UK Data Service Study Number 854293

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

Wave 2 Supporting documents

12/03/2020

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

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Funded jointly by the Economic and Social Research Council (UK) and the National Institute for Health Research (UK), ES/L001853/2

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

Version 1. 14/06/2015

The IDEAL study: Key contacts

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For project updates and other information please visit:
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). Professor Fiona Matthews will join the team of co-investigators in 2015, and will provide statistical oversight of the study. 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, now based at the University of Exeter. The REACH group based in Exeter and the North Wales Organisation for Randomised Trials in Health (NWORTH) Clinical Trials Unit based at Bangor University are the co-ordinating centres for this study.

Project partners are the Alzheimer's Society, Bangor University, Brunel University, Cardiff University, Innovations in Dementia CIC, Kings College London, London School of Economics, NWORTH, Sussex University, and RICE. We work closely with the UK research networks – NIHR Clinical Research Network (CRN): Dementia and Neurodegenerative Diseases in England, NISCHR CRC in Wales, and the Scottish Dementia Clinical Research Network (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 did not require an ethics review under the provisions of the Adults with Incapacity (Scotland) Act 2000.

Portfolio Registration

The IDEAL study is registered with United Kingdom Clinical Research Network (UKCRN), registration number 16593.
http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=16593

The IDEAL Time 2 Handbook for Researchers

In this handbook we have included the key information that you, as a researcher working on the IDEAL study, will need. There are five parts to this handbook: Time 2 follow-ups, Document management, monitoring and reporting, Time 2 Case Report Forms, Data linkage, and Additional guidance.

- The first part of this handbook, Time 2 follow-ups, is a practical guide to what exactly is involved in your work and outlines the process for the assessment of participants at Time 2 (T2).
- The second part of this handbook describes the systems used for monitoring and reporting, and managing study data and documents.
- The third part focuses on the Case Report Forms (CRFs) and contains details of the CRFs that will be used in the IDEAL study at T2. It provides instructions about how to administer and complete the CRFs.
- The fourth part of the handbook contains information about data linkage, a new addition to the study at 12 month follow-up, and what it will involve for participants. This includes a section on questions you may get asked about data linkage.
- The last part of the handbook provides additional guidance on what to do in situations where there has been a change in a participant's circumstances, for instance where the carer has changed or person with dementia has moved or gone into a care home. There is also guidance on what to do if a participant withdraws at T2.

Study Guidelines:

- The study should be conducted in compliance with the most recent version of the IDEAL study protocol that has received REC approval.
- Each individual involved in conducting the study should be qualified by education, training, and experience to perform his or her respective task(s).
- Informed consent should be obtained from every person prior to study participation.
- The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
- Researchers should be aware of their local policies on the management of scientific fraud and misconduct.

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List of acronyms

ACE-III	The Addenbrooke's Cognitive Examination-III
ADRN	Administrative Data Research Network
CRN	Clinical Research Network
CRF	Case Report Form(s)
CSRI	Client Services Receipt Inventory
ESRC	Economic and Social Research Council
FAST	Functional Assessment Staging
GCP	Good Clinical Practice
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
NRS	National Records of Scotland
NWORTH	North Wales Organisation for Randomised Trials in Health – the Bangor clinical trials unit
ONS	Office for National Statistics
PI	Principal Investigator
SDCRN	Scottish Dementia Clinical Research Network
T1	Time 1 (baseline)
T2	Time 2: 12 month follow-up
T3	Time 3: 24 month follow-up
TSI	Test for Severe Impairment

Part I. Time 2 Follow-ups

1. A brief guide to changes at Time 2

In Time 2 (T2) of the study you will be conducting follow-up assessments with participants approximately one year after they were seen for the initial assessment. At T2 there are a number of changes to the study and new elements have been added. It is also possible that participants' circumstances will have changed since Time 1 (T1) and this has been addressed in both the design of the CRFs and in the systems we use to record this information. The T2 changes are briefly outlined below and will be fully explained in the Handbook.

- There has been a reduction in the number of visits required. In T2 all assessments must be completed within two visits except in exceptional circumstances.
- The content of the CRFs has altered. Most standardised measures remain the same as T1, but we have removed questions that only needed to be administered at T1. Consequently the CRFs are now shorter; there are now only **2 CRFs each** for the person with dementia and carer.
- It is recognised that people with dementia may experience some decline between the time-points and may become more impaired. In this case, in some of the measures we have identified core questions that need be administered if the person with dementia cannot complete the full set of items. In addition, cognitive assessments will be administered which are appropriate to the severity of dementia.
- We will be asking people with dementia to consent to data linkage. Network staff will be involved in gaining this consent but will not be involved in the actual data linkage process. This gives the research team permission to get further information about the participants from records that the NHS and public organisations, such as the Office for National Statistics, hold about them. This gives us information about their present, past and future health circumstances.
- There may have been changes in the circumstances of the carer and/or person with dementia. The person with dementia may have gone into a care home and, where possible, for those people their assessments will need to be conducted in the home. In addition, for those people with dementia in a care home who do not have a carer taking part in the study we would ask you to collect additional information about them from a paid carer working in the care home. Consequently, we have developed a short CRF for paid carers.
- You may be unable to locate some participants and this will be recorded as 'lost to follow-up'. If participants have moved outside your site's catchment area we will ask you to inform us and seek permission from them for you to pass on their new

contact details to the University of Exeter co-ordinating centre who will then explore options for continuing to involve the person.

- If a person with dementia who is taking part in IDEAL at T1 relocates to within your site's catchment area at T2 then we may ask your site to conduct the follow-up assessments with this person.
- During 2015 we will commence the qualitative arm of the study. A small sample of participants taking part in the study will be interviewed by a researcher who is based at Cardiff University. She will be exploring longitudinal changes in the lived experience of people with dementia and their carers. Piloting of the interviews will be conducted in the autumn of 2015 and the interviews will take place in 2016.

1.1. New developments in the IDEAL Study

As research network staff you will have a responsibility for ensuring the 12 month follow-up is conducted as per the protocol. We would also like to make you aware of other projects linked to the IDEAL study that will involve IDEAL participants.

At T2 there will be three additional studies that will run alongside IDEAL. These studies will involve IDEAL participants and will either focus on specific sub-groups of IDEAL participants e.g. carers who work or will explore alternative ways of disseminating the findings from IDEAL. The researchers working on these studies will be contacting **some** of the participants taking part in IDEAL to see if they are willing to take part in these linked studies. These researchers will seek the necessary NHS permissions and ethical approval and will be responsible for conducting the visits and assessments. Two of these studies will be PhD studentships funded by IDEAL and the third study is being led by the Principal Investigator:

IDEAL Arts based project: A Life More Ordinary

Drawing on the findings of the IDEAL study there will be a programme of arts-based activities and outputs which provide a positive but realistic interpretation and portrayal of the experience and impact of dementia. This project will enrich the IDEAL study by contributing to our understanding of what it means to live well with dementia. By using arts-based activities this offers participants a different way of expressing what it means to them to live with dementia. Some of the participants taking part in IDEAL will be approached to take part in these activities. This project will also utilise data collected for IDEAL; for instance, data collected during T1 and T2 of the study will be used to develop the focus of workshops which aim to enable people with dementia and carers to illustrate what living well with dementia means to them. This will enrich the understanding that we gain from the data collected in the CRFs and will help us to interpret the data and to more accurately convey the nature of participants' experiences. This project will also use the creative arts to disseminate the findings from IDEAL; for instance we plan to develop short books, which

illustrate key aspects of everyday life that are affected by dementia. These will stimulate awareness about dementia and how to support people who have dementia to live their daily lives within the community among the general public. This work will commence in 2015.

The role of social class in the experience of dementia

A PhD student at Cardiff University (starting in September 2015) will undertake a mixed-methods study to examine the role of social class in the experience of dementia, dementia care and treatment, and people's capacity to live well with dementia. This will involve the PhD student analysing some of the data collected for the study. She will also interview a small sample of participants, exploring how their class backgrounds and class identity relate to their experiences of dementia, their understanding of their condition, their everyday lives and their capacity to adapt to their condition.

Experience of working carers

A PhD student at Sussex University (starting September 2015) will undertake a mixed-methods study to explore factors associated with psychological health and quality of life in carers maintaining employment alongside the caring role. This study will use data collected from working carers at T1 to determine which factors are relevant to successful and unsuccessful coping in caregivers who maintain employment. A small sample of carers will then be interviewed to further explore the areas which hinder and assist the retention of employment alongside the caring role.

1.2. A brief reminder of the IDEAL study design

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.

1.2.1. Design

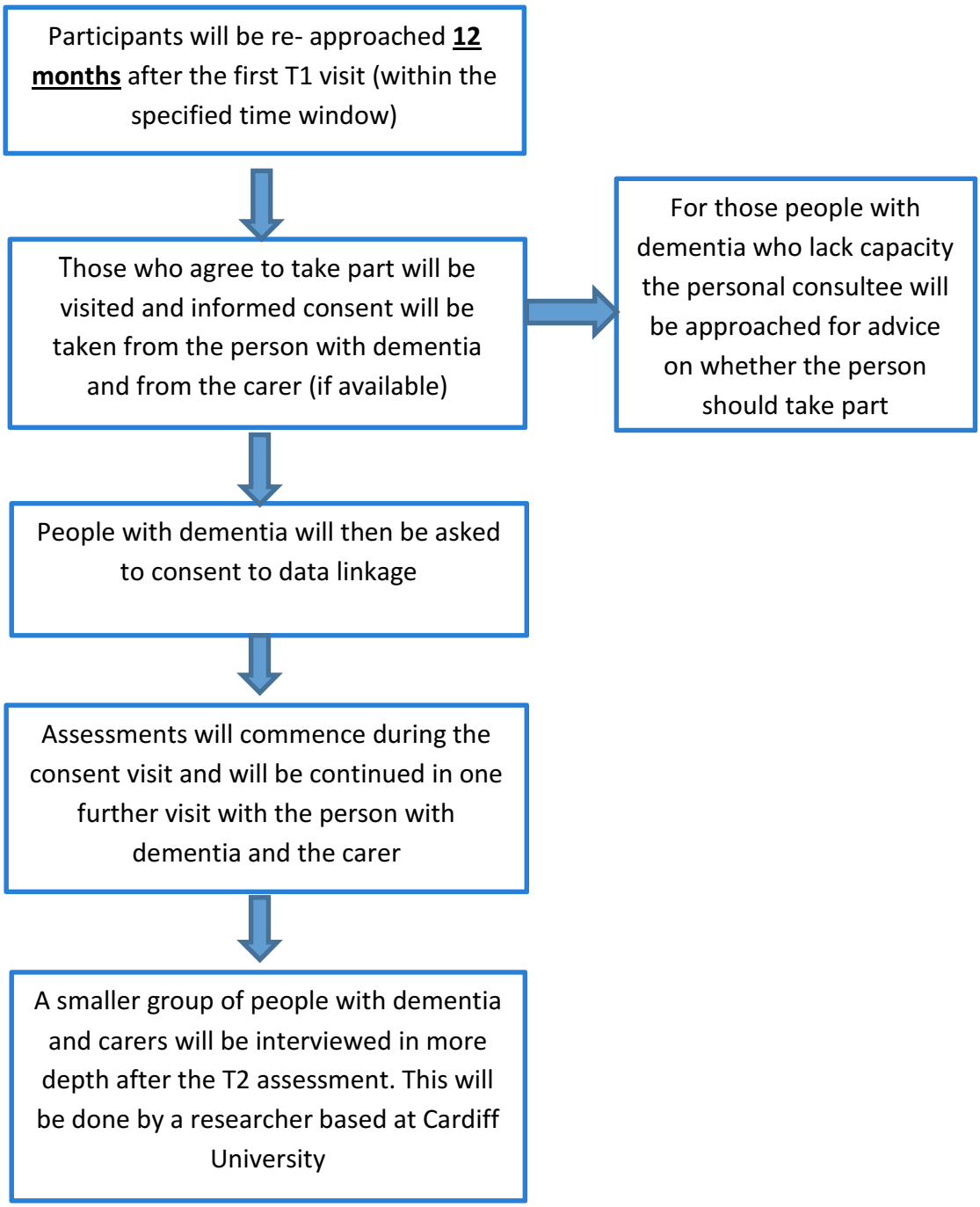
This is a mixed-method, longitudinal cohort study of people with dementia and their primary carers. Quantitative assessments and questionnaires will be conducted at **baseline** (T1), **12 months** (T2) and **24 months** (T3). Qualitative interviews will be conducted by a researcher, based at Cardiff University, at the 12 and 24 month time points with a sample of participants showing evidence of change in indicators of living well. This will enrich the quantitative findings by illuminating the reasons and subjective experiences underlying these changes. Figure 1 shows the participant pathway through Time 2 of the study.

1.2.2. Procedure

After T1 assessments participants are followed up 12 (T2) and 24 (T3) months later. At T2 and T3 assessments will be completed in **two visits** to the **participant's place of residence** 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 are expected to last up to 2 hours each. Participants will be offered a small shopping voucher (one voucher per dyad) as a token of appreciation for taking part in the study upon the completion of the assessments at each time point.

Figure 1. Participant pathway through the study: Time 2



1.2.2.1. Qualitative interviews

A researcher from Cardiff University will be conducting interviews with a small sample of participants: 30 people with dementia and their carers (if available). These interviews will be conducted at T2 and T3. By exploring T1 data, participants showing positive or negative changes in indicators of living well will be selected for interview. These interviews will help us to further understand the lived experiences of people with dementia and carers, their social networks, their use of social space and community resources, what help or hinders the possibility of living well, and what factors are particularly important to them in relation to being able to live well. Piloting of the interviews will be conducted in the autumn of 2015 and the interviews will take place in 2016.

1.2.2.2. Study timelines

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
Time 3 Follow-up assessment completed	30/09/18

1.2.3. Ethical approval

The IDEAL study was approved for the United Kingdom (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 did not require it to be ethically reviewed under the provisions 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). We have made a number of amendments to REC to incorporate data linkage and to resolve other study related issues. Please ensure you are up to date with the most current versions of ethically approved documents.

1.3. T2 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 co-ordinating centre. During IDEAL T2 training, you will have the opportunity to familiarise yourself with the procedures for T2, learn about data linkage, understand the content of the revised CRFs and practise administering the CRFs. We require all research staff to provide details of their training attendance for our records.

1.3.1. Training requirements

As a researcher 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 and has important implications for the quality of the data we collect.

IDEAL T2 Training

1. We will organise training sessions to provide detailed information on T2 of the study. 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 **latest** version of the IDEAL study protocol and the IDEAL Time 2 Researcher's Handbook. All researchers are required to become familiar with the CRFs **before** they commence assessments. This includes understanding the types of questions used and response keys for all items within the CRFs.

3. We would encourage all staff to complete the free online training programme designed to help staff administer the Addenbrooke's Cognitive Examination-III (ACE-III): https://www.fom.gla.ac.uk/aceiiitrainer/

Training verification

As with T1, we will be continuing with training verification in T2. This process will help us to resolve any issues at an early stage and will help with further assessments to check the quality of data collected. We would appreciate your co-operation with this process.

For each researcher we will need to see the following CRFs for his/her **first** T2 participant:

Participant Time 2 CRF Part 1

Participant Time 2 CRF Part 2

If you are only involved in collecting the Part 1 CRF data or the Part 2 CRF data, then please send us the CRF you have completed. Please ensure you return the CRFs at the earliest opportunity. We would like to provide feedback early in the T2 process and before further follow-up assessments are conducted if feasible.

The systems for returning the CRFs for verification will be different to that for T1. You can return then to us for checking by either:

- Sending an electronic copy of the CRFs to c.quinn@exeter.ac.uk
- Photocopying the CRFs and returning the copies to the co-ordinating centre at the University of Exeter using the envelope provided. (Note: the original CRFs should still be sent as part of the **courier returns** to **Bangor University**).

Time 2 CRF Part 1 and Participant Time 2 CRF Part 2 documents will be checked for accuracy of completion and, where relevant, accurate scoring of the measures. If you have completed these CRFs accurately, you will receive an email to confirm this. If there are issues or errors in the completion of your CRFs, we will provide feedback on how to resolve these issues and to improve completion of the CRFs. You will be asked to confirm that you have received and read this feedback. Please take the time to read this feedback and incorporate the information into your assessments to ensure these issues do not arise again.

2. Re-contacting study participants

2.1. Timescales

The T2 follow-up should be conducted **12 months** after the first T1 visit (entry into the study). 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. At T1, we provided you with an Excel file that auto-generated the follow-up date to help you schedule your follow-ups.

For some sites, recruitment and T1 assessment will be ongoing as T2 commences. You should plan ahead so that you can facilitate these follow up visits as T1 recruitment and assessments continue. This also involves managing the appropriate documents at each time point; for instance, ensuring you bring the CRFs for the correct time point to assessments.

2.2. T2 participants: who can take part?

On entry to the study, potential participants were identified using specific inclusion/exclusion criteria. These criteria do not apply at T2. We would like to follow up everyone who participated at T1. At T2, people with dementia can still participate in the study if their Mini-Mental State Examination (MMSE) falls below 15, and participants can be visited if they move into residential care. As you prepare for T2 there may be a situation whereby a participant may be excluded if there is a potential for home visits to pose a significant risk to research network staff. If the person's situation has changed so that there is now a significant risk to the researcher, she/he could be excluded at follow-up. This reason for exclusion would be recorded as a withdrawal in MACRO under the section: 'Other - please specify'.

2.3. Pre-contact checks

Participants' circumstances can change over a year and it is possible that there may have been changes in the health and/or living situation of the person with dementia or carer. In some cases the person with dementia or carer may have died. If you have access to information held about the participants, for instance memory clinic notes or an electronic notes system, it would be advisable to check this information to see if there have been any changes in participants' circumstances before you contact them.

2.4. Contacting participants

Participants can be contacted by telephone or by letter to establish whether they are interested in continuing to participate in the study. If you are contacting participants by telephone you will need to ensure they have received the ***Summary of the study for follow-up (See Appendix 1)*** and ***Data linkage information pamphlet for participant*** before you visit them. The ***Summary of the study for follow-up*** contains information about the change of the study sponsor and provides the new contact details for the Principal Investigator (PI) should the participant wish to make a complaint. This is especially relevant for participants who entered the study and received the information sheet prior to the change in sponsorship from Bangor University to the University of Exeter in March 2015.

2.4.1. Postal Invitation

Participants can also be re-approached with the ***Follow-up letter and reply slip*** (**see Appendix 2**). You will need to include the ***Summary of the study for follow-up*** and ***Data linkage information pamphlet for participant*** with the letter. Participants who receive the letter will be able to contact you directly (either by telephone, email or using the ***reply slip*** attached to the ***follow-up letter***) to indicate whether or not they are still interested in taking part in the study. Non-responses to this initial contact can be followed up (e.g. by telephone or another letter) to compensate for the possibility that letters and messages could be mislaid due to memory difficulties.

If a participant wishes to withdraw from the study then please ensure this withdrawal and the reason (if known) is recorded in MACRO (guidance on withdrawals is in **Chapter 7** and **10**).

2.4.2. Arranging the follow-up visits

Once the person has expressed an interest in continuing to take part in the study, she/he should be contacted to arrange a visit. This contact should cover the following:

- Explain that you would like to meet with him/her to reaffirm their informed consent to participate and to start completion of the CRFs. This visit will last for two hours.
- Arrange a time and date to meet. If the person has a carer who is taking part in the study, you need to arrange the visit so that both the person with dementia and carer are present.
- Ask if she/he has a calendar or diary to write down the appointment. Suggest that she/he write~~s~~ down your name and telephone number so that she/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.

Other things to consider:

- It would be useful to use your initial contact with the person with dementia to find out if there have been any changes or a deterioration in his/her condition.
- If you feel that there has been a deterioration in the person's condition, you could consider inviting the personal consultee to be present at the visit so you can seek his/her advice if you decide that the person with dementia lacks capacity.

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 she/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.

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

We would like to ensure that we see as many people as possible at follow-up, and we need your assistance and perseverance in maintaining the cohort numbers. We would encourage you to consider these other options to help renew contact with participants:

- If the person has provided you with his/her mobile number or email address you could use these to try and get in contact with him/her.
- Check clinic charts or hospital records for any changes in circumstances e.g. move to residential care or death.
- Check with the carer or personal consultee about the person's continued participation in the study.
- If you cannot contact or locate the person with dementia/carer you will need to record this in *CONSORT Time-point 2* (the content of *CONSORT Time-point 2* is explained in **Chapter 7**).
- If you have located the participant but she/he has moved outside your site's catchment area you will need to follow the procedure outlined in **Chapter 14.**

2.4.4. Changes in participants' circumstances

If it possible that at T2 there may have been changes in the participant's circumstances. She/he may have moved or may now wish to withdraw from the study.

- If the person with dementia has moved outside your site's catchment area, you will need to inform us so that we can explore other options for visiting the person with dementia (see **Chapter 14** for further details).

2. Re-contacting study participants

- If the person with dementia has moved to a care home which is still in your site's catchment area, we expect you to visit the person in the care home to conduct your assessments (see **Chapter 15** for further details).
- During T2, if the person with dementia decides to withdraw the carer can still continue to take part and vice versa. Similarly, if the person with dementia cannot take part in the study, e.g. because of illness, the carer can still take part and vice versa (see **Chapter 10** for further details).
- It is possible that the carer may have changed since the T1 assessment. In this instance if the new carer is willing to take part in the study she/he should complete the CRFs (see **Chapter 12** for further details).

3. Structure of visits

At T2, participants taking part in IDEAL will be visited on **two** occasions and all the assessments **must** be completed during these two visits (see Figure 2 for a brief summary of the content of these visits). The length of time allocated for these visits is:

- Visit 1: Two hours
- Visit 2: Two hours

These **two follow-up** visits will last a total of **four** hours and we have allocated an appropriate amount of time for each visit so that you are able to complete the required assessments. The T2 CRFs were piloted with both people with dementia and carers to ensure that they can be completed within this allotted time-frame.

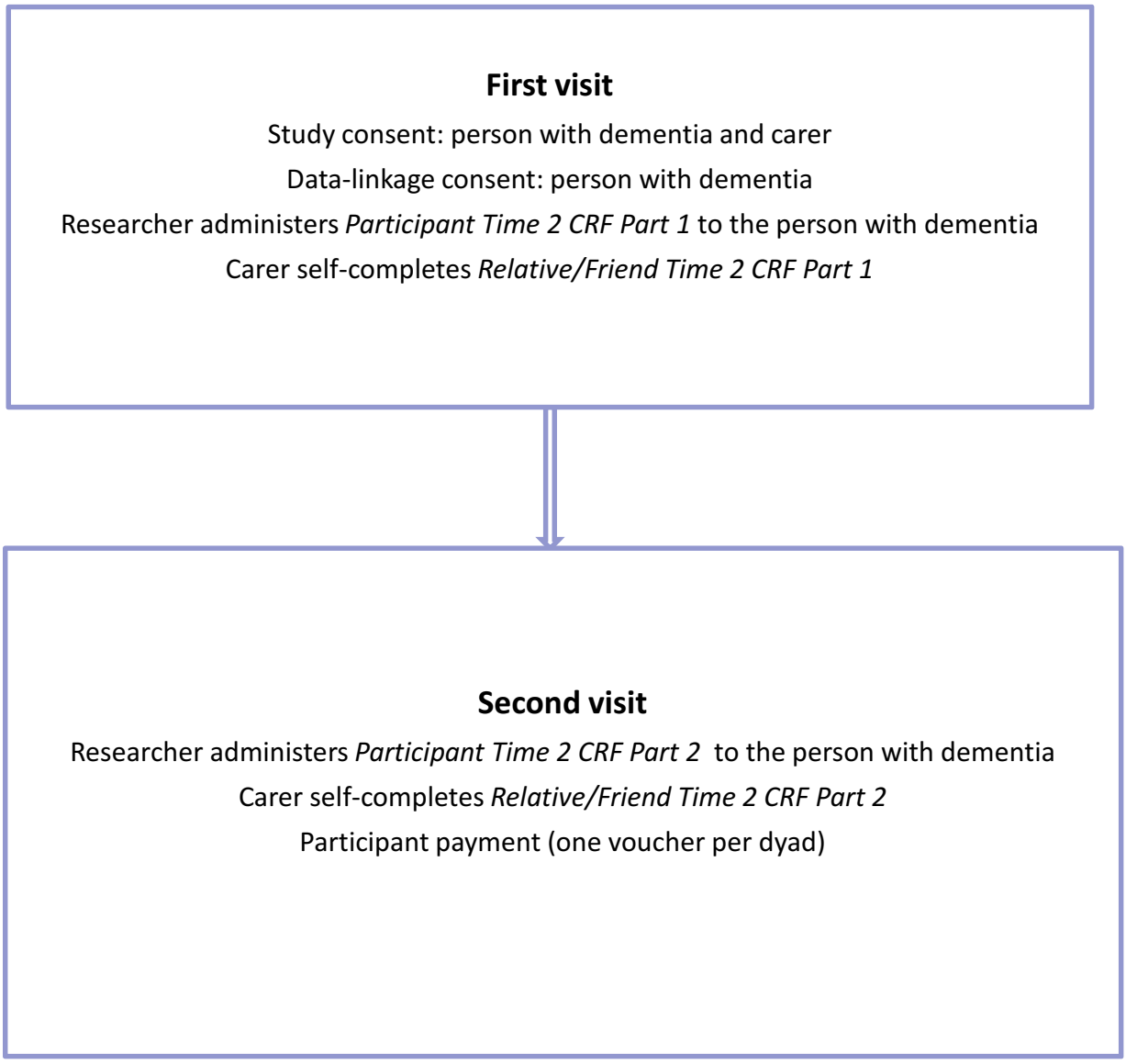
We do allow some flexibility; for instance if both the carer and the person with dementia were willing to complete more of the CRF in Visit 1, then Visit 1 could last three hours and Visit 2 one hour, etc. In addition, the carer CRFs could be completed in one visit. You will need to make sure that **both** the person with dementia and carer (if present) agree to a longer visit. Please be considerate to the participants and ensure they are comfortable during the visits.

You can start to administer Participant Time 2 CRF Part 2 in Visit 1; however, you need to ensure that the **MMSE** and **ACE-III/Test for Severe Impairment (TSI)** are administered on separate visits to avoid any carry over effects (guidance on administering the CRFs is provided in **Chapter 8**).

T2 Visit schedule

We recommend that the two visits at this time point are conducted within a 4 week time frame. This is different to the assessment timeframe for T1 as in T2 you only have to complete visits with the participants on two occasions. We realise people may not be available within these 4 weeks and it may take longer if you need to approach the personal consultee, but we encourage researchers to try to remain within this target to facilitate follow-up visits.

