend CRF Part 2***
3. ***Showcards visit 2***
4. ***Participant CRF Part 3***
5. ***Relative/Friend CRF Part 3***
6. ***Showcards visit 3***

Visit 3

1. ***Participant CRF Part 3***
2. ***Relative/Friend CRF Part 3***
3. ***Showcards visit 3***

We recommend that you take Part 1 and Part 2 CRFs to visit 1 and Part 2 and Part 3 CRFs to visit 2. This is because you may find that you have time to start another CRF during the visit.

4.3. Participant payment

As a token of appreciation, participants who complete all 3 visits of the T1 assessment will receive a shopping voucher as a small token of appreciation. The documents you will need to provide participants who have completed all T1 assessments with their shopping vouchers are:

1. ***Receipt of payment*** form (a copy is provided in Appendix 8) which the participant must sign as evidence of having received payment. This form must be sent to the Bangor co-ordinating centre (more details are provided in *Chapter 15: Data and document management)*.
2. ***Thank-you note*** which is given with the shopping voucher.
3. ***The shopping voucher***

4.4. Follow-ups

Participants should be contacted one month prior to the follow up assessment. An acceptable window for follow-up will be no earlier than one month prior to scheduled follow-up date and no later than two months after the scheduled follow-up date at each time point.

Part II. Instructions

Part II of this Handbook describes key procedures involved in your work as a researcher for IDEAL. It aims to provide clear instructions on what to do and when, with some necessary explanations and references to other chapters where relevant.

5. Identification of study participants

5.1. Recruitment target

At the feasibility stage of the IDEAL study, sites provided information on their expected recruitment targets. Research staff at each site should be fully aware of the target for that particular site. We expect that 50% of this recruitment target should be achieved within the first 12 months of the site start date.

5.2. Identifying potential participants

The recruitment strategy for the IDEAL study is quite open, allowing for the inclusion of potential participants who may have been excluded from other studies. You may have turned people down for inclusion in other studies in the past but find they meet the IDEAL inclusion criteria.

Please consider where in your local area you could identify suitable participants. Participants will be recruited from PICs such as memory services and old age mental health services. In addition there are other services that will specialise in other types of dementia, for instance, people with Parkinson's disease dementia might be identified from movement disorders clinics rather than memory clinics. There will be specialist memory clinics that have a particular focus on fronto-temporal dementia and working age dementia services for people with young onset dementia. The research team at each site should discuss viable recruitment options at the start of the recruitment process to ensure they are maximising all local resources.

You will need to ensure that, where needed, you have **local approval** to recruit from these PICs.

5.3. Pre-screening and referrals

Once you have identified suitable PICs you will need to screen the patient records, clinic files and other databases, e.g. databases of people interested in taking part in research, to identify eligible participants. In order to assist with this screening you should use the IDEAL **pre-screening and referral information** form**.** The form includes the study inclusion criteria and enables you to record whether a participant is eligible or ineligible. There is a section on the form which requires a signature from a member of the patient's clinical team to authorise the person being approached about the study and to confirm that there are no known risks that would make visits by the researcher to the person's home inappropriate.

For those participants who are screened and eligible to take part in the study there is a section on the form to record their contact details.

5.3.1. Recording the number of people screened

You will need to keep an accurate record of this **pre-screening** process. You will need to record:

1. The number of people with dementia who were **screened** for study eligibility.
2. The number of people with dementia who were **excluded** after screening:
   (a) The number of people excluded for not meeting the inclusion criteria.
   (b) The number of people excluded for other reasons - you will need to specify the reason (e.g. medical records specified s/he was not interested in research).

It is important to keep track of who has been approached about the study to avoid approaching (and counting) the same people more than once. These screening numbers and information will need to be reported to the Bangor co-ordinating centre through the MACRO database (see *Chapter 16: Study monitoring and reporting*). It is important for us to know how many people were ineligible for inclusion in the IDEAL study and the reasons why.

5.4. Inclusion criteria for people with dementia

You will need to screen all participants for eligibility and ensure that they meet the following **inclusion criteria for entry into the study**:

1. A clinical diagnosis of dementia, any sub-type (specific guidance on sub-types is provided in 1.*3.3. Participants,* page 16).

2. In the mild to moderate stages of dementia as indicated by an MMSE score of 15 or above (or an appropriate equivalent, further guidance will be provided in a separate document) at T1.

3. Living in their own homes (i.e. not in residential or nursing homes) at T1.

Inclusion criteria 2 and 3 **only apply at T1;** at the T2 and T3 follow-up assessments people with dementia can still participate in the study if their MMSE falls below 15 or if they move into residential care.

There will be no restrictions on age and we will not exclude people who do not have a carer. Importantly, participation in the IDEAL study will not preclude participation in other studies or intervention trials. We will ask you to keep a record of the number and type of studies people are currently involved in whilst taking part in IDEAL.

You will need to screen all participants for eligibility and ensure that the following **exclusion criteria** are absent:

1. Co-morbid terminal illness in the person with dementia at T1.

2. Any known potential for home visits to pose a significant risk to research network staff.

3. Inability to provide informed consent at T1.

4. Inability to speak English sufficiently well enough to allow completion of the assessment measures (unfortunately we do not have provision within the study to translate the CRFs to other languages).

If home visits are a significant risk but you could arrange for the person to come to another setting, such as a clinic or hospital, to complete the assessments, then that person could take part in the study providing there were **no** other risks to the researcher. In addition, you would need to check that you have local approval to conduct assessments at another location.

Exclusion criterion 2 (risk to research staff) will **still apply** at the T2 and T3 follow-up assessments. If a person's situation has changed so that there is now a risk to the researcher, s/he would have to be excluded at follow-up.

5.5. Inclusion criteria for carers

If the person with dementia is eligible and consents to take part in the study then his/her primary carer is also eligible to take part in the study. For the purposes of this study we consider a primary carer to be someone who looks after a relative or friend and provides practical or emotional **unpaid** support. This could be their spouse/partner, adult child, other relative etc.

Contact details of carers may be available from participant files at the relevant clinical service. Early liaison with potential participants should involve a discussion about the potential involvement of a carer. In some instances the carer may not live with the person with dementia or be available to meet with the researcher in person, but may be willing to provide information by postal return of the CRF, and this should be negotiated wherever possible.

5.6. Our sampling strategy: potential stratification

In this study we aim to achieve a sample of participants who have a range of: **MMSE scores, dementia sub-types, ages, gender, living situations and relationships with the primary carer**. To ensure that we are achieving our target sample we will examine our T1 data at pre-determined times (6 months, 12 months, 18 months) to evaluate the distribution of these parameters within our sample and adjust recruitment targets if necessary.

What does this mean for the research site?

This may result in researchers at your site focussing specifically on recruiting people within a certain MMSE score range, or people with a specific sub-type of dementia, such as fronto-temporal dementia. We might ask you to focus on recruiting from PICs that specialise in these types of dementia. At these stages we will also assess our sample in relation to indices of social deprivation (by postcode) and, if necessary, adjust our recruitment targets to sample more intensively from areas with higher or lower social deprivation.

The information you provide on recruitment numbers from individual sites will be vital in allowing us to track this type of information, and to adjust the sampling strategy if required. We will appreciate your support in providing this information and helping us ensure that the sample we achieve is as representative of people with dementia and their carers as possible.

6. Recruitment of study participants

6.1. Recording the number of people approached

You will need to record information about the people who were approached to take part in the study:

People with dementia

1. The number of people with dementia who were approached to take part in the study.
2. The number of people with dementia who refused to participate.
3. The number of people with dementia who were found not to meet the inclusion criteria. You will need to specify which inclusion criterion was not met:
    (a) MMSE below 15
    (b) Co-morbid terminal illness
    (c) Inability to speak English
    (d) In residential or nursing home
    (e) Known risk to research staff prevented inclusion

Carers

1. The number of carers who were approached to take part in the study.
2. The number of carers who refused to participate.

This information will need to be reported to the Bangor co-ordinating centre through the MACRO database (see *Chapter 16: Study monitoring and reporting*). It is important for us to know how many people refused or were ineligible to take part in the study.

6.2. Initial contact with participants

6.2.1. Approaching participants

People with dementia who meet the inclusion criteria can be approached about the study. They can be contacted by telephone, by letter or in person during memory clinic appointments to establish whether they are interested in participating in the study. At initial contact they should be provided with the ***information pamphlet*** or the ***introduction to the study for participant, family members, friends and personal consultees*** document. If they are interested in the study they should be provided with the PIS.

Face-to-face contact

People with dementia may be approached face-to-face, for instance during memory clinic appointments. This type of approach provides an opportunity for you to describe the study and answer any initial questions. The initial conversation about the project should briefly explain the study and why it is important. The person should be informed about what taking part would involve. If the person with dementia expresses an interest in the study, then a visit could be arranged right away, or a follow up telephone call could be made to arrange an initial visit.

Postal Invitation

Participants can also be approached with an ***invitation letter*** (see Appendix 1). You will need to arrange for the letter to be signed by the responsible clinician (or his/her nominee). Participants who receive the letter will be able to contact you directly (either by telephone, email or using the ***reply slip*** attached to the ***invitation letter***) to indicate whether or not they are interested in taking part in the study. Non-responses to this initial contact can be followed up **once** (e.g. by telephone or another letter) to compensate for the possibility that letters and messages could be mislaid due to memory difficulties.

If the person with dementia has a carer who resides with him/her then s/he can be approached at the same time as the person with dementia. For non-resident carers they will need to be contacted separately to identify whether they are interested in taking part in the study. The carer will **only** be eligible to take part in the study if the person with dementia consents to take part.

6.2.2. Initial conversation about the study

Once the person has expressed an interest in the study s/he should be contacted to arrange an initial visit. This contact should cover the following:

- Explain that you would like to meet with him/her to describe the study in more detail and, if s/he is willing, to take informed consent and start the assessments. This visit will last for about one hour.
- Arrange a time and date to meet. Ask if s/he has a calendar or diary to write down the appointment. Make sure that s/he writes down your name and telephone number so that s/he can call you if there is a need to cancel the visit.
- If possible, send a letter confirming the date and time of the appointment.

After arranging the initial visit, we advise that you telephone the person the day before to remind him/her of the scheduled visit and to check that s/he is still available. This is particularly relevant for people with dementia who do not have a carer to remind them that you are coming. Be sure to follow your local lone worker policy when arranging visits and visiting participants.

7. Case Report Forms

This section briefly describes the CRFs (**Questionnaires**) being used in IDEAL (the actual CRFs can be found in the *IDEAL Time 1 Case Report Forms Handbook)*.

7.1. Development of the CRFs

Initial versions of the CRFs went through a refinement process. The CRFs were piloted with people with dementia and carers. In the piloting phase we explored ease of completion, length of time for completion, acceptability of questions, and appropriateness of the order of questions. The CRFs were also subject to a consultation process, in which carers of people with dementia commented on the content, format and length. The piloting and consultation phases of the study led to the reformatting and shortening of the CRFs. Importantly the piloting phase demonstrated that the CRFs were acceptable to people with dementia and their carers, and showed that the CRFs could be completed within the allocated time frames for assessment.

7.2. Content of the CRFs

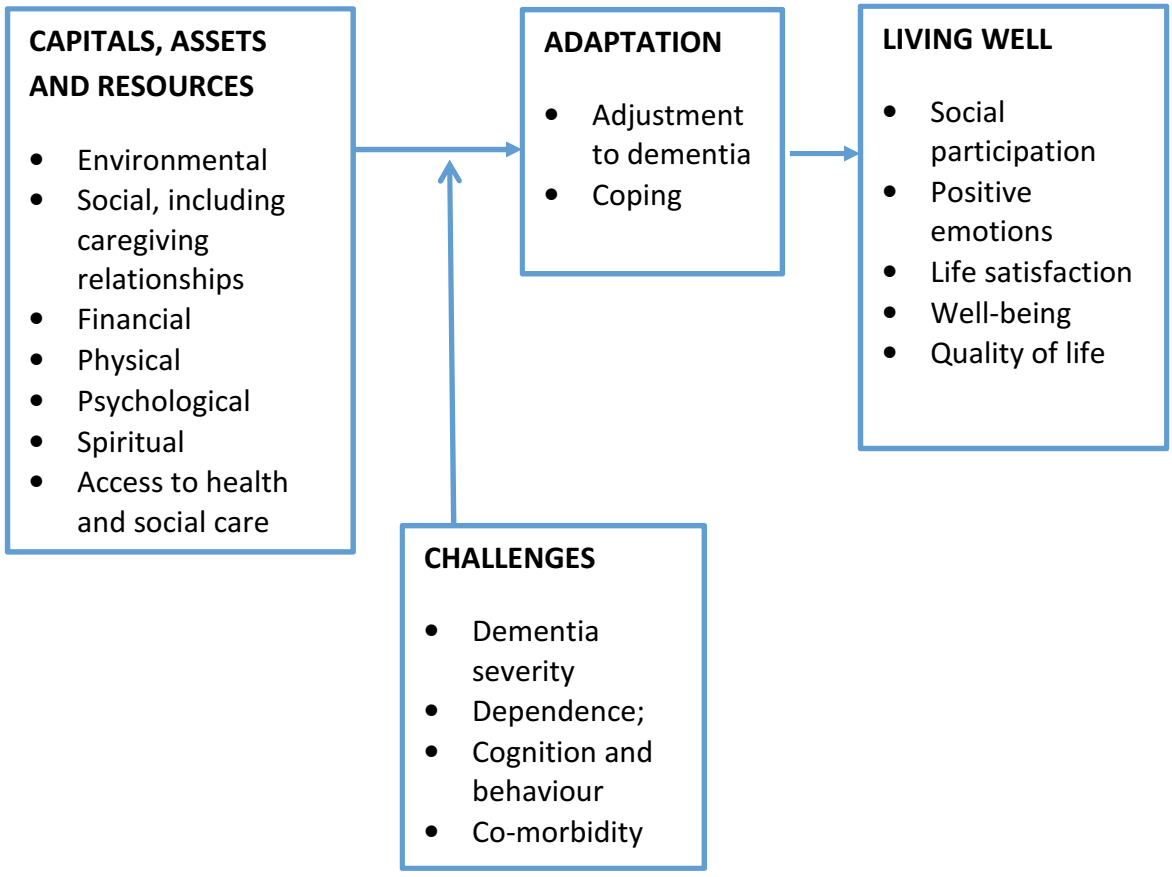
The content of the CRFs relates to each component of a hypothesised model of factors affecting the ability to live well with dementia (see Figure 4). The CRFs consist of standardised measures and single items taken from existing questionnaires to provide a streamlined assessment (see the Appendix of the IDEAL *Time 1 Case Report Forms Handbook* for a full list of measures). The CRFs include assessments focusing on ***capitals, assets and resources*** (social, financial, environmental, physical, psychological), access to and use of social and health care, including community resources, and quality of the caring relationship (where relevant); dementia-related and other ***challenges***, including dementia severity, co-morbidity (with regard to both physical and mental health) and dependence; ***adaptation***; and indicators of ***living well*** (well-being, life satisfaction, quality of life, social participation, and expression of positive emotions).