Figure 2. Summary of the content of the T2 visits

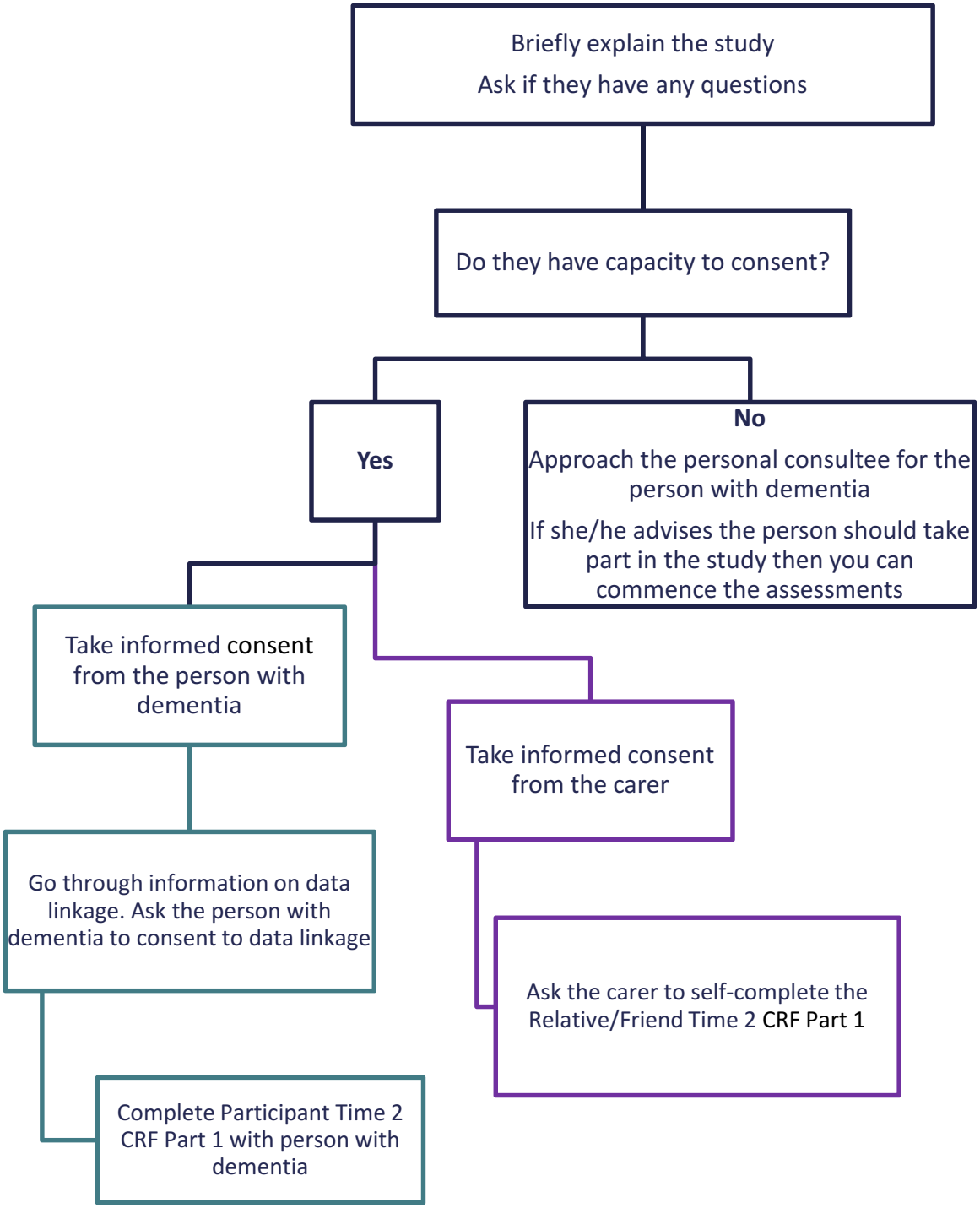


4. First visit

4.1. Outline of the first visit

The aim of the first visit is to reaffirm consent with the person with dementia and the carer (if taking part in the study) and to commence the assessments. Figure 3 below outlines the procedure for the first visit if both the carer and person with dementia are present.

Figure 3. 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). If only the person with dementia taking is part in the study then you just need to focus on the guidance for the person with dementia.

4.2. 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. Look up the participants' ID number (This **ID does not change** throughout the study, even if the carer changes or a different researcher is administering the CRFs). Please ensure you use the correct ID number on all study documents.

4.2.1. Documents to take with you

- Contact details form: T1 (in case there are any changes to participant details or should you need to contact the participant's personal consultee)
- Demonstration of capacity checklist (to document whether or not the person with dementia has capacity).
- Consent form for participant **12 month follow-up**
- Consent form for family member/friend **12 month follow-up**
- Data Linkage information pamphlet (in case it is needed)
- Data linkage consent form
- Personal consultee information sheet (in case it is needed)
- Consent form for personal consultee **12 month follow-up** (in case it is needed)
- Data linkage information pamphlet for personal consultee (in case it is needed)
- Data linkage personal consultee consent form (in case it is needed)

4.2.2. Assessment materials to take with you

- Participant Time 2 CRF Part 1
- Participant Time 2 CRF Part 2 (in case there is time to start this)
- Relative/Friend Time 2 CRF Part 1
- Relative/Friend Time 2 CRF Part 2 (in case there is time to start this)
- Showcard booklet
- **[MMSE information removed]**

4.3. During the first visit

The first visit should last approximately **2 hours**. The content of the visit is provided below:

4.3.1. Summary of the study

The first visit should start with a brief overview of the study and what taking part at T2 will involve. Participants should be reminded of their involvement in the study at T1 and given the opportunity to ask any questions. Once the participant expresses willingness to continue to take part in the study, you can then obtain informed consent.

4.3.2. Obtaining informed consent

This section outlines the procedure for obtaining informed consent in this study. T2 involves re-affirming participants' consent and monitoring their continuing willingness to take part in the study. All participants have the right to withdraw from the study at any time, with no need to give a reason.

4.3.2.1. Demonstration of capacity

At T1 in order to be eligible to take part in the study, all participants would have had to have demonstrated their capacity to consent. At T2, it is likely that for some participants there may have been a deterioration in their condition which impacts on their capacity to consent. Unlike at T1, there is not an information sheet for T2. Instead, the participant will be sent the ***Summary of the study for follow-up,*** which contains brief information about the study. You will need to explain the study to him/her to assess whether she/he has the capacity to re-affirm consent to take part in the study. If you were involved in the participant's T1 assessments, you may be able to judge whether she/he has deteriorated since T1. If the person's carer is taking part in the study she/he may be able to help you decide whether the person has capacity.

The Mental Capacity Act (2005), that covers *England* and *Wales,* 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 3)***. 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.

4.3.2.2. Does the person lack capacity to consent?

In order to demonstrate lack of capacity you would need to 'show that, on the balance of probabilities, the individual lacks the capacity to consent to participation in the research at the time that the consent is required to be made' (British Psychological Society, 2008 p17).

The guidelines from the British Psychological Society (2008) state that if the person cannot:

- Understand information given about the research;
- Retain information given about the research; and
- Weigh up the information to reach a decision

then, on the balance of probabilities, the person cannot reach a decision and cannot consent to continued participation in the study. You should document your decision in the ***Demonstration of capacity checklist***.

In England and Wales, if the person lacks capacity you will need to seek advice from his/her personal consultee. In **Scotland,** you will need to seek advice from his/her guardian, welfare attorney or nearest relative. Guidance on approaching personal consultees etc. is provided in **Chapter 11.**

If the personal consultee is not present during the visit and the person with dementia does not have capacity to consent, you will need to **end** the visit and contact the personal consultee.

In these exceptional circumstances, if the personal consultee advises that the person can take part, you can then return to the residence of the person with dementia to complete your two visits with the participant. This means that after you have received a signed consent from the personal consultee you can re-start Visit 1 and then proceed to Visit 2 with the participant.

4.3.2.3. The consent form

If the person with dementia has the capacity to consent, you will need him/her to initial and sign the consent form. Copies of the ***Consent form for participant 12 month follow-up*** and ***Consent form for family member/friend 12 month follow-up*** can be found in **Appendix 4** and **Appendix 5** respectively. Please ensure that that you have used the correct consent forms and the latest versions:

- Consent form for participant **12 month follow-up**
- Consent form for family member/friend **12 month follow-up**

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. Check that they have completed all sections of the consent form.

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

Below are common errors the co-ordinating centre identified in the completion of consent forms at T1. Errors in consenting procedures will result in an **exception report** being sent to sites. This may result in research staff having to re-contact participants to sign or date forms. Consent form omissions or errors may result in the withdrawal of the participant from the study.

Common errors identified in consent forms completed at T1

- The wrong consent form used (e.g. qualitative interview form used in error; incorrect version used)
- Researcher signature and date missing from the consent form
- Participants ticking instead of initialling the boxes on the form
- The participant not initialling all the non-optional boxes
- The participant not initialling the last statement on the consent form 'I agree to take part in the study'
- Incorrect ID number added to the consent form

Please ensure all elements of the consent form are completed correctly.

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 University of Exeter co-ordinating centre. The consent forms must be returned separately to the participants' data (further information on returning of data is given in **Chapter 6)**.

4.3.3. Consent for data linkage

After taking consent to participate in T2, you next need to ask the **person with dementia** for his/her consent for data linkage (see ***Chapter 11*** for guidance if the person does not have capacity to consent; ***Chapter 9*** contains information about data linkage). You should check that she/he has read the data linkage information pamphlet for participants. A showcard has been provided with a script introducing data linkage. You will need to read out the script from the showcard. She/he will have the opportunity to ask you questions about data linkage prior to consenting to data linkage.

If the person with dementia consents to data linkage she/he will need to sign the ***Data linkage consent form*** (see **Appendix 6**)**.** You will be asked to record the number of people with dementia who consent to data linkage in MACRO in *CONSORT Time-point 2*.

If, after asking any questions, the person with dementia is still undecided and wants more time to think about consenting to data linkage, you may ask for consent again at the second visit.

If the person does not wish to consent to data linkage she/he can still carry on taking part in the IDEAL study. You will be asked to record this in MACRO in *CONSORT Time-point 2*.

4.3.4. Administration of assessments

After you have obtained consent, you will be able to administer the assessments (guidance on administering the CRFs is provided in **Chapter 8**). As with T1, the CRF for carers is designed to be self-completed.

You will need to:

(a) Administer the *Participant Time 2 CRF Part 1* to the person with dementia and complete the checklist at the back of the CRF.
(b) Give the carer the *Relative/Friend Time 2 CRF Part 1* to self-complete. Ensure the carer knows how to complete the CRF. Ideally, the carer should do this in a separate room.

4.4. End of the first visit

Prior to ending the first visit please:

(a) Ensure you have asked all the *Participant Time 2 CRF Part 1* questions, or take some time to revisit topics that may have been missed earlier.
(b) 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 you see in his/her responses (e.g. selecting multiple answers to a question that requires only one response). If the carer has experienced difficulty in completing the CRF, you may find that you have some time to help him/her to complete it.
(c) Thank the participants for their continued involvement and establish the next visit date.

4.5. After the visit

(a) Check that you have filled in all the appropriate sections on the CRFs.
(b) Complete any researcher ratings as required in the CRFs.
(c) Record any field notes or comments on the CRFs (if you have not already done so).
(d) Check the CRFs for any errors or missing data. Ensure that the checklist at the back of the CRF has been accurately completed.
(e) Record the MMSE score, which will be needed for Visit 2.
(f) Sign the Demonstration of capacity checklist (if you have not already done so). If the person with dementia does not have capacity, you need to document this on the form.
(g) Photocopy the participants' consent forms and file appropriately.
(h) Ensure that the participants' documents are stored securely in a locked filing cabinet. Participants' consent forms and the Contact details form must be stored separately to the CRFs.

4.5.1. Completing the Contact details form: T2 (12 month) follow-up

The **Contact details form: T2 (12 month) follow-up** must be completed for <u>all</u> participants at T2. On the form, you will note whether their contact details remain the same or if they have changed and what the changes are.

4.5.1.1. NHS/CHI number for data-linkage

On the **Contact details form: T2 (12 month) follow-up** you will need to record the NHS number (for participants in England and Wales) or the CHI number (for participants in Scotland) for the person with dementia only if:

- the person with dementia has **consented to data linkage**, or
- the personal consultee has advised that the person with dementia would want to give consent to **data linkage**

Having participants' NHS/CHI numbers will improve the chances of us successfully linking their data so it is very important for us to have this information for data linkage. You will need to look up the participant's NHS/CHI number in the health records from which you obtained his/her current address and contact details. You need to record this number in the **Contact details form: T2 (12 month) follow-up**. If you have no access to records with the NHS/CHI number or are unable to find the NHS/CHI numbers, you should record this on the form in the space provided.

5. Second visit

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

5.1. Before the second visit

You should contact the participant (and carer if applicable) the day before to remind them of the scheduled visit.

5.1.1. Assessment materials to take with you

- MMSE score from T2 visit 1 to decide whether to administer the ACE-III or TSI
- Participant Time 2 CRF Part 2
- Relative/Friend Time 2 CRF Part 2
- Showcard booklet
- Items needed for the ACE III: pencil, one sheet of A4 paper, stopwatch (or mobile phone with stopwatch function)
- TSI equipment (sites will be provided with this equipment)

5.2. During the second visit

The second visit should last approximately **2 hours**. Guidance on administering these CRFs is provided in **Chapter 8**. You will need to:

(a) Give the carer the *Participant Time 2 CRF Part 2* to self-complete. Ideally, the carer should do this in a separate room.
(b) Administer the *Participant Time 2 CRF Part 2* to the person with dementia. Complete the checklist at the back of the CRF.
(c) If the carer is present, the carer and the person with dementia should be jointly administered ***Section B*** of the *Participant Time 2 CRF Part 2*.

5.3. 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) 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 University of Exeter co-ordinating centre to have their contact details). They can also access updates about the project on the IDEAL website**.**

5.3.1. Participant payment

As a token of appreciation for their participation, if the person with dementia and carer complete all the visits for the time-point then they should be given the ***Participant thank-you note*** and the **shopping voucher**. Each dyad receives **one voucher** (**participants do not receive one voucher each**). If the participants do not complete all of the visits, for example if they decide to withdraw after visit 1, 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 she/he can still receive payment.

The documents you will need to provide to participants who have completed T2 assessments with their shopping vouchers are:

1. The ***Receipt of payment: T2*** (a copy is provided in **Appendix 7**) which the participant must sign as evidence of having received payment. This form must be sent to the **University of Exeter** co-ordinating centre (more details are provided in **Chapter 6)***:*
2. ***Participant thank-you note*** which is given with the shopping voucher.

5.4. After the 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) Check the CRFs for any errors or missing data. Ensure that the checklist at the back of the CRF has been accurately completed.
(d) Score the ACE-III or the TSI (depending on which one you administered).
(e) Ensure that the participants' documents are stored securely in a locked filing cabinet.
(f) Complete any researcher ratings as required in the CRFs.

Part II. Document management, monitoring and reporting

6. Data and document management

6.1. IDEAL site Excel file for T2

To support the upload of the monitoring information required by the project your site will be sent an electronic version of an Excel file which can be used to record the information needed for *CONSORT Time-point 2* (the content of *CONSORT Time-point 2* is explained in **Chapter 7**).

6.1.1. CRFs and associated materials

The CRFs and associated material that you will need for this study are:

- Participant Time 2 CRF Part 1
- Participant Time 2 CRF Part 2
- Relative/Friend Time 2 CRF Part 1
- Relative/Friend Time 2 CRF Part 2
- Paid carer Time 2 CRF
- Showcard Handbook
- Test for Severe Impairment (TSI) equipment pack

The T2 CRFs and associated showcards will be sent directly to your site. The number of CRFs your site receives will be based on your T1 recruitment target or may have been adjusted by the co-ordinating centre. We will send your site a smaller number of paid carer T2 CRFs as we do not envisage that you will need as many of these as the other types of CRFs. Requests for additional CRFs should be sent to the IDEAL Administrator with a justification for the request.

We will also send you the materials you will need to administer the TSI in the TSI equipment pack. One pack will be provided for each researcher and the site is responsible for maintaining the kit and for replacing any lost items.

We will send you envelopes for returning study documents either to the **University of Exeter co-ordinating centre** or to the **NWORTH Clinical Trials Unit** (based at Bangor University).

6.1.2. Other key study documents needed for T2

Other key documents needed for T2 are:

Correspondence

- Follow-up letter and reply slip
- Personal consultee invitation letter 12 month follow-up

Participant information forms

- Summary of the study for follow-up
- Personal consultee information sheet
- Information sheet for paid carers
- Data linkage information pamphlet for participant
- Data linkage information pamphlet for personal consultee

Consent forms

- Consent form for participant **12 month follow-up**
- Consent form for family member/friend **12 month follow-up**
- Data linkage consent form
- Consent form for personal consultee **12 month follow-up**
- Data linkage personal consultee consent form
- Consent form for paid carer **12 month follow-up**

Researcher forms

- Contact details form: T2
- Demonstration of capacity checklist
- Adverse event reporting form
- Receipt of Participant Payment Vouchers: T2
- Receipt of payment:T2
- Participant thank-you note (to go with the shopping voucher)
- CRF returns checklist: T2
- Participant information documents checklist: T2
- Telephone summary form

Some of these documents will be provided to your site electronically so that they can be populated with your site information, e.g. the information sheet. Other documents (e.g.

Participant thank-you note) will be printed and sent to you with the CRFs. We will provide electronic copies of other supporting documents.

6.1.3. Participant payment vouchers

Each site will be provided with shopping vouchers to give to participant dyads **(do not give participants one each)** who complete all the sessions as a token of appreciation for their participation in the study. Each site will be responsible for keeping the vouchers in a **secure location**.

Each site is responsible for:

1. Confirming that the vouchers have been received by the site. This will be done by completing the ***Receipt of Participant Payment Vouchers: T2 (see Appendix 8)*** following the receipt of documents for T2. This is to be sent to the: IDEAL Project Administrator**,** College of Life and Environmental Sciences – Psychology, Washington Singer, Perry Road, Exeter EX4 4QG, United Kingdom.
2. Following completion of T2 assessments you must ensure that the participants sign the ***Receipt of payment: T2*** (***see Appendix 7***) so that there is a record they have received payment.
3. When returning payment documents to us, you will need to return:
    a. A copy of the ***Receipt for participant payment vouchers: T2***
    b. Signed ***Receipt of payment: T2*** for each participant with all information added.

6.2. Returning documents to the co-ordinating centres

6.2.1. Which documents do you retain at the site?

- Demonstration of capacity checklist
- Copies of the consent forms
- Copies of the data linkage consent forms
- Contact details form: T2 (12 month) follow-up.

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

Sites will continue to return CRFs to the NWORTH Trials Unit who manage the data for the study. Other documents need to be returned to the co-ordinating centre now based at Exeter. Please note the returns procedures below:

Each site will need to return to the **University of Exeter** co-ordinating centre:

1) **Consent forms**: We will need a copy of the consent form for the person with dementia, for the carer (if applicable), for the personal consultee (if applicable) and for the paid carer (if applicable). These should be correctly completed.
2) **Data linkage consent form:** We will need a copy of the data linkage consent form for the person with dementia or the personal consultee (if applicable). These should be correctly completed.
3) **Contact details form T2 (12 month) follow-up:** this must be completed for all participants who have consented to take part in T2. It will note whether details remain the same or have changed and what the changes are. In addition, we need the NHS/CHI number for all T2 participants who have consented to data linkage.
4) Signed **Receipt of payment: T2** form**:** we will need this document returned as evidence that participants have been paid**.**
5) **Participant information documents checklist:** This **must** be completed so that we have a record of which documents have been returned. Please ensure you have recorded on the form the date sent. At T2, we have amended the form so that for participants who have withdrawn you need to record the time point of withdrawal and the number of completed CRFs.

Each site will need to return to the **Bangor University** trials unit (NWORTH):

1) **CRFs:** all the CRFs need to be returned (this includes incomplete CRFs). If participants have withdrawn from the study, you **still need** to return any CRFs they have completed. Please write 'WITHDRAWN' on the CRF.
2) It is essential that only **full sets of data** are returned for participants who have completed T2 (i.e. if the participant has only done CRF 1, only return his/her data when you have completed CRF 2). Please collate all CRFs (participant/ carer/paid carer as appropriate) and return together within the one courier collection). If a participant withdraws from the study during assessments then just return what has been done up to that point (please write 'withdrawn' on the CRF).
3) **CRF returns checklist:** you will need to complete this form to inform us which CRFs you are returning.

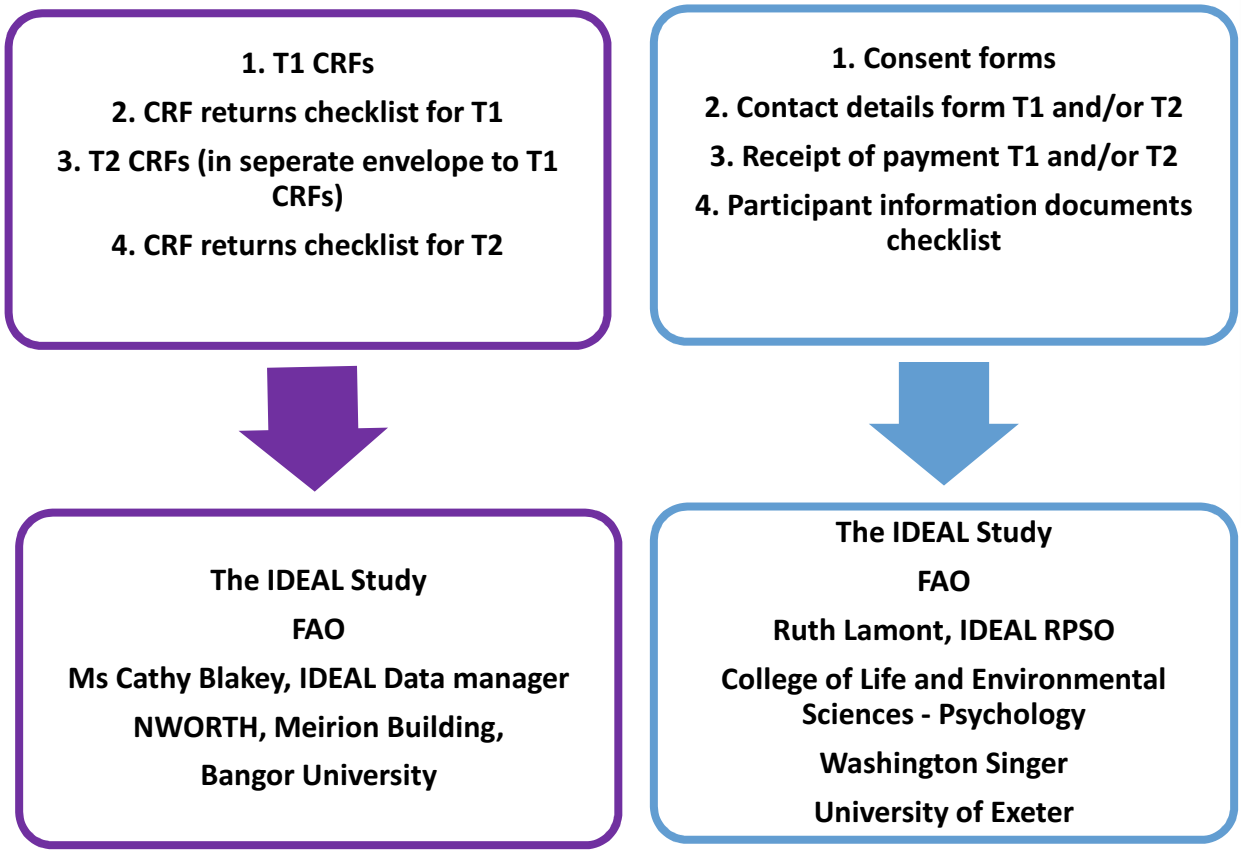
6.2.3. How to return documents

We will arrange for a courier to collect study documents from each site approximately every two or three months dependent on the site recruitment target.

You will be supplied with a cover sheet to complete (**Participant information documents checklist and CRF returns checklist)** 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.

You will need to return T1 and T2 CRFs in **separate envelopes**; these will be labelled accordingly.

Figure 4. Returning study documents



7. Study monitoring and reporting

7.1. Time 2 monitoring information

Previously we used the monitoring system to provide information on the sample entering into the study and this monitoring will continue for sites who have not, as yet, recruited all their target participants for T1. At T2, we would like to monitor how participants progress through the study. We are particularity interested in the numbers of people with dementia and carers who continue, withdraw, and who may be lost to follow-up. We also need additional information on the profile of participants at follow-up to allow us to change our sampling strategy for baseline recruitment if required. This will include information on diagnostic types, gender, age, living situation, carer relationship etc. We will ask sites to provide this information to enable us to monitor the cohort, and we really appreciate your work in collating and providing this information.

In addition, we would like to monitor the number of people of people who have consented to data linkage. As this is a new addition to the study and we would like to see how data linkage is received by IDEAL participants.

We will also ask sites to provide information on people who may have moved out of the site catchment area so they may be followed-up in another way.

How and when will monitoring information be collected?

We will continue to use the MACRO web-based data entry system that enables the co-ordinating centres to monitor the progress of the study at each site and across all the sites. We require information to be provided for the full calendar month of activity at the site. The monitoring information for T2 must be uploaded to the MACRO database by the **5th of the next month**; for example site activity conducted between June 1st to 30th must be uploaded to the MACRO database by July 5th.

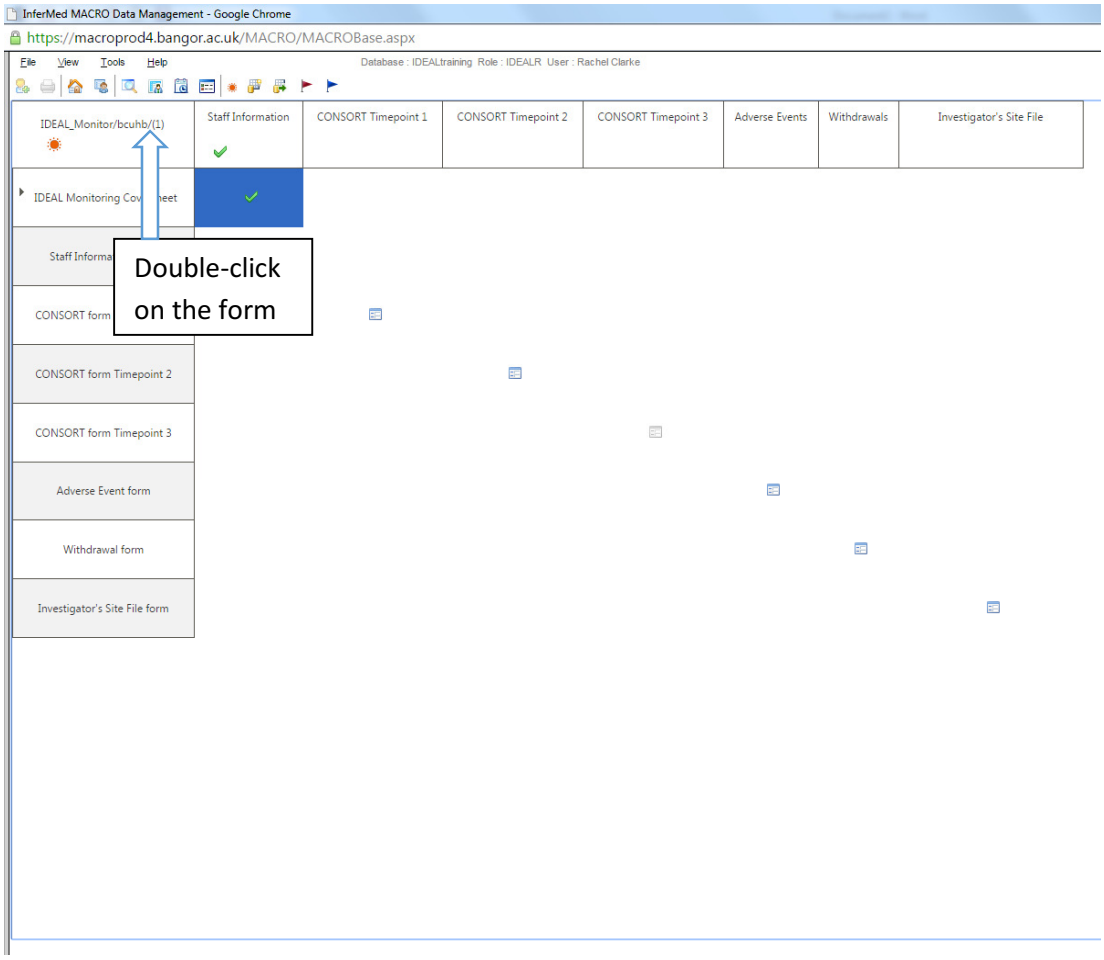
For T2 the monthly upload will only relate to participants followed up during the previous month. For most sites, this uploaded information will be for a relatively small number of people (most sites' monthly recruitment figures at baseline were 3-4 people per month and follow-ups will relate to these baseline figures). To facilitate the collation of the information for the T2 upload we have provided the sites with an **Excel file** outlining all the information required. Researchers are advised to populate this Excel file and ensure the site MACRO contact has access to this information to allow the MACRO upload prior to the 5th deadline. Please ensure that a member of site staff is available to upload the information.

At T2, the person(s) at your site responsible for entering information into MACRO will need to access the *CONSORT Time-point 2* form. In addition researcher details will need to be updated in the staff information form as well as updating the Adverse Event form, Withdrawal form and ISF form as required

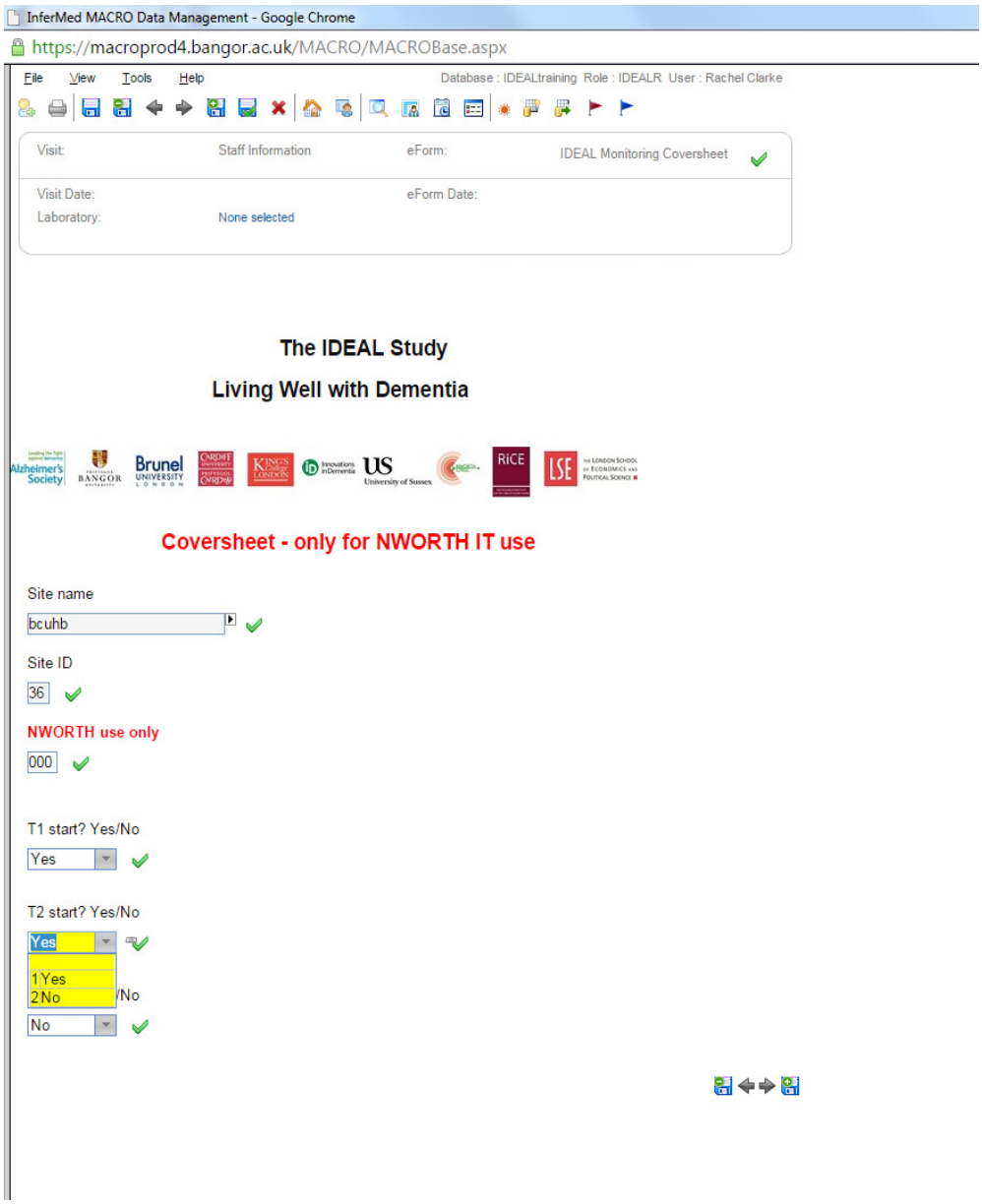
7.2. CONSORT Time-point 2

7.2.1. Activating CONSORT Time-point 2

Before entering follow-up data, the *CONSORT Time-point 2* form will need to be activated. To do this, double click the IDEAL Monitoring Coversheet.



When the IDEAL Monitoring Coversheet is open, select 'Yes' from the drop-down menu under 'T2 Start? Yes/No'.



7.2.2. What data needs to be entered for Time-point 2?

The monthly MACRO upload should reflect contact with participants during the previous month. There is a permissible follow-up window of one month prior to scheduled follow-up date and no later than two months post the scheduled follow-up date. This means that participant date entered at T2 will not necessarily be recorded in the same month at follow-up as it was recorded at baseline.

For Time-point 2, you will be asked:

a) Month: specify the month for the current upload

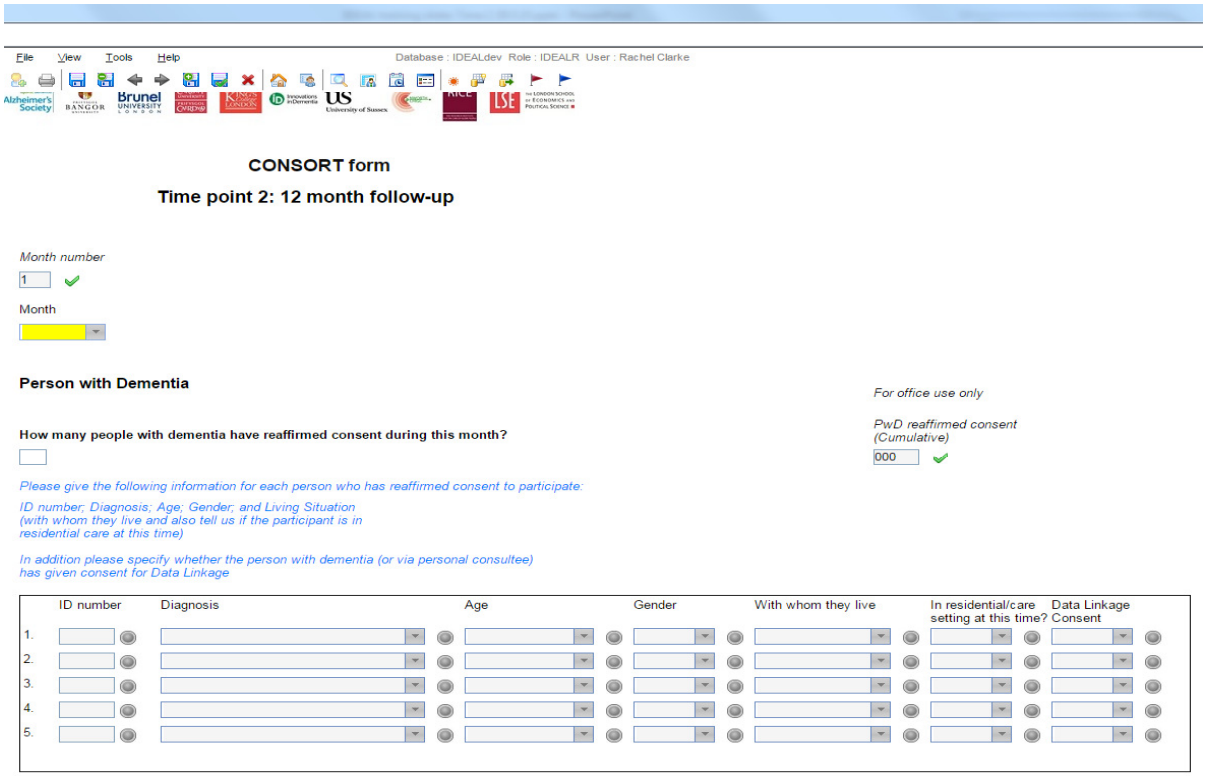
7.2.2.1. People with dementia

a) The total number of people with dementia who have reaffirmed consent during this month.

For each person with dementia who has reaffirmed consent you will be asked:

a) The ID number of the person with dementia (same as baseline).
b) The diagnosis of the person with dementia (drop down options will be provided).
c) Age on entry to the study (aged under 65 or over 65).
d) The gender of the person with dementia.
e) The living situation of the person with dementia (whether they live alone or with others).
f) Whether the person with dementia is in a residential care setting at this time (yes/no).
g) Whether the person with dementia has provided consent for data linkage (yes/no).

Screenshot: recording people with dementia who have re-affirmed consent



People with dementia who have withdrawn from the study at follow-up please provide:

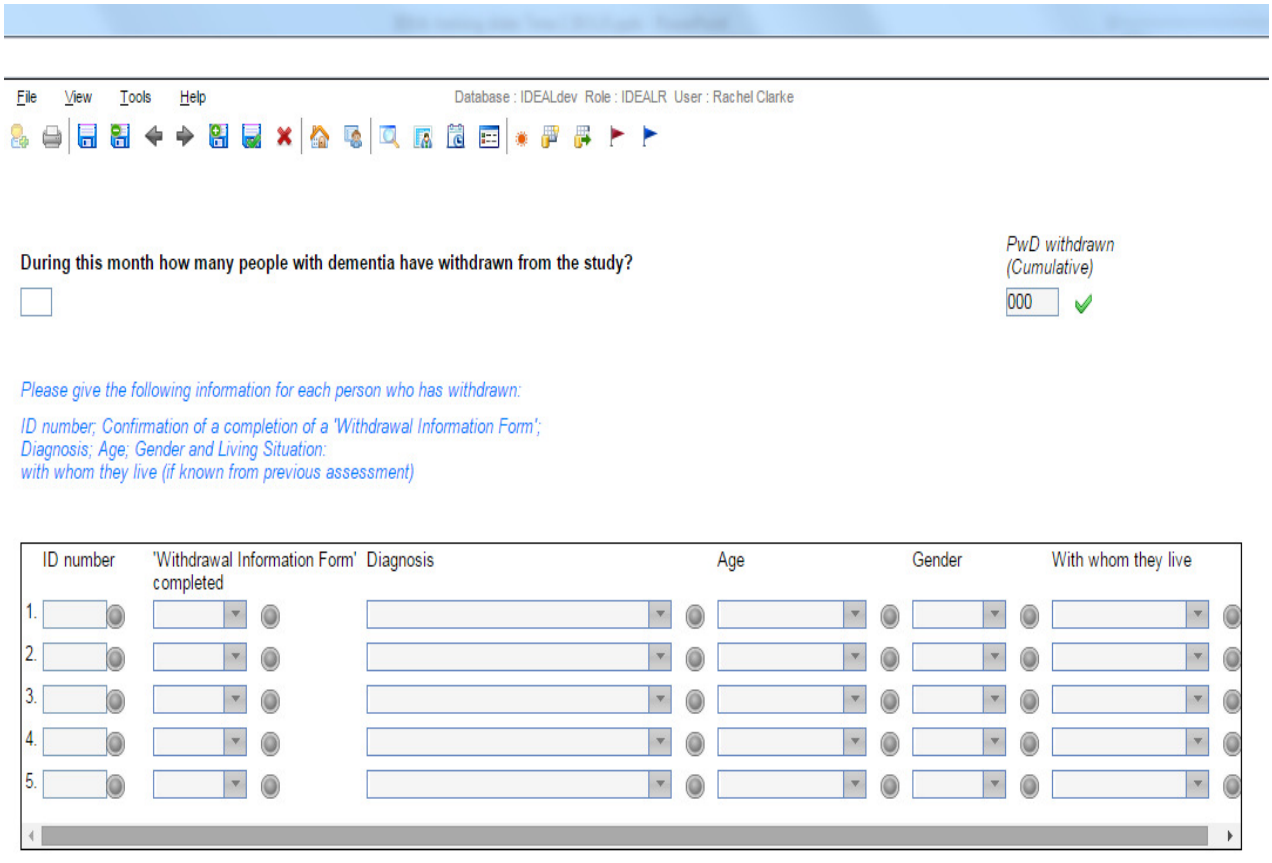
You will be asked to provide information regarding the number of participants that have withdrawn from the study during this month. For Time-point 2 monthly withdrawal information, you will be asked:

a) The total number of people with dementia who have withdrawn from the study during this month.

For each person who has withdrawn from the study at follow-up please provide the following:

a) The ID number of the person with dementia who has withdrawn from the study.
b) Confirmation that a 'Withdrawal Information Form' has been completed in MACRO for the participant.
c) The diagnosis of the person with dementia who has withdrawn from the study.
h) The age on entry to the study (aged under 65 or over 65) of the person with dementia who has withdrawn from the study.
d) The gender of the person with dementia who has withdrawn from the study.
e) The living situation of the person with dementia who has withdrawn from the study (whether they live alone or with others).

Screenshot: recording people with dementia who have withdrawn from the study



People with dementia who are lost to follow-up

You will also be asked to provide information regarding the number of participants who have been lost to follow-up during this month:

a) The total number of people with dementia who have been lost to follow-up during this month.

For each person with dementia who has been lost to follow-up:

a) The ID number of the person with dementia who has been lost to follow-up (same as baseline).
b) The diagnosis of the person with dementia who has been lost to follow-up.
c) The age on entry to the study (aged under 65 or over 65) of the person with dementia who has been lost to follow-up.
d) The gender of the person with dementia who has been lost to follow-up.
e) The living situation of the person with dementia who has been lost to follow-up (whether the person lives alone or with others).

People with dementia who have moved out of the site catchment area

You will be asked to provide information regarding the number of participants that have moved out of the site catchment area during this month (guidance on the procedure for participants who have moved outside the site catchment area is provided in **Chapter 15**). For Time-point 2 site catchment information you will be asked:

a) The total number of people with dementia who have moved out of the site catchment area during this month.

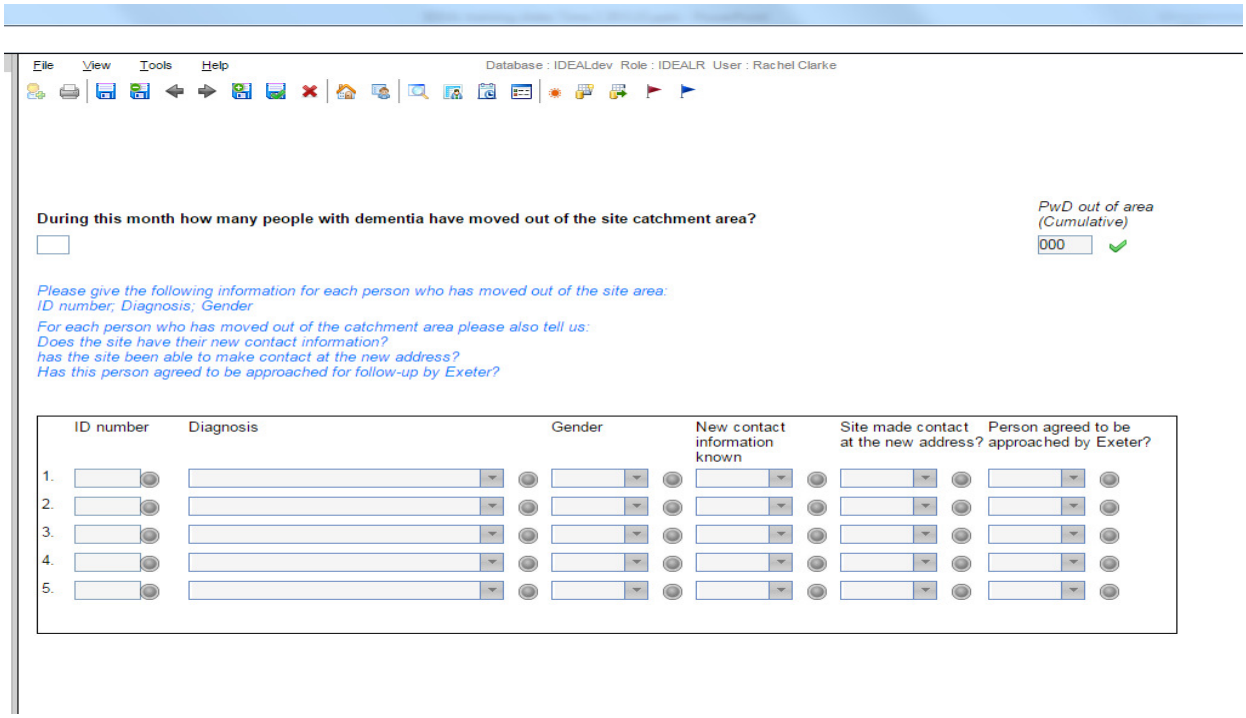
For each person who has moved out of the site catchment area during this month:

a) The ID number of the person with dementia.
b) The diagnosis of the person with dementia.
c) The gender of the person with dementia.
d) Whether the new contact information of the person with dementia is known (yes/no).
e) Whether the site made contact with the person with dementia at the new address. Whether the person with dementia agreed to be approached by Exeter.
f) During this month, the total number of people with dementia who have been transferred to this site for follow-up (if applicable).

In addition, if a person with dementia has been transferred to your site, you will need to record:

a) The ID numbers of people with dementia who have been transferred to this site for follow-up (if applicable). NOTE: although this ID will include another site's ID it should still be used (do not change it).

Screenshot: Recording people with dementia who have moved out of the site catchment area



7.2.2.2. Informants/carers

You will be asked to provide information regarding the number of informants/carers who have reaffirmed consent during the month. You will be asked:

a) The total number of informants/carers who have reaffirmed consent during this month.

<u>For each informant/carer who has reaffirmed consent:</u>

a) The ID number of the informant/carer.
b) The informant's/carer's relationship to the person with dementia (Spouse/Partner, Adult Child or Other).
c) Whether the informant/carer is the same carer/informant as at the previous time point or whether they are a different carer from the previous time point.

Informants/carers who have withdrawn from the study

You will be asked:

a) The total number of informants/carers who have withdrawn from the study during this month.

For each informant/carer who has withdrawn:

a) The ID number of the informant/carer who has withdrawn from the study (same as baseline).
b) Confirmation that a Withdrawal Information Form has been completed in MACRO for the informant/carer.
c) The informant's/carer's relationship to the person with dementia (Spouse/Partner, Adult Child or Other).

Informants/carers who have been lost to follow-up

You will be asked:

a) The total number of informants/carers who have been lost to follow-up during this month.

For each informant/carer who has been lost to follow-up:

a) The ID number of the informants/carers who have been lost to follow-up.
b) The informant's/carer's relationship to the person with dementia (Spouse/Partner, Adult Child or Other).

Informants/carers who have moved out of the site catchment area

You will be asked:

a) The total number of informants/carers who have moved out of the site catchment area during this month.

For each informant/carer who has moved out of the site catchment area:

a) The ID numbers of the informant/carers who have moved out of the site catchment area.
b) Whether the new contact information of the informant/carer is known.
c) Whether the site made contact with the informant/carer at the new address.
d) Whether the informant/carer agreed to be approached by Exeter.
e) During this month, the total number of informants/carers who have been transferred to this site for follow-up (if applicable).

In addition, if a carer has been transferred to your site, you will need to record:

a) The ID numbers of paid carers who have been transferred to this site for follow-up (if applicable).

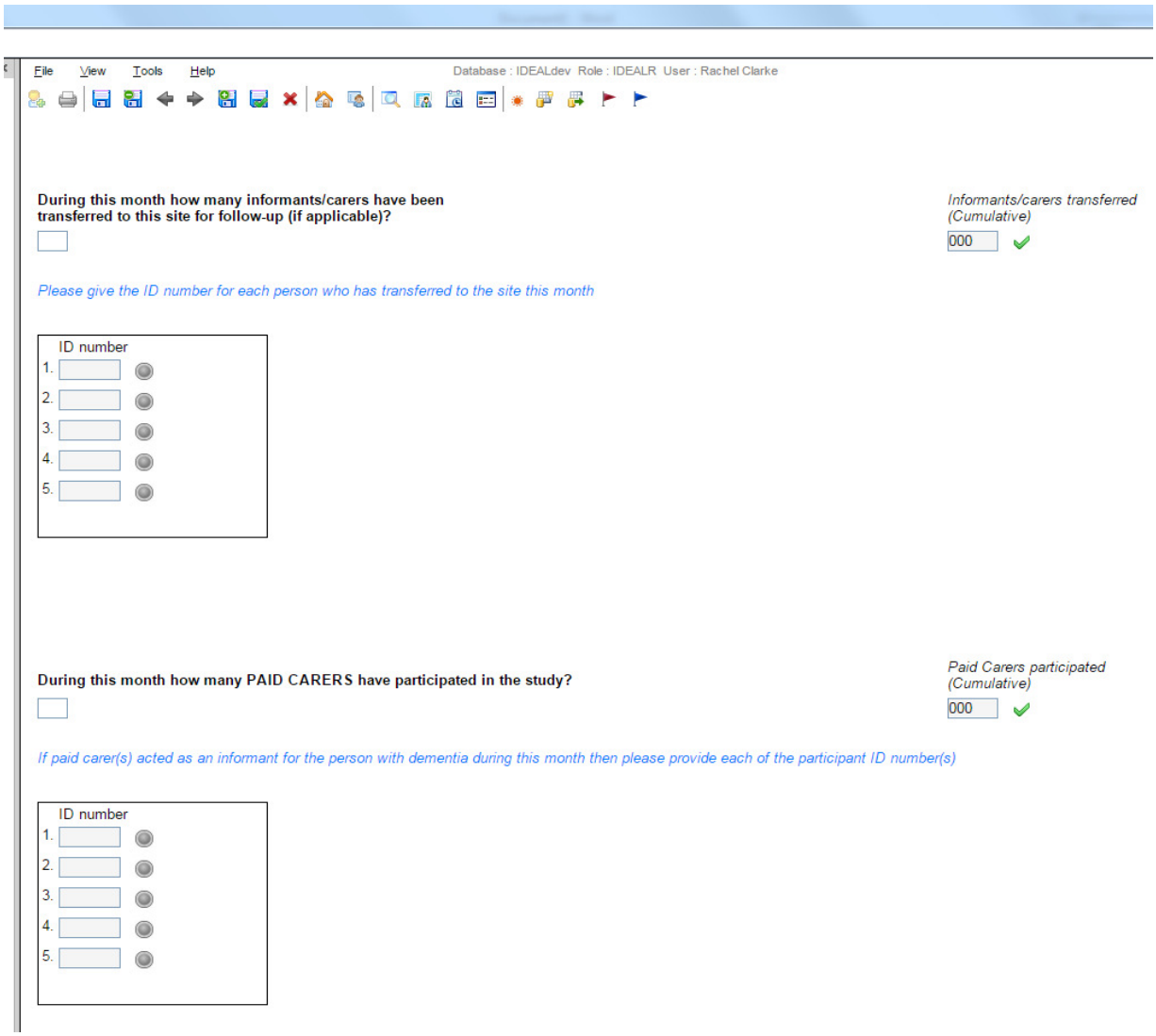
7.2.2.3. Paid Carers

Chapter 15 explains why paid carers may take part in the study.

For each paid carer who has participated in the study:

a) During this month, the total number of paid carers who have participated in the study.
b) The ID number of paid carers who have participated in the study (this ID will be the same as the participants' ID).

Screenshot: Recording carers who have transferred to your site and the number of paid carers taking part in the study



7.3. Updating staff information

At T2, the staff information in MACRO will need to be updated to record whether the researcher has received T2 training. Other details about the researcher may also need to be updated e.g. GCP refresher training.

New researchers will need to add their:

(a) Researcher name and email address.
(b) Researcher start date and end date (if applicable) on the study.

For each researcher, the researcher form will need to be updated with:

(a) Whether the researcher has received GCP and GCP refresher training and the date of the training.
(b) Whether the researcher's CV and GCP record has been added to the ISF and sent to the co-ordinating centre (at the University of Exeter)
(c) Whether the researcher has received IDEAL Time 2 training and if so:
    i. The date of the training.
    ii. Whether the training was provided by the co-ordinating centre team or by research staff at the site. **Please note** that MACRO will still refer to the Bangor co-ordinating centre; please select this option if you were trained by the team from the co-ordinating centre, which is now based at the University of Exeter.
(f) Whether the researcher has read the IDEAL Time 2 study handbooks. **Please note** that at T2 there is only one study handbook.

7.4. Adverse Events

All adverse events or serious adverse events should be recorded in the Adverse Event form. If an adverse event results in a withdrawal ensure you complete both the Adverse Event form and the Withdrawal form in MACRO.

7.5. Investigator Site File (ISF)

Sites are required to record any updates to the ISF by confirming the following information in MACRO:

a) Whether the site has received any new documents from the University of Exeter co-ordinating centre (in the past month) to add to the file.
b) If so, you will need to confirm these documents have been added to the site file.

7.6. Withdrawal information

For all participants (people with dementia and carers) who withdraw from the study we need a record of this withdrawal in the Withdrawal information form. If a participant withdraws from the study, you will need to record the reasons why (if known) and record this information in the MACRO database. The same withdrawal form can be used for carers and people with dementia. For each participant who withdraws you will need to record:

a) The ID number of the participant
b) Date notified of withdrawal.
c) The time point of withdrawal:
    i. T1
    ii. T2
    iii. T3
d) The number of CRFs completed prior to withdrawal (**this is a new addition**)
e) The reasons for withdrawal:
    i) Health reasons - person with dementia
    ii) Health reasons - carer
    iii) Death of person with dementia
    iv) Death of carer
    v) Bereavement, other - please specify
    vi) Unhappy with time commitment involved in taking part
    vii) Not interested
    viii) Unknown
    ix) Other - please specify

If the reasons for withdrawal include an adverse event e.g. death of person with dementia, please ensure that you also complete an Adverse Events form in MACRO.

This is all the information that is required for updating the MACRO database at T2.

Common errors and how to avoid them when entering Monitoring Data for the IDEAL Study:

 In MACRO this symbol represents missing data. Wherever you see this symbol, you will need to complete some data entry.

 In MACRO this is a warning symbol and means that some of the data entered is incorrect (often seen when a derived total does not match up with data entered). Wherever you see this symbol, you will need to re-check the inputted figures to ensure they tally with the end total.

In MACRO this red flag represents a discrepancy that has been raised on your data. If you see this symbol you will need to view the discrepancy (right click on the flag, go down to DCRs, then 'view') and respond / correct the error. When you have addressed the discrepancy it will change to a blue flag

Once you have entered your monthly data please check over the form.

If you see any of the above symbols your data is not complete!

Once the data has been entered correctly, you will see a green tick alongside the form:

Please take note of the following common errors when entering monthly monitoring data:

1. **Wrong month entered**
   Please be sure to select the correct month. Remember you are reporting on the previous month/s not the current month.

2. **Leaving questions blank**
   If the answer to a particular question is zero then this must be entered rather than leaving the box blank. If you have not consented any participants in a particular month, the form must still be completed for that month with zero values.

3. **Late data entry**
   Some sites are not completing their monthly updates by the given deadline. As these figures form part of a further report for the study it is vital that this data is available to us by the 5th of every month. If you are having trouble with your data entry please contact us as early as possible so that we can assist you in resolving the issue before the deadline.

4. **Using MACRO reserve contacts**
   The purpose of having two MACRO contacts is to ensure that monthly data can be entered into MACRO before the deadline if the main contact is unable to do so for some reason. If you are responsible for entering the data but you know that you will not be able to do so before the deadline, please liaise with another MACRO contact to ensure that the data is entered on time.

7.7. CONSORT Time-point 1: Additional guidance

At T2, it is likely that you will still be recruiting participants for T1. We have added some guidance about recording this information. You will still need to record information about the:

(a) People screened
(b) People approached
(c) Participants consented

7.7.1.1. Recording the number of people screened

You will need to keep an accurate record of:

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

7.7.1.2. 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

a) The number of people with dementia who were approached to take part in the study (this figure is derived by adding the number of participants screened and subtracting the number of participants who were excluded).
b) The number of people with dementia who refused to participate.
c) 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:
   i. MMSE score below 15
   ii. Co-morbid terminal illness at baseline
   iii. Person does not speak English
   iv. In a residential or nursing home
   v. Known risk to research staff prevented inclusion

The 'Consented to participate' total is derived by subtracting the number of participants who refused to participate and participants who did not meet the inclusion criteria from the 'Approached to take part' figure.

Carers

a) The number of carers who were approached to take part in the study.
b) The number of carers who refused to participate.

The 'Consented to participate' total is derived by subtracting the number of carers who refused to participate from the 'How many carers were approached to take part this month?' figure.

7.7.1.3. Recording the number of people consented

You will need to compile the following information for people who have consented to take part each month:

People with dementia

a) The Study Participant ID number, Investigator name (person who took consent) and Study Entry Date (date consented).
b) The **diagnoses** of those who consented - 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 dementia (Yes/No). You will need to specify the diagnosis
c) The **ages** of the people with dementia who consented - the number of people aged:
    i. Aged under 65
    ii. Aged 65 or over
d) The **gender** of the people with dementia who consented - the number of people who are:
    i. Male
    ii. Female
e) The **living situation** of the people with dementia who consented - the number of people who:
    i. Live alone
    ii. Live with others

Carers

a) The Study Participant ID number, Investigator name (person who took consent) and Study Entry Date (date consented).
b) For those carers who consented, the number who were:
    i. The spouse/partner of the person with dementia
    ii. The adult-child of the person with dementia
    iii. In another type of relationship with the person with dementia

7.7.2. Common errors identified in MACRO data in T1

Below is some guidance on common errors that have occurred in the MACRO T1 data.