At the end of some of the CRFs there are open-ended questions. These are **optional** and offer the participants an opportunity to provide further information about their experiences.

There is an optional section for researchers to record any **field notes** or comments about the visit. For instance you might want to record whether the participant was alert or apathetic; this is particularly important if the participant's demeanour has an impact on his/her ability to select a response to the questionnaires, whether there were relevant

interruptions such as if the participant receives a telephone call just after s/he has been given **[MMSE information removed]** the three words to remember in the Addenbrooke's Cognitive Examination - III (ACE-III) when the participant has to remember the name and address, whether the participant was responsive to the questions or whether the participant seemed uninterested or bored, or whether it was a bad day for the participant due to fatigue, low mood or feeling unwell. It is important to note any reasons for delays in completing the three CRFs; for example the participant may have been unwell for six weeks and this meant that there was an unexpected delay between completing Part 1 and Part 2. It is also important to note whether during the administration of the MMSE or ACE-III the relative/friend was in the room helping the participant with some of the answers and whether this assistance was taken into consideration when scoring these tests. For Participant Part 2, please use the field notes at the end of the CRF to record the reasons why you decided on a particular score for the GDS and FAST.

Figure 4. Model of factors affecting the ability to live well with dementia that will be tested in the study



7.3. Types of CRFs

The CRFs for the person with dementia are called **'Participant CRF'** and the CRFs for the carer are called **'Relative/Friend CRF'**. Information about the number of CRFs is provided in Figure 5.

Figure 5. CRFs for the person with dementia and carer

CRFs for the person with dementia:

1. **Participant CRF Part 1**
2. **Participant CRF Part 2**
3. **Participant CRF Part 3**

CRFs for the carer:

1. **Relative/Friend CRF Part 1**
2. **Relative/Friend CRF Part 2**
3. **Relative/Friend CRF Part 3**

7.3.1. CRFs for the person with dementia

Participant CRF Part 1

The MMSE is at the start of this CRF. The MMSE is a brief measure used to screen for cognitive impairment, and will be used to check the eligibility of the person with dementia for inclusion in this study.

The rest of the CRF contains questions that provide demographic information about the person with dementia e.g. education, occupation, health status.

We will ask you to gather this information at the consent visit.

Participant CRF Part 2

The ACE-III is at the start of this CRF. The ACE-III is a brief test used to measure cognitive ability in five domains: attention, memory, fluency, language and visuo-spatial functioning.

The rest of the CRF has questions on interests and activities, attitudes to ageing, mood, quality of life, sleep, well-being, social participation, self-efficacy, satisfaction with life, social networks, relationship quality, everyday activities, difficulties the person experiences, stigma, optimism, sense of self, loneliness and self-esteem

The last part of the CRF contains the Global Deterioration Scale (GDS) and Functional Assessment Scale (FAST). The GDS/FAST is a widely-used brief system for categorising severity of impairment in people with dementia. These complementary measures present the progression of dementia in seven stages from normal (stage 1) to very severe dementia

(stage 7). These measures are rated by the researcher based on information gained through working with the person with dementia.

Participant CRF Part 3

Section A of the CRF contains questions on physical health, dignity and respect, psychological well-being, personality, access to green/blue spaces, social capital, social activities, cultural activities, and resources.

Section B of the CRF contains questions on health conditions and income. This CRF also contains the Client Services Receipt Inventory (CSRI). The CSRI provides an economic evaluation of participants' use of health care services. The questions cover contact with a range of health and social care professionals, prescription of medications, hospital appointments and stays, home help, travel costs, and use of community services.

7.3.2. CRFs for carers

Relative/Friend CRF Part 1

This CRF contains questions that provide demographic information about the carer e.g. education, occupation. We will ask you to gather this information at the consent visit.

Relative/Friend CRF Part 2

In this CRF the carer is asked to answer questions about him/herself and the person with dementia.

In the first part of the CRF there are questions about the person with dementia. These cover quality of life, well-being, activities, satisfaction with life, difficulties, and emotional well-being.

In the second part of the CRF there are questions about the carer. These cover support from others, relationship quality, physical health, well-being, quality of life, feelings about his/her self, satisfaction with life, mood, experiences and feelings about providing care.

Relative/Friend CRF Part 3

In the first part of the CRF there are questions about the person with dementia. These cover physical heath, emotions, support networks, accommodation, interests and activities, entertainment activities, decision-making, dignity and respect, and life events.

In the second part of the CRF there are questions about the carer. These cover health conditions, neighbourhood, activities and interests, support from others and social networks.

8. Structure of visits

Participants taking part in IDEAL will be visited on **three** occasions and all the assessments **must** be completed during these three visits (see Figure 6 for a brief summary of the content of these visits). The length of time allocated for these visits is:

- Visit 1: One hour
- Visit 2: Two hours
- Visit 3: Two hours

These three visits will last a total of **five** hours and we have allocated an appropriate amount of time for each visit for you to complete your assessments for that visit. We do allow some flexibility; for instance if both carer and person with dementia were willing to complete more assessments in Visit 2 then Visit 2 could last 3 hours and Visit 3 one hour, etc. You will need to make sure that **both** the person with dementia and carer (if present) agree to a longer visit.

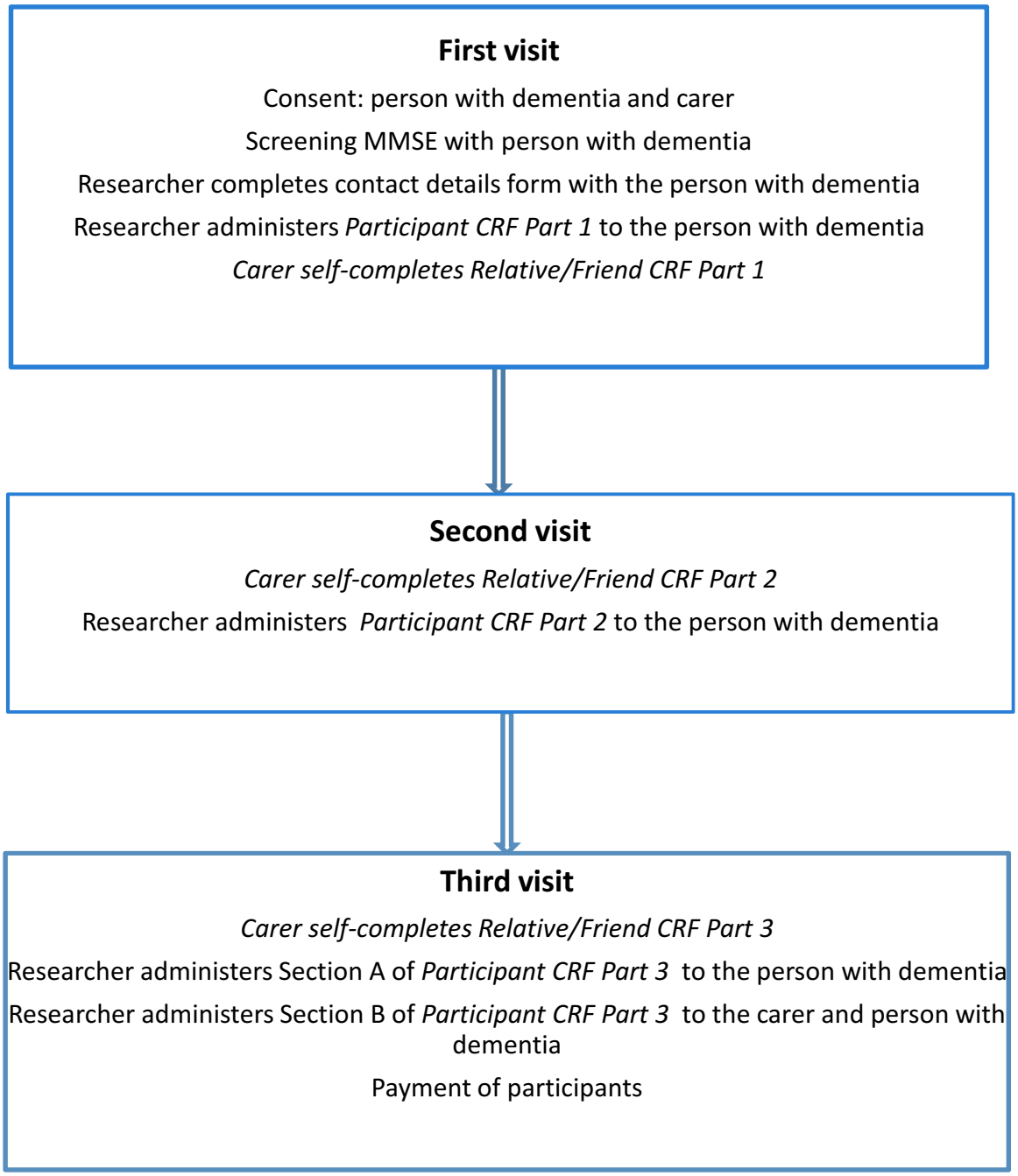
You can administer two CRFs in a visit; however, you need to ensure that the **MMSE** and **ACE-III** are administered on separate visits to avoid any carry over effects.

If you start another CRF during a visit (e.g. you've completed Participant CRF Part 1 and find that you have some time to start Participant CRF Part 2) and continue the CRF during the next visit (so the CRF has been administered on two dates) you should indicate in the **field notes** which questions were completed at a date other than the date written on the front of the CRF.

Visit schedule

We would hope that all visits at each time point are conducted within a 6 week time frame. We realise people may not be available within these 6 weeks but we encourage researchers to try to remain within this target to facilitate follow up visits.

Figure 6. Summary of the content of the 3 visits

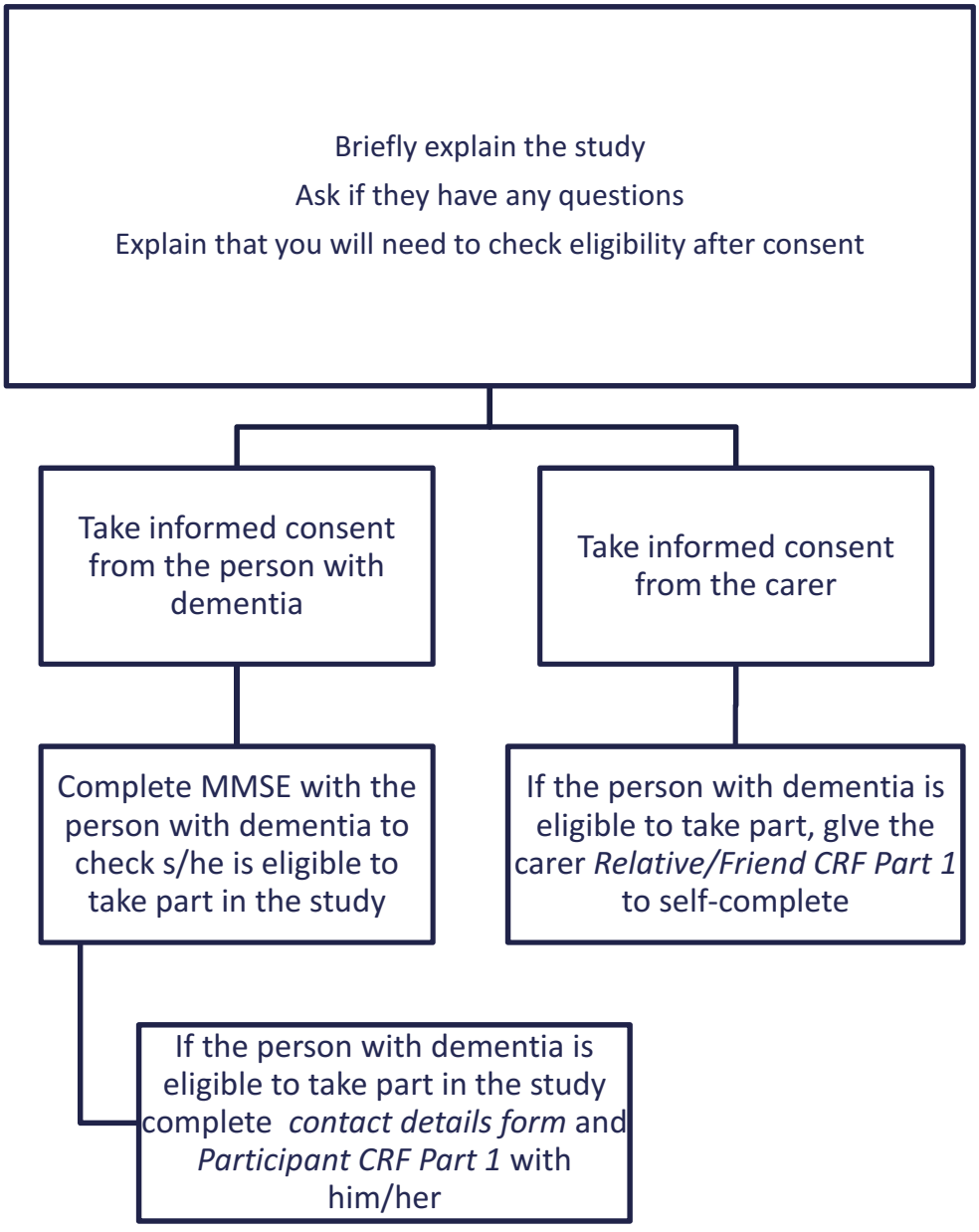


9. First visit

9.1. Outline of the first visit

The aim of the first visit is to obtain informed consent from the person with dementia and the carer and to screen the person with dementia in order to check eligibility. If the person with dementia (and carer) consent to take part in the study then you can commence the assessments. Figure 7 below outlines the procedure for the first visit if both the carer and person with dementia are present.

Figure 7. Outline of first visit for both person with dementia and carer



The sections below provide guidance about tasks you will need to do before, during and after your visit with the participant(s).

9.2. Before the first visit

1. Contact the person with dementia (and carer if applicable) the day before to remind them of the scheduled visit.
2. Assign the person with dementia (and carer if applicable) a unique ID number.

Information about participant ID numbers is provided in *Chapter 15: Data and document management*. The participant and carer will have the **same** ID. This ID does not change throughout the study, even if the carer changes.

3. You will need to take the following with you to the visit:
   (a) Folder containing: PIS, consent forms, demonstration of capacity checklist and contact details form
   (b) Folder containing:
      i. *Relative/Friend CRF Part 1, Relative/Friend CRF Part 2* (in case there is time to start this).
      ii. *Participant CRF Part 1, Participant CRF Part 2*(in case there is time to start this).
      iii. Showcards Visit 1, Showcards Visit 2 (in case they are needed).
   (c) **[MMSE information removed]**

9.3. During the first visit

The first visit should last approximately **1 hour**. The content of the visit is provided below.

9.3.1. Summary of the study

The first visit should start with a brief overview of the study. Key areas to focus on would be:

- The aim of the study.
- The longitudinal nature of the study.
- What taking part would involve.
- The right to omit any questions they do not wish to answer.
- The right to withdraw at any time.
- Confidentiality- all data collected will be kept confidential.