1. **Difficulty calculating the totals for participants 'Screened' and 'Approached to take part'.**
   The 'Screened' figure should be the total number of participants actually approached and screened (including participants who have been excluded after screening, for example due to low MMSE scores). Once totals for 'Not meeting inclusion criteria' and 'Other reason for exclusion' have been included (if necessary), the system will automatically calculate the 'Approached to take part' total in MACRO. If you have approached any participants and are awaiting a response to a call/invitation letter etc., then only add these figures to the CONSORT form under the month they refuse participation or consent to participate in the study.
2. **Missing diagnostic information in the CONSORT form.**
   Please ensure that local site procedures are followed accurately to record participant information throughout the month and that this information is only entered in the MACRO system when it is up-to-date.
3. **Entering incorrect participant ID numbers on the CONSORT form.**
   The participant ID numbers are 7 digit numbers assigned to each participant and consist of the site number (two digits), the researcher ID (provided when researcher information is added to the 'Staff Information' form in MACRO) and the participant number (e.g. participant 04, 05 etc.). All sites have been provided with a **Participant ID number and accrual information Excel sheet** to create participant ID numbers.
4. **Entering the wrong year in 'Study Entry Date', e.g. 2014 instead of 2015, or failing to input a date.**
   Please double check that MACRO data has been entered and adjust incorrect data accordingly. If data is not precise, this can corrupt our reporting procedures to the UKCRN and may result in data having to be re-entered.
5. **Data from the following month inputted in the previous month's accrual e.g. data from April 1st inputted into 'March' accrual (CONSORT form).**
   Monitoring information required from sites must be uploaded to the MACRO database by the **5th of the next month**. For example, site activity conducted between June 1st and 30th must be uploaded to the MACRO database by July 5th.

6. **Failing to set boxes to '0' when no participants have consented or responded to an invitation.**
   If participants have not yet responded to an invitation to participate in the study, then all the boxes still need to be completed with a '0' on the MACRO database until they do respond.
7. **Duplicating participant ID numbers across CONSORT form entries.**
   Please keep accurate records of participant ID numbers and double-check that newly created ID numbers are not duplicates before entering them on MACRO, CRFs, Consent forms etc. Duplicate entries affect the UKCRN upload for accrual data and have to be removed from CONSORT forms to allow uploads. Sites have already been provided with an Excel spreadsheet to assist with creating participant ID numbers *(IDEAL Participant ID number and accrual information v1).*
8. **Entering accrual data past the recommended deadline.**
   Please ensure that MACRO data is entered by the recommended deadline issued in the 'Reminder' email sent from the co-coordinating centre, as failure to do this can result in missing data from your site and additional work for staff who have to follow-up missing data. If the main MACRO contact is unavailable, please use the reserve contact to enter data.

Part III. Case Report Forms

8. Case Report Forms

This section contains details of the CRFs that will be used in the IDEAL study at T2. It provides instructions on how to complete the CRFs. There are specific instructions for the administration and scoring of the cognitive assessments, including one new assessment for T2 which is to be administered to people who are more impaired.

8.1. Development of the CRFs

At T2 the CRFs were shortened in consultation with the IDEAL study team. Some IDEAL researchers provided feedback about measures that were proving challenging to administer and this also helped with the final selection of the measures. The shortened CRFs were piloted with the same people that took part in T1 piloting. In the piloting phase we explored ease of completion, length of time for completion, acceptability of questions, and appropriateness of the order of questions for a more impaired group of people. CRFs were completed within the allocated time, and the participants said that they were happy with the length and content of the questionnaires.

8.2. Changes in CRFs for T2

New CRF items/reduced items

At T2 we have reduced the numbers of items in the CRFs. Some measures have been removed and with others measures we have reduced the number of items, for instance the 6-item optimism scale has been reduced to a single item. A few new measures have been added into the CRFs. There is a cognitive measure for people with more severe dementia, there is one new questionnaire called “Life Space” (Participant Time 2 CRF Part 2 Q199-204; Relative/Friend Time 2 CRF Part 1 Q119-124) which contains six items with no/yes responses. There are one or two new single item questions, such as Participant Time 2 CRF Part 1 Q25 which is a question about subjective memory ability.

Administration of measure specific to a task/circumstance

Due to the potential decline of people with dementia and changes that may occur with the carers most CRFs have been split into different sections to account for various different situations that may occur at T2. In certain situations some sections may be skipped and clear

guidance about when it is appropriate to skip a section has been provided in the CRF. For example, in Participant Time 2 CRF Part 2 there is a section that should only be completed if there is no relative/friend taking part in the study at this time.

Minimal data items highlighted in CRF

A further substantial change is the addition of a box that highlights specific items in the CRF. There is guidance on the front of the CRFs to explain this formatting decision. It is important that you understand the reason for this addition as it may impact on the data that you collect. Some participants at T2 will be more impaired and they may be less likely to be able to complete the CRFs in full, although we anticipate that the majority of people will still be able to complete the CRFs in full in the time available. For those not able to complete the CRFs in full, the items inside these boxes should be used. The items have been selected in each case as they best represent the whole measure from which they are taken; we have chosen this item or these items so that we can get some information from the participant for that construct rather than none. It is therefore **essential** that this question/these questions are completed by **every** participant in the study. It is important to note that some participants may find it difficult to complete one section but may find it less difficult to complete another section. Please do not assume that, if the participant is unable to use the response keys for one section or finds it difficult to understand the questions, the same participant will also find it difficult to complete another section. You should therefore only use the item(s) in boxes after trying the first question in the section to see how the participant will be able to respond to those questions. Further information is provided in 8.2.3.

New Paid Carer CRF

For T2 there is a new CRF that has been designed to be completed by a paid carer who works in a care/residential home. This new CRF should only be used in instances where the participant has moved into a residential care facility and when there is no available informal carer taking part in the study. Thus, if the person with dementia is in a residential care facility but the carer is taking part, the paid carer CRF should not be used. **Chapter 15** provides guidance on the procedure for people with dementia who move into care homes.

8.3. Content of the CRFs

The content of the T2 CRFs relates to components that we anticipate will change over time and that will have an effect on or influence quality of life, well-being and life satisfaction. The CRFs consist of standardised measures and single items taken from existing questionnaires; with one or two exceptions the same measures and questionnaires that were included at T1 have been used in T2. The structure of the CRFs is similar to T1. The MMSE starts the first visit; however the score on the MMSE at T2 will not affect the

participant's suitability to be included in the study. The ACE-III starts the second visit if the person scored 10 or more on the MMSE during the first visit. If the participant scored less than 10 the participant should complete the TSI, which is a new assessment for T2.

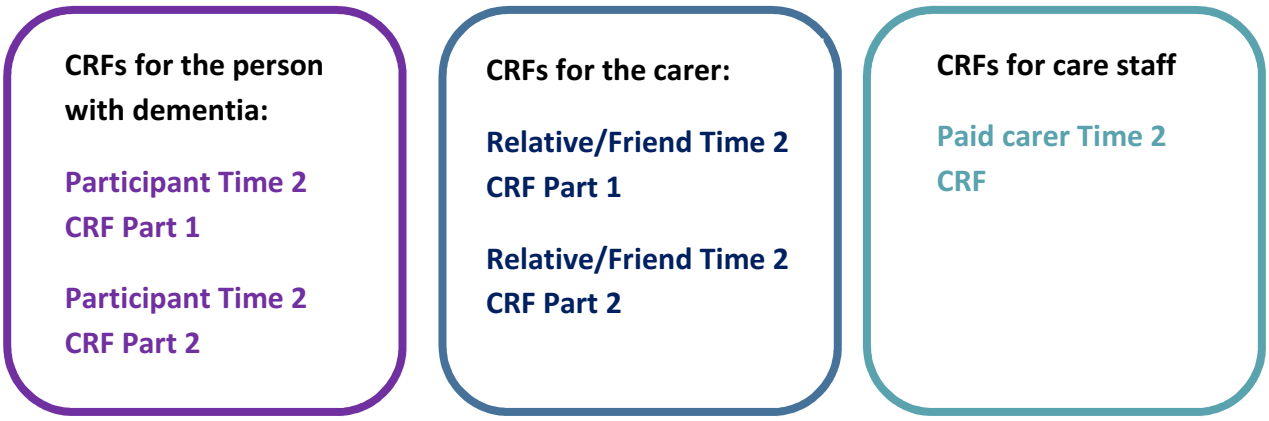
At the end of some of the CRFs there are open-ended questions. These must be asked, but the participant does not have to answer the questions. These open-ended questions offer the participants an opportunity to provide further information about their experiences in their own words.

For the carer the structure of the CRFs has changed from T1. At T1 each CRF was split between asking questions about the participant and asking questions about the carer. At T2 the first CRF contains only questions about the person with dementia whereas the second CRF contains only questions about the carer. Each end with open questions which offer the opportunity for carers to provide information about their experiences in their own words.

8.4. Types of CRFs

This section describes the CRFs being used in IDEAL. The titles of the CRFs are the same as they were at T1. The CRFs for the person with dementia are called **'Participant CRF'** and the CRFs for the carer are called **'Relative/Friend CRF'**. New for T2 is a CRF for Paid carers called **Paid carer CRF**. Information about the number of CRFs is provided in Figure 5.

Figure 5. CRFs for T2



8.4.1. CRFs for the person with dementia

8.4.1.1. Participant Time 2 CRF Part 1

The MMSE is at the start of this CRF.

The rest of the CRF begins with a section that you must complete that includes diagnostic information about the participant, the accommodation situation of the participant and a question about previous research projects undertaken in the last 12 months. The remainder

of the CRF has questions on education, employment, religious activity, health, health state, diet, pets, life events, mood, self-esteem, optimism, sense of self, sleep, quality of life, well-being, social participation, satisfaction with life, social networks, current relationship quality, everyday activities, difficulties the person experiences and stigma. There are a number of open-ended questions that you should encourage the participant to answer. The last section consists of the FAST as the sections relevant to your completion of this question (everyday activities) are included in Participant Time 2 CRF Part 1 and the Relative/Friend Time 2 CRF Part 1.

Some elements can be skipped; for example there are two questions about education. The first question is a screening question and if applicable - i.e. the participant has not undertaken an education or training course over the last 12 months - the second question should be skipped, as it does not apply to this participant. This is indicated on the CRF.

8.4.1.2. Participant Time 2 CRF Part 2

Before the second visit you must be familiar with the MMSE score from CRF 1. If another researcher administered CRF 1 you will need look-up the participant's MMSE score which will be recorded in CRF 1.

At the beginning of the Participant Time 2 CRF Part 2 there are a number of screening questions to help you select the appropriate cognitive test for the participant. This is why you need to know what score the participant achieved on the MMSE.

Instructions for the researcher: To be completed by the researcher

What score did the participant achieve on the MMSE during Part 1 of the Time 2 IDEAL assessment? ☐☐

Instructions for the researcher: Please cross the appropriate box:

☐ If the MMSE score was less than ten: **Please administer the TSI only**

☐ If the MMSE score was ten or more: **Please administer the ACE-III only**

You must administer the appropriate test to each participant. Please be aware that **no** participant at T2 should have both a score for both the TSI and a score for the ACE-III.

The TSI is at the start of this CRF. The TSI is a brief test used to measure cognitive ability in people with more advanced dementia. The **TSI must only be administered if a person with dementia scored between 0 and 9 on the MMSE** during Participant Time 2 CRF Part 1.

The ACE-III follows the TSI. The ACE-III is a brief test used to measure cognitive ability in five domains: attention, memory, fluency, language and visuo-spatial functioning. The **ACE-III must only be administered if the person with dementia scored 10 or more on the MMSE** during Participant Time 2 CRF Part 1. The ACE-III administration and scoring is the same as for T1 but we have provided additional guidance for you and some additional boxes to cross where the participant is unable or unwilling to provide information.

The rest of Participant Time 2 CRF Part 2 is split into four sections:

First section

This has questions on physical health, dignity and respect, psychological well-being, accommodation, green/blue spaces, life space (new for T2), society and community, social capital, social activities, cultural activities, and interests and activities. Some of the accommodation and the green/blue spaces questions can be skipped if the participant has not moved since the T1 visit.

Section B

This contains questions that should be administered to the person with dementia and carer together. This section contains questions on satisfaction with health services, medication, and household income. If there is no relative/friend taking part at this time this section should be administered to the participant only. We have added a screening question where you must tell us who answered the questions in Section B.

Section C

This contains questions that should be administered to the person with dementia **ONLY** if there is no relative/friend taking part in the study. This section contains questions on health conditions, sources of income and the CSRI.

Section D

The last section consists of the GDS since the relevant sections for this question (ACE-III/TSI) are included in this pack. You may also use information from the MMSE included in CRF 1 to help you make a judgement about the participant on the GDS.

Some elements in CRF 2 can be skipped, e.g. there are 8 questions about accommodation; the third question is a screening question and if applicable - i.e. the participant has not moved address in the last 12 months - the subsequent accommodation questions should be skipped, as they do not apply to this specific participant. This is indicated on the CRF.

8.4.2. Relative/friend CRFs

8.4.2.1. Relative/Friend Time 2 CRF Part 1

As a change from T1 this CRF contains questions that are only about the person with dementia. It is split into sections and should still be self-completed by the carer.

Briefly explain the CRF to the carer and how she/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 she/he does not understand any of the questions then she/he

can ask for your help. Ideally she/he should come to speak to you after you have finished working with the person with dementia so as to not interrupt the session.

We have added statements at the end of each CRF to ask the carer to make sure that all items have been completed. However, at the end of the session you must check that the carer has provided complete information in the CRF. You will need to check the relative/friend pack for any missing data **immediately** after she/he has returned this to you, and review any missing data together with the carer. You should be particularly mindful that carers may accidentally skip a page by turning over two pages instead of one. Ask the carer to complete any missing questions if she/he is able and willing to; otherwise, please record the reason for missing data in the appropriate checklist section at the back of the CRF. You will also need to check that the carer has completed the CRFs accurately, for example that she/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.

First section

The first section of the CRF has questions about the person with dementia covering his/her background, employment, quality of life, well-being, activities, satisfaction with life, everyday activities, emotional well-being, emotions, health, health conditions, sleep, health state, support network, life space, accommodation, interests and activities, involvement in decision-making, dignity and respect, life events, sources of income, and service use (CSRI). This section is the main part of the CRF and must be completed in full by every carer taking part in the study at this time-point.

Section B

The second section contains questions that should only to be completed if the person with dementia is not taking part at this time. This section contains questions on satisfaction with health services, medication, and household income; these would otherwise be completed in Participant Time 2 CRF Part 2 Section B. If the carer incorrectly completes this section you must correct the CRF by crossing out the information completely, drawing a line through each response box and initialling and dating each response box.

Section C

The third section contains a number of open-ended questions that you should encourage the carer to answer.

Please make sure that all sections have been completed accurately.

8.4.2.2. Relative/Friend Time 2 CRF Part 2

As a change from T1 the Relative/Friend Time 2 CRF Part 2 contains questions that are only about the carer and the CRF is split into three sections. The CRF begins with a screening question. This tells the relative/friend that there are different sections to be completed:

1. Did you take part in this study a year ago?
(If you are not sure please ask the researcher who gave you this questionnaire)

☐ No (please be sure to complete Section B of this questionnaire)

☐ Yes (you do not need to complete Section B of this questionnaire)

The first question of *Relative/Friend Time 2 CRF* 2 (question 1 above) asks the carer to say whether s/he took part in the study at T1. It is feasible for carers to not know or remember taking part in the IDEAL study at T1, especially if they have taken part in other research projects, and therefore you will need to be fully prepared to be able to say whether they were or were not taking part in the study at T1. If you did not see the participants at T1 you should consult your site's internal records to see who acted as the relative/friend at T1; you could also ask the researcher who conducted the assessments to tell you who the carer was. It is essential that you know who acted as the carer at T1, since not only will you have to tell the carer if required whether s/he took part at T1 but you will also have to record whether the carer has or has not changed from T1 in the researcher ratings at the beginning of participant Time 2 CRF 1. If the carer is new to the project at T2 you should inform him/her that there is a section at the back that they must complete. You should also make sure that this section has been completed when you check through the CRFs. If the carer is the same person as at T1 you should tell him/her before giving the CRF that Section B should be left blank.

First section

The rest of the CRF has questions on the carer's background, religious activity, education, employment, health, health conditions, health state, physical health, life events, accommodation, neighbourhood, society and community, support from others, current relationship with the participant, well-being, quality of life, satisfaction with life, and mood, on the experience of supporting the participant and on how the carer is managing. This section is the main part of the CRF and must be completed in full by every carer taking part in the study at this time-point.

Section B

Section B contains questions eliciting background information and details of education, employment, religious beliefs, accommodation, and neighbourhood. Section B contains questions that should **only** be completed if the carer did not take part at T1 (guidance about changes in carers is provided in **Chapter 12**).

If the carer incorrectly completes this section you must correct the CRF by crossing out the information completely, draw a line through each response box and initial and date each response box.

Section C

The third section contains a number of open-ended questions that you should encourage the carer to answer.

Please make sure that all sections have been completed accurately.

In some situations the carer may not be present at the visits. In these instances, you should post the CRFs to the carer and check through the completed CRFs when they are returned to you. If there are any errors or missing items you should telephone the carer to obtain the correct information and amend the CRF accordingly.

8.4.3. CRF for paid carers

This paid carer CRF is new for T2. This CRF should only be completed if the participant resides in a residential care home, nursing home or similar facility and **does not** have a carer taking part in the study at this time. The CRF has been designed to be self-completed by the paid carer. Ideally the paid carer CRF should be self-completed by a paid carer who knows the participant well (see **Chapter 15** for guidance on identifying a paid carer). The CRF contains questions about the background of the paid carer, his/her employment history and his/her education. The rest of the CRF is about the participant (referred to as the "study participant" in the CRF). The CRF has questions on health conditions, neuropsychiatric behaviour, quality of life, well-being, activities, satisfaction with life, emotions, everyday activities and medication. These questions are specially adapted versions of questionnaires included in the other CRFs. The final part contains a number of open-ended questions that you should encourage the paid carer to answer.

Please make sure that all sections have been completed accurately. You must check the CRF before leaving the care facility so that any missing or incorrectly recorded information can be corrected with the paid carer taking part in the study.

8.5. Completion guide

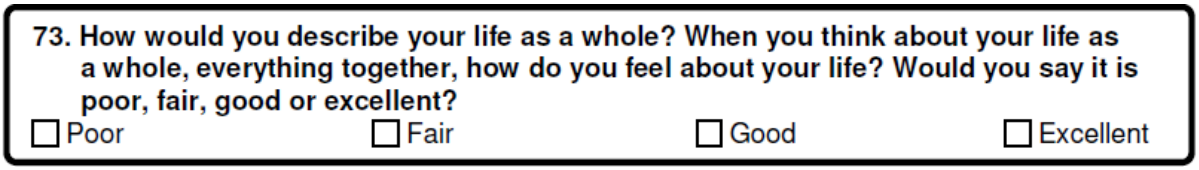
It is essential that the ID numbers allocated to participants at T1 are used with the same participants at T2. Please make sure that an ID number corresponds to the same participant in all time points of the study. If a paid carer is involved in the study his/her ID number will be the same as that allocated to the participant.

All the CRFs follow the same format:

- Where text is written in *italics* this represents information or instructions that you will give to the participant and these sections should be read out word for word e.g. *I'm going to start by asking you some questions about you, your life and your family.*
- Specific instructions for the researcher are highlighted using the underlined phrase 'Instructions for the researcher' followed by the instruction or information. e.g. 'Instructions for the researcher: Please cross all that the participant says apply to him/her.
- All questions for the participant are written in **bold text** and they should be read out word for word.
- Showcards: For many questions you will need to show the participant a showcard containing the range of responses to the question. Instances where you need to show the showcard will be clearly marked in the CRF and each showcard has a different identifying number e.g. **(USE SHOWCARD 2E).**

New for Time 2

- A small percentage of people may find the assessment difficult to complete at this time point. To allow for this we have, for some measures, identified core questions that should be completed even if the rest of the items in that measure cannot be answered. These are highlighted in boxes like this:



- We strongly encourage you to complete all individual items within each measure.
- However, if this is not possible then completion of the items highlighted within boxes is the minimum requirement for that measure.
- This approach should only be used if the participant is finding the items in that questionnaire particularly challenging.

How to complete the CRFs

All the CRFs have been formatted using Teleform to enable completed CRFs to be electronically scanned. In order for the CRFs to be scanned you will need to complete them using the guidelines provided; if the guidelines are not followed then the CRFs will not be scanned properly. This will trigger a data query and you will need to provide the requested information. When completing CRFs:

- Please use blue or black ink only.
- For each response provided, you must place a ☒ in the box to ensure that it is processed correctly.

- You must **NOT** tick or circle the answer box.
- If the person with dementia/carer changes his/her mind to a response already provided, or you have placed a ☒ in the incorrect box, simply **fill in** the correct box ■ and place a ☒ in the correct box. You should **draw a line** through the incorrectly selected box and then **initial and date** the box to make it clear that this response should be ignored. This is important as without this clarification we may not be able to use the data. **There have been a number of instances where researchers have not blacked out the box and drawn a line through the box at T1. It is essential that this procedure is followed as we have had to lose data at T1 where it is not clear which of the two responses is the correct one to include.**
- Most questions only require **one** answer to be selected. Please check that you have not selected more than one response.
- Please also be aware that some questions will have the option of completing more than one response (these instructions will be provided in Instructions for researchers in the CRFs).
- Based on the participant's responses to a previous question, some questions can be skipped. Please look out for these types of questions and **do not** administer them if they can be skipped.
- For some questions you will be asked to write information in boxes. When you see boxes like these, please write a single letter or number in each box provided. For example: what is your age?

6	5

- If you make a mistake or if the participant changes his/her mind you **must not** overwrite the new information in a box that already has information inside it. The correct information may be obvious to you, but there is no way for us to know what is the correct information; for example in the 'what is your age?' box above if you try to overwrite the 5 with a 6 there is no way for us to know whether the correct answer is 65 or 66. In this instance you must completely cross out the box and write the correct information as close to the box as possible.
- For some questions you will need to write the participant's response; please ensure that your handwriting is legible. If we cannot process the CRF because we cannot understand your handwriting then we will contact you and ask you to clarify what you have written.
- **[MMSE information removed]** Where the participant has to write a sentence in the ACE-III and you cannot read what the participant has written, please ask for clarification and write this clarification beneath the sentence that the participant has written. Do not cross out the original text that the participant has written.
- Do not make any notes on the CRFs as this will affect the scanning of the CRF. If you need to make any notes either use the field note section at the back of the CRF.

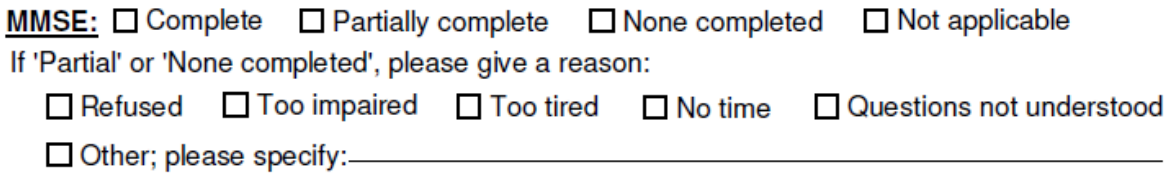
- Please ensure that all the sheets in the CRFs are kept in good condition. If the CRFs are creased, bent, ripped, stapled, stained, hole-punched etc. then the scanner may be unable to process some or all of the responses.
- Please remember that if you do not complete all of CRF 1 in the first visit you must start the second visit by completing the items not completed in CRF 1. You should not start CRF 2 until all items in CRF 1 have been completed.
- If the participant finds certain questions difficult to answer, you should be prepared to give additional prompts or assistance if required. **Further prompting is preferable to having missing data.** This prompting can take many forms, for instance you could give additional examples of situations relevant to the question, or you could limit the possible answers to either the positive or negative responses on the Showcard based on what the participant says or how she/he says something (e.g. his/her intonation).

8.5.1. Completing the CRF checklist

Each CRF contains a checklist which must be completed before CRFs are returned. It is essential that you complete the checklist since it is the only way for us to know the reasons for missing data in the CRFs. It is very important that you provide accurate information in the checklist.

The checklist is the only place where reasons for missing data should be recorded. Please do not record reasons for missing data in the field notes.

For T2 the checklist has changed slightly from that included at T1:



Specific guidance

You should only cross “Complete” if **all** questions in the corresponding section have been completed. Even if there is just one item that was not completed, you should not cross the “Complete” box. Instead, you should cross the “Partially complete” box and explain the reason for the missing item with one of the subsequent options, either “Refused”, “Too impaired”, “Too tired” or “Questions not understood”.

The “No time” box should only be used once you have completed the two visits and it should only be used for sections that were not completed in the two visits. Therefore, if you complete all items in CRF 1 and most items in CRF 2, the “No time” box should not be used in CRF 1 at all, and it should only be used for the remaining uncompleted sections of CRF 2.

If there was no time to complete a section or sections please do not forget to cross the "None completed" box in the applicable sections.

Due to the way that the CRFs have been designed, some sections may not be applicable; in this instance you should put a cross in the "Not applicable" box. For example, when a participant has a relative/friend taking part in the study, each checklist in Section C of Participant Time 2 CRF Part 2 should have the "Not applicable" box crossed.

8.5.2. Field notes

At the end of the CRFs 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 as 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 **[MMSE information removed]** during the 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 two CRFs; for example the participant may have been unwell for four weeks leading to 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.

When not to use the Field notes

The field notes section **should not** be used to record reasons for missing data. You may choose to write in the field notes the reasons for missing data as you are going through the CRF with the participant. However, once you have completed the visit you should copy the relevant information from the field notes into the checklist section and cross out any notes about missing data that you made in the field notes before returning the CRFs.

The checklist is the only place where reasons for missing data should be recorded.

Unlike T1, please do not include your reasons for giving a certain score for the GDS or the FAST in the field notes; you must instead record your reasons using the specific sections that have been included into the CRFs after each scale.

8.5.3. People with moderate or severe dementia: minimal data items

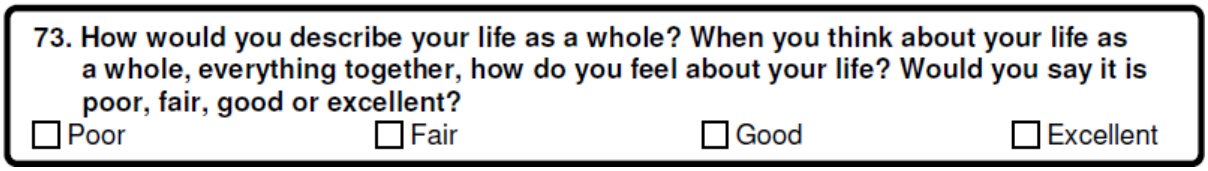
At T2 we anticipate that most of the participants will have declined in some areas. The CRFs have been shortened to allow their full completion in the timeframe. Some participants may

have declined more than others, for example those who entered the study at T1 with an MMSE score of 15 may now be in the more severe stages of dementia. People in the more severe stage of dementia may have very severe memory loss and difficulty communicating.

To help you we have now included showcards for many of the individual questionnaires in the study. This should make it easier for people with poor hearing to understand what you are asking them to do as well as help limit the number of times that you will be asked to repeat the possible responses.

We have also included specific guidance or instructions in the CRFs when participants may find the questionnaires difficult to answer.

It should be noted that there is a specific cut-off for the MMSE for when the TSI should be administered. There is however, no specific cut-off for when the guidance for people with severe dementia should be used. People at a more severe level of impairment may still be able to complete the CRFs in full and we encourage you to attempt to complete all questions with all participants irrespective of level of dementia severity. However, for situations where this is not possible and the participant is having difficulty completing the questions in a given section, we have identified specific items that must be completed at a minimum. These questions are now highlighted by having a box around them. For example:



This box indicates that if the participant is finding completing the question in that section difficult this single item must be completed at a minimum. We advise that all questions should be asked, but if after additional prompting the participant is still finding it very difficult to give an answer then we accept that there will be missing data. You must however persevere with the items inside the boxes as this information is essential for the study.

In some instances we have adapted the questionnaire. For the "Everyday activities" section we have kept the original response items but we have included an alternative no/yes response as well:

112. Can you write cheques, pay bills, and keep financial records?

☐ Dependent on others

☐ Require assistance but can still do the task

☐ Have difficulty but do by self

☐ Never did, and would have difficulty now

☐ Normal (as you have always done)

☐ Never did, but could do now ☐ No ☐ Yes

It is important to note that:

1) You must use the same response key for the whole of the section; i.e. if the participant is unable to use the usual responses in the first question and is only able to say yes or no to the question, after extensive prompting from yourself, then you must only use the no/yes responses for the rest of this set of questions. Similarly, if the participant is able to use the usual response for the first question then she/he must also be able to use the same responses for the remainder of the given set of questions.
2) If the participant is finding the questions difficult to answer then please prompt them. There are a number of different prompts that are available to you. For example, you may rephrase the question so that it is more easily understood. You may reduce the number of responses based on what the participant says, for instance if the participant says that she/he can do the task you could say "can you do that task as well as you always have or do you have a bit of difficult now, but that you can still do it?". You may infer what the participant wants to indicate based on how she/he gives his/her response, for instance, the participant may say yes, but the intonation suggests to you that the participant is really saying "sort of" rather than a definite "yes!". In this instance, you could ask the participant to clarify whether she/he "Has difficulty, but does by him/herself" or "Never did, and would have difficulty now".

Below are three examples of everyday activity questions completed by researchers. The first two examples are completed correctly while the third example is completed incorrectly.

In this example, the participant was able to use the usual responses for all questions:

112. Can you write cheques, pay bills, and keep financial records?

- [x] Dependent on others
- [ ] Require assistance but can still do the task
- [ ] Have difficulty but do by self
- [ ] Never did, and would have difficulty now
- [ ] Normal (as you have always done)
- [ ] Never did, but could do now

[ ] No [ ] Yes

113. Can you assemble tax records, make out business or insurance papers?

- [ ] Dependent on others
- [ ] Require assistance but can still do the task
- [ ] Have difficulty but do by self
- [ ] Never did, and would have difficulty now
- [x] Normal (as you have always done)
- [ ] Never did, but could do now

[ ] No [ ] Yes

In this example, the participant is unable to use the usual responses but was able to say yes or no to all the questions:

112. Can you write cheques, pay bills, and keep financial records?

- [ ] Dependent on others
- [ ] Require assistance but can still do the task
- [ ] Have difficulty but do by self
- [ ] Never did, and would have difficulty now
- [ ] Normal (as you have always done)
- [ ] Never did, but could do now

[ ] No [x] Yes

113. Can you assemble tax records, make out business or insurance papers?

- [ ] Dependent on others
- [ ] Require assistance but can still do the task
- [ ] Have difficulty but do by self
- [ ] Never did, and would have difficulty now
- [ ] Normal (as you have always done)
- [ ] Never did, but could do now

[x] No [ ] Yes

This is an example of what is **not permitted**, the participant answered the first question using the usual responses but in the second question the researcher did not prompt the participant and instead the researcher recorded "no". Since the participant said "no" the researcher could have said something like, "okay, so you say you can't do this task, would you say that others have to do the task for you or can you still do it but you need help from someone else?" If the participant says that she/he needs help you would cross the "Requires assistance" box, if the participant says that she/he is unable to do the task at all then you would cross the "Dependent on others" box.

112. Can you write cheques, pay bills, and keep financial records?

☐ Dependent on others
☐ Require assistance but can still do the task
☒ Have difficulty but do by self
☐ Never did, and would have difficulty now
☐ Normal (as you have always done)
☐ Never did, but could do now ☐ No ☐ Yes

113. Can you assemble tax records, make out business or insurance papers?

☐ Dependent on others
☐ Require assistance but can still do the task
☐ Have difficulty but do by self
☐ Never did, and would have difficulty now
☐ Normal (as you have always done)
☐ Never did, but could do now ☐ No ☒ Yes

8.5.4. Troubleshooting: issues that may arise with CRF completion

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. You must not start CRF 2 until you have completed all the items in CRF 1. 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 second 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. Please provide this date in the field notes.

2. ***The person with dementia completes all of the questions in CRF 1 with time to spare:*** Some participants may be able to complete CRF 1 well within the allocated time. If the participant is willing you should be prepared to start CRF 2 during the first visit. If this situation occurs you should administer the questions in CRF 2. You must not administer the TSI or ACE-III in the same visit as the MMSE; therefore, the ACE-III or TSI, if applicable, must be administered during the second assessment visit. It is particularly important that the date and day of the week boxes at the start of CRF 2 are completed on the day that you administer the ACE-III or TSI. Please make sure that there are no missing items in CRF 1 before administering CRF 2.
3. ***Completing missing items at the end of the visit:*** If the participant was unable to answer a question or questions during the visit, you must go back to the missing question or questions and see whether the participant is willing to answer that question/those questions. You must do this at the end of the visit with the participant. If the participant is still unable/unwilling to answer the question you should record the reason in the checklist.

8.6. Specific guidance on the completion of measures

This section provides additional guidance on the administration and completion of some of the measures in the CRFs.

8.6.1. MMSE

The MMSE is located in the *Participant Time 2 CRF Part 1.* Please use the guidance below to help you learn how to administer and score it if you are unfamiliar with it. If you are already familiar with the MMSE, please use this section to refresh your knowledge. It is important that everyone completes the measure consistently in the same way. Although the MMSE is unchanged from T1, please read through the guidance, as we have provided a number of clarifications based on the data that we have received from researchers.

Guidance on the administration and scoring of the MMSE

[MMSE information removed]

[MMSE information removed]

8. Case Report Forms

[MMSE information removed]

8.6.2. Test for Severe Impairment

The TSI is a cognitive screening tool for people with more advanced dementia. It consists of five subscales: Motor Performance, Language, Memory, General Knowledge, and Conceptualization. The TSI has been designed to minimise the need for participants to utilize language skills, since severely impaired participants generally have minimal verbal skills remaining. Indeed, except for the language subsection, correct responses require no verbal output by the participant, with pointing, gesturing or manipulating objects sufficient for a correct score. The TSI was designed to last no longer than 10 minutes.

The TSI is located at the front of the Participant Time 2 CRF Part 2. The version of the TSI that will be administered to the participants has been formatted using Teleform to make it suitable for scanning.

Guidance on the administration and scoring of the TSI

The TSI should only be administered to participants who scored between 0 and 9 on the MMSE during Participant Time 2 CRF Part 1. Score 1 point for each correct response (maximum for the measure is 24). The TSI subscale scores are summed to produce an overall total score. Try to score the person's responses discreetly. If the person refuses to answer any question or the person is unable to answer the question, score his/her response as '0'. For many of the questions it will be obvious as to whether or not the participant has given a correct or incorrect response.

If the participant does not hear a question or is distracted, you may repeat the question up to **three times** in order to engage his/her attention. If the participant requires the question to be repeated for a fourth time you should instead score this as 0 and move onto the next question of the test. Please note that this does not mean that participants have three attempts to do the task correctly; they have only one attempt at doing the task.

The TSI makes use of everyday objects, and we have therefore provided each researcher with a TSI assessment pack that contains:

- 1 comb
- 20 sheets of A4 paper (1 page required per assessment)
- 2 red pens
- 1 green pen
- 1 blue pen
- 1 key
- 2 large paperclips
- 1 spool of thread

The contents of this pack are for you to use when you administer the TSI to IDEAL participants with an MMSE of less than 10. It is your responsibility to ensure that all items

are in the pack after you receive it. If any items are lost during your assessment visits it is up to you to replace them.

Starting the TSI:

Motor Performance Part 1

The TSI begins as you meet the participant and there are instructions on the front page of the CRF booklet that you must follow:

Instructions for the researcher: If the participant scored less then 10 on the MMSE as part of the Time 2 Part 1 assessment you should greet the participant by saying:

"**Thank you for spending time with me**" and extend your hand to shake hands.

You should note the participant's response in the Motor Performance Part 1 space on the next page.

For this test if the participant correctly shakes your hand she/he should be awarded 1 point. Not shaking your hand or doing anything else will be scored as 0.

Motor Performance Part 1 **Score out of 1:** ☐ 0 ☐ 1

Thank you for spending time with me. Extend hand to shake hands. (You should score this from when you meet the participant at the start of the visit, as described on the front cover page).

0 ☐

Correctly shakes hand 1 ☐

Motor Performance Part 2

For **Motor Performance Part 2** you will need some equipment. In this subsection you will need to use the **comb**, **pen and top** (any colour), **pen** and **paper**.

Motor Performance Part 2 **Score out of 3:** ☐ 0 ☐ 1 ☐ 2 ☐ 3

Use: Comb

Hand the participant the comb. **Show me how you would use this comb.** 0 ☐

Correctly demonstrates combing 1 ☐

Use: Pen and Top

Remove the top from the pen in full view of the participant. Hand the pen and top to the participant.

Can you put the top on the pen? 0 ☐

Correctly puts top on pen (not on bottom of pen) 1 ☐

Use: Pen and Paper

Hand the participant the pen (without the top) and place a piece of paper on a table/clipboard in front of him/her. **Write your name.** 0 ☐

Writes name correctly (first or last name legible) 1 ☐

Instructions for the researcher: The separate sheet of paper in which the participant wrote his/her name **should not** be returned with this CRF since it contains personal information. The researcher should dispose of it securely, or leave it behind in the home of the participant.

For the **comb** test if the participant correctly uses the comb she/he should be awarded 1 point. It is enough to merely demonstrate the action of using the comb, it is not necessary for the participant to actually run the comb through his/her hair to score the 1 point.

Doing anything other than appropriately demonstrating using a comb will be scored as 0.

For the **pen** and **top** test if the participant correctly puts the top back on the pen she/he should be awarded 1 point. The top must be placed over the ballpoint of the pen to score the 1 point. If the participant puts the pen top on the bottom of the pen with the ballpoint still exposed or if she/he does anything else this will be scored as 0.

For the **pen** and **paper** test the participant must write his/her name on the paper. To score the 1 point the participant can write just his/her first name, last name or his/her name in full. To score 1 point his/her name must be legible to you. If the participant does anything other than writing his/her name legibly this will be scored as 0.

It is important that you do no not include the piece of paper with the name written on it with the CRF since this contains personally identifying information. You must either destroy the paper securely or leave it behind in the home of the participant.

Language Comprehension

For **Language Comprehension** you will need some equipment. In this subsection you will need three pens: one **red**, one **blue** and one **green** pen.

Language-Comprehension	**Score out of 4:** ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Point to your ear	0 ☐
	Correctly points to his/her ear 1 ☐
Close your eyes	0 ☐
	Correctly closes his/her ear 1 ☐
Use: Three pens: Red, Blue, Green Place the three pens on the table spread out so that they have some space between them. **Show me the red pen.**	0 ☐
	Correctly points to red pen 1 ☐
Show me the green pen	0 ☐
	Correctly points to green pen 1 ☐

For the **point to your ear** test if the participant correctly point to his/her ear she/he should be awarded 1 point. Doing anything else, including pointing to the researcher's ear, will be scored as 0.

For the **close your eyes** test if the participant correctly closes his/her eyes she/he should be awarded 1 point. Doing anything else will be scored as 0.

For the next two parts of this subsection you will require 3 pens; 1 red pen, 1 green pen and 1 blue pen. You must have use of a desk or other flat surface for this test.

For the **red pen** test you should spread the pens out so that there is a good distance (around 10 centimetres) between each pen. The pens can be placed in any order of colour. Once this has been done you must ask the participant to show you the red pen. If the participant correctly points to the red pen she/he should be awarded 1 point. Pointing to any of the other pens on the desk or doing anything else will be scored as 0.

For the **green pen** test the pens should still be spread out. If the participant picked up the red pen during the previous task it must be put back down in its original position before commencing the green pen task. When the pens are in the same position as in the red pen task you must ask the participant to show you the green pen. If the participant correctly points to the green pen she/he should be awarded 1 point. Pointing to any of the other pens on the desk or doing anything else will be scored as 0.

Language Production

For **Language Production** you will need some equipment. In this subsection you will need two pens: one **red** and one **green** pen. You will also need a key; we have provided you with a key.

Language-Production	Score out of 4: ☐0 ☐1 ☐2 ☐3 ☐4
Point to your nose. **What is this called?**	0 ☐
	Correctly names nose 1 ☐
Use: Two pens: Red, Green Hold up a **red** pen in front of the participant. **What colour is this pen?**	0 ☐
	Correctly names red 1 ☐
Hold up a **green** pen in front of the participant. **What colour is this pen?**	0 ☐
	Correctly names green 1 ☐
Use: Key Show the participant the key. **What is this called?**	0 ☐
	Correctly names key 1 ☐

For the **identifying a nose** test you must point to your nose and ask the participant to name it. If the participant says nose she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

For the **red pen** test you should hold the red pen up so that the participant can see it. If the participant correctly says that the colour of the pen is red she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

For the **green pen** test you should hold the green pen up so that the participant can see it. If the participant correctly says that the colour of the pen is green she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

For the **key** test you should hold the key up so that the participant can see it. If the participant correctly says that the object is a key she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

Memory: Immediate

For **Memory: Immediate** you will need some equipment. In this subsection you will need one **large paperclip**; we have provided you with a large paperclip.

Memory-Immediate **Score out of 3:** ☐ 0 ☐ 1 ☐ 2 ☐ 3

Use: One large paperclip

Watch carefully. Place paper clip in your hand so that the participant can see it. Hold both of your hands out to the participant.
With hands open. **Which hand is the clip in?** 0 ☐

Correctly points to clip 1 ☐

With hands closed. **Which hand is the clip in?** 0 ☐

Correctly points to hand with clip 1 ☐

Watch carefully. Move hands behind back. **Which hand/side is the clip in/on?** 0 ☐

Correctly points to hand with clip 1 ☐

For this section of the test you will be manipulating a paperclip with your hands. It is recommended that you do not score this subsection of the test until completing all three parts.

For the **first part** of this test you will put the paperclip in one of your hands. Both hands must be open so that the participant can see in which hand the paperclip is in. Ask the participant to point or say in which hand the paperclip is in. If the participant correctly points to or says in which hand the paperclip is in she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

The **second part** of this test should be administered as soon as the participant completes the first part. The paperclip should still be in the same hand as in the first part of the subsection. All you do in this part of the test is close your hands. Ask the participant to point or say in which hand the paperclip is in. If the participant points to or says in which hand the paperclip is in she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

The **third part** of this test should be administered as soon as participant completes the second part. The paperclip should still be in the same hand as in the second part of the

subsection. All you do in this part of the test is to move both of your hands behind your back. Ask the participant to point or say in which hand/side the paperclip is in. If the participant points to or says in which hand/side the paperclip is in she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

General Knowledge

For this section of the test you will be asking some general knowledge questions.

General Knowledge	Score out of 4: ☐0 ☐1 ☐2 ☐3 ☐4
How many ears do I have?	0 ☐
	Correctly states two 1 ☐
Place hands in front of the participant with fingers pointing up, palms toward the participant. **Count my fingers and thumbs.** Give credit even if no one to one correspondence between fingers and numbers. If the participant only gives the final answer of ten, ask, **Can you count to 10 starting at 1?**	0 ☐
	Correctly counts to 10 1 ☐
How many weeks are there in a year?	0 ☐
	Correctly states 52 1 ☐
I'm going to sing a song. If you know the words, I want you to sing along with me. Softly sing "Happy Birthday".	0 ☐
	Sings most of the words 1 ☐

For the **number of ears** test you will ask the participant to tell you how many ears you have. If the participant says two she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

For the **finger and thumbs** test you will hold out your hands with palms facing the participant with your fingers and thumbs pointing upwards. You will then ask the participant to count the number of fingers and thumbs that you have. If the participant says ten without counting your fingers and thumbs you should instead ask the participant to count from 1 to 10. If the participant counts from 1 to 10 she/he should be awarded 1 point. 1 point would be awarded even if the participant counts to 9 on one of your hands and to 10 on the other hand; the important part of this test is that the participant counts from 1 to 10 correctly with no missing numbers. Doing or saying anything else will be scored as 0.

For the **number of weeks** test you will ask the participant to tell you how many weeks there are in a year. If the participant says 52 she/he should be awarded 1 point. Doing or saying anything else will be scored as 0.

For the **singing happy birthday** test you should say "**I'm going to sing a song. If you know the words, I want you to sing along with me**." This test may require some encouragement from you since some people may be reluctant to sing the words. If the participant correctly

sings most of the words to "happy birthday" she/he should be awarded 1 point. Doing, saying or singing anything else will be scored as 0.

Conceptualization

For **Conceptualization** you will need some equipment. In this subsection you will need **two large paperclips** and two pens, one **red pen** and one **green pen**.

Conceptualization	Score out of 4: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4
Use: Two large paperclips, one pen	
Spread objects on the table. **Which one of these is different from the other two?**	0 ☐
Correctly points to pen or states pen	1 ☐
Use: Two red pens, one green pen	
Place 1 red and 1 green pen spread out on the table. Hand the participant the other red pen. **Put this next to the pen that is the same colour.**	0 ☐
Correctly places the red pen next to the other red pen	1 ☐
Use: One large paperclip	
Place hands out in front of the participant. **Watch me move the paperclip**. Alternate the paperclip between your open hands 4 times. **Which hand will I put the paperclip in next?**	0 ☐
Correctly points to correct hand	1 ☐
After the participant responds, place clip in the correct hand. (If the participant is incorrect say **I'd put the clip in this hand**). Then say, **Which hand will I put the clip in next?**	0 ☐
Correctly points to correct hand	1 ☐

For the **two large paperclips, one pen part** of this test you must have use of a desk or other flat surface. You should spread the pen and paperclips out so that there is a good distance (around 10 centimetres) between each object. The objects can be placed in any order. Once this has been done you must ask the participant to point or say which object is different from the others. If the participant correctly points to the pen she/he should be awarded 1 point. Pointing to any of the other paperclips or doing anything else will be scored as 0.

For the **two red pens, one green pen** test you must have use of a desk or other flat surface. You should place one of the red pens and the green pen a good distance apart (around 10 centimetres). The pens can be placed in any order. Once this has been done you should give the participant the other red pen and ask him/her to "**put this next to the pen that is the same colour"**. If the participant correctly places the red pens together she/he should be awarded 1 point. Placing the red pen next to the green pen or doing anything else will be scored as 0.

For the final two parts of this section of the test you will be manipulating a paperclip with your hands. It is recommended that you do not score these two parts of the test until completing both parts.

For the **first part** of this test you will put the paperclip in one of your hands. Both hands must be open so that the participant can see in which hand the paperclip is in. You should say to the participant "**watch me move the paperclip**". You should then move the paperclip from one hand to the other hand four times. The paperclip should be visible to the participant at all times. After the fourth time you should ask the participant to point or say in which hand you will put the paperclip next. If the participant correctly points to or says in which hand the paperclip will be in next s/he should be awarded 1 point. If the participant points to or says in which hand the paperclip is currently in she/he should be awarded 0 points. Doing or saying anything else will be scored as 0.

The **second part** of this test should be administered as soon as the participant completes the first part. If the participant correctly states the hand the paperclip will be in, next move the paperclip to that hand. If the participant was incorrect say "**I'd put the clip in this hand**" and then move the paperclip to the other hand. After moving the paperclip to the other hand you should ask the participant "**Which hand will I put the clip in next?"** If the participant correctly points to or says in which hand the paperclip will be in next she/he should be awarded 1 point. If the participant points to or says in which hand the paperclip is currently in she/he should be awarded 0 points. Doing or saying anything else will be scored as 0.

Memory-Delayed

For **Memory-Delayed** you will need some equipment. In this subsection you will need some **thread**, a **key** and a **paperclip**; we have provided you with a spool of thread.

Memory-Delayed	Score out of 1: ☐ 0 ☐ 1
Use: Thread, key, paperclip	
Place objects spread out on the table. **Which one of these haven't we done something with while you were here with me?**	0 ☐
	Correctly points to thread 1 ☐

For the **thread, key, paperclip** test you must have use of a table or other flat surface. Spread the spool of thread, the key and the paperclip out so that there is a good distance (around 10 centimetres) between each object. The objects can be placed in any order. Once this has been done you must ask the participant to point or say which object has not been used previously in the test. If the participant correctly points to the spool of thread she/he should be awarded 1 point. Pointing to any of the other objects or doing anything else will be scored as 0.

You should then total the scores for each section and write the total score in the box provided. Skip the ACE-III section and start to administer the following questions to the participant. At the end do not forget to put a cross in the "not applicable" box in the ACE-III section in the checklist.

8.6.3. ACE-III

The ACE-III is a cognitive screening tool that consists of five subscales: Attention, Language, Fluency, Memory and Visuospatial; each subscale represents a cognitive domain. The ACE-III subscale scores are summed to produce an overall total score (maximum 100 points). The ACE-III is located in the *Participant Time 2 CRF Part 2*.

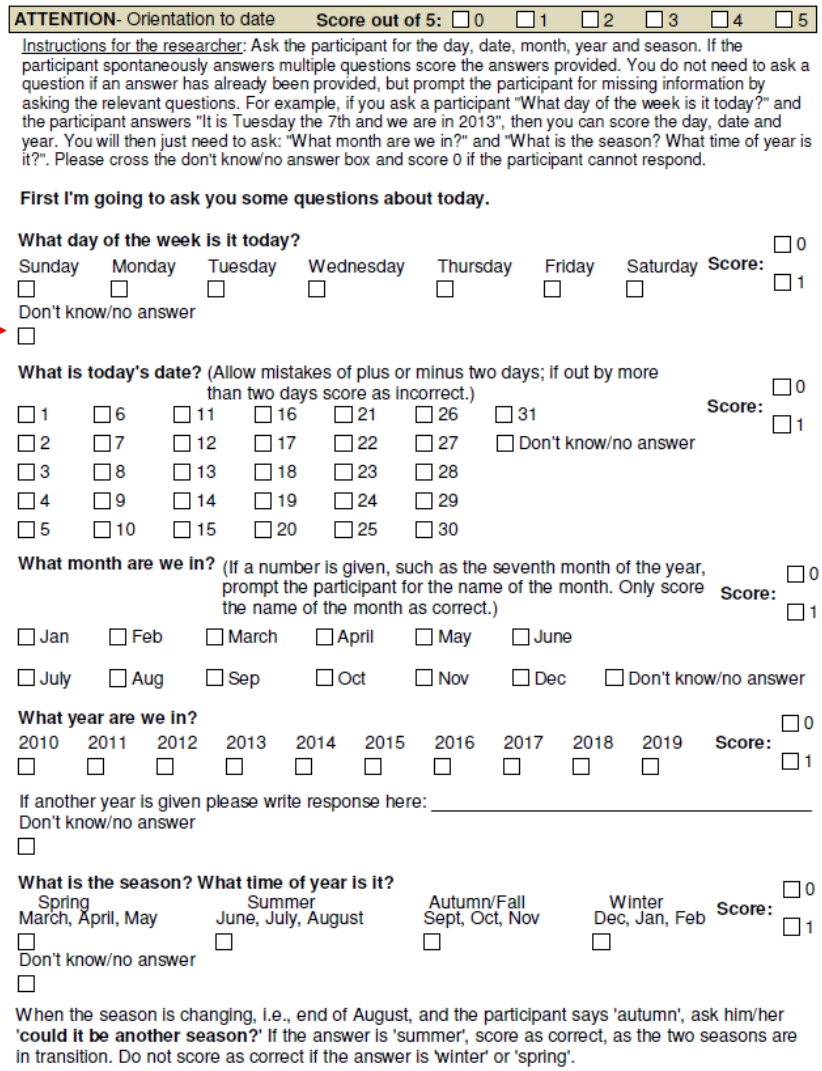
There have been a number of small changes to the ACE-III since T1. The following will highlight the changes and also provide some scoring or administration hints for commonly seen issues that occurred in the T1 assessment. One important change to note is that the ACE-III at T2 should only be administered to participants if they scored 10 or more on the MMSE.

Guidance on the administration and scoring of the ACE-III

ATTENTION- Orientation to date

Remember to total the sections

Allow mistakes of ± 2 days



ATTENTION- Orientation to date **Score out of 5:** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5

Instructions for the researcher: Ask the participant for the day, date, month, year and season. If the participant spontaneously answers multiple questions score the answers provided. You do not need to ask a question if an answer has already been provided, but prompt the participant for missing information by asking the relevant questions. For example, if you ask a participant "What day of the week is it today?" and the participant answers "It is Tuesday the 7th and we are in 2013", then you can score the day, date and year. You will then just need to ask: "What month are we in?" and "What is the season? What time of year is it?". Please cross the don't know/no answer box and score 0 if the participant cannot respond.

First I'm going to ask you some questions about today.

What day of the week is it today?
Sunday ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday ☐ Saturday ☐ **Score:** ☐0 ☐1
Don't know/no answer ☐

What is today's date? (Allow mistakes of plus or minus two days; if out by more than two days score as incorrect.) **Score:** ☐0 ☐1
☐1 ☐6 ☐11 ☐16 ☐21 ☐26 ☐31
☐2 ☐7 ☐12 ☐17 ☐22 ☐27 ☐Don't know/no answer
☐3 ☐8 ☐13 ☐18 ☐23 ☐28
☐4 ☐9 ☐14 ☐19 ☐24 ☐29
☐5 ☐10 ☐15 ☐20 ☐25 ☐30

What month are we in? (If a number is given, such as the seventh month of the year, prompt the participant for the name of the month. Only score the name of the month as correct.) **Score:** ☐0 ☐1
☐Jan ☐Feb ☐March ☐April ☐May ☐June
☐July ☐Aug ☐Sep ☐Oct ☐Nov ☐Dec ☐Don't know/no answer

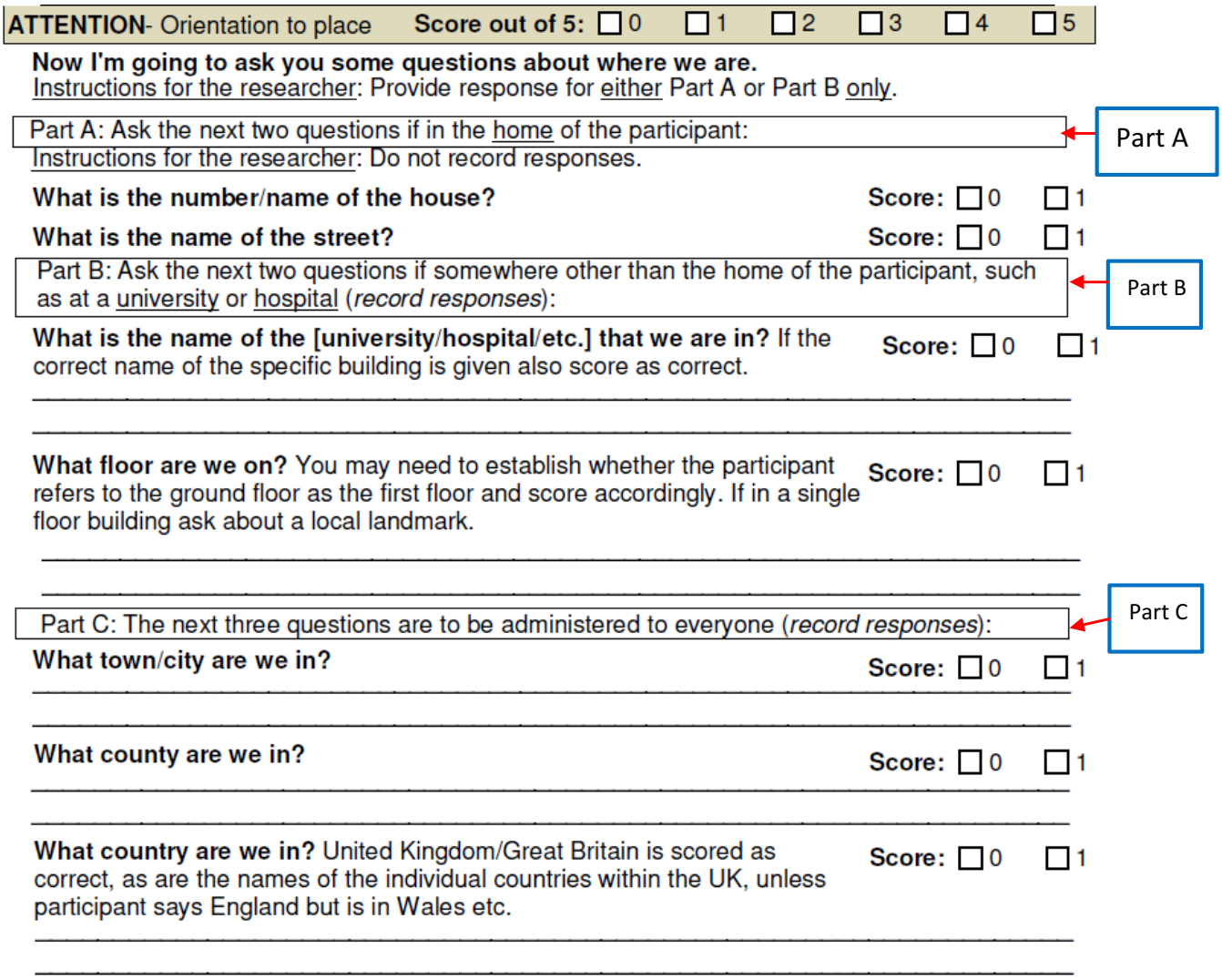
What year are we in? **Score:** ☐0 ☐1
2010 ☐ 2011 ☐ 2012 ☐ 2013 ☐ 2014 ☐ 2015 ☐ 2016 ☐ 2017 ☐ 2018 ☐ 2019 ☐
If another year is given please write response here: _____
Don't know/no answer ☐

What is the season? What time of year is it? **Score:** ☐0 ☐1
Spring March, April, May ☐ Summer June, July, August ☐ Autumn/Fall Sept, Oct, Nov ☐ Winter Dec, Jan, Feb ☐
Don't know/no answer ☐

When the season is changing, i.e., end of August, and the participant says 'autumn', ask him/her '**could it be another season?**' If the answer is 'summer', score as correct, as the two seasons are in transition. Do not score as correct if the answer is 'winter' or 'spring'.