Participants should be given the opportunity to ask any questions. Check that the participants have read the **PIS**. Explain to participants with dementia that once they have consented to take part you will need to check that they are **eligible** to take part in the study

(you will administer the MMSE to check their score meets the inclusion criteria). Once the participant expresses willingness to take part in the study you can then obtain informed consent.

9.3.2. Obtaining informed consent

This section outlines the procedure for obtaining informed consent in this study. For researchers already experienced in collecting informed consent this section should serve as a refresher.

Informed consent is a continuous process that involves providing potential participants with sufficient information during the recruitment phase and subsequently monitoring their continuing willingness to take part in the research project. Participants should be informed that they have the right to withdraw from the study at any time, with no need to give a reason.

Before completing the consent form participants must have:

1. **Received and read the PIS**.
2. **Been given sufficient time** to consider the information.
3. **Had the opportunity to ask** the researcher any questions about the study and have had these questions answered satisfactorily.

Demonstration of capacity

People with dementia taking part in the IDEAL study will be in the mild to moderate stages of dementia and are expected to have capacity to consent to participation. The Mental Capacity Act proposes that people should be assumed to have capacity unless otherwise demonstrated. Capacity in this sense is demonstrated by the ability to understand the information given about the research, to retain the information for long enough to be able to weigh up that information in order to reach a decision, and to state a decision clearly.

When assessing capacity you can make use of the ***demonstration of capacity checklist*** (see Appendix 2). This is a checklist of items that should be considered when seeking informed consent from participants. Using this will help to ensure that these aspects are evaluated and that the criteria for capacity are met. The checklist should be completed and signed after the first visit. If there is any doubt about capacity then consent must not be taken and the participant should be excluded from the study.

You will need to informally check the participant's ongoing capacity to consent at each home visit through conversation with the participant.

The consent form

Copies of the consent form for the person with dementia and carer for T1 can be found in Appendix 3 and Appendix 4. When you give the consent forms to the person with dementia and carer, please ensure that they understand each point and answer any questions they have.

Participants do not need to agree to all of the points in the consent form to take part in the study. In particular in the consent form for the person with dementia points 8, 9, 10 and in the consent form for the carer points 6, 7, 8 are **optional**. These points relate to the sharing of the participants' contact details and data archiving. These items may raise queries from participants about confidentiality and as we hope that participants will agree to these points it is important that you address their concerns appropriately using the information provided in the PIS. As a legacy of the study we will be archiving the study data for use by other researchers in the future and we hope participants will be willing to contribute to this process

The participants must sign and date the form themselves. The researcher must also sign and date the consent form. When completing the consent form it is essential the participants **initial** (rather than tick) the boxes.

You may need to help the person with dementia by reminding him/her of the date. However, if you do this please be aware that you will shortly be administering the MMSE to the person with dementia **[MMSE information removed]**. We suggest that when it comes to signing and dating the consent form you ask the participant what s/he thinks today's date is before allowing him/her to date the consent form. **[MMSE information removed]**. This will ensure that both the consent form and the MMSE are recorded accurately.

The person with dementia and the carer will need copies of their consent forms; this can be done by photocopying the signed consent form and giving it to them on your next visit. A copy of these consent forms will need to be sent to the Bangor co-ordinating centre. The consent form must be returned separately to the participants' data (further information on returning of data is given in *Chapter 16: Study monitoring and reporting*).

9.3.3. Identification of a personal consultee

As this is a longitudinal study it is expected that some of the participants may lose their capacity to consent during the course of the study. Under the Mental Capacity Act (2005), which applies to people in **England** and **Wales**, if the person loses capacity then an identified 'consultee' can advise the research team about the appropriateness of the person

continuing in the study. In **Scotland** if the person has given informed consent to take part in research and subsequently loses capacity, the consent previously given when capable remains valid.

In this study every person with dementia recruited to take part in the study will be asked to identify a personal consultee who could be approached to decide whether the person should continue taking part in the study should s/he lose the capacity to consent. If the person with dementia does not have a carer then the personal consultee could also be contacted at follow-up, if you are having difficulty contacting the person with dementia, to see if there have been any changes in the person's circumstances. A personal consultee is someone who has a personal interest in the person with dementia and it should be someone whom the person with dementia would trust with important decisions about his/her welfare. Usually it will be someone with a close personal relationship with the person with dementia. A personal consultee could be:

- A family member, family carer or friend.
- An attorney acting under a Lasting Power of Attorney (LPA).
- A court-appointed deputy, provided that s/he had a relationship with, or personal knowledge of, the person lacking capacity before the appointment as deputy (for example, a deputy could be a family member).

A personal consultee **CANNOT** be:

- A formal carer who is **paid** to look after the person with dementia.
- A health care professional treating the person with dementia.

If the informal carer of the person with dementia is taking part in this study then s/he could act as the personal consultee.

You will need to record on the **contact details form** the name and contact details for the personal consultee. If the person with dementia is unable to identify a personal consultee this should be recorded on the form. People with dementia who cannot identify a personal consultee **can still be** included in the study.

9.3.4. Contact details form

The contact details of the person with dementia and carer (if different) should be recorded in the contact details form. This should also contain the contact details for the GP and the personal consultee of the person with dementia. You will need to ask the person with dementia for the contact details for his/her GP, explaining this is because you will need to inform the GP that the person is taking part in the study. A copy of this form will need to be sent to the Bangor co-ordinating centre (provided the person has consented for you to do this).

9.3.5. Screening using the MMSE

You will need to administer the MMSE to the person to check that s/he is eligible to take part in the study. The MMSE is located in the first part of *Participant: CRF Part 1.* You should discretely score the MMSE; the person will need to score 15 or above to take part in the study (Information about scoring the MMSE is provided in the IDEAL *Time 1 Case Report Forms Handbook).*

9.3.6. Decision on eligibility

Following on from administering the MMSE you will need to make a decision about whether the person with dementia is eligible to take part in the study:

(a) If the person with dementia does not meet the inclusion criteria (e.g. MMSE score) then debrief the person with dementia and the carer. Politely explain that the study will not be suitable for them. You could mention that there may be other more suitable studies that you could let them know about. It may be helpful to bring with you some literature on dementia or local services e.g. support groups that you could give to them.
(b) If the person is eligible to take part in the study then you can start the assessments.

9.3.7. Administration of assessments

(a) Give the carer the *Relative/Friend CRF Part 1* to self-complete. Ideally the carer should do this in a separate room.
(b) Administer the *Participant CRF Part 1* to the person with dementia. Complete the checklist at the back of the CRF.

9.4. End of the first visit

(a) Check that the carer has completed the CRF accurately, and complete the checklist at the back of the CRF. Ask the carer about any missing data or any errors in his/her responses (e.g. selecting multiple answers to a question that requires only one). If the carer has struggled to complete the CRF you may find that you have some time to help him/her to complete it.
(b) Establish the next visit date.

9.5. Post-visit

(a) Check that you have filled in all the appropriate sections on the documents.
(b) Record any field notes or comments on the CRF (if you have not already done so).
(c) Sign the demonstration of capacity checklist (if you have not already done so).
(d) If the participant has consented to take part in the study, send the ***letter to GP or hospital consultant*** (see Appendix 5)**.** You will need to enclose the Participant Information Sheet for the person with dementia with this letter.
(e) Photocopy the participants' consent forms and file appropriately.
(f) Ensure that the participants' documents are stored securely in a locked filing cabinet. Participants' consent forms and contact details forms must be stored separately to the CRFs.

9.6. Recording the number of people consented

Participants are only counted as recruited/taking part in the study if they have consented. The Bangor co-ordinating centre will require **MONTHLY** updates on recruitment numbers. You will need to compile the following information for people who have consented to take part each month:

People with dementia

1. The total number of **people with dementia** who consented to participate in the study.
2. The **diagnoses** of those who consented - the number of people with:
    - *(a)* Alzheimer's disease
    - *(b)* Vascular dementia
    - *(c)* Mixed dementia
    - *(d)* Fronto-temporal dementia
    - *(e)* Parkinson's disease dementia
    - *(f)* Dementia with Lewy bodies
    - *(g)* Unspecified dementia
    - *(h)* Other. You will need to specify the diagnosis
3. The **ages** of the people with dementia who consented - the number of people aged:
    - *(a)* Aged under 65
    - *(b)* Aged 65 or over
4. The **gender** of the people with dementia who consented - the number of people who are:
    - *(a)* Male
    - *(b)* Female
5. The **living situation** of the people with dementia who consented - the number of people who:
    - *(a)* Live alone
    - *(b)* Live with others

Carers

6. The total number of **carers** who consented to participate in the study.
7. For those carers who consented, the number who were:
    - *(a)* The spouse/partner of the person with dementia
    - *(b)* The child of the person with dementia
    - *(c)* In another type of relationship with the person with dementia

This information will need to be reported to the Bangor co-ordinating centre through the MACRO database (see *Chapter 16: Study monitoring and reporting*). We need to monitor this information so that we can achieve a sample of participants who have a range of MMSE scores, dementia sub-types, ages, gender, living situations and relationships with the primary carer. The information you provide will allow us to adjust the sampling strategy if required.

10. Second visit

The aim of the second visit is to complete *Part 2* of the CRFs with the participants.

10.1. Before the second visit

1. Contact the participant (and carer if applicable) the day before to remind them of the scheduled visit.
2. You will need to take the following with you to the visit:
   (a) Folder containing:
      i. *Relative/Friend CRF Part 2 , Relative/Friend CRF Part 3* (in case there is time to start this)
      ii. *Participant CRF Part 2 , Participant CRF Part 3* (in case there is time to start this)
      iii. Showcards Visit 2, Showcards Visit 3 (in case they are needed).
   (a) Items needed for the ACE III: pencil, one sheet of A4 paper, stopwatch (or mobile phone with stopwatch function).

10.2. During the second visit

The second visit should last approximately **2 hours**.

(a) Re-confirm the participants' willingness to continue in the study.
(c) Give the carer the *Relative/Friend CRF Part 2* to self-complete. Ideally the carer should do this in a separate room.
(b) Administer the *Participant CRF Part 2* to the person with dementia. Complete the checklist at the back of the CRF.

10.3. End of the second visit

(a) Check that the carer has completed the CRF accurately and complete the checklist at the back of the CRF. Ask the carer about any missing data. If the carer has struggled to complete the CRF you should have some time to help him/her to complete it.
(b) Establish the next visit date.

10.4. Post-visit

(a) Check that you have filled in all the appropriate sections on the documents.
(b) Record any field notes or comments on the CRF.
(c) Score the ACE-III (located at the start of the CRF), ensuring that your handwriting is legible and the scoring is accurate. Information about scoring the ACE-III is provided in the *IDEAL Time 1 Case Report Forms Handbook.*
(d) Ensure that the participants' documents are stored securely in a locked filing cabinet.

11. Third visit

The aim of the third visit is to complete *Part 3* of the CRFs with the participants and give the participants the shopping voucher

11.1. Before the third visit

1. Contact the participant (and carer if applicable) the day before to remind them of the scheduled visit.
2. Complete the participant payment record (see Appendix 7).
3. You will need to take the following with you to the visit:
   (a) Folder containing:
      i. *Relative/Friend CRF Part 3*
      ii. *Participant CRF Part 3*
      iii. Showcards Visit 3
   (b) Participant payment voucher, receipt of payment form and thank-you note

11.2. During the third visit

The third visit should last approximately **2 hours**.

(a) Re-confirm the participant's willingness to continue in the study.
(b) Give the carer the *Relative/Friend CRF Part 3* to self-complete. Ideally this will be in a separate room.
(c) Administer Section A of the *Participant CRF Part 3* to the person with dementia.
(d) Administer Section B of the *Participant CRF Part 3* with both the person with dementia and carer present.

11.3. End of the visit

(a) Check that the carer has completed the CRF accurately and complete the checklist at the back of the CRF. Ask the carer about any missing data. If the carer has struggled to complete the CRF you should have some time to help him/her complete it
(b) As a token of appreciation for their participation, give the participants the **thank-you note** and the **shopping voucher**. Ask the participants to sign the **receipt of payment form** as a record that they received the voucher.
(c) Thank the person with dementia and the carer for their time. Remind them that you will be back next year to see them again. In the meantime they will receive

newsletters to update them on the progress of the study (if they have opted for the Bangor co-ordinating centre to have their contact details). They can also access updates about the project on the IDEAL website: **www.IDEALproject.org.uk.**

12. Withdrawal information

If a participant withdraws from the study you will need to record the reasons why (if known) and inform the Bangor co-ordinating centre of the withdrawal through the MACRO database (see *Chapter 16: Study monitoring and reporting)*.

12.1. Recording the number of people who withdraw from the study

You will need to record withdrawal information for carers and people with dementia separately. For each participant who withdraws you will need to record:

1) The ID number of the participant.
2) Date notified of withdrawal.
3) The time point of withdrawal:
    a) T1
    b) T2
    c) T3
4) The reasons for withdrawal:
    a) Health reasons - person with dementia
    b) Health reasons - carer
    c) Death of person with dementia
    d) Death of carer
    e) Bereavement, other - please specify
    f) Unhappy with time commitment involved in taking part
    g) Not interested
    h) Unknown
    i) Other - please specify

13. General guidance on conducting assessments

This section provides guidance on conducting assessments with people with dementia and carers. Parts **13.1** and **13.2** have been written for researchers who are **new** to working with people with dementia. For those researchers who are more experienced and very familiar with conducting assessments with people with dementia and carers, please treat these parts as a refresher.

13.1. Guidance from the ALWAYS group

The ALWAYS group is a group of people with dementia and carers who act as advisors to the IDEAL project. Below is some guidance they provided on doing research with people with dementia and their carers. They provided some tips for contacting and interacting with participants:

In advance of the visit

1. **"Need to be flexible"**
   People with dementia often have quite set routines that need to be accommodated when planning a visit. It is important to take mealtimes into account. It was suggested that researchers call either the day before or on the morning of the visit to confirm the appointment as "things do change". This can help to avoid a wasted visit.

2. **"Preparation is important"**
   The researcher should have the appropriate amount of information to be able to engage with the person with dementia and carer during the visit. Participants may ask for information about dementia. In addition, it is important that the person with dementia and carer are adequately prepared for the visit. Providing information about the study before the visit will allow them time to think about the study. It may be useful to bring some information on local services (e.g. Alzheimer's café, carers' support groups etc.) to provide to participants.

3. **"If you are living on your own it's a different situation"**
   People living on their own may feel more vulnerable. It was felt that it would be helpful if there was someone else there who could support the person with dementia, particularly on the occasion of the researcher's first visit.

During the visit

4. **"What's in it for me? What good can I do for other people by being involved in it?"**
   It is important to get across the value of the research, particularly any benefits for those taking part and for other people in the future. People should have the opportunity to ask questions about the study.

5. **"Someone you can believe is doing it for the right reasons"**
   It is important to build rapport with the person with dementia and the carer. This can be done by being a "good listener" and by being "friendly". This will help put the person at ease. Researchers should try and sit directly opposite the person with dementia and make eye contact with him/her.

6. **"Be clear what you are asking and what the value will be"**
   The researcher may need to explain why s/he is asking certain questions. People should be given reassurance that they do not have to answer any questions they do not wish to, and they do not have to continue if they do not want to. Some people feel they are not very good at answering questions and the researcher should adapt his/her approach with them. There is no need to rush, and it is important to spend some time with the person building rapport.

7. **"I want to feel relaxed talking to someone"**
   The researcher should think about how s/he would feel being asked those questions. The CRFs should be introduced in a conversational way.

8. **"We're open with each other but we'd like to do tests separately"**
   It is preferable for the person with dementia to be administered the CRFs separately from the carer, particularly during cognitive assessments. The carer and person with dementia can have very different perceptions about their lives. The person with dementia may also appreciate the opportunity to speak to someone one-to-one. However, the carer may get anxious about what the person will say, or have concerns that the person will not know how well s/he is coping. Carers may need to be reassured that the researchers are interested in people's subjective opinions. However, if the person with dementia is being asked factual questions, such as about medical matters, then it may be useful for the carer to be present.

9. **"People will come out with a range of emotions"**
   It is important to be aware that the person may be experiencing a range of emotions. Every person is different and it is difficult to predict which questions will trigger an emotional response. Should participants not want to answer certain

questions it is important that they are reassured that this is acceptable. Researchers should deal with any emotional expression sensitively.

10. "Things change"

It is important to be flexible, as people can get tired on certain days and may not be able to do as much.

At the end of the session

11. "I forget what they say to me but I remember how I felt"

People with dementia may have difficulties recalling the questions they were asked during the session, but they will remember how they felt. It is important that the sessions end on a positive note. Finishing the session with a brief, more social chat with the person can help with this. Mementos in the room, such as family photographs, can help to open up conversation.

12. **"I don't always remember the person coming in"**

The person with dementia may forget that s/he has been visited by a researcher. It is helpful to leave behind some information about the study which can act as a memory aid.

13. "A year is a long time to wait"

Researchers need to be aware that when they enter into a person's life they have an impact. A year can seem a long way away and it is important that the research team stays in contact with the person. In the IDEAL study the project team will keep in contact with participants by sending them newsletters.

13.2. Assessment environment

When carrying out your assessments at the participant's home, try to ensure that the conditions are suitable for an effective assessment to take place.

1. Check whether the person with dementia needs to wear glasses for reading. If the person uses a hearing aid, check that it is in place and switched on.
2. The CRFs should be administered in a quiet, non-distracting environment. Sometimes this may mean politely asking for things to be changed. For example, you may need to ask if the television or radio could be turned off, or if lively dogs could be taken to another room.
3. Ideally the CRFs should be administered to the person with dementia one-to-one with no one else in the room. If the carer is there politely ask him/her to leave the room. You can explain that people often feel uncomfortable and/or distracted when answering

questions in front of others. In addition, if the carer is taking part in the study then s/he may be better able to concentrate on completing the CRFs in a quiet room. If the carer wishes to remain present then explain that s/he should not help the person answer any of the questions, as we are interested in the person's perspective. Carers should not provide any cues or hints for the cognitive assessments, as this will invalidate the assessment.

4. Try to ensure that the environment is suitable for assessment purposes. For instance, you need to position yourself so that the person can see your face, and so that you can show the person the showcards. **[MMSE information removed]** If you do not have a spare clipboard the person will need to use a table for the writing tasks in the ACE-III.
5. Make use of the showcards provided to help with responses.

13.3. Administering CRFs to the person with dementia

1) The CRFs for the person with dementia are to be administered by the researcher. The way in which CRFs are administered can have a substantial effect on the participants' responses, and so must be **standardised** as much as possible. The CRFs should be administered in a conversational manner.
2) The CRFs have been structured to help the researcher explain the process to the person with dementia. The CRFs includes what the researcher should say at each stage to explain the current set of questions and signal a change of topic.
3) If the person is having difficulties answering a question, firstly repeat the question and possible responses. If this does not help, try explaining the question to him/her. If the person still does not answer, move onto the next question. If the person does not wish to answer a question then move onto the next one. If appropriate come back to that question at a later stage and see if the person wishes to answer. If not record the reason for the missing data at the back of the CRF.
4) When administering cognitive assessments you will need to read out the questions verbatim and follow the given order. It is useful to point out that the tasks are designed to be a challenging, and while some aspects may be hard, this does not necessarily mean a bad result. During the administration of these assessments it is important to encourage the person with dementia throughout. Do not point out any errors.
5) When administering the other types of questions it can be helpful to say to the participants that there are no right or wrong answers and that you are interested in their opinion.
6) Some people may get upset when asked certain questions; if this happens, respond empathically and check whether the person feels able to continue. If so move on to a different question. If appropriate come back to that question at a later stage and see if the person wishes to answer. If not record the reason for the missing data at the back of the CRF.

7) After completing each CRF with the person with dementia, ensure that all questions have been completed. Any non-completion of a question or section must be documented in the checklist at the back of the CRF. We need this information because when we analyse the data it is important for us to understand the reasons for any missing data. In the checklist, for each section of the CRF you will need to record whether there was any missing data or whether the CRF was completed in full. If the CRF was completed in full you should check the "All items have been completed" option at the back of the CRF. If there was any missing data you will need to record:

   a) Whether all the data for that section is complete.
   b) Whether the participant refused to complete that section.
   c) Whether questions in that section were not completed because there was no time to compete them.
   d) If that section was only partially completed you will need to record the reason:
      i. Participant too impaired to answer
      ii. Tiredness
      iii. Question not understood
      iv. Other - specify the reason

13.4. Carer self-complete CRFs

1. The **CRFs for the carer are designed to be self-completed**. Briefly explain the CRF to the carer and how s/he needs to complete it. It is important that you point out that there are questions on both sides of the paper. You may find it helpful to go through the first question with the carer to demonstrate how to complete it. Explain to the carer that if s/he does not understand any of the questions then s/he can ask for your help. Ideally s/he should come to speak to you after you have finished working with the person with dementia so as to not interrupt the session.

2. At the end of the session you will need to check that the carer has provided complete information in the CRF. You will need to check the carer pack for any missing data immediately after s/he has returned this to you, and review any missing data with the carer. Ask the carer to complete any missing questions if s/he is able and willing to; otherwise, please record the reason for missing data in the appropriate section at the back of the CRF. You will also need to check that the carer has completed the CRFs accurately, for example that s/he has provided one response for single-response questions rather than selecting several responses. In this situation ask the carer to indicate the correct response and clearly amend this on the CRF.

13.5. Why these checks are needed: the impact of missing data

Missing data is like the missing jigsaw pieces in a puzzle. If the puzzle is missing pieces then the full picture may not be clear. In some instances, it may be easy to work out what the missing pieces represent and therefore appreciate the complete picture - for example, when there are few missing pieces and they are scattered across the entire picture. In other instances it may be difficult to work out what the missing pieces represent and hence to identify the picture - for example, when there are many missing pieces clustered together.

Missing data can undermine the validity of a study's statistical conclusions. Similarly, if there are missing jigsaw pieces we might make a wrong assumption about what the completed picture is. Ideally, we want no missing data, but in practice, this is not always possible and we have to apply statistical techniques to work out what the missing data is most likely to be. It is preferable to base our statistical conclusions on actual data rather than on assumptions, just as it is better to base our interpretation of the jigsaw picture on actual jigsaw pieces rather than on what we imagine the jigsaw pieces to represent. Therefore it is important to do all you can to keep missing data to a minimum.

Missing data may occur during several stages of the IDEAL study, and there will be different ways of minimising occurrences of missing data:

1. Missing data may initially occur when administering the CRF. The researcher may inadvertently miss out a question, or the answer recorded by the researcher may be illegible due to poor handwriting, or multiple answers may be recorded for a question that only requires one. Care must therefore be taken to ensure that *all* answers are clearly and correctly recorded.
2. Participants may be reluctant or decline to answer a question. Participants should be encouraged to answer all the questions if possible; however, it is important to respect the participant's decision not to answer a question.
3. After the CRF has been completed, there is a possibility that the CRF could be mislaid because it has not been correctly filed or handled. Care must be taken to ensure that CRFs are filled in correctly, securely stored and returned to the Bangor co-ordinating centre in accordance with study procedures.
4. Missing data can also be the result of failure to conduct follow up assessments. This may be because the participant's contact details were incorrectly recorded or not kept up to date. Hence, the researcher should be diligent when trying to contact the participant about participating in the follow up assessments and ensure that contacts details are accurate and up to date.
5. Throughout the study participants may choose to withdraw and this will obviously result in missing data. It is important that we make participating as agreeable and easy as possible for the participant.

13.6. Troubleshooting: issues that may arise with assessment

This part provides some guidance on issues that may arise during the IDEAL study

1. ***The person with dementia does not complete all of the questions in the CRF:*** The CRFs have been piloted to ensure it is feasible for the person with dementia to complete them within the allotted time. However, it is possible that some participants will take longer to complete the questions. For those participants who are particularly 'chatty', try to steer them back onto the questions. Try to complete as much of the CRF as you can within the allotted time. If you do not finish a CRF during a visit you should **continue** the CRF in the next visit. If you are going to continue the CRF in another visit do not complete the checklist for that section of the CRF until that visit, particularly the checklist option about there being enough time to complete the section. The checklist option about there not being enough time to complete should only be used at the end of the third session when there is no more time left to finish the assessment. When you continue the CRF you should indicate in the **field notes** which questions were completed at a date other than the date written on the front of the CRF.

2. ***Difficulties with completing the assessments in three visits:*** We appreciate that for some people completing all the required information within 3 visits will be difficult. In **exceptional** circumstances it may be possible to make an additional visit. However, researchers need to bear in mind the implication of this additional visit in terms of their own workload and capacity but also in terms of the costs attached to this visit. Invoicing the study for this visit will require **substantive justification** and costs may not be reimbursed.

3. ***The carer has difficulty completing the CRFs:*** The carer CRFs are designed to be self-completed but it is possible that some carers may struggle to complete the CRFs. Ultimately you need to focus your time on the person with dementia but you may have some time at the end of the session to give the carer some help. It can be helpful when you are introducing the carer to the CRFs to go through the first couple of questions with him/her to demonstrate how s/he should complete them.

4. ***The person with dementia does not have a carer:*** People with dementia who do not have a carer are still eligible to take part in the study. Just follow the procedure for assessing the person with dementia.

5. ***The carer wishes to take part in the study but cannot attend any of the sessions:*** Ideally the person with dementia and carer will be able to attend the same sessions, but some carers work or may have other responsibilities. In this situation:

a) Make initial contact with the carer over the phone and explain the study to him/her. Find out his/her availability.
b) For those carers with limited availability, see if they are willing to just come to the first visit. It is also worth finding out if they would prefer to be contacted by email rather than telephone (it can be difficult to get hold of carers who work full-time on the telephone).
c) If the carer cannot come to the first meeting, post the carer consent form to him/her and explain that s/he cannot take part in the study until the signed consent form is returned to you. If you do not receive the signed consent form re-contact the carer to check that s/he is still interested in taking part in the study.
d) Once the signed consent form has been returned, contact the carer either by phone or email and explain the procedure for completion of the CRFs. Tell him/her that s/he can contact you if s/he has any queries. Post the CRFs to the carer with an addressed return envelope. Provide the carer with a return date.
e) If the carer does not return the CRFs by the return date re-contact him/her to check if there are any problems completing the CRFs and remind him/her that s/he needs to return the CRFs.

6. ***The person with dementia and/or carer withdraw from the study****:* During the T1 assessments if the carer withdraws from of the study the person with dementia can still continue to take part; however, if the person with dementia withdraws the carer should discontinue participation in the study. During the follow-up assessments if the person with dementia decides to withdraw the carer can still continue to take part and vice versa. If the person with dementia cannot take part in the study, e.g. because of illness, the carer can still take part.

7. ***The carer for the person with dementia changes at follow up:*** It is possible during the period before the follow-ups that the carer may have changed. In this instance if a new carer is willing to take part in the study s/he should complete the CRFs. This should be recorded within the recruitment information at follow-up and space will be provided on the CRFs to note this change. **Do not** change the ID number for that dyad.

8. ***Payment of participants*****:** If the person with dementia completes, or the person with dementia/carer dyad complete, all the visits for that time-point then they should be given the shopping voucher. Dyads only receive one voucher (not one each). If the participants do not complete all of the visits, for example if they decide to withdraw after visit 2, then they should not receive payment. However, if only one member of the dyad decides to withdraw and the other one completes all of the visits then s/he can still receive payment.

14. Follow-up assessments: T2 and T3

You will receive separate training on the follow-up assessments. Below is some brief information about the follow-ups and the scheduling of visits.

14.1. Changes to the CRFs

The content of the CRFs will alter at each time-point. Some questions, such as those covering basic personal information that will not change (e.g. education, employment status), will only be administered at T1.

It is recognised that people with dementia may experience some decline between time-points and may become more impaired. In this case they will be administered shorter versions of the CRFs. We will identify or create a single global question for that component (where relevant) that could to be administered where the person with dementia is no longer able to complete the full set of items.

The person will also be administered cognitive assessments appropriate to the severity of dementia.

Informant ratings by the carer about the person with dementia will be obtained alongside self-ratings throughout, to help the interpretation of informant ratings at later time points where the person with dementia is unable to provide self-ratings.

14.2. Scheduling follow-ups

Participants will be followed up 12 (T2) and 24 (T3) months later, completing the assessment in two home visits at each time point (see Figure 2, Participant pathway through the study). The first follow-up should be **12 months** after the first T1 visit and the second follow-up should be **24 months** after the first T1 visit. An acceptable window for follow-up will be **no earlier** than one month prior to scheduled follow-up date and **no later** than two months post the scheduled follow-up date at each time point.

We will email you an Excel file (see *Chapter 16: Study monitoring and reporting*) that you can use to schedule your follow-ups, or alternatively you can just follow your local systems to provide reminders of follow up dates.

Sites should plan ahead to be able to facilitate these follow up visits. Please note that T1 recruitment will still be ongoing as T2 (first follow up) commences.

14.3. Minimising drop-out

One important way of minimising drop-out is to ensure that participants' interest in the study is maintained between the follow-up visits. Those participants who have consented for their contact details to be given to the Bangor co-ordinating centre will be sent a twice-yearly study newsletter. Participants can also find out about the progress of the study by accessing the IDEAL website: **www.IDEALproject.org.uk.**

14.4. Re-contacting participants

Participants should be contacted one month prior to the follow up assessment. Participants can indicate their willingness to continue taking part in the study by sending back the reply slip. Non-responses can be followed up with a telephone call. Participants' circumstances can change over a year and it is possible that in some cases the person with dementia or carer may have died. This issue will need to be dealt with sensitively. If the person with dementia or carer has moved into residential care or moved into another area then we would still approach them for follow-ups. Where possible you should check clinic/hospital records for any information about changes in circumstances before contacting the participant.

The following are tips that can facilitate the follow up process.