For T2 we have added a **"don't know/no answer"** box to each of the orientation to date items. Please use this if the participant is unable to provide or does not give an answer.

ATTENTION- Orientation to place



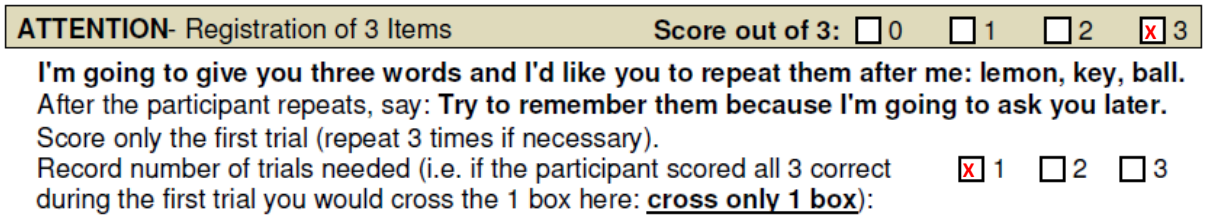
For T2 we have split the orientation to place items into different sections. A number of researchers at T1 were asking questions that they should not have been asking. For instance, the participants were assessed at home yet participants were asked what floor they were on. To clarify, researchers should ask the participant to answer **either** Part A **or** Part B depending on testing location. All participants should be administered Part C. Please note that there are no lines for researchers to write any information for Part A; please do not write the address of the participant as this is personally identifiable information.

ATTENTION- Registration of 3 Items

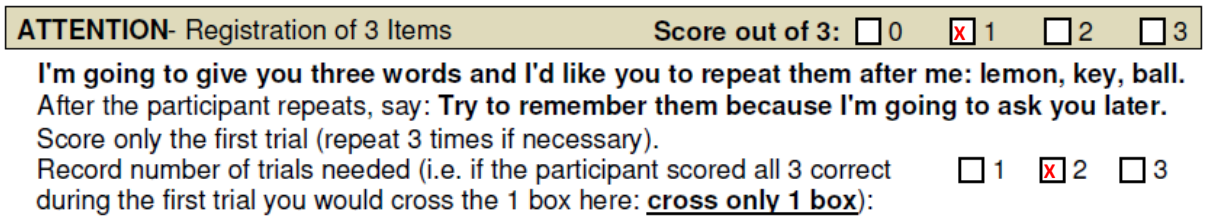
The scoring of this part of the test has proven to be quite problematic for researchers. For T2 we have expanded the instructions concerning recording the number of trials that the participant takes to complete the task successfully.

Below are some examples of possible scores with illustrations of how the CRF should look.

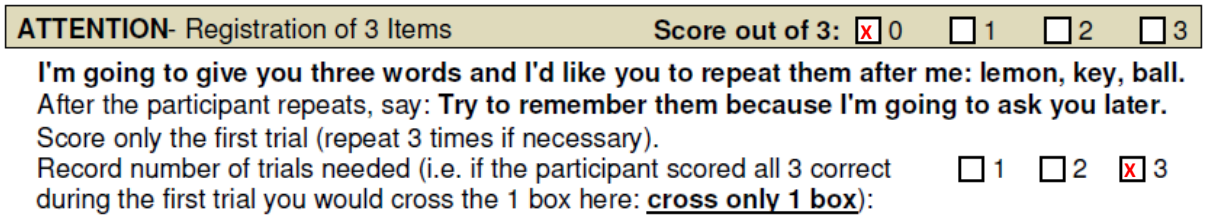
1) A participant has correctly said all three words during the first trial. You would put a cross in the 3 box to indicate that the participant said all 3 words correctly. This person would score 3 out of 3 for this task. As the participant needed one trial to successfully say all 3 words so you would put a cross in the 1 box:



2) A participant has correctly said all three words but took 2 trials. During the first trial the participant said one correct word. You would put a cross in the 1 box to indicate that the participant said 1 word in the first trial. This person would score 1 out of 3 for this task. The participant needed 2 trials to successfully say all 3 words so you would put a cross in the 2 box:



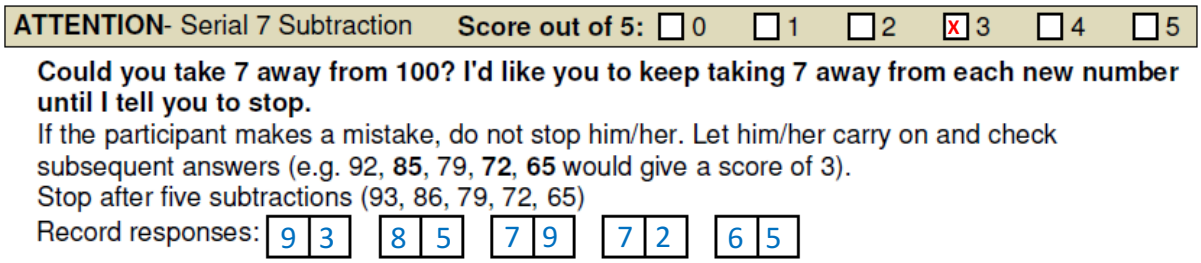
3) A participant has correctly said two words in the 3 trials that are allowed for this task. During the first trial the participant said no correct words. You would put a cross in the 0 box to indicate that the participant said no correct words during the first trial. This person would score 0 out of 3 for this task. As the participant used all 3 allowable trials for this task you would put a cross in the 3 box:



As a final note, it is impossible for a participant to both score 3 out of 3 on this task and need more than one trial.

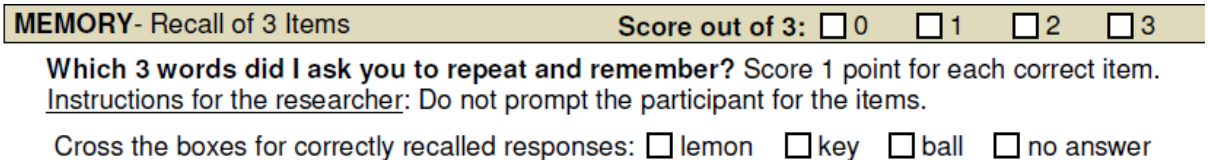
ATTENTION- Serial 7 Subtraction

For the Serial 7s task an answer is correct if it is exactly 7 less than the previous answer so in the example below **93**, 85, 79, **72**, **65** three are correct:



If the participant is unable to complete the task or abandons his/her attempt please leave the remaining boxes blank.

MEMORY- Recall of 3 Items



For T2 we have added a "don't know/no answer" box to this question. Please use this if the participant is unable to provide or does not give an answer.

Verbal Fluency - Letter Fluency

We have added more scoring guidance into the CRF for you at T2, particularly regarding how to convert raw scores into converted scores.

We have added the letter P into the first box to remind researchers that only words beginning with the letter P are to be scored as correct. If the participant starts the test with letters other than P you should stop the test, remind the participant that the letter is P and then start the test again. She/he may have simply misheard the letter. However, if they change letter part way through the test you should not correct them. Words that begin with any letter other P should not be scored as correct.

Please make sure that your handwriting is legible; all words that you record the participant as saying are being entered into a database so it is important that we are able to read them correctly. Please make sure that you transcribe the words clearly; if this impossible during the test then please re-write the words more clearly later on.

VERBAL FLUENCY Score out of 14: ☐0 ☐1 ☐2 ☐3 ☐4 ☒5 ☐6 ☐7 ☐8 ☐9 ☐10 ☐11 ☐12 ☐13 ☐14

I'm going to give you a letter of the alphabet and I'd like you to generate as many words as you can beginning with that letter, but not names of people or places. For example, if I give you the letter "C", you could give me words like "cat, cry, clock" and so on. But, you can't give me words like "Catherine" or "Canada". Do you understand?
Are you ready? You have one minute. The letter I want you to use is the letter "P".

0-15 seconds	16-30 seconds	31-45 seconds	46-60 seconds
P			
petal	post		
pancake	powder		
powder			
Paul			
point			
0 4	0 1	0 0	0 0

Incorrect response circled

Total number of correct words

Count the total number of correct words, which do not include: (1) repetitions, (2) perseverations (e.g., pay, paid, pays, if all 3 are given, score 1), (3) intrusions (i.e., words beginning with other letters), (4) proper names (i.e., names of people or places. For guidance, words often have more than one meaning i.e. peter can be the name of a person or it could also mean to get smaller and smaller, to peter out. Only score proper names as incorrect if they are unambiguous, for example if a participant says Peter along with other proper names such as Peter, Paul, Brian, or if the participant says 'Peter, as in the boys' name') and (5) plurals (e.g., pot, pots, if both are given, score 1).

To help us, please circle all the words that the participant says which are incorrect.

Use the table to obtain the final score for this test. i.e. if a participant says 14 words you would write 14 in the "total responses" box, if only 10 were correct you would write 10 in the "correct responses" box. You would cross the 8-10 box in the first column and the "4" box in the second column.

☐ >=18	☐ 7
☐ 14-17	☐ 6
☐ 11-13	☐ 5
☐ 8-10	☐ 4
☐ 6-7	☐ 3
☒ 4-5	☒ 2
☐ 2-3	☐ 1
☐ 0-1	☐ 0
Total responses: 0 7	Correct responses: 0 5

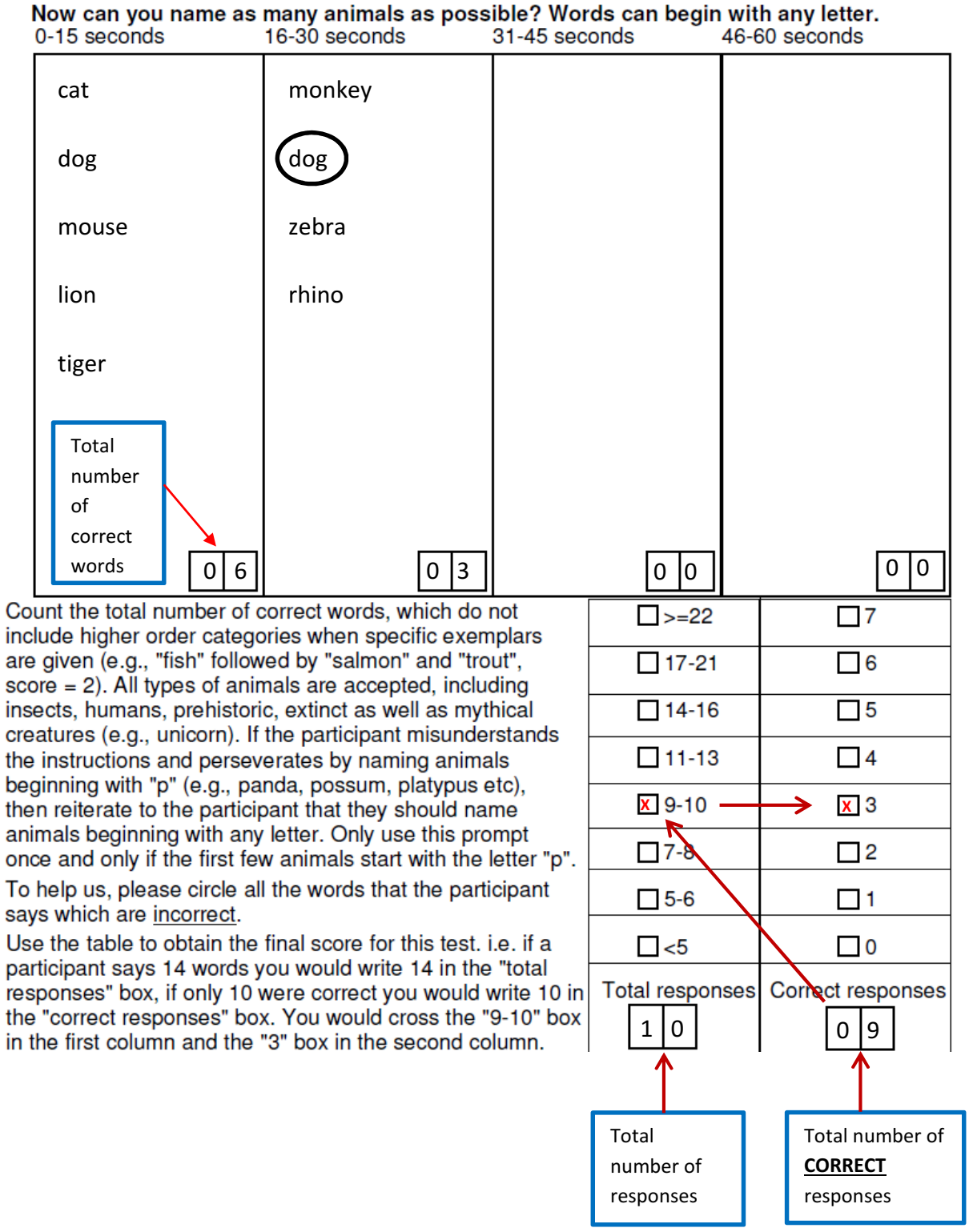
Total number of responses

Total number of **CORRECT** responses

Please make sure that you include only correct words when you score the test. If the participant says 20 words but only one is correct, his/her score in the “Correct responses” box would be 01 and not 20. You should write 20 in the “Total responses” box.

Please make sure that there are numbers written in all boxes. If the particiapnt did not say any words in one or more of the 15 seconds response blocks you should write a 0 in each box.

Verbal Fluency - Category Fluency



Additional scoring guidance for category fluency.

- Names that represent different genders of the same animals are scored as correct e.g. cow, bull; sheep, ram; etc.
- Words that represent animals at different developmental stages are all scored as correct, e.g. kitten, cat; foal, colt, horse; cow, calf; etc.
- Different breeds of the same animal are all scored as correct, so collie, Rottweiler, boxer, sheepdog etc. would all be scored as correct, as would tabby, Persian, Siamese, etc.
- However, if a participant says 20 different breeds of dog, but also says 'dog', s/he would only score 1 correct point rather than 21. This is because "dog" is a higher order categorical word while different breeds of dog are exemplars of dog. If the participant said 20 different breeds of dog but did not say "dog" she/he would score 20.
- Please remember that the converted score is used in the scoring of this subtest and not the total number of words produced by the participant.

MEMORY-Anterograde Memory-Name and Address

MEMORY-Anterograde Memory-Name and Address **Score out of 7:** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

I'm going to give you a name and address and I'd like you to repeat the name and address after me. So you have a chance to learn, we'll be doing that 3 times. I'll ask you the name and address later. If the participant starts repeating along with you, ask him/her to wait until you give the name and address in full. Score only the third trial, but record responses for all three trials (ticks and crosses are enough, unless incorrect responses are names of actual places).

	1st Trial	2nd Trial	3rd Trial
Harry Barnes 73 Orchard Close Kingsbridge Devon			

We have added more guidance into the CRF for you at T2. Please make sure that you record responses for all three trials, not just for the third trial. If the participant does not remember a word, please indicate this with a cross. No line should be left blank for any of the trials.

MEMORY-Retrograde Memory-Famous people

MEMORY-Retrograde Memory-Famous people **Score out of 4:** ☐0 ☐1 ☐2 ☐3 ☐4

	Participant's response if not correct	
What is the name of the current Prime Minister?		**Score:** ☐0 ☐1
What is the name of the woman who was Prime Minister? (Margaret Thatcher)		**Score:** ☐0 ☐1
What is the name of the US president?		**Score:** ☐0 ☐1
What is the name of the US president who was assassinated in the 1960s? (John F. Kennedy)		**Score:** ☐0 ☐1

Allow surnames (e.g., "Obama") and ask for a surname if only the first name is given (e.g., "Maggie"). If the full name given is incorrect (e.g., "June Thatcher"), then the score would be 0. If there has been a recent change in leaders, probe for the name of the outgoing politician.

You should record incorrect responses in the spaces provided. Where a participant could not give an answer, please note this with a cross in the space provided as well as the scoring box.

LANGUAGE-Comprehension

LANGUAGE-Comprehension **Score out of 3:** ☐0 ☐1 ☐2 ☐3

Place a pencil next to a piece of paper in front of the participant. As a practice trial, ask the participant to: **Pick up the pencil and then the paper**. If incorrect, score 0, cross the "failed the practice trial" box and do not continue further. If the participant is correct on the practice trial, continue with the following three commands below. A score of 1 is given for each command.

☐ Failed the practice trial.

Place the paper on top of the pencil. (Reposition the pencil next to the paper in front of the participant.)	**Score:** ☐0 ☐1
Pick up the pencil but not the paper. (Reposition the pencil next to the paper in front of the participant.)	**Score:** ☐0 ☐1
Pass me the pencil after touching the paper.	**Score:** ☐0 ☐1

For T2 we have slightly amended the instructions and have added a checkbox for when participants fail the screening test. If the participant fails the screening test, please cross the "Failed the practice trial" and skip to the next subtest after scoring the test as 0.

LANGUAGE-Sentence Writing

LANGUAGE-Sentence Writing **Score out of 2:** ☐0 ☐1 ☐2

Now I'm going to ask you to write two (or more) complete sentences about your last holiday (or **weekend** or **Christmas** if the time of year is applicable). **Write in complete sentences and do not use abbreviations**.

Give 1 point if there are two (or more) complete sentences about the one topic; and give 1 point if grammar and spelling are correct. If grammar and spelling are correct give this point even if the two sentences are on different topics.

Scoring guide

- To score any points the topic of the sentences must be based on recent experiences and cannot be about something that happened years ago.
- Sentences should be legible. If the participant's handwriting is illegible you should rewrite the sentence below to clarify hard to read parts.

Score of two points:

To get the full two points participants must produce two sentences on the same topic with good grammar and spelling. They cannot use abbreviations such as 'Xmas'. Punctuation is not necessary for the full two points, though to make it clear that there are two sentences obvious breaks in sentences will need to be made. If there are no full stops this could be signified by each sentence being on a new line.

Score of one point:

To score one point the participant must either write two sentences on the same topic but with incorrect grammar and spelling OR write two sentences on different topics but with correct grammar and spelling.

Score of zero:

If only one sentence is produced, irrespective of good grammar and spelling, this would score zero. If there is nothing written in the space provided, this would be scored as zero.

LANGUAGE-Single Word Repetition

LANGUAGE-Single Word Repetition **Score out of 2:** ☐ 0 ☐ 1 ☐ 2

I'm going to read out four words, and I'd like you to repeat each word after me. Say only one word at a time. Only the first attempt is scored.

Caterpillar	Eccentricity	Unintelligible	Statistician
☐ Correct ☐ Incorrect	☐ Correct ☐ Incorrect	☐ Correct ☐ Incorrect	☐ Correct ☐ Incorrect

Score 2 if all are correct; score 1 if 3 are correct; and score 0 if 2 or less are correct.

Please make sure that you put a cross in the correct box. Some researchers have crossed all the 'incorrect' boxes but then scored it as 2. In this instance it is not clear whether the participant actually said all four words correctly and was rightly given a score of 2, or whether the participant said all 4 words incorrectly but was incorrectly given a score of 2.

LANGUAGE-Proverb Repetition

LANGUAGE-Proverb Repetition **Score out of 2:** ☐ 0 ☐ 1 ☐ 2

I'm going to read out two proverbs, and I'd like you to repeat each proverb after me.

Proverb	Participant's response if not correct		
All that glitters is not gold	_____	**Score:** ☐ 0	☐ 1
A stitch in time saves nine	_____	**Score:** ☐ 0	☐ 1

Do not accept partially correct repetitions (e.g., "all that glistens is not gold"). Score 1 point for each proverb. Only the first attempt is scored.

Please make sure that you record incorrect responses in the space provided.

LANGUAGE-Object Naming

LANGUAGE-Object Naming **Score out of 12:** ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12

(USE SHOWCARD 2A)

Here are some pictures; could you tell me the name of each object in the picture. Score 1 point for each item.

Acceptable answer(s)	Participant's response if not correct		
1. Spoon	_____	**Score:** ☐ 0	☐ 1
2. Book	_____	**Score:** ☐ 0	☐ 1
3. Kangaroo or Wallaby	_____	**Score:** ☐ 0	☐ 1
4. Penguin	_____	**Score:** ☐ 0	☐ 1
5. Anchor	_____	**Score:** ☐ 0	☐ 1
6. Camel or Dromedary	_____	**Score:** ☐ 0	☐ 1
7. Harp	_____	**Score:** ☐ 0	☐ 1
8. Rhinoceros or Rhino	_____	**Score:** ☐ 0	☐ 1
9. Barrel, Keg or Tub	_____	**Score:** ☐ 0	☐ 1
10. Crown	_____	**Score:** ☐ 0	☐ 1
11. Crocodile or Alligator	_____	**Score:** ☐ 0	☐ 1
12. Piano accordion, Accordion or Squeeze box	_____	**Score:** ☐ 0	☐ 1

Please make sure that all boxes are crossed. If the participant's response was incorrect, it should be written in the space provided. If no response is given this should also be recorded by the researchers. You do not need to write the correct response in the space.

LANGUAGE-Comprehension

LANGUAGE-Comprehension **Score out of 4:** ☐0 ☐1 ☐2 ☐3 ☐4

Ask the participant to point to the pictures according to the statement read. Do not provide any feedback regarding the word meaning. Score 1 point for each item. Self-corrections are allowed.

	Participant's response if not correct
Point to the one which is associated with the monarchy (Crown, 10)	**Score:** ☐0 ☐1
Point to the one which is a marsupial (Kangaroo, 3)	**Score:** ☐0 ☐1
Point to the one which is found in the Antarctic (Penguin, 4)	**Score:** ☐0 ☐1
Point to the one which has a nautical connection (Anchor, 5)	**Score:** ☐0 ☐1

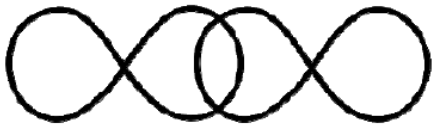
Please make sure that you record incorrect responses in the space provided. Incorrect responses can be recorded as either the name of the incorrect picture or the number, i.e. if the participant said "spoon" for which object is associated with the monarchy you would write either 'spoon' or '1' in the space. What you write in the space does not need to match what the participant says, i.e. if they said "spoon" you can still write '1'.

VISUOSPATIAL ABILITIES- Intersecting Infinity Loops

VISUOSPATIAL ABILITIES- Intersecting Infinity Loops **Score out of 1:** ☐0 ☐1

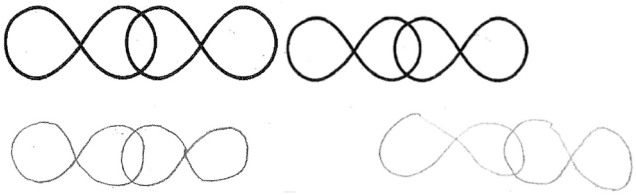
Copy the shape in the space next to it.
A score of 1 is given if two infinity loops are drawn and overlap. Both infinity loops must come to a point/cross and must not look like circles.

Please copy this shape in the space provided

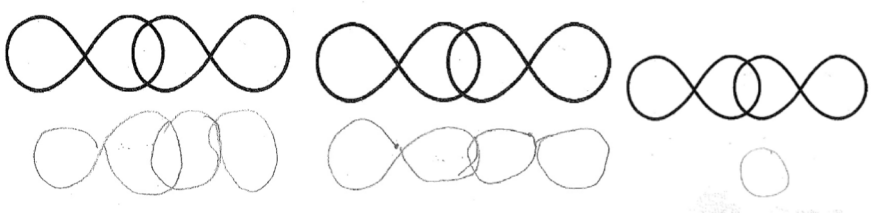


For one point both infinity loops must cross somewhere and they must not look like circles.

These are examples of what would score **one** point:



These are examples of what would score **zero**:

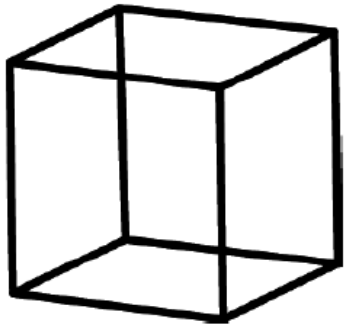


VISUOSPATIAL ABILITIES- 3D Wire Cube

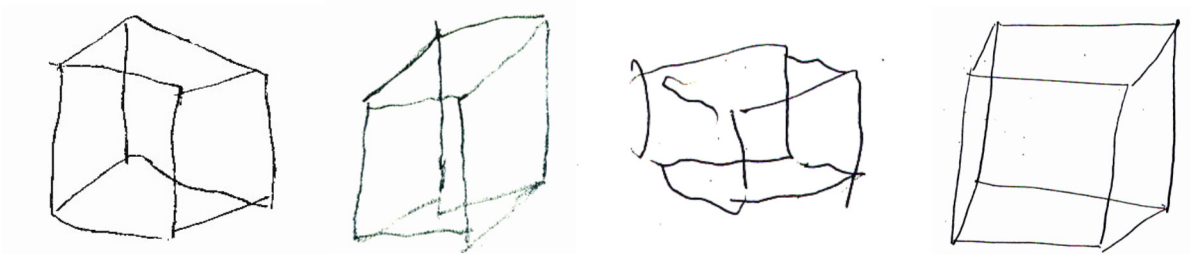
VISUOSPATIAL ABILITIES- 3D Wire Cube **Score out of 1:** ☐ 0 ☐ 1 ☐ 2

Copy the shape in the space next to it.
The cube should have 12 lines to score 2 points, even if the proportions are not perfect. A score of 1 is given if the cube has fewer than 12 lines but a general cube shape is maintained.

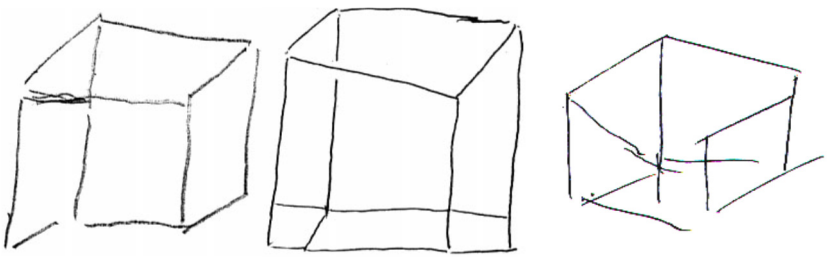
Please copy this shape in the space provided



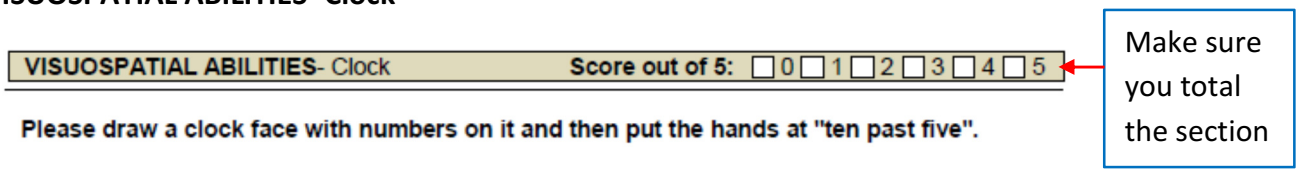
To score two points: The cube should have 12 lines even if the proportions are not perfect.



To score one point: The cube has fewer than 12 lines but a general cube shape is maintained.



VISUOSPATIAL ABILITIES- Clock



VISUOSPATIAL ABILITIES- Clock **Score out of 5:** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5

Make sure you total the section

Please draw a clock face with numbers on it and then put the hands at "ten past five".