To prevent losing participants to follow-up:

- Update contact information at every visit.
- Find out if the participant expects to move within the next 6 - 12 months.
- Ask for any new phone numbers, including mobile phone numbers.
- Check the address and phone number of the carer and personal consultee at each visit.
- Keep a record of all contact information. This should contain name, address, date of birth, phone numbers, email address (if available), contact details for the carer, contact details for the personal consultee, participant GP contact details and participant study ID.
- Ask the participant if they have a second residence. If yes, get numbers for this residence.
- If possible, phone the participant at different times of the day in order to speak with him/her in person to arrange follow-up visits.

If you have a problem reaching the participant at follow up:

- Check clinic charts or hospital records for any changes in circumstances (e.g. move to residential care, death).
- Check with the carer or personal consultee about his/her continued participation in the study.
- Please record all reasons for loss to follow up (e.g. deceased, ill health, unable to contact etc.).

14.5. Recording the number of people re-affirming consent at follow up

The Bangor co-ordinating centre will require MONTHLY updates on follow-up numbers (when this is relevant for your site). You will need to record information about the people who re-affirmed consent at follow-up:

People with dementia

1) The number of people with dementia who re-affirmed consent to participate in the study at follow-up.
   a) The diagnoses of those who re-affirmed consent - the number of people with:
      i) Alzheimer's disease
      ii) Vascular dementia
      iii) Mixed dementia
      iv) Fronto-temporal dementia
      v) Parkinson's disease dementia
      vi) Dementia with Lewy bodies
      vii) Unspecified dementia
      viii) Other - specify the diagnosis
2) The number of people with dementia who were lost to follow-up.
3) The number of people with dementia who refused to participate.

Carers

7. The number of carers who re-affirmed consent to participate in the study at follow-up.
8. The number of carers who refused to participate.
9. The number of carers who were lost to follow-up.

This information will need to be reported to the Bangor co-ordinating centre through the MACRO database (see *Chapter 16: Study monitoring and reporting*).

Part III. Monitoring and reporting

15. Data and document management

15.1. IDEAL site Excel file for generating participant IDs and follow-up dates

This Excel file will be emailed to the person at each site who has been nominated to update the MACRO database (see *Chapter 16: Study monitoring and reporting*). This person will then distribute the file to all the researchers working on the study. This same file will be used to record the information needed for study monitoring purposes (explained in *Chapter 16: Study monitoring and reporting)*.

15.1.1. Participant IDs

The Excel file must be used to generate participant IDs. The participant and carer will have **the same ID**. This ID does not change throughout the study, even if the carer changes. The first part of the participant ID is generated from the **site number** (provided in Excel). The second part is your ID number (Researcher IDs are generated in MACRO; see *Chapter 16: Study monitoring and reporting*). The third part is a sequence number generated in Excel. The table below provides an example of how Participant IDs are generated in Excel.

Site number	Researcher ID number	Sequence number	Participant ID
This will be provided in the Excel file	You will need to get this from the MACRO database	This will be provided in the Excel file	This will be the combination of these 3 numbers

15.1.2. T2 and T3 follow-up visits

You can use the IDEAL site Excel file to schedule your T2 and T3 follow-up visits, or alternatively you can just follow your local systems to provide reminders of follow up dates. You will need to enter in the date of your first visit with the participant and the file will generate the date of your T2 and T3 follow-up visits.

15.1.3. Study monitoring information

Researchers can record information needed for study monitoring purposes in the IDEAL site Excel file, e.g. the dementia diagnoses of consented participants.

15.2. Study documents

15.2.1. Investigator Site File

The Investigator Site File (ISF) refers to the regulatory and approval documents that need to be maintained at each research site. It offers a standard filing system which allows the effective storage and location of essential documents.

We have initiated a study specific ISF for use at all IDEAL sites. At the time of site set-up you will receive a set of documents required for the ISF, and a checklist indicating what documents need to be added throughout the study.

It will be your responsibility as a research site to keep the file organised and to add any new relevant documents.

You can find more information about ISFs from the Bangor Coordinating unit. See the NWORTH SOP 3.04 Trial Master File & Investigator Site File (3.04): available at:

http://www.bangor.ac.uk/imscar/nworth/specservices.php?menu=3&catid=2236&subid=0

Some basic principles for maintaining good ISF files are as follows:

• All study documents must be stored in a safe, secure and confidential environment.

• Avoid leaving study related documents for others to see and remove.

• Control access to the study files to prevent documents going missing.

• Treat documents (e.g. consent forms, recruitment information) like 'gold' and ensure they do not get lost or destroyed.

• The local PI has the responsibility of maintaining the ISF. S/he may in turn delegate this responsibility to a member of the local research team.

• The ISF must contain all essential documents applicable to each phase of the study.

• Any alteration to a document contained, or which has been contained, in the ISF must be traceable and documents should be version controlled.

• Outdated copies should remain in the ISF and marked as superseded.

• The checklist of essential documents should be inserted into each ISF.

• The study file must be kept up to date.

• Ensure all new documents provided by the co-ordinating centre are added to the ISF.

15.2.2. CRFs

The CRFs (and associated showcards) will be sent directly to your site. In these packs you will find address labels for returning study documents to the Bangor co-ordinating centre. We will monitor the number of participants each site recruits and send more CRFs when necessary. **Ms Lester Bath** who is at the Bangor co-ordinating centre will be responsible for checking that each site receives the CRFs. If you have not received your CRFs, or need more CRFs, you should contact her: Tel: 01248 388085, Email l.bath@bangor.ac.uk.

15.2.3. Other key study documents

Other key documents needed for this study are:

(a) Factsheet for memory clinic staff
(b) Pre-screening and referral information
(c) Information poster
(d) Invitation letter and reply slip
(e) Information pamphlet
(f) Introduction to the study for participant, family members & friends, and personal consultees
(g) Participant information sheets
(h) Consent forms
(i) Demonstration of capacity checklist
(j) Contact details form
(k) Letter to GP or hospital consultant
(l) Receipt for participant payment vouchers
(m) Participant payment record
(n) Receipt of payment
(o) Participant thank-you note (to go with the shopping voucher)
(p) Adverse event reporting form

These documents will be made available to the PI at each site so that they can be submitted for local R&D/SSI approval. Copies of these documents will also be available in the ISF.

15.2.4. Participant payment vouchers

Each site will be provided with shopping vouchers to give to participants who complete all the sessions as a token of appreciation for their participation in the study. Each site will be responsible for:

1. Confirming that the vouchers have been received by the site by completing the **receipt for participant payment vouchers** (see Appendix 6) and posting it to:

Ms Lester Bath, IDEAL Project Administrator**,** School of Psychology, Bangor University, Bangor, Gwynedd, LL57 2AS.

2. Keeping the vouchers in a **secure location**.
3. Keeping a record of participant payments by completing the **participant payment record** (see Appendix 7)**.** You will need to enter the date, the participant's name, and the participant's ID number, and state whether they have been paid. A copy of this form will need to be returned to the Bangor co-ordinating centre.
4. Ensuring that the participants sign the **receipt of payment** (see Appendix 8) so that there is a record they have received payment. A copy of these receipts must be returned to the Bangor co-ordinating centre.

15.3. Data storage

It is important to follow the guidelines of the Data Protection Act to ensure that all information collected about the participants is:

- Used fairly and lawfully.
- Used for limited, specifically stated purposes.
- Used in a way that is adequate, relevant and not excessive.
- Accurate.
- Kept for no longer than is absolutely necessary.
- Handled according to people's data protection rights.
- Kept safe and secure.
- Not transferred outside the UK without adequate protection.

(Guidance taken form: https://www.gov.uk/data-protection/the-data-protection-act)

Please be sure to follow your local regulations and procedures to ensure effective data protection. Below are guidelines for the storage of IDEAL participant data:

1. All IDEAL participant data must be stored in a locked filing cabinet in a secure room.
2. All IDEAL participant data must be locked away if unattended.
3. No one should access IDEAL participant data unless authorised to do so by members of the research team.
4. Participant confidentiality should be ensured by use of participant IDs on study documents (only record participant names where requested on the document).
5. All electronic data must be password-protected.
6. Personal data that has the potential to identify IDEAL participants should be kept in a secure place, separate from the CRFs. The signed consent forms, Contact details forms and Receipt of payment forms should be kept separately for the CRFs and other documents.
7. CRFs should be stored together.

15.4. Returning documents to the Bangor co-ordinating centre

We will arrange for the CRFs and other study documents (e.g. consent, contact details etc.) to be regularly collected from each site. This will be via a courier pick up from your site and a schedule of collection dates will be provided.

15.4.1. Which documents do you retain at the site?

Each site will need to retain: pre-screening and referral Information forms, consent forms, participants' contact information and the demonstration of capacity checklist for all participants.

1) **Pre-screening and referral information** forms**:** Follow your local procedure for the storage of these forms.
2) **Consent forms:** Keep the consent forms signed by the person with dementia and the carer.
3) **Participants' contact information:** Keep a record of the participants' contact information; this will include information about the personal consultee for the person with dementia.
4) **Demonstration of capacity checklist:** as evidence that the person has shown capacity to consent.

15.4.2. Which documents need to be returned to the co-ordinating centre?

Each site will need to return to the Bangor co-ordinating centre:

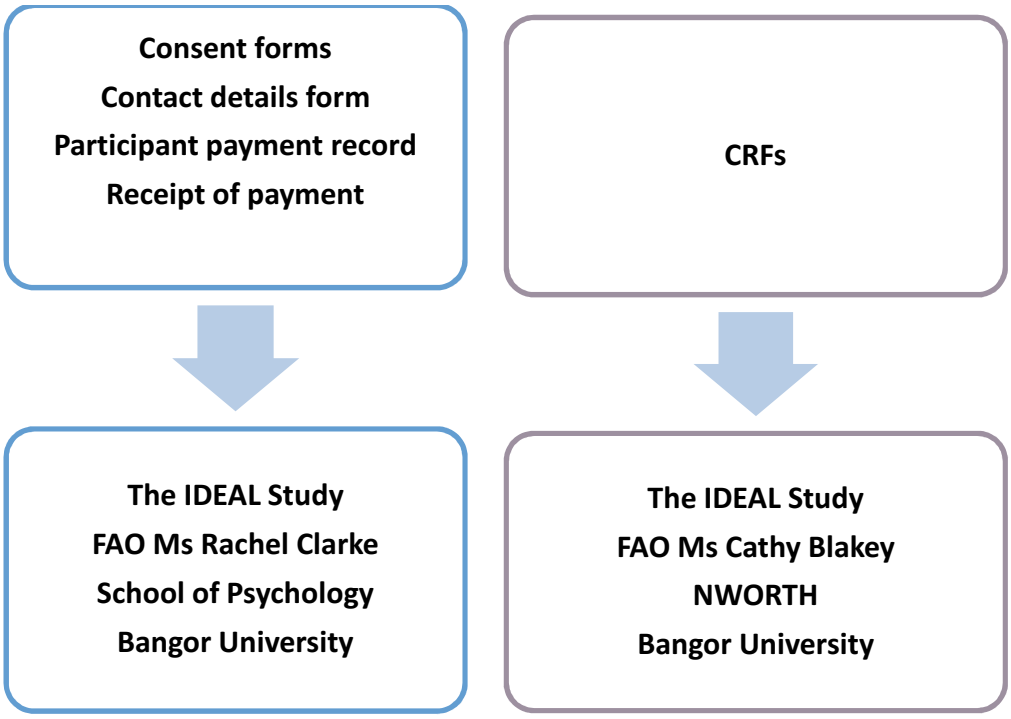
1) **Consent forms**: We will need a copy of the Consent forms for the person with dementia and carer.
2) **Contact details form:** If the participant has agreed on the Consent form that his/her contact details can be shared with the Bangor co-ordinating centre then a copy of this form should be returned.
3) **Participant payment record:** we need this document as a record of participant payment.
4) **Signed receipt of payment form:** we will need this document returned as evidence that participants have been paid**.**
5) **CRFs:** all the CRFs need to be returned.

15.4.3. How to return documents

We will arrange for a courier to collect study documents from each site approximately every 2 or 3 months (the collection schedule will depend on your recruitment target, i.e. sites recruiting larger numbers of participants will have documents collected more regularly).

1. Only return **full sets** of data for participants i.e. If the participant has only done CRFs 1 and 2 only return his/her data when you have completed CRF 3. If a participant withdraws from the study during assessments then just return what has been done up to that point.
2. You will be supplied with a cover sheet to compete, on which you will list all the documents that you are returning. You will need to retain a copy of this sheet at the site as a record of what data and documents have been returned.
3. In order to comply with data protection requirements, consent forms and other personal documentation will need to be returned separately to the CRFs (i.e. in a separate envelope/box). In addition these two sets of documents will be delivered to two different locations in Bangor (see Figure 8 below). You will be provided with address labels.

Figure 8. Returning study documents



15.4.4. Data entry

Data entry clerks based at NWORTH will be responsible for entering the CRF data. Ms Rachel Clarke (IDEAL Research Project Support Officer) will be dealing with the other documents. You will be contacted by the Bangor co-ordinating centre if there are queries about the data or information you have collected. We will appreciate your co-operation in responding to these queries in a timely manner so data entry may proceed as planned.

16. Study monitoring and reporting

16.1. Safety monitoring and reporting

16.1.1. Protection of Vulnerable Adults (POVA)

People with dementia are potentially vulnerable, and as such we all have a duty of care to deal with issues giving rise to serious concern. If you observe or hear anything that causes serious concern about a participant's health, safety or well-being, you must take appropriate action, as described in your local policy for protecting vulnerable adults. Your local PI should be informed. A sample POVA protocol is provided in Appendix 9.

16.1.2. Adverse Events/Serious Adverse Events

Please record any Adverse Events (AEs) and Serious Adverse Events (SAEs) that occur during the assessment period. AEs/SAEs can result in delays in completing assessments or result in the participant no longer being in the study. If an AE/SAE occurs you need to inform the local PI and record it using the **adverse event reporting form** and store this form at your site in the Investigator's site file. AEs/SAEs must be reported in the MACRO database. Examples of AEs/SAEs are provided below.

Adverse Events

An AE is any adverse occurrence happening to the participant that, while not necessarily related to the study, is temporally associated with the study (i.e. it arises during the period that the participant is in the study).

Examples of AEs include:

1. An exacerbation of a pre-existing illness that is more severe than expected.
2. A condition that is detected after the participant entered the study (even though it may have been present prior to the start of the study).

Examples of events that are not classed as AEs include:

- Pre-existing diseases or illnesses present before treatment that do not worsen more than expected for the condition.
- Symptoms of dementia, unless more severe than expected for the condition of the person with dementia.
- Medical or surgical procedures – these in themselves are not classed as adverse events, but the condition that led to the need for them may have been classed as such.

Serious Adverse Events

Some adverse events are classed as serious. A SAE is an untoward occurrence experienced by either the participant or carer that meets one of the following criteria:

1. Results in death.
2. Is life-threatening.
3. Requires hospitalisation or prolongation of existing hospitalisation.
4. Results in persistent or significant disability or incapacity.
5. Is considered clinically significant by the investigator.