Could you draw a clock face with numbers on it? When the participant has finished, say:
Can you put the hands at ten past five? If the participant does not like his/her first drawing and would like to draw it again, you can allow for that and score the second clock. Participants may correct their mistakes by erasing it while drawing.
The following scoring criteria are used to give a total of 5 points (please choose the number for each of the three parts).

Circle	☐ 1	point maximum if it is a reasonable circle
	☐ 0	
Numbers	☐ 2	points if all numbers are included and well distributed within the circle
	☐ 1	point if all numbers are included but poorly distributed or outside of the circle
	☐ 0	points if not all numbers are included
Hands	☐ 2	points if both hands are well drawn, different lengths and placed on correct numbers (you might ask which one is the small and big one)
	☐ 1	point if both placed on the correct numbers but wrong lengths OR
	☐ 1	point if one hand is placed on the correct number and drawn with correct length OR
	☐ 1	point if only one hand is drawn and placed at the correct number i.e. 5 for 'ten past five'
	☐ 0	
Total:		

Remember if the hands are the same length you should ask the participant to clarify which is the small hand and which is the big hand

Make sure you complete the scoring

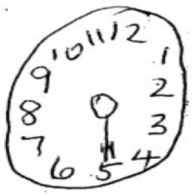
Scoring guide: *Example clocks that scored two*:

Circle (1); one hand placed correctly (1)

Circle (1); all the numbers but not placed inside the circle (1)

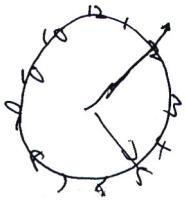
Example clocks that scored three:

Circle (1); all the numbers but not proportionally distributed (1), one hand placed correctly (1)



Circle (1), all the numbers but not placed inside the circle (1), one hand placed correctly (1).

Circle (1), note that numbers are not inside the circle and there are 2 number 10s (0), hands placed correctly (2)



Example clocks that scored four:

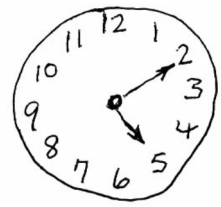
Circle(1); numbers proportionally distributed (2); one hand placed correctly (1)

Circle (1); all the numbers but not proportionally distributed (1); both hands placed correctly (2)

Circle (1); numbers proportionally distributed (2), one hand placed correctly (1)

Example clock that scored five:

Circle (1); numbers proportionally distributed on both halves of the clock face (2); hands placed correctly (2)



PERCEPTUAL ABILITIES- Counting Dots

PERCEPTUAL ABILITIES- Counting Dots **Score out of 4:** ☐0 ☐1 ☐2 ☐3 ☐4

(USE SHOWCARD 2C)

Show the participant the showcard that contains the four dots. **Count the number of dots in each square without pointing to them.** Score 1 point for each correct answer.

Cross the boxes against the correct answers; record incorrect answer(s) in the space provided:

8 ☐ 10 ☐ _____

7 ☐ 9 ☐ _____

Please record incorrect responses in the space provided. If the participant starts to count the dots while pointing, remind him/her that she/he should complete the task without pointing.

PERCEPTUAL ABILITIES- Identifying Letters

PERCEPTUAL ABILITIES- Identifying Letters **Score out of 4:** ☐0 ☐1 ☐2 ☐3 ☐4

(USE SHOWCARD 2D)

Show the participant the showcard that contains the four letters.
Could you identify the letter in each square? The participant is allowed to point. Score 1 point for each correct answer.

Score the correct answers: ☐K ☐M ☐A ☐T ☐Don't know/no answer

For T2 we have added a box so that you can record whether participants were unable or unwilling to give any answers. If the participant does not or is unable to give any response for the four letters please remember to cross the 0 box in the total score box.

MEMORY- Recall of Name and Address

MEMORY- Recall of Name and Address **Score out of 7:** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Now tell me what you remember of that name and address we were repeating at the beginning. Score 1 point for each item recalled. Score 0 for incorrect or unrecalled items. For each element of the recall task either a 0 or 1 must to be crossed, i.e. if the participant says s/he could not recall anything you should cross the 0 box for each item.

Harry	**Score:** ☐0 ☐1	73	**Score:** ☐0 ☐1	Kingsbridge	**Score:** ☐0 ☐1
Barnes	**Score:** ☐0 ☐1	Orchard	**Score:** ☐0 ☐1	Devon	**Score:** ☐0 ☐1
		Close	**Score:** ☐0 ☐1		

We have added extra guidance in the CRF for this item. Many researchers were not completing this subtest correctly. Boxes are often left blank, presumably because the participant is unable to give any response, which is common in people with dementia. The zero boxes should be crossed for incorrect answers and non-responses. For each answer one of the two boxes must always be crossed.

In the example below the participant failed to recall 3 items. The participant either got the answers wrong or could not remember them at all; in each instance the 0 box has been crossed and there is no distinction between them.

MEMORY- Recall of Name and Address **Score out of 7:** ☐0 ☐1 ☐2 ☐3 ☒4 ☐5 ☐6 ☐7

Now tell me what you remember of that name and address we were repeating at the beginning. Score 1 point for each item recalled. Score 0 for incorrect or unrecalled items. For each element of the recall task either a 0 or 1 must to be crossed, i.e. if the participant says s/he could not recall anything you should cross the 0 box for each item.

Harry	**Score:**	☐0	☒1	73	**Score:**	☐0	☒1	Kingsbridge	**Score:**	☒0 ☐1
Barnes	**Score:**	☐0	☒1	Orchard	**Score:**	☒0	☐1	Devon	**Score:**	☐0 ☒1
				Close	**Score:**	☒0	☐1			

MEMORY- Recognition of Name and Address

MEMORY- Recognition of Name and Address **Score out of 5:** ☐0 ☐1 ☐2 ☐3 ☐4 ☐5

This test should only be done if the participant failed to recall one or more items above. If all items were recalled, skip the test and score 5. If only part was recalled start by crossing off items recalled in the column on the right hand side, and then test non-recalled items by telling the participant:

OK, I'll give you some hints:

Was it	Jerry Barnes	☐0	Harry Barnes	☐1	Harry Bradford	☐0	Recalled 1☐
Was it	37	☐0	73	☐1	76	☐0	Recalled 1☐
Was it	Orchard Place	☐0	Oak Close	☐0	Orchard Close	☐1	Recalled 1☐
Was it	Oakhampton	☐0	Kingsbridge	☐1	Dartington	☐0	Recalled 1☐
Was it	Devon	☐1	Dorset	☐0	Somerset	☐0	Recalled 1☐

Each recognised item scores one point, which is added to the point gained by recalling. Every item recognised correctly scores 1 point. Add the correctly recalled and recognised items to give a total of 5 points for this condition.

We have added extra guidance in the CRF for this item. Many researchers were not completing this subtest correctly. The recalled box is often crossed incorrectly. The recalled box should only be crossed if the participant recalled these items in the memory recall task. If Harry was recalled but Barnes was not, the 'recalled' box **should not** be crossed; you would instead read out the three options and cross the one that the participant says.

We have provided guidance about this in the CRF, please make sure that you are familiar with how this subtest is administered and scored. In the example below we continue from the example in the MEMORY- Recall of Name and Address section. The participant scored 4 out 7 with 3 items not recalled. The sections that were recalled (Harry Barnes, 73, and Devon) have crosses in the recalled section because they were recalled in full.

MEMORY- Recognition of Name and Address **Score out of 5:** ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☒ 4 ☐ 5

This test should only be done if the participant failed to recall one or more items above. If all items were recalled, skip the test and score 5. If only part was recalled start by crossing off items recalled in the column on the right hand side, and then test non-recalled items by telling the participant:

OK, I'll give you some hints:

Was it	Jerry Barnes	☐	0	Harry Barnes	☐	1	Harry Bradford	☐	0	Recalled 1	☒
Was it	37	☐	0	73	☐	1	76	☐	0	Recalled 1	☒
Was it	Orchard Place	☒	0	Oak Close	☐	0	Orchard Close	☐	1	Recalled 1	☐
Was it	Oakhampton	☐	0	Kingsbridge	☒	1	Dartington	☐	0	Recalled 1	☐
Was it	Devon	☐	1	Dorset	☐	0	Somerset	☐	0	Recalled 1	☒

Each recognised item scores one point, which is added to the point gained by recalling. Every item recognised correctly scores 1 point. Add the correctly recalled and recognised items to give a total of 5 points for this condition.

In this example the participant only needed two subsections administered to him/her. She/he incorrectly said that street name was "Orchard Place" so scored 0 for that item and correctly recognised that the town was "Kingsbridge" and scored 1 for this. She/he already scored 3 for this subtest from the items that she/he correctly recalled, so she/he scored 4 for this subtest. If the participant is unsure of the answer, you should prompt the participant to have a guess so that an option can be recorded. One of the four boxes on each row must be crossed.

Total scores: For T2 we have added maximum possible scores for each subtest and the total possible overall score. If your subtotals exceed these numbers then you have scored the tests incorrectly and you will need to correct your scores before returning the CRFs. We cannot accept CRFs that do not have the ACE-III scored.

		(maximum possible score)
Attention	☐☐	/ 18
Memory	☐☐	/ 26
Fluency	☐☐	/ 14
Language	☐☐	/ 26
Visuospatial/Perceptual	☐☐	/ 16
TOTAL ACE-III SCORE:	☐☐☐	/ 100

8.6.4. Global Deterioration Scale (GDS) and Functional Assessment Staging (FAST)

The GDS and FAST are measures 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). For T2 the FAST is located in the *Participant Time 2 CRF Part 1* (Q170-171) and the GDS is located in the *Participant Time 2 CRF Part 2* (Q334-335). The CRF contains brief descriptions of the stages with fuller descriptions available in the showcards which you must consult before making your decision.

Global Deterioration Scale (GDS)

Stage	Description
1.	**No cognitive impairment** Unimpaired individuals experience no memory problems and none are evident to a health care professional during a medical interview.
2.	**Very mild cognitive decline** Individuals at this stage feel as if they have memory lapses, especially in forgetting familiar words or names or the location of keys, eyeglasses or other everyday objects, but these problems are not evident during a medical examination or apparent to friends, family or co-workers.
3.	**Mild cognitive decline** Friends, family or co-workers begin to notice deficiencies. Problems with memory or concentration may be measurable in clinical testing or discernible during a detailed medical interview. Common difficulties include: • Word- or name-finding problems noticeable to family or close associates. • Decreased ability to remember names when introduced to new people. • Performance issues in social or work settings noticeable to family, friends or co-workers. • Reading a passage and retaining little material. • Losing or misplacing a valuable object. • Decline in ability to plan or organise.
4.	**Moderate cognitive decline** At this stage, a careful medical interview detects clear-cut deficiencies in the following areas: • Decreased knowledge of recent occasions or current events. • Impaired ability to perform challenging mental arithmetic-for example, to count backward from 100 by 7s. • Decreased capacity to perform complex tasks, such as shopping, planning dinner for guests or paying bills and managing finances. • Reduced memory of personal history. • The affected individual may seem subdued and withdrawn, especially in socially or mentally challenging situations.

5.	**Moderately severe cognitive decline** Major gaps in memory and deficits in cognitive function emerge. Some assistance with day-to-day activities becomes essential. At this stage, individuals may: • Be unable during a medical interview to recall such important details such as their current address, their telephone number or the name of the college or high school from which they graduated. • Become confused about where they are or about the date, day of the week, or season. • Have trouble with less challenging mental arithmetic; for example, counting backward from 40 by 4s or from 20 by 2s. • Need help choosing proper clothing for the season or the occasion. • Usually retain substantial knowledge about themselves and know their own name and the names of their spouse or children. • Usually require no assistance with eating or using the toilet.
6	**Severe cognitive decline** Memory difficulties continue to worsen, significant personality changes may emerge and affected individuals need extensive help with customary daily activities. At this stage, individuals may: • Lose most awareness of recent experiences and events as well as of their surroundings. • Recollect their personal history imperfectly, although they generally recall their own name. • Occasionally forget the name of their spouse or primary carer but generally can distinguish familiar from unfamiliar faces. • Need help getting dressed properly; without supervision, may make such errors as putting pyjamas over daytime clothes or shoes on wrong feet. • Experience disruption of their normal sleep/waking cycle. • Need help with handling details of toileting (flushing toilet, wiping and disposing of tissue properly). • Have increasing episodes of urinary or faecal incontinence. • Experience significant personality changes and behavioural symptoms, including suspiciousness and delusions (for example, believing that their carer is an impostor); hallucinations (seeing or hearing things that are not really there); or compulsive, repetitive behaviours such as hand-wringing or tissue shredding. • Tend to wander and become lost
7	**Very severe cognitive decline** This is the final stage of the disease when individuals lose the ability to respond to their environment, the ability to speak and, ultimately, the ability to control movement. • Frequently individuals lose their capacity for recognisable speech, although words or phrases may occasionally be uttered. • Individuals need help with eating and toileting and there is general incontinence of urine. • Individuals lose the ability to walk without assistance, then the ability to sit without support, the ability to smile, and the ability to hold their head up. Reflexes become abnormal and muscles grow rigid. Swallowing is impaired.

Functional Assessment Staging (FAST)

Stage	Description
1.	**No objective or subjective functional decrement.**
2.	**Subjective deficit in recalling names or other word finding and/or subjective deficit in recalling location of objects and/or subjectively decreased ability to recall appointments.** No objectively manifest functional deficits.
3.	**Deficits noted in demanding occupational and social settings** (e.g., the individual may begin to forget important appointments for the first time; work productivity may decline); problems may be noted in travelling to unfamiliar locations (e.g., may get lost travelling by car and/or public transportation to a "new" location or place).
4.	**Deficits in performance of complex tasks of daily life** For instance paying bills and/or balancing chequebook; decreased capacity in planning and/or preparing an elaborate meal; decreased capacity in shopping, such as in the correct purchase of grocery items).
5.	**Deficient performance in choosing proper attire, and assistance is required for independent community functioning** The spouse or other carer frequently must help the individual choose the appropriate clothing for the occasion and/or season (e.g., the individual will wear incongruous clothing); over the course of this stage some individuals may also begin to forget to bathe regularly (unless reminded) and car driving capability becomes compromised (e.g., carelessness in driving a car and violations of driving rules).
6a	**Requires actual physical assistance in putting on clothing properly** The carer must provide increasing assistance with the actual mechanics of helping the individual clothe himself/herself properly (e.g., putting on clothing in the proper sequence, tying shoelaces, putting shoes on proper feet, buttoning and/or zipping clothing, putting on blouse, shirt, trousers, skirt, etc., correctly).
6b.	**Requires assistance bathing properly** The individual's ability to adjust bathwater temperature diminishes; the individual may have difficulty entering and leaving the bath; there may be problems with washing properly and completely drying oneself.
6c.	**Requires assistance with mechanics of toileting** Individuals at this stage may forget to flush the toilet and may begin to wipe themselves improperly or less fastidiously when toileting.
6d.	**Urinary incontinence** This occurs in the absence of infection or other genitourinary tract pathology; the individual has episodes of urinary incontinence. Frequency of toileting may mitigate the occurrence of incontinence somewhat.
6e.	**Faecal incontinence** In the absence of gastrointestinal pathology, the individual has episodes of faecal incontinence. Frequency of toileting may mitigate the occurrence of incontinence .
7a.	**Speech limited to about 6 words in the course of an average day** During the course of an average day the individual's speech is restricted to single words (e.g., "Yes," "No," "Please") or short phrases (e.g., "please don't hurt me"; "get away"; "get out of here"; "I like you").

7b.	**Intelligible vocabulary limited to generally a single word in the course of an average day** As the illness progresses the ability to utter even short phrases on a regular basis is lost so that the spoken vocabulary becomes limited to generally 1 or 2 single words as an indicator for all things and needs (e.g., "Yes," "No," "O.K." for all verbalisation-provoking phenomena).
7c.	**Ambulatory ability lost** Individuals gradually lose the ability to ambulate independently; in the early part of this sub-stage they may require actual support (e.g., being physically supported by a carer) and physical assistance to walk, but as the sub-stage progresses, the ability to ambulate even with assistance is lost; the onset is somewhat varied with some individuals simply taking progressively smaller and slower steps-other individuals begin to tilt forwards, backwards or laterally when ambulating; twisted gaits have also been noted as antecedents of ambulatory loss.
7d.	**Ability to sit up lost** The individuals lose the ability to sit up without assistance (e.g., they need some form of physical brace-an arm rest, a belt, or other brace or other special devices to keep them from sliding down in the chair).
7e.	**Ability to smile lost** Individuals are no longer observed to smile, although they do manifest other facial movements and sometimes grimace.
7f.	**Ability to hold head up lost** Individuals can no longer hold up their head unless the head is supported.

Administration of the GDS and FAST

The GDS/FAST is to be completed by the researcher on the basis of information gained through working with the person with dementia and through the information obtained from the questionnaires with the person with dementia and the carer or paid carer if applicable. The most relevant sections of the CRF for the FAST are the "everyday activities" sections (*Participant Time 2 CRF Part 1* Q112-128) and (*Relative/Friend Time 2 CRF Part 1* Q44-71). The most relevant sections of the CRF for the GDS are the cognitive screening measures (MMSE, ACE-III, TSI). A good working knowledge of the criteria is essential for you to collate information that will be used to make the rating. It is recommended to discuss a case with your Principal Investigator to help decide how you would rate an individual on these measures.

Scoring of the GDS and FAST

Both the GDS and FAST are hierarchical lists of seven stages of impairment. Please choose the most appropriate stage for the person, based upon his/her cognition and function. These difficulties must be related to dementia e.g. 'Difficulty putting clothing on properly' must be due to the person having dementia and not another health condition such as arthritis. There should not be a wide discrepancy in GDS and FAST scores. For Participant Time 2 CRF Part 1 there is now a numbered question where you must record the reasons

why you decided on a particular score for the FAST. There is a corresponding question in Participant Time 2 CRF Part 2 where you must record the reasons why you decided on a particular score for the GDS. These sections must be completed by you before returning the CRFs.

The GDS/FAST are dementia staging assessments and as such represent different stages of the dementia process. Stage 1 is considered clinically normal for both measures, while a score of 3 is roughly the least severe stage for both measures that someone with Alzheimer's disease should be scoring. Given the description of GDS 1 "**No cognitive impairment.** Unimpaired individuals experience no memory problems and none are evident to a health care professional during a medical interview." and FAST 1 "**No objective or subjective functional decrement."** we do not contemplate any of our IDEAL participants will be in these categories. If you give a score of 1 for the GDS or FAST you will receive a data query.

8.6.5. Representations and Adjustment to Dementia Index (RADIX)

Completing the RADIX

At T2 the RADIX has been shortened, with questions mainly focusing on coping. The RADIX is located in *Participant Time 2 CRF Part 1* under the heading. 'Difficulties that you may experience'. The first part involves trying to find out the person's *label* for his/her condition.

When introducing the RADIX you will be asked:

'During your time with the participant has she/he acknowledged noticing or experiencing changes or difficulties in memory or other symptoms related to his/her dementia?'

It is possible that during your time with the participant she/he may have already acknowledged having difficulties with his/her memory or other difficult relating to his/her dementia. If she/he has then this can help you to introduce the questions. You will need to present a list of symptoms to the participant and see if she/he acknowledges having any of these difficulties. For instance a person may not admit to having dementia but may acknowledge being forgetful. Equally the person may not feel that she/he has experienced any of the symptoms but may have previously mentioned to you that she/he has dementia.

If the person does not acknowledge having any of these difficulties and has not previously mentioned having any problems related to dementia then please discontinue administering the RADIX. **Only** do this if it is very clear that the person has no awareness of his/her difficulties. To help you determine whether a person with dementia should discontinue the RADIX and skip to the open-ended question we have added a box around all the applicable screening questions. Every screening question inside the box needs to be crossed "No" to discontinue the RADIX. If any of the answers to the first part of the questionnaire are **YES** you should continue with the RADIX.

Difficulties that you may experience (RADIX)

Now I'm going to talk to you about any difficulties you may have experienced

129. To be completed by the researcher: During your time with the participant has s/he acknowledged noticing or experiencing changes or difficulties in memory or other symptoms related to his/her dementia? (if so you can start by saying something like **Earlier on you mentioned you had problems with [your memory]')**	☐ No ☐ Yes
130. Have you, a family member or doctor noticed that you have been having difficulty with concentration?	☐ No ☐ Yes
131. Have you, a family member or doctor noticed that you have been having difficulty with being forgetful?	☐ No ☐ Yes
132. Have you, a family member or doctor noticed that you have been having difficulty with remembering (e.g. recent events)?	☐ No ☐ Yes
133. Have you, a family member or doctor noticed that you have been having difficulty with thinking?	☐ No ☐ Yes
134. Have you, a family member or doctor noticed that you have been having difficulty with your ability to say what you want to say?	☐ No ☐ Yes
135. Have you, a family member or doctor noticed that you have been having difficulty with your ability to manage your day-to-day activities?	☐ No ☐ Yes
136. Have you, a family member or doctor noticed that you have been having difficulty with planning ahead?	☐ No ☐ Yes
137. Have you, a family member or doctor noticed that you have been having difficulty with making decisions?	☐ No ☐ Yes
138. Are you different in some way to how you used to be?	☐ No ☐ Yes

Instructions for the researcher: If all the answers to the questions in the box are 'no' skip to question 162 - the optional open ended questions.

Continuing the RADIX

Here are the next three questions in the RADIX. Each one must be completed if the RADIX is continued.

139. Instructions for the researcher: Acknowledge any difficulties that the person has discussed e.g. 'You said you were having difficulty with [your memory]' and then say; **What do you call [this difficulty/these difficulties/this condition] that you have?**

_____

_____

_____

_____

140. Are you aware of a specific diagnosis? What does the doctor call it?

☐ No ☐ Yes, if yes please specify:

_____

_____

_____

_____

141. Instructions for the researcher: Please record the person's label for his/her condition here. How does s/he refer to his/her condition; does s/he call it dementia or something else e.g. short-term memory problems, forgetfulness. Use this term, referred to as [label] in all subsequent questions. If the participant does not give a label, replace [label] with "your condition" or "your difficulties" instead. If the [label] is the same as that in question 139, please still write the term here.

_____

_____

_____

_____

For question **139** you will need to find out the *label* the person uses to describe his/her condition, using the terms the person used to describe his/her difficulties:
'What do you call [this difficulty/these difficulties/this condition] that you have?'
For example, you might say:
'So you feel your memory is terrible these days. What do you call this difficulty with memory that you have?'
Record the person's response. This could be "memory loss", or "Alzheimer's".
For the question **140** you will also ask him/her if she/he is aware of a specific diagnosis or what does his/her doctor call it. This question is asked because it may result in the person using a diagnostic term such as dementia or Alzheimer's disease.

You will also need to record the *label* the person used to describe his/her condition in question **141**. Please note that is essential that you write down the label that you are using in the RADIX in the space provided for Q141 even if it is the same word or words that you have written in the previous questions (Q139-140). For example, the label could be 'short-

term memory loss' or 'forgetfulness', or perhaps 'dementia' or 'Alzheimer's disease'. You will need to use this label in all subsequent questions in the RADIX as you will need to replace the word *label* with the person's own label. For example:

I find myself worrying about my [label] becomes:

I find myself worrying about my forgetfulness if the label the participant uses is "forgetfulness".

I find myself worrying about my dementia if the label the participant uses is "dementia".

In the next part of the RADIX you will ask the participant questions about practical coping, and emotional coping. For most of these questions you will need to use the person's label. In addition, after the RADIX there are four questions about stigma, which require you to use the person's label.

8.6.6. Client Services Receipt Inventory (CSRI)

At T2, we will continue to collect data to examine the following economic questions in the course of the IDEAL study:

- What health and social care services are used by the participant with dementia?
- What are the costs of supporting the participant to (a) the health and social care system and (b) unpaid carers?

To support this analysis, we have devised a data collection method that draws largely on the *Client Service Receipt Inventory* (CSRI).

Introduction to the interview schedule

The overall aim of the *Client Service Receipt Inventory* is to collect information that describes in detail the types of services that comprise the care package of each participant, and the levels of use of those services. The questions are designed so that service use data are recorded in a standardised way in order to facilitate the estimation of indicative costs of support for each client. Just as needs or outcome data are collected at the individual level, from an economic perspective it is important to measure the costs of the resources that may be associated with those outcomes for each client.

The collection of service use data is the first of three stages in the costing process. The second stage is to list all services used by all clients in the study and estimate a unit cost for each service, or service type. For many services, say, social workers or community mental health nurses, the variation in costs between service contexts and between geographic areas is likely to be small and unit costs can be taken from an annual compilation of nationally applicable unit costs. However, for services which are innovative or specific to the local area, it may be necessary to estimate new service-specific unit costs.

The third and final step in the costing process is to combine information on the frequency and duration of service use with the unit costs of each service. Thus, the cost ascribed to each person reflects the intensity with which she/he uses a range of support services. On completion of this stage, the costs data are ready to be analysed.

Guidance on completing the CSRI at T2

Researchers can help us to gather the data required to estimate costs by recording in detail the service use information that the participant provides. You may find it helpful to have a blank piece of paper to write down any notes (record the question number by any notes). Do not write any notes on the CRF (expect in the field notes section).

Who answers the CSRI questions?

At T2, the CSRI questions are located in different CRFs and which section you complete will depend on the availability of the carer. If the carer is taking part in the study, she/he will be asked to complete the CSRI questions about service use. If the person with dementia does not have a carer taking part in the study then she/he will be asked to answer these questions.

The person with dementia does not have a carer taking part in the study

If the person with dementia does not have a carer then she/he will need to answer the CSRI questions. The CSRI *medication use* questions are in *Section B of the Participant Time 2 CRF Part 2*. The CSRI *service use* questions are located in *Section C of* the same CRF. These questions should be completed *face-to-face.*

The person with dementia has a participating relative/friend who is present at the visit:

If the carer is present then both the carer and person with dementia should jointly be asked the CSRI *medication* questions, which are in *Section B of the Participant Time 2 CRF Part 2*.

The carer will then self-complete the CSRI *service use* questions, which start at *Q.161 of Relative/Friend Time 2 CRF Part 1*. While the CRF is set up so that the relative/friend can self-complete these questions, in order to get the best-possible quality data from these questions, researchers should offer to assist relatives/friends to complete this section if they find it difficult to complete on their own for any reason.

The participating person with dementia has a participating relative/friend who is not present at the visit

In this case, the person with dementia will need to answer the CSRI *medication use* questions, in *Section B of the Participant Time 2 CRF Part 2*. The carer will self-complete the CSRI *service use* questions, which start at *Q.161 of Relative/Friend Time 2 CRF Part 1*.

Only the carer is taking part in the study

If only the carer is taking part in the study then she/he will self-complete the CSRI *service use* questions, which start at *Q.161 of Relative/Friend Time 2 CRF Part 1*. The carer will also self-complete two brief *medication* questions, which are in *Section B of the Relative/Friend Time 2 CRF Part 1*.

Guidance on specific questions

Medications: Questions 256-259, Section B of the Participant Time 2 CRF Part 2

This question is asked of the person with dementia and his/her carer (or just person with dementia if she/he does not have a carer). It is designed to collect data on the use of medications for mental health and not for general health conditions. A list of relevant medications is provided for the researcher's reference (Showcard 3C). If the person with dementia or carer is uncertain about what medications the person with dementia is taking then you could ask to see his/her prescription.

It will often be the case that the person with dementia has been using the medication for more than 3 months. However, it is also possible a participant cannot recall the exact date of starting a medication, and does not have a repeat prescription readily available. In this case, use 01/01/00 for the first day. If the person with dementia is still taking the medication, then tick the 'ongoing' box. You should write the name of the medication in the free text question in the left-hand column, either under the 'dementia drugs' header or the 'other mental health drugs', as appropriate. The medication unit code boxes should be filled out using the list of codes just below the medications table, as should the frequency code boxes. Although use of these codes may initially slow down the completion of the table, this will improve the quality and speed of data entry later on.

All the advice below is for interviewers asking the questions of the person with dementia or assisting the carer to answer the questions if requested.

Medications: Questions 234-235, Section B of the Relative/Friend Time 2 CRF Part 1

When only the carer is taking part in the study, the carer completes section B.

Hospital services

Question 267, Section C of the Participant Time 2 CRF Part 2
Question 161, Relative/Friend Time 2 CRF Part 1

If you are administering the Participant CRF, please ask the initial filter question as worded, so that the participant considers and attempts to recall all forms of hospital use, including visits to A&E/casualty, inpatient and outpatient services.