If an SAE has occurred please note down on the **adverse event reporting form** which of the above points it relates to e.g. life threatening. In MACRO you will be asked to indicate whether the adverse event you are reporting meets one of these criteria and therefore counts as an SAE.

16.2. THE IDEAL monitoring system: the MACRO database

MACRO is a web-based data entry system that enables the co-ordinating centre to monitor the progress of the study at each site. We are employing this system due to the large number of sites involved in the study.

The MACRO database will be used to:

- Monitor the progress of the study at your site. It will provide site information on recruitment numbers and other details of the participants from the site.
- Record the occurrence of AEs/SAEs.
- Record the details of staff involved in the study at each site and information on their training records.
- Generate researcher IDs.
- Record updates to the ISF.
- Record withdrawal information.

16.2.1. Monthly progress reports in MACRO

Research sites will be required to provide information on a monthly basis in MACRO. Sites will identify one key person who will take responsibility for uploading information to the MACRO database. This person will be provided with a username and password from the Bangor co-ordinating centre. This will allow the person to access MACRO and enter the required information. Information that researchers have recorded in the IDEAL site Excel file can contribute to this update.

We require information to be provided for the full calendar month of activity at the site. Monitoring information required from sites must be uploaded to the MACRO database by the **5th of the next month** (*please note this date differs from the date provided in the training slides*) to allow the co-ordinating centre to compile relevant information for internal and external reports, for example site activity conducted between June 1st to 30th must be uploaded to the MACRO database by July 5th.

Your co-operation with this process will be appreciated. Failure to upload the information will have a significant impact for the project in terms of our ability to report to our funders, sponsors and Ethics Committee.

16.2.2. What information needs to be recorded in MACRO?

We have listed below the information that will need to be recorded in the MACRO database:

1. **Recruitment information:** You will need to record information about:
   (a) People pre-screened (discussed in *Chapter 5: Identification of study participants*).
   (b) People approached (discussed in *Chapter 6: Recruitment of study participants*).
   (c) Participants consented (discussed in *Chapter 9: First Visit*).
2. **Researcher information.** You will need to record information about researchers working on the study:
   (a) Researcher name and email address.
   (b) Researcher start date and end date (if applicable) on the study.
   (c) Whether the researcher has received GCP and GCP refresher training and the date of the training.
   (d) Whether the researcher has received IDEAL training and if so:
      i. The date of the training.
      ii. Whether the training was provided by the Bangor co-ordinating centre or by research staff at the site.
   (e) Whether the researcher has read the IDEAL handbooks.
   (f) Whether the researcher's CV and GCP record has been sent to the Bangor co-ordinating centre and added to the ISF.
3. **Withdrawal information**: You will need to record information about people who have withdrawn from the study (discussed in *Chapter 12: Withdrawal information*).
4. **AEs/SAEs:** You will need to record any AEs/SAEs.
5. **ISF:** You will need to record any updates to the ISF:
   (a) Whether the site has received any new documents from the from the Bangor co-ordinating centre to add to the file.
   (b) If so, you will need to confirm these documents have been added to the site file.
6. **Follow-ups:** You will need to record information about the people who re-affirmed consent at follow-up (as discussed in see *Chapter 14: Follow-up assessments T2 and T3*).

16.2.3. Generating researcher IDs

Each researcher will be assigned an ID number, which they **will need** in order to generate the Participant IDs (see 15.1.1. Participant IDs). Researcher IDS will be automatically generated in the MACRO database once information about the researcher (e.g. name) has been entered into MACRO.

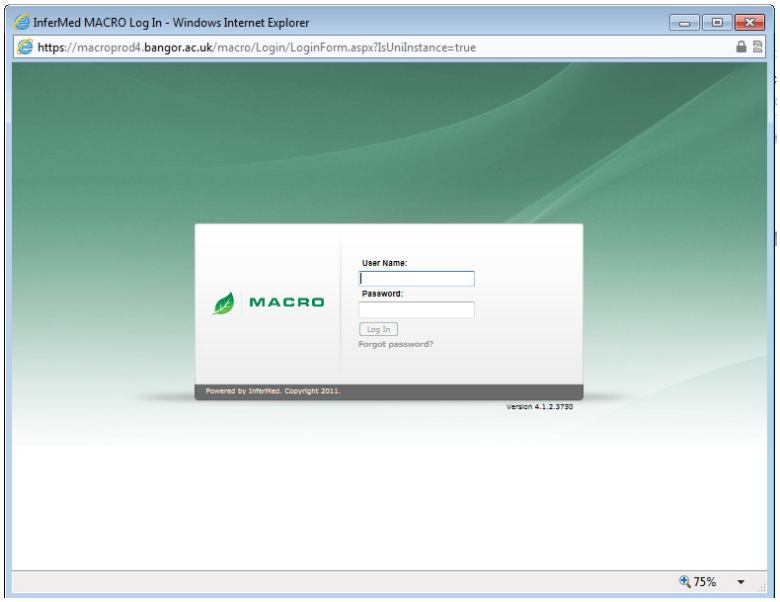
16.2.4. How to use MACRO: a brief guide

This section provides brief information about the MACRO database; more detailed information is provided in the *MACRO users training guide* which will be sent to the nominated MACRO user from each site.

The nominated MACRO user will be emailed a username, password and the MACRO website address (https://macroprod4.bangor.ac.uk/macro). Please keep a record of this username as it will be required for the length of the study.

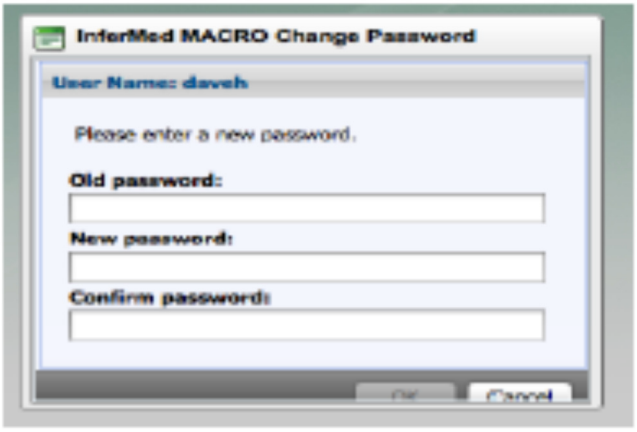
The MACRO system will be accessible via the internet. Once you have accessed the MACRO site you will need to log in using your username and password:

Screen shot 1: The MACRO Interface



The first time you log in to the MACRO system it will automatically ask you to change your password:

Screen shot 2: Changing your password

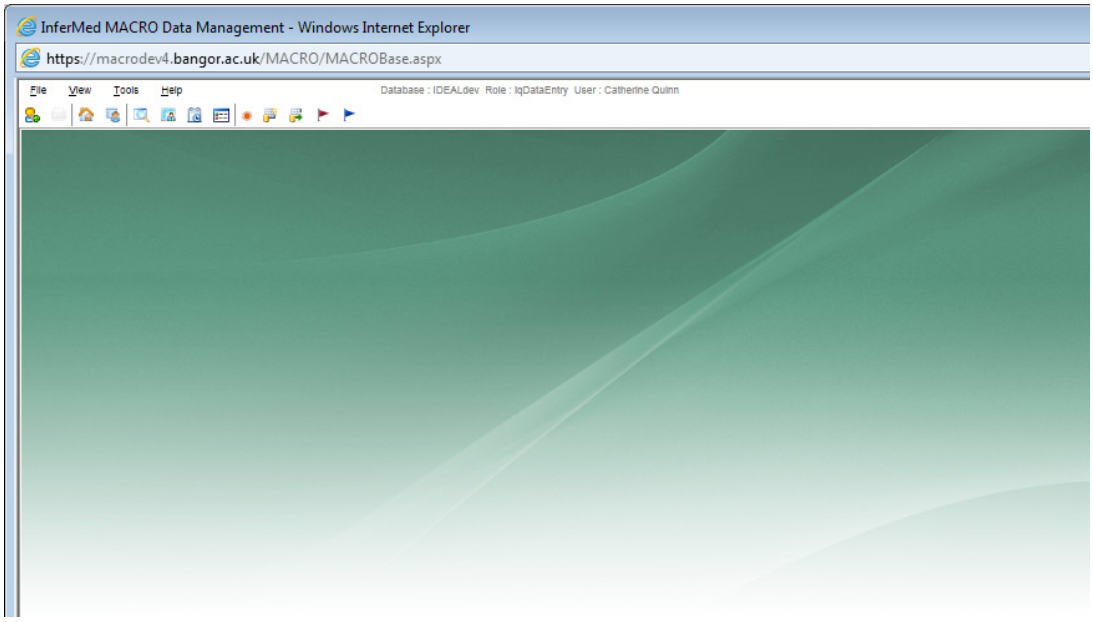


New password convention

When selecting your new password it must be longer than 6 characters, and must contain both numbers and upper and lower case characters. It must also not be based on any of your previous passwords as the system will not allow this. Do not share your password with anyone.

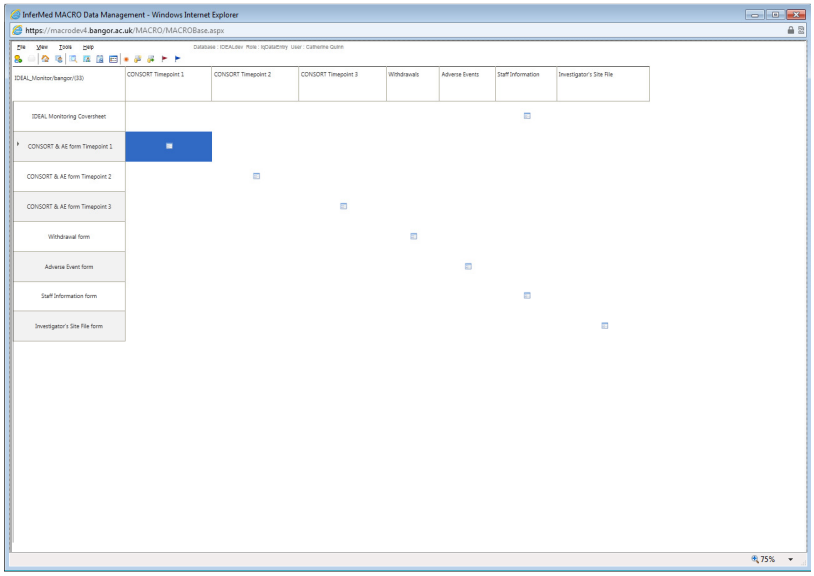
Entering information in MACRO

Once you have logged in you will see this screen:



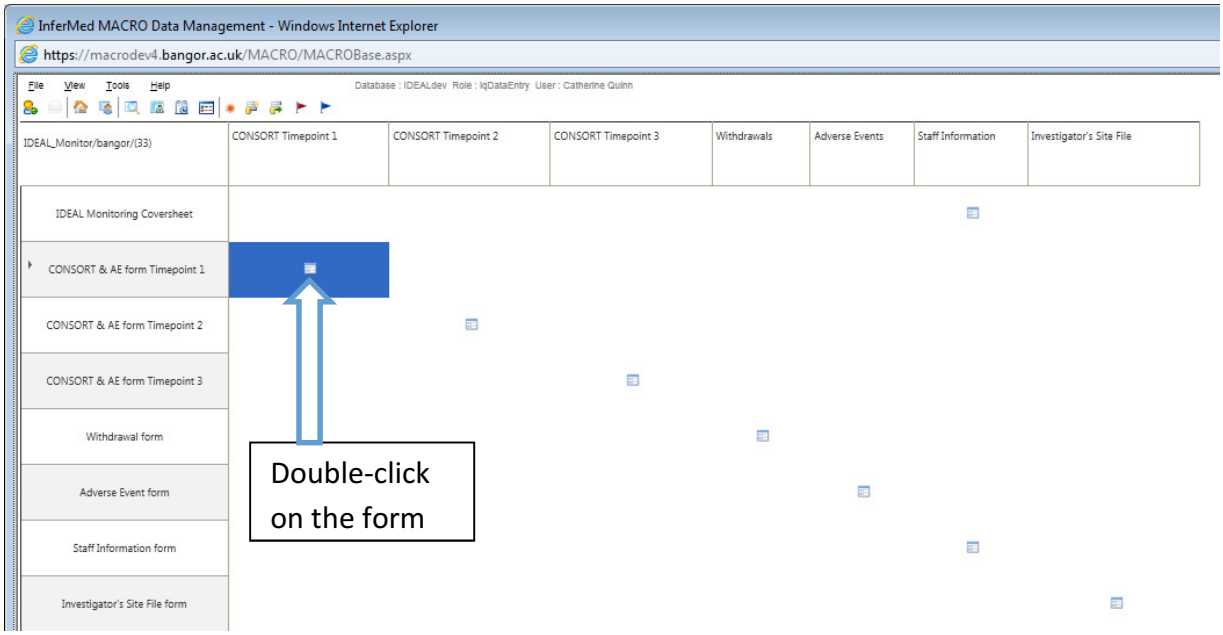
You will need to click on this icon  to create a new record.

Once you have created a new record the screen will look similar to this

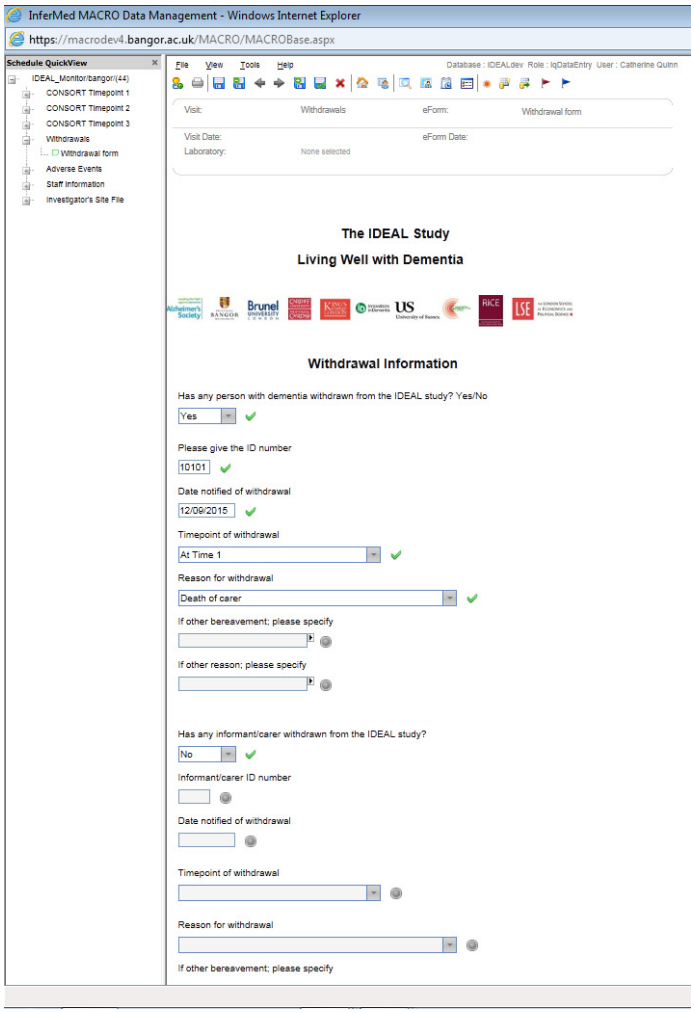


Note: the MACRO site was still under development during the writing of this handbook and so the content of the final version of the site may be different to the images presented here.

To navigate the database you should double-click on the form you wish to open



Once you have opened a form it will look like this. You can then just enter in the data.



Guidance

If the information has been entered in correctly you will see a:

If there are issues with the information you have entered e.g. date not in correct format (dd/mm/yyyy) will receive a warning:

If information is missing from the form you will see a:

Key points

- Once you have saved a form MACRO will generate a new one.
- If you return to a form after you have saved it in order make changes to it you will be asked to record the reason for the changes. This is so we know why information has been changed.
- When working with MACRO please be aware that after a period of inactivity, if you are not actively entering data, the site will log you out and you will need to log back in.

[All appendices have been removed from this archived document]

Appendices

Appendix 1. Invitation letter and reply slip

Appendix 2. Demonstration of capacity checklist

Appendix 3. Consent form for the person with dementia

Appendix 4. Consent form for the carer

Appendix 5. Letter to GP or hospital consultant

Appendix 6: Receipt for participant payment vouchers

Appendix 7: Participant payment record

Appendix 8. Receipt of payment

Appendix 9. POVA protocol

Improving the experience of dementia and enhancing active life: living well with dementia - the IDEAL study

Short Title: Enhancing active life and living well: the IDEAL study

Factsheet for Clinic Staff

What is the purpose of the IDEAL study?

Living well with dementia, whether as a person with dementia or primary carer, means experiencing optimal well-being, life satisfaction, and the best possible quality of life (QoL). Enabling people with dementia and carers to live well with dementia is a key UK policy objective, but we need to know more about what can help people to live well with this type of long-term, progressive disability. In this project we will find out how social and psychological assets and resources, and the extent to which people are able to engage in activities and participate in the community, affect the way in which people adapt to the effects of the condition and the challenges it presents, and how this changes over time as dementia progresses.

What is the design of the study?

The IDEAL study is a major, five-year longitudinal cohort study of 1500 people with dementia and their family carers throughout the UK using mixed methods. Participants will be recruited over a 24-month period and assessed at baseline and on two further occasions 12 months apart. Participants will be recruited from Memory Services and other specialist clinics, and from databases listing people with dementia who are interested in research participation, through UK research networks (DeNDRoN in England, NISCHR CRC in Wales and the Scottish Dementia Network), also drawing on contacts with community mental health teams, GP practices, social services and voluntary sector groups as appropriate.

Who can take part?

Recruitment will target people who have mild to moderate dementia on entry to the study.

Inclusion criteria for the person with dementia will be:

- A clinical diagnosis of dementia (any sub-type).
- MMSE score of 15 or above (or an appropriate equivalent).

There will be no restrictions on age. We will focus on people who, on entry to the study, are living in their own homes**.** Participation in the IDEAL study will not preclude involvement in other studies or intervention trials.

Exclusion criteria will be

- Co-morbid terminal illness in the person with dementia at baseline.
- Inability to provide informed consent at baseline.
- Any known potential for home visits to pose a significant risk to research network staff.

What does the study involve?

Research network staff will recruit and assess participants. Assessments and interviews will be conducted in participants' own homes with two home visits at each time point. Visits are expected to last no more than 2 hours each.

How can you help?

We are recruiting participants starting in July 2014. We are inviting memory clinics and related services to collaborate in IDEAL by speaking with patients about the study. Please contact the local network research staff if you have details of any patients who might be suitable to take part. Ethical approval and R & D permission will be in place for local network research staff to assist you with identifying potential participants.

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY

A BRIEF INTRODUCTION

What is the study about?

As we get older we experience various changes in memory and other abilities which can affect our well-being and quality of life. It is very important for people to be able to maintain well-being and to live well as things change in later life. The IDEAL project will investigate what helps people to live well and what makes it difficult to live well in this situation.

What does the research hope to achieve?

IDEAL is the first large-scale research project of its kind, and what we find out will be used to influence policy and practice to try to ensure better well-being for older people experiencing these changes in the future. The results will be used to encourage greater awareness of the needs of older people, and will help to improve health and social care and to create more supportive communities.

How is the study funded?

The study is funded by a joint initiative with the Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR). It is supported by a number of NHS clinical research networks, and NHS staff from these networks will be involved in conducting the research.

Who is carrying out the study?

We are a national group of researchers working in partnership with the Department of Health. The project is led by researchers at the University of Exeter, and this will be the co-ordinating centre for the study.

Where is it taking place, and who will take part?

The IDEAL study is a UK-wide study which started in January 2014. Over the first two years we will recruit up to 1500 people who have experienced changes in their memory, other thinking abilities, or how they manage in day-to-day activities. We will also speak

to a key family member or close friend wherever possible. By taking part and giving your perspective, you will help us to gain a more comprehensive view of what it is like to experience these changes, what helps people to live with these changes, and what needs to be done to improve things.

What does taking part involve?

Local NHS staff will visit people who agree to take part at home. During these visits people will be asked to provide some background information and to complete some questionnaires. We will visit everyone on two more occasions, one year apart, to find out how things develop or change over time. Some people who take part will also be interviewed about their experiences to help enrich the other information we collect.

By taking part you can make a big difference, and we thank you for considering taking part in this research.

[To be printed on Participant Identification Centre headed notepaper]

[Name and address of Memory Clinic or other specialist clinic]
[date]

Dear

Enhancing active life and living well

I am writing to tell you about a new project which I thought you might be interested in. This project, called Enhancing active life and living well: the IDEAL study, is being run by our colleagues at [NAME OF SITE] for people who have attended a Memory Clinic or another specialist NHS clinic and those close to them.

The project will explore what 'living well' means from the point of view of people who have experienced changes in memory, other thinking abilities, or the ability to manage day-to-day activities, and those close to them. Finding out the views of people like you will help us to identify what helps people to live well or what makes it difficult to live well in this situation. I have enclosed a brief outline of the project that gives more details.

If you feel that you may be interested in contributing and giving your point of view, or would like to find out more, please fill in the attached reply slip and return it in the freepost envelope provided. This reply slip will go directly to the local NHS research staff. They will then contact you to tell you more about the project and to arrange to meet you if you are willing.

We only pass on details of projects that have been properly approved through all the NHS procedures. Whether or not you decide to take part will not affect your future NHS care in any way.

Thank you for considering this invitation. If you are interested in taking part or finding out more, we will be delighted to hear from you.

Yours sincerely

[Name and position of clinician]
[Name and address of Memory Clinic]

[To be printed on Participant Identification Centre headed notepaper]

ENHANCING ACTIVE LIFE AND LIVING WELL

REPLY SLIP

If you are interested in contributing to the IDEAL project, please fill in this reply slip and post it in the envelope provided.

If you prefer, you can telephone the local NHS research staff and leave a message. Please make sure you say your name and telephone number clearly so that we can call you back. The telephone number to call is [TELEPHONE NUMBER]

You can also send an email to the local NHS research staff at [EMAIL ADDRESS].

To: [NAME AND ADDRESS OF PROJECT TEAM MEMBER]

I am interested in taking part Enhancing active life and living well. I would like someone from the local NHS research staff to contact me to tell me more about the project.

My name:

My telephone number:

My email address:

My postal address:

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY
BRIEF SUMMARY

What is the purpose of the study?

We would like to invite you to take part in a research project that aims to find out what it means to 'live well' whilst experiencing changes in memory or other changes. We would like to speak to people who have attended NHS clinics and who are living with these kinds of changes, and to those close to them. This will help us to identify what helps people to live well or what makes it difficult to live well in this situation. The information we gain will be used to show how policy and practice could change in order to help more people to live well in this situation.

What is involved?

If you take part in the study, a researcher will come to see you at your home. The researcher will ask you to complete some questionnaires and some measures of mental fitness. This would happen once a year for three years. You may also be invited to have an additional interview where the researcher would ask about how things are for you and how you are managing.

Deciding to take part

For more detailed information on what it means to take part we would like you to read the information sheet called ‘Enhancing active life and living well: the IDEAL study: Information for participants.’

For general information about taking part in research, please see our booklet ‘Taking part in research: a guide to understanding what is involved’, which is available from the research team.

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY INFORMATION FOR PARTICIPANTS

We would like to invite you to take part in a research study investigating what 'living well' means from the view of people who have experienced changes in changes in memory, other thinking abilities, or the ability to manage day-to-day activities, and those close to them. Your contribution will help us to identify what helps people to live well or what makes it difficult to live well in this situation.

This information sheet explains what taking part would involve. Please read it carefully, discuss it with others if you wish, and ask us if there is anything that is not clear or if you would like more details. You can take as long as you like to decide whether or not you want to take part. Thank you for reading this information sheet.

Why have I been invited?

We are inviting you to take part because you have attended a Memory Clinic or another specialist NHS clinic.

Can I choose whether or not to take part?

It is up to you to decide whether or not you want to take part. If you do, we will give you this information sheet to keep and we will ask you to sign a consent form. If you change your mind after agreeing to take part, you can withdraw at any time and you do not have to say why. If you decide not to take part, or to withdraw, this will not make any difference to your health care and it will not affect your rights in any way.

What will happen if I decide to take part?

Everyone who takes part in the study will be visited at home by a researcher. If you agree to take part, the first visit will happen soon afterwards to check you are ready to take part and to answer some initial questions. Following this we will arrange two other visits to your home at

a time which suits you. At these visits, the researcher will ask you to complete some questionnaires and some measures of mental fitness. Each of these visits should last no more than 2 hours. With your consent, the researcher will also ask a family member/friend to complete some questionnaires at the same time. We would like to return to see you again one year and two years after our first visits.

Some of the people taking part in the study will also be asked to take part in an interview with another researcher who will ask more open questions about their experiences. This would be audio-recorded and then printed out. If you agree to be interviewed we will remove any information that could identify you from the print-out.

What are the possible disadvantages and risks of taking part?

We do not think that taking part will involve any disadvantages or any specific risks to you or that it could cause you any harm. In the very unlikely event that you were harmed by taking part in the study, there are no special compensation arrangements. If you were harmed due to someone's negligence, then you might have grounds for a legal action, but you might have to pay your own legal costs.

What are the possible benefits of taking part?

You may find it interesting and enjoyable to talk with the researcher and complete the questionnaires. The information we get from this study will help us understand more about ways of living well with memory and other changes. This information will be helpful to health care staff, policy-makers, and other people who may experience similar changes in the future.

Will I be paid for taking part in the study?

We are very grateful for your contribution. You and your relative/friend will be offered a small shopping voucher as a token of our appreciation for taking part.

What if something goes wrong?

If you are unhappy or dissatisfied with any aspect of your participation, we would ask you first talk to the researcher, so that they can try to address your concerns and find a solution. You can also talk to [LOCAL PI NAME AND CONTACT DETAILS] or you can contact the Chief Investigator, Professor Linda Clare, at the College of Life and Environmental Sciences – Psychology, Washington Singer Laboratories, Perry Road, University of Exeter, Exeter EX4 4QG. Tel. 01392 724659. E-mail l.clare@exeter.ac.uk. If you are not satisfied with the response, you can make a complaint to Gail Seymour, Research and Knowledge Transfer, Streatham Campus, Innovation Centre, Rennes Drive, University of Exeter, Exeter, EX4 4 RN. Tel. 01392 726621. E-mail G.M.Seymour@exeter.ac.uk. You can also raise any concerns through the NHS complaints process [NHS LOCAL].

How is the study organised?

The project is led by the University of Exeter, and this will be the co-ordinating centre for the study. As the co-ordinating centre it will oversee the overall running of the project, manage the anonymised data, and conduct the analysis. The co-ordinating centre will also keep participants informed about study progress.

Local research network staff employed by the NHS will be involved in identifying people to take part in the study through contact with specialist clinics. These local NHS staff members will make the initial contact with you, and they will also conduct all the home visits.

Will my taking part in the study be kept confidential?

Your participation will be confidential, but we would like your permission to send your GP and (where relevant) your Hospital Consultant a short letter telling them that you have agreed to take part in the research.

All information that we collect about you during the course of the study will in normal circumstances be kept strictly confidential. Only NHS staff will have access to your personal

information (name, address, telephone number and email address) initially. If you agree to take part, we will ask you to give permission for NHS staff to pass your personal contact details to the co-ordinating centre at the University of Exeter.

The research team at the University of Exeter will keep this information confidential, and may use the information to contact you in the future about the study. We may provide updates about the project, or tell you about other areas of the project; for example, we may invite you to take part in an additional interview.

Any records that we make during the course of the study will be stored securely and will be kept separate from any of your personal details. No-one outside the research team will be able to identify you personally from these records, and no-one will ever be able to identify you personally from anything that we write or say in public about the research.

The only situation in which we might need to share information about you with other professionals would be if the researchers observe or hear anything that causes very serious concern about your health, safety or well-being. If this happens the researchers have a duty to inform an appropriate professional, such as your GP or social worker. We would make every effort to explain to you why we need to share this information before doing so.

If you agree to take part in an additional interview, we may want to quote some of the things you said during the interview in our publications and reports. We will ask your permission to do this. We will make sure that no-one will be able to identify you from any quotations that we use.

We will ask if you are willing for the research team to keep your contact details (name, address, telephone number and email address) on record after the end of the study. This is because it is possible that in the future we may be able to obtain funding to keep in touch and find out how you get on in the longer term. You do not have to agree to this. If you do agree, your contact details will be kept securely and only the original research team will be able to access them.

We will also ask if you are willing to allow the longer-term storage of information we collect. At the end of the study we would like to add the information we collect, including any interviews, into data archives such as the UK Data Archive and ESDS Qualidata. This is so that the information can be used by researchers in the future to understand more about the lives of people who have been to these clinics and their families. The information stored would be anonymous and no-one would ever be able to identify you personally from this information.

What will happen if I change my mind about taking part?

You can withdraw from the study at any time without giving a reason. If you withdraw from the study it will not affect your health care in any way. We will continue to use the information that we collected before you decided to withdraw, unless you tell us that you do not want us to do so.

As part of the initial visit we will ask you to identify someone to act as a personal consultee. This person should be someone who knows you well and understands your wishes and preferences, such as a next of kin, other relative or close friend. If during the time that you are participating in the study you become unable to decide whether or not you want to continue taking part, for example because of ill-health, we will approach your chosen personal consultee, who will then advise us about whether you should continue to take part. Based on the advice of your personal consultee, you may be withdrawn from further participation in the study; however, if your personal consultee is in favour of you continuing in the study, you will continue in the study for as long as you do not object.

What will happen to the results of the research study?

When the study is complete, we will present the results at scientific conferences and publish them in scientific journals, and we will prepare information for health and care professionals and for policy-makers. If you would like to know about the results, we will be very happy to give you information about the findings. We expect results to start becoming available towards the end of 2016, but we will keep you updated on the project with regular newsletters.

Who is organising and funding the research?

This research project is led by Professor Linda Clare at the University of Exeter and is taking place in England, Wales and Scotland. In [centre], the local lead is [Name of local PI]. The research is funded by the Economic and Social Research Council. This funding covers the running costs of the research project. The researchers do not receive any personal financial benefits as a result of the study.

Who has reviewed the study?

All research with NHS patients is reviewed by an independent group of people, called a Research Ethics Committee, to protect patients' safety, rights, well-being and dignity. This study has been reviewed by the North Wales - West Research Ethics Committee.

Who can I contact for further information?

For more information, please contact:
[local PI details to be added]

(local NHS and local information service organisations to be added)

Thank you for reading this information sheet and for considering taking part in this research study.

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY
BRIEF SUMMARY

What is the purpose of the study?

We would like to invite you to take part in a research study investigating what 'living well' means from the view of both people who have experienced changes in their memory or other changes and of those who are close to them. This will help us to identify what helps people to live well or what makes it difficult to live well in this situation. The information we gain will be used to show how policy and practice could change in order to help more people to live well in this situation.

Who can take part?

We are inviting you to take part because you support a person who has attended a Memory Clinic or other specialist clinic who is being invited to take part.

What is involved?

The researcher will ask you to complete some questionnaires over a number of visits. The questions will be about the person who has been to the clinic and about you. You may also be interviewed about how things are for you and how you are feeling.

Deciding to take part

For more detailed information on what it means to take part we would like you to read the attached sheet called: Enhancing active life and living well: the IDEAL study: Information for family members/friends.

For general information about taking part in research, please see our booklet ‘Taking part in research: a guide to understanding what is involved’, which is available from the research team.

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY INFORMATION FOR FAMILY MEMBERS/FRIENDS

Your family member or friend, who recently attended a Memory Clinic or other specialist clinic, has given us permission to invite you to take part in a research study investigating ways of helping people to live well with changes in memory, other thinking abilities, or the ability to manage day-to-day activities.

We would like to invite you to take part in a research study investigating what 'living well' means from the view of people who have experienced any of these changes, and of those close to them. Your participation will help us to identify what helps people to live well or what makes it difficult to live well in this situation.

This information sheet explains what taking part would involve. Please read it carefully, discuss it with others if you wish, and ask us if there is anything that is not clear or if you would like more details. You can take as long as you like to decide whether or not you want to take part. Thank you for reading this information sheet.

Why have I been invited?

We are inviting you to take part because you support a person who has attended a Memory Clinic or other specialist NHS clinic, who is being invited to take part.

Can I choose whether or not to take part?

It is up to you to decide whether or not you want to take part. If you do, we will give you this information sheet to keep and we will ask you to sign a consent form. If you change your mind after agreeing to take part, you can withdraw at any time and you do not have to say why. If you decide not to take part, or to withdraw, this will not make any difference to your health care and it will not affect your rights in any way.

What will happen if I decide to take part?

Everyone who takes part in the study will be visited at home by a researcher. If you agree to take part, the first visit will happen soon afterwards to check you are ready to take part and to answer some initial questions. Following this we will arrange two visits during which the researcher will ask the person who has been to the clinic to complete some questionnaires and carry out some measures of mental fitness. These will be at a level suitable for the current abilities of the person you support. Each of these visits should last no more than 2 hours. The researcher will also ask you to complete some questionnaires at the same time. The questions will be about the person who has been to the clinic and about you. If it is not convenient to visit you and the person whom you support at the same time it may be possible for you to complete the questionnaires on your own. We would also like to return to see you again one year and two years after our first visits.

Some of the people taking part in the study and their family members/friends will also be asked to take part in an interview with another researcher who will ask more open questions about their experiences. This would be audio-recorded and then printed out. If you agree to be interviewed we will remove any information that could identify you from the print-out.

What are the possible disadvantages and risks of taking part?

We do not think that taking part will involve any disadvantages or any specific risks to you or that it could cause you any harm. In the very unlikely event that you were harmed by taking part in the study, there are no special compensation arrangements. If you were harmed due to someone's negligence, then you might have grounds for a legal action, but you might have to pay your own legal costs.

What are the possible benefits of taking part?

You may find it interesting and enjoyable to talk with the researcher and complete the questionnaires included in the study. The information we get from this study will help us understand more about ways of living well with memory and other changes. This information

will be helpful to health care staff, policy-makers, and other people who may experience similar changes in the future.

Will I be paid for taking part in the study?

We are very grateful for your contribution. You and your relative/friend will be offered a small shopping voucher as a token of our appreciation for taking part.

What if something goes wrong?

If you are unhappy or dissatisfied with any aspect of your participation, we would ask you first talk to the researcher, so that they can try to address your concerns and find a solution. You can also talk to [LOCAL PI NAME AND CONTACT DETAILS] or you can contact the Chief Investigator, Professor Linda Clare (College of Life and Environmental Sciences – Psychology, Washington Singer Laboratories, Perry Road, University of Exeter, Exeter EX4 4QG. Tel. 01392 724659. E-mail l.clare@exeter.ac.uk). If you are not satisfied with their response you can make a complaint to Gail Seymour, Research and Knowledge Transfer, Streatham Campus, Innovation Centre, Rennes Drive, University of Exeter, Exeter, EX4 4 RN. Tel. 01392 726621. E-mail G.M.Seymour@exeter.ac.uk. You can also raise any concerns through the NHS complaints process [NHS LOCAL].

How is the study organised?

The project is led by the University of Exeter, and this will be the co-ordinating centre for the study. The co-ordinating centre will oversee the overall running of the project, manage the anonymised data, and conduct the analysis. The co-ordinating centre will also keep participants informed about study progress.

Local research network staff employed by the NHS will be involved in identifying people to take part in the study through contact with the specialist clinics. These local NHS staff members will make the initial contact with you, and they will also conduct all the home visits.

Will my taking part in the study be kept confidential?

Your participation will be confidential. All information that we collect about you during the course of the study will in normal circumstances be kept strictly confidential. Only NHS staff will have access to your personal information (name, address, telephone number and email address) initially. If you agree to take part, we will ask you to give permission for NHS staff to pass your personal information to the co-ordinating centre at the University of Exeter.

The University of Exeter will keep this information confidential, and may use the information to contact you in the future about the study. We may provide updates about the project, or tell you about other areas of the project, for example, we may invite you to take part in an interview.

Any records that we make during the course of the study will be stored securely and will be kept separate from any of your personal details. No-one outside the research team will be able to identify you personally from these records, and no-one will ever be able to identify you personally from anything that we write or say in public about the research.

The only situation in which we might need to share information about you with other professionals would be if the researchers observe or hear anything that causes very serious concern about your health, safety or well-being. If this happens the researchers have a duty to inform an appropriate professional, such as your GP or social worker. We would make every effort to explain to you why we need to share this information before doing so.

If you agree to take part in the additional interview, we may want to quote some of the things you said during the interview in our publications and reports. We will ask your permission to do this. We will make sure that no-one will be able to identify you from any quotations that we use.

We will ask you if you are willing for us to keep your contact details (name, address, telephone number and email address) on record after the end of the study. This is because it is possible that in the future we may be able to obtain funding to keep in touch and find out how you get on in the longer term. You do not have to agree to this. If you do agree, your contact details will be kept securely and only the original research team will be able to access them.

We will ask you if you are willing to allow the longer-term storage of the information we collect. At the end of the study we would like to add the information we collect, including any interviews, into data archives such as the UK Data Archive and ESDS Qualidata. This is so that the information can be used by researchers in the future to understand more about the lives of people with changes in memory, other thinking abilities, or the ability to manage day-to-day activities, and their families. The information stored would be anonymous and no-one would ever be able to identify you personally from this information.

What will happen if I change my mind about taking part?

You can withdraw from the study at any time without giving a reason. If you withdraw from the study it will not affect your health care, or that of the person you support, in any way. We will continue to use the information collected before you decided to withdraw, unless you tell us that you do not want us to do so.

If during the time that you are participating in the study you become unable to decide whether or not you want to continue taking part, for example because of ill-health, we will withdraw you from the study. We will continue to use the information that we have collected up to that point.

What will happen to the results of the research study?

When the study is complete, we will present the results at scientific conferences and publish them in scientific journals, and we will prepare information for health professionals. If you would like to know the results, we will be very happy to give you information about the findings. We expect results to start becoming available towards the end of 2016, but we will keep you updated on the project with regular newsletters and information will be provided on a study website.

Who is organising and funding the research?

This research project is led by Professor Linda Clare at the University of Exeter and is taking place in England, Wales, and Scotland. In [centre], the local lead is [Name of local PI]. The research is funded by the Economic and Social Research Council. This funding covers the running costs of the research project. The researchers do not receive any personal financial benefits as a result of the study.

Who has reviewed the study?

All research with NHS patients is reviewed by an independent group of people, called a Research Ethics Committee, to protect patients' safety, rights, well-being and dignity. This study has been reviewed by the North Wales - West Research Ethics Committee.

Who can I contact for further information?

For more information, please contact:

[local PI details to be added]

(local NHS and local information service organisations to be added)

Thank you for reading this information sheet and for considering taking part in this research study.

Participant ID:

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY

DEMONSTRATION OF CAPACITY

CHECKIST FOR RESEARCHER TAKING CONSENT FROM PARTICIPANTS WITH MILD TO MODERATE DEMENTIA

The Mental Capacity Act 2005 proposes that people should be assumed to have capacity unless otherwise indicated. People with early-stage, mild to moderate dementia are normally expected to have capacity to give informed consent to research participation. Capacity in this sense is demonstrated by the ability to understand the information given about the research, retain it for long enough to weigh up that information in order to reach a decision, and to state a decision clearly. The following checklist should be used when seeking informed consent from such individuals to ensure that these aspects are evaluated and that the criteria for capacity are met. If there is any doubt about capacity then consent must not be taken.

Ability	**Examples of how ability may be demonstrated**	**Ability demonstrated?**	**Comments and notes**
Understanding the information given about the research	Describing what the study involves. Asking appropriate questions. Seeking clarification.	yes/no	
Retaining the information given about the research	Referring back to information given earlier in the meeting. Referring to the information sheet.	yes/no	
Weighing up the information to reach a decision	Identifying advantages of participating or concerns about participating. Asking relevant questions. Discussing the information with a third party e.g. a family member.	yes/no	
Communicating a clear decision	Giving a clear and unambiguous indication of willingness to take part	yes/no	

[To be printed on Participant Identification Centre headed notepaper]

IDEAL Pre-screening & Referral Information

To be completed by a person recruiting from the memory assessment services

Participant Identification Centre: _____(e.g. NHS Trust, Memory Clinic)

	Eligibility check	Tick as appropriate		Comments
1	**Does the person have a clinical diagnosis of dementia (any sub-type).** Specify diagnosis ☐ Alzheimer's disease ☐ Vascular dementia ☐ Mixed dementia ☐ Frontotemporal dementia (FTD) ☐ Parkinson's disease dementia (PDD) ☐ Dementia with Lewy bodies (DLB) ☐ Unspecified dementia ☐ Other: _____ **Date of diagnosis** (dd/mm/yyyy):_____	☐ Yes	☐ No	
2	**Does the person have an MMSE score of 15 or above (or equivalent)?** **(If no score available, clinician to use clinical judgment to identify early-stage dementia.)** MMSE score: _____ Other measure: _____ Score: _____ **For participants with Parkinson's disease dementia (PDD) please record the Hoehn and Yarh Scale score:** **Hoehn and Yarh score:** _____ **Date** (dd/mm/yyyy):_____ **Hoehn and Yarh score not available:** _____	☐ Yes	☐ No	
3	**Does the person have a co-morbid terminal illness at baseline?**	☐ No	☐ Yes	
4	**Does the person speak English?**	☐ Yes	☐ No	
5	**Does the person currently reside in his/her own home** (i.e. not in a residential or nursing home) **at baseline?**	☐ Yes	☐ No	
6	**Is there any known potential for home visits to pose a significant risk to research network staff?**	☐ No	☐ Yes	

	Note: The person is ineligible for IDEAL if any of the options in the shaded column are ticked.			
7	**Does the person have a carer/next of kin who might be willing to participate in the study?**	☐ Yes	☐ No	☐TBC (please specify):

Method of pre-screening: ☐ Face-to-face / ☐ Note-screened

Current involvement in research: ☐ No / ☐ Yes (please specify study; start and end date)

_____

Details of person completing this form:

Name: _____ Date: _____ Signature: _____

Signature from a member of the patient's clinical team authorising research invitation and to confirm that there are no known risks that would make visits by the researcher to the patient's home inappropriate:

Name: _____ Date: _____ Signature: _____

If you think this person is unsuitable to join the study at present, please specify a reason as we can then give this person the opportunity to take part in the study in the future if the person's situation changes:

_____

_____

Any other comments:

Contact Information *(Please Print Clearly)*

Participant information:		**Carer Information:** *(if available)*	
Name:		Name	
Address		Address	
Tel. (home)		Tel. (home)	
Tel. (mobile)		Tel. (mobile)	
Email:		Email:	
		Relationship to the participant *(e.g. spouse, sister etc.)*	

Initial contact to be made to: ☐ Participant / ☐ Carer/Next of kin

Living well and enhancing active life: the IDEAL study

Contact details form: T1: On Entry to the study

Please complete the following information for people who have entered the study at T1:

Researcher Identification number: _____ **Date:** _____

Participant Identification number: _____

Please Print Clearly

Participant information:		**Carer Information:** *(if available)*	
Name:		Name	
Date of Birth (DD/MM/YY)		Date of Birth (DD/MM/YY)	
Address		Address	
Postcode		Postcode	
Tel. (home)		Tel. (home)	
Tel. (mobile)		Tel. (mobile)	
Email:		Email:	
		Relationship to the participant *(e.g. spouse, sister etc.)*	

Name of GP or clinic: _____

Address : _____

Postcode _____

Tel. _____

Is the carer also the personal consultee? (please tick)

Yes

No **<u>If no, then please provide the name and contact details for the personal consultee:</u>**

Name of Personal Consultee: *(Must be taken at the initial time point)* _____

Address: _____

Postcode _____

Tel. (home) _____

Tel. (mobile) _____

Email: _____

Relationship to participant *(e.g. spouse, sister etc.)*

Any other comments: (e.g. plans to move in the next year, second home, alternative relative contact details etc.)

_____

_____

_____

One copy to be kept at the research site, one copy returned to the coordinating centre at the University of Exeter

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY

Adverse Event Reporting Form

1. Reporting

Adverse Event reported to:	**By:**	**On:** (dd/mm/yyyy)
Principal Investigator		
Other personnel (Please Specify)		
Adverse Event recorded in Macro		

2. Adverse Event

Participant ID
Date incident occurred (dd/mm/yyyy)
Date researcher informed of/made aware of Adverse Event
Summary of Adverse Event

3. Any other relevant information

Please provide any additional information relevant to the Adverse Event

Report completed by:	**Date**

A copy of this form should be placed in the Investigators site file