A&E

Questions 268 – 270, Section C of the Participant Time 2 CRF Part 2
Questions 162 – 164, Relative/Friend Time 2 CRF Part 1

In some areas, there may be walk-in centres situated in the hospital near to the A&E. If the person reports attending this kind of service, record it as A&E and write that it was a hospital-based walk-in centre in the lines provided for "what was the reason for using the service"(Q269 of Section C Participant CRF/ Q163 of Relative/Friend CRF). Also, if there are multiple A&E visits and the participant reports visiting A&E for more than one reason, list the reasons separately, separated by semi-colons.

Inpatient care

Questions 271 – 279, Section C of the Participant Time 2 CRF Part 2
Questions 165 – 173, Relative/Friend Time 2 CRF Part 1

When asking for the reason for inpatient admissions, we are looking for as detailed a set of information as the person is able to give. For instance, we would like to know that the admission was for "breathing problems", or was for "dizziness and cardiac investigations", rather than "saw a consultant" or "went for tests". The questions are structured so that the reason and then the number of days spent in hospital is asked for up to 4 separate admissions, starting with the most recent.

Outpatient services

Questions 280 – 284, Section C of the Participant Time 2 CRF Part 2
Questions 174 – 178, Relative/Friend Time 2 CRF Part 1

This question is picking up on any outpatient clinic visit or daytime stay. A daytime stay means that the person did not stay in hospital overnight. Outpatient services include any clinics that took place at a hospital facility, including memory clinics. In this section, we ask the person to give reasons for up to 4 outpatient and/or day visits, in order of use, from most to less recent. As with the inpatient services questions, we are looking for as detailed a set of information on the reason for use as possible. As an example, suppose that the person with dementia had visited a memory clinic, a diabetes clinic, and an outpatient eye clinic to check up on previous day case cataract surgery, and before that, had day case cataract surgery (that is, the person had not stayed in hospital overnight for this surgery). Then the first reason would be recorded as "memory clinic", the second reason would be recorded as "diabetes clinic", the third reason would be recorded as "follow-up appointment at eye clinic after cataract surgery", and the fourth "cataract surgery, day case". It is important not to double count. For example, if the person with dementia attended a (hospital-based) memory clinic and saw several professionals while at the clinic, please only record this as one attendance. Do not write in contacts with, for instance,

memory clinic consultant, memory clinic occupational therapist, memory clinic nurse as separate appointments if it is clear that all those contacts took place in the context of one multidisciplinary memory clinic appointment. The unit cost assigned to that visit will take into account that the clinic is multidisciplinary.

Use of primary, community health and social services

Questions 285 – 297, Section C of the Participant Time 2 CRF Part 2
Questions 179 – 191, Relative/Friend Time 2 CRF Part 1

It can be helpful for researchers to write clarification notes on a blank piece of paper (record the question number by it). For instance, if participants report visit frequencies in terms of numbers of visits *per week or per month*, it may be easier to write this information down as reported and calculate the frequency for entry into the appropriate boxes *after* the visit.

Help in the home

Questions 298 – 303, Section C of the Participant Time 2 CRF Part 2
Questions 192 – 197, Relative/Friend Time 2 CRF Part 1

Some questions in this section are slightly different from those on primary and community health care. People can receive many visits per month from (paid) home carers and meals on wheels, so the tick boxes offer some relevant choices of visit frequency. For instance, a person receiving once-weekly visits occurring throughout a three-month period would have had 13 visits altogether, so this option has been provided. Daily visits would amount to 91 visits. The laundry service question refers to incontinence laundry services (e.g. cleaning soiled linens) run by the local authority and not to private ironing/or dry cleaning services. In this section, we are also gathering data on whether the person with dementia or his/her family has made a financial contribution. We are <u>not</u> asking for detail as to how much has been paid, just whether they have paid all of the cost of the service (“yes, all”) or whether they have paid something towards the cost of the service (“yes, part”). We ask this because people with dementia and their families may bear some, or even all, of the costs of essential support services and we would like to track the extent to which this is occurring for people in this study.

Community services

Questions 304 – 305, Section C of the Participant Time 2 CRF Part 2
Questions 198 – 199, Relative/Friend Time 2 CRF Part 1

The sub-questions contain check boxes. Depending on the participant’s answer, you can either fill out how many trips were made per week (for instance weekly visits to a mental health day centre that occurred consistently over the prior 3 months) or if the attendance was less frequent, the number of times altogether (e.g. attended the day centre 3 times).

Accommodation away from home

Questions 306 – 307, Section C of the Participant Time 2 CRF Part 2
Questions 200 – 201, Relative/Friend Time 2 CRF Part 1

If the person with dementia has had a stay away from home, the researcher should ask for the reason for using this service. Because the costs of a stay in a care home can vary considerably depending on the type of provider, we have asked researchers to classify the organisation that runs the home into local authority/council, NHS, voluntary/ charitable or private. If the person is unable to give details on the type of organisation running the service but can give the name of the home, the researcher could note the home name on a blank piece of paper (with the question number by it) and check on the internet for further details in order to classify the provider.

Equipment and adaptations (checklist)

Questions 308 – 324, Section C of the Participant Time 2 CRF Part 2
Questions 202 – 218, Relative/Friend Time 2 CRF Part 1

In this section, we ask for use and receipt of equipment and adaptations in the past *year* rather than three-month period. If you are administering the *Participant Time 2 CRF Part 2,* you can ask whether the participant *uses* any of the items on showcard 2Z.

Items 308 and 309 of Section C, Participant CRF/Items 202 and 203 of Relative/Friend CRF: Electronic medication reminder dispensers and calendar clocks are two types of memory aids that may be used by people with dementia. Researchers **should not** tick yes if the person mentions having a standard dosette box or medication organiser, but only if they have a pillbox that can issue reminders automatically.

On item 310 of Section C, Participant CRF/ item 205 of Relative/Friend CRF in the checklist: if the person with dementia has a pull-cord alarm system, or a pendant or bracelet alarm, then the researcher should tick yes for “community/personal alarm”.

Unpaid help and support

Questions 325 – 326, Section C of the Participant Time 2 CRF Part 2

The questions being asked of the person with dementia refer to time spent by any relatives/friends providing assistance with tasks the person with dementia had difficulty with or could not do. With these questions, we are asking about currently typical weekly patterns of caregiving. If you are asked for a reference period, they should think about the situation over the past 3 months.

Questions 219 – 222, Relative/Friend Time 2 CRF Part 1

The carer is first asked about time she/he has spent providing assistance with the tasks

listed in Q219. She/he is then asked about the time spent by other relatives/friends providing the person with dementia with assistance with tasks she/he had difficulty with or could not do.

With these questions, we are asking about currently typical weekly patterns of caregiving. If you are asked for a reference period, they should think about the situation over the past 3 months.

Travel costs:

Questions 327, Section C of the Participant Time 2 CRF Part 2
Questions 223, Relative/Friend Time 2 CRF Part 1

Question 223, ***Relative/Friend*** *Time 2 CRF* ***Part 1***: This question addresses the costs to the person with dementia and to the carer of travelling to dementia-care related services only, and not travel to other general health services (e.g. travel to see a cardiac specialist or to see the GP for blood pressure). The question includes instances of travel where the carer accompanied the person with dementia.

Question 327, ***Section C of the*** *Participant Time 2 CRF Part 2*: This question addresses the costs to the person with dementia of travelling to dementia-care related services only, and not travel to other general health services (e.g. travel to see a cardiac specialist or to see the GP for blood pressure).

Modes of transport to services

Questions 328-333 Section C of the Participant Time 2 CRF Part 2
Questions 224-229 Relative/Friend Time 2 CRF Part 1

This asks about the usual form of transport. If the person with dementia has used more than one form, it will be necessary to choose only one; for instance, the one that was used for the longest part of the journey. If the person with dementia uses different forms of transport for visits to different kinds of services, it will be necessary to choose the service the person with dementia most frequently attended and concentrate on how the person with dementia travelled there.

The questions that follow should be answered as applicable; for instance if the person with dementia did not use a taxi the question is not relevant and can be skipped. For the items that have been skipped, please tick the "not applicable" box. So if the usual mode of transport is driving, then please tick "not applicable" for the cost of a one-way fare for public transport and for a taxi ride. When checking through the self-completed ***Relative/Friend Time 2 CRF Part 1, you should check that, where relevant,*** the "not applicable" boxes have been crossed for these questions.

Part IV. Data linkage

9. Data linkage

This section provides information about data linkage, a new addition to the study at 12 month follow-up, and what it will involve for participants. This includes a section on how to explain data linkage to participants. Research network staff will have the responsibility for taking consent for data linkage. The linkage process will be conducted by the project statistician and economist.

9.1. What is data linkage?

At T2, we will be asking people with dementia participating in the study for consent to data linkage. With consent, the study team will link the participants' data collected in the CRFs to NHS health records and to mortality records.

Data linkage involves matching datasets together. The datasets could consist of records from government departments, health and social care, education, or criminal justice organisations. The datasets could also consist of questionnaire responses from surveys. In IDEAL we are seeking to link data from the CRFs, e.g. on health service usage, with external datasets on health service use.

9.2. How will the IDEAL study data be linked?

We are arranging to link the IDEAL study dataset with health service use administrative datasets in England, Scotland and Wales with the assistance of the ESRC-funded Administrative Data Research Network (ADRN). The ADRN offers a liaison service between data controllers and researchers to identify administrative datasets. Prior to approving a project, the ADRN's approval panel carefully vets projects and researchers, and all data controllers must agree to the data sharing arrangement. The ADRN provides a Trusted Third Party data matching service and a secure setting for all access to the resultant linked and de-identified data.

Further information on how the service works can be found on the ADRN website: http://adrn.ac.uk/

9.3. What information do we need for data linkage?

We are seeking to link health resource use, diagnosis and mortality data of each participant who consents to data linkage. This will require sufficient identifiable data to allow the matching of participants to their administrative records.

As part of the data collection process for IDEAL we already have some of the necessary information for data linkage:

- Name
- Address including postcode
- Sex
- Date of Birth

In addition to this information, we will also need to know the participants'

- NHS numbers (or for participants in Scotland their CHI number).

Having the participants' NHS/CHI number will significantly improve the chances of successful linking of the data so it is very important for us to have this information.

9.4. What are the benefits of including data linkage in IDEAL?

We are extending the study to link the data collected in the CRFs with administrative datasets (on hospital inpatient and outpatient care and treatment, on mental and primary healthcare services, and on mortality). Our aim is to supplement the quantity and quality of our current data collection on health care service use and mortality outcomes through data linkage.

Data linkage will strengthen evidence emerging from the study in the following ways:

- The study will be able to access continuous data on health service use for all participants who consent to data linkage. While self-reported service use is being collected in the CSRI, this is episodic (3 months' worth of retrospectively reported data, at three time points) and limited to the duration of the study.
- Linkage will improve the quantity and quality of data available for longitudinal analysis of use of health care services and mortality
- The study will be able to collect data on the mortality of participants when other sources of information on drop out due to death are unavailable.

9.5. Have other studies used data linkage?

A number of studies have begun to request participant consent for data linkage, for instance:

Hertfordshire Cohort Study (http://www.mrc.soton.ac.uk/herts/): Data from the study questionnaires have been linked with hospital records data to examine rates of admission in the 'young-old' and will allow examination of determinants of hospital admission (Simmonds et al., 2014).

Born in Bradford (http://www.borninbradford.nhs.uk/): This is a study of child health in the Bradford area. Linked health records have helped researchers to improve the evidence base on the relationship between childhood growth and ethnic differences (Bryant et al., 2015).

Avon Longitudinal Study of Parents and Children (ALSPAC): a study conducted in the Bristol area to examine impacts of environmental and genetic factors on development from childhood to adulthood (http://www.bristol.ac.uk/alspac/). Researchers have used linked data to examine the relationship between parental socio-economic status and chronic childhood illnesses (Cornish et al. 2013), and to examine how well parent-reported data on a diagnosis of asthma agrees with a GP's recorded diagnosis of asthma (Cornish et al., 2014).

9.5.1. Questions you may get asked on data linkage

The ALWAYS group is a group of people with dementia and carers who act as advisors to the IDEAL study. We asked them to think about the questions they might ask if they were being approached to consent to data linkage. Below are some of the questions they asked us:

What information will you be accessing?

We are asking for permission to link to data on: hospital episodes; contact with health professionals, such as General Practitioners and community nurses; information on any health problems; and the date and cause of their death. We would like to link information on previous use of these services and use of services up to the end of the study. We are **NOT** linking to the Department for Work and Pensions, which holds benefits data.

The Data linkage information pamphlet refers to the study accessing data held by public organisations. What are these "public organisations"?

Mortality statistics are kept by the Office for National Statistics (ONS) in England and Wales, and by the National Records of Scotland (NRS) in Scotland, which are not NHS organisations, so we are asking participants for permission to link to data held by these "public organisations."

Who will access the data on participants' health service use?

The ADRN process means that we are only allowed to access the linked data in strictly controlled conditions, i.e. in a "secure environment". Each researcher that uses the data in this environment must be individually accredited by the ADRN before gaining access. An accredited researcher must be a 'fit and proper' person capable of carrying out the research, who works in academia, or for government or an independent research organisation (eligible to receive Research Council UK funding) recognised by the ADRN Board, and must be conducting research that has been approved by the ADRN Approvals Panel of independent experts. The researcher has to take a training course about security standards and managing administrative data. The researcher has to sign a declaration confirming her/his understanding of their responsibilities and obligations. The researcher will not be able to access any personally-identifying information in the secure setting.

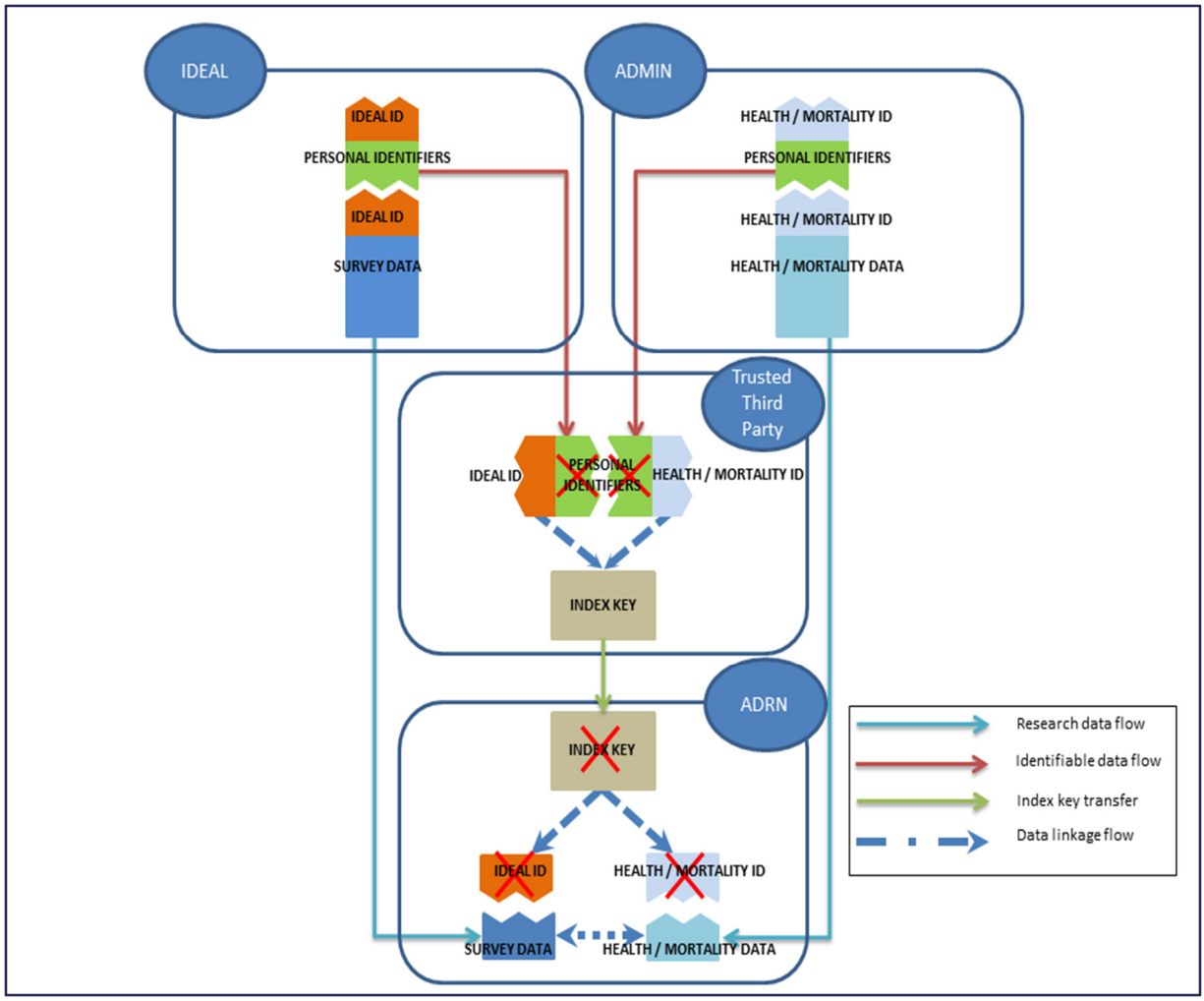
The data linkage information pamphlet states that personal details will be kept confidential. What procedures will be undertaken to ensure that this happens?

The ADRN has a principle of separation of roles and providing access to safe, de-identified data (see Figure 6). Using this system, the Network keeps directly identifying personal information and research data separate:

- The data custodians of the health data and the mortality data (e.g. NHS and ONS/NRS) give each record a unique reference/ID number. They separate the personal information which can directly identify people (such as names, dates of birth and addresses) from their health/mortality data.
- The IDEAL coordinating centre will do the same for the data collected through IDEAL, giving each participant a unique IDEAL ID number.
- The research data is sent to a 'secure environment' (in another part of the ADRN). Each research dataset has unique reference numbers attached but no personally-identifying information.
- At the same time, the identifying personal information from the NHS, ONS/NRS and the IDEAL survey is sent to the Trusted Third Party, together with unique reference numbers for each record – but not the research (e.g. IDEAL or health or mortality) data.
- The Trusted Third Party uses the personal information to match the data and then deletes the personally-identifying information, leaving only the matched unique reference numbers, known as an index key.
- This index key shows which reference numbers relate to the same person in the separate datasets. The Trusted Third Party sends the index key to the 'secure environment'.
- The 'secure environment' uses the index key from the Trusted Third Party to link the data collections together and then removes and deletes the index key and reference numbers, before finally allowing the researcher to see the linked data.

The Trusted Third Party only sees the identifying information and the reference numbers. They never see any of the research data. Researchers only see the data they have requested – not the index keys or the personal information – and only in 'secure environments'. Staff members working for ADRN never see any identifying information. Further information on Trusted Third Parties can be found at this link: http://adrn.ac.uk/protecting-privacy/de-identified-data/trusted-third-parties.

Figure 6. Data linkage



How is the information stored? Is it encrypted?

The ADRN has strict statistical disclosure control procedures to prevent data that could disclose anyone's identity from leaving the secure environment. The original administrative data or "raw data" - such as the specific details of a hospital episode - cannot be copied, removed or published. The ADRN encrypts the data to be linked prior to transfer to the secure setting.

Will you pass on the information you collect to anyone else?

The information collected will be used for the purposes of the IDEAL study. The IDEAL researchers accessing the linked health service and mortality data **WILL NOT** pass this information onto to other organisations such as banks, commercial organisations, insurance companies, the DVLA or employers.

The data linkage information pamphlet says that university researchers can access the linked data; what does this mean?

When we say "researchers from organisations like universities" can use the linked data, we do not mean that undergraduate students can look at people's data. Only appropriate professional researchers from the IDEAL team will work on the linked data in the secure environment.

How will the information be used and disseminated?

We will use the information to calculate the amount and costs of health and social care used by people with dementia in the study. We will analyse it to examine the relationship between health services received and how people with dementia and their carers are living with the condition. The results that will be published drawing on this data will **NEVER** discuss any individual cases of service use. The information on what services were used will always be presented in terms of *total* and *average* use and costs, not on what any specific individual's costs and services used were.

How long will the data be kept?

The "raw" administrative data used in the analyses will not be kept/stored by the IDEAL study team.

During the analysis in the secure environment, we will derive variables for costs and health service use. For instance, we will calculate annual total number of contacts with primary care practitioners, numbers of general and mental health hospital admissions and numbers of outpatient clinic visits, and the costs of these contacts. We have asked the ADRN whether we can keep these calculated ('derived') variables in the IDEAL dataset: our request will be considered by the ADRN Approvals Panel. If we are permitted by the ADRN to retain these service use totals and costs, we would keep just these 'aggregate' data with the survey data.

At the end of the study, all the data collected will be added to data archives (providing the participant has consented to this) such as the UK Data Archive and ESDS Qualidata. This is so that the information can be used by researchers in the future. The IDEAL dataset will be anonymised; it will not contain any personal identifiers. Researchers who wish to access the IDEAL dataset will have to meet strict criteria for access.

What happens after a participant's death?

Should a participant who consented to data linkage die during the study, we would request the administrative data for that person for linkage, unless she/he has withdrawn permission. That person's data will be treated in exactly the same way as the data of living participants and be subject to all the same privacy and security arrangements. We want to explore whether people who have apparently been lost to follow-up have died, so that we can understand if there was any the relationship between the way they were living and their deaths and so that we can take this into account in our analyses.

***What happens if the participant changes her/his mind after she/he has consented to data linkage*?**

The Data linkage information pamphlet gives details of how to get in touch with the IDEAL team to withdraw consent. You will need to record his/her ID number on it so that if she/he contacts us we can update his/her records. Please advise the participant to keep the *Data linkage information pamphlet* in a safe place.

9.6. Data linkage consent: Steps for researchers

- As explained in **Chapter 2** please ensure that the person with dementia has received the ***Data linkage information pamphlet for participant*** before you visit him/her to ensure that she/he has had time to consider the request.
- As explained in **Chapter 4** after you have taken consent for the person with dementia to take part in the study you will need to introduce data linkage using the script in the showcard provided. You should have a copy of the ***Data linkage information pamphlet for participant*** with you in case the person requires any clarification.
- You will need to take informed consent for data linkage using the ***Data linkage consent form***, ensuring all sections are completed (guidance on taking consent for data linkage is provided in **Chapter 4**). If the person lacks the capacity to consent you will need to seek the advice of his/her personal consultee (guidance on the procedure for obtaining consent for data linkage from a personal consultee is provided in **Chapter 11**).
- For participants who consent to data linkage, please source their NHS/CHI number (as explained in **Chapter 4**) and add it to the **Contact details form: T2 (12 month follow-up. .**
- IDEAL participants have already been entered the study and listed as accrual on the UKCRN. Data linkage is now part of the IDEAL protocol this consent will not count as additional accrual.

Part V. Additional guidance

10. Person with dementia or carer withdraws from the study

At T2, it is possible that some participants may wish to withdraw from the study. They may choose not to participate in any of the T2 assessments, or may withdraw during the T2 assessment.

10.1. Who is withdrawing from the study?

- If ***both*** members of the dyad (person with dementia and carer) withdraw from the study, you will need to note the reasons why (if known) and record this information in the MACRO database. Participants have the right to withdraw without giving any reason, but we would very much like to know why they have withdrawn if they are willing to give this information.
- If the ***carer*** withdraws from the study, the person with dementia **can** still take part. You would need to record the withdrawal of the carer in the MACRO database.
- If the ***person with dementia*** withdraws from the study, the carer **can** still take part. You would need to record the withdrawal of the person with dementia in the MACRO database. If the carer still resides in your site's catchment area, you can still visit him/her to take informed consent and explain the CRFs to him/her. She/he would still need to self-complete the CRFs (as the CRFs are designed to be self-completed). You would need to arrange for the carer to post back the CRFs to you or alternatively you could arrange a suitable time to collect the CRFs.

10.2. At what point have they withdrawn from the study?

If the participant withdraws after Visit 1 then you **still need** to return any CRFs s/he has completed. Please write 'WITHDRAWN' on the CRF. You will be asked to record in MACRO the withdrawal information and how many CRFs have been completed

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11. The person with dementia lacks the capacity to consent

If you feel that the person with dementia no longer has the capacity to reaffirm consent to take part in the study you will need to seek advice from a personal consultee (Wales/England) or the person's guardian, welfare attorney or nearest relative (Scotland). The guidance provided below relates to the Mental capacity Act (2005) and researchers based in Scotland should follow the guidance provided in the Adults with Incapacity (Scotland) Act 2000.

11.1. Consulting personal consultees

Under the Mental Capacity Act (2005) if a person loses capacity then an identified 'consultee' can advise the research team about the appropriateness of the person continuing in the study. At T1, all participants were asked to identify someone to act as their personal consultee and the contact details of the consultee were recorded in the ***Contact details form*.** If the person with dementia was unable to identify a personal consultee and she/he does not have capacity to consent then she/he will have to be withdrawn from the study. For the majority of IDEAL participants the personal consultee was also the carer/relative participating in the study and you will be contacting them about the follow-up visits. For some other participants the personal consultee has not been involved or informed about the study until this time point.

11.1. Does she/he accept the invitation to act as personal consultee?

First, you will need to check that the person is willing to act as a personal consultee and you will need to explain to him/her what it involves. If she/he does not feel it would be appropriate for him/her to act as personal consultee then she/he may be able to suggest an alternative consultee. Information for any new personal consultee must be recorded in the **Contact details form: T2 (12 month) follow-up**.

11.1.1. Contacting the personal consultee

The process of contacting a person's personal consultee will depend on who the consultee is and whether she/he was present at Visit 1.

11.1.1.1. Personal consultee is present at Visit 1

If the personal consultee is the carer or someone else who is present at Visit 1 then you will need to seek advice from him/her about whether the person should participate in the study. This should be done during Visit 1 so that if she/he advises that the person should take part then you can carry on with the assessments at Visit 1. First, you will need to give him/her the following documents:

- ***Personal consultee information sheet***
- ***Consent form for personal consultee 12 month follow-up***

If she/he advises the person should take part, you will need him/her to sign the ***Consent form for personal consultee 12 month follow-up*** (see ***Appendix 9***). You will then need to seek his/her advice on data linkage. You will need to give him/her the:

- ***Data linkage information pamphlet for personal consultee***
- ***Data linkage personal consultee consent form*** (see ***Appendix 10***)

The personal consultee should read the ***data linkage information pamphlet for personal consultee***. A showcard has been provided with a script for explaining data linkage and you will need to read out the script from that showcard.

11.1.1.2. Personal consultee is not present at Visit 1

If the personal consultee is not present at Visit 1 then you will need to contact the personal consultee. It is likely that, unless the personal consultee lives nearby and can come over, you will need to **end** the visit and then contact the consultee. If she/he is a family member or friend then you may be able to telephone them directly to seek his/her advice. If she/he is not a family member or friend or if you are uncertain as to whether she/he is aware that the person with dementia has identified him/her as a personal consultee then you can approach the consultee by sending the ***Personal consultee invitation letter 12 month follow-up.*** Whichever method you chose to use to contact the personal consultee you will need to ensure she/he has received the following documents:

- ***Personal consultee information sheet***
- ***Consent form for personal consultee 12 month follow-up***
- ***Data linkage information pamphlet for personal consultee***
- ***Data linkage personal consultee consent form***

You will then need to speak to the personal consultee; this can either be done over the phone or the personal consultee may be willing to come to the participants' home. You **should not** visit the personal consultee at his/her own home unless there are exceptional

circumstances. Invoicing the study for this visit will require **substantive justification** and costs may not be reimbursed.

11.2. What are you asking the consultee to do?

A personal consultee is someone who has a personal interest in the person with dementia and is normally someone whom the person with dementia would trust with important decisions about his/her welfare. You will be consulting this person about what the participant's wishes and feelings about his/her continued participation in the study would be if s/he had capacity. You are seeking advice from the consultee about:

- What the person's wishes and feelings would be about continuing to take part.
- Whether it is likely that the person would decline to take part if s/he had the capacity to decide.
- Whether the person should continue to take part in the study.

When talking to the personal consultee, check his/her general understanding of the study. You will need to make it clear that you are seeking the consultee's views about whether or not the participant may wish to continue to take part, not the personal consultee's own views about the project. It is important that she/he understands that the participant had previously consented to take part in T1 of the project. You may want to consider asking the consultee whether the person would give any signs, and if so, what these would be, to indicate that s/he was not happy about continuing with the project.

11.3. Advice received: person with dementia should not continue to participate

If the consultee advises that the person would not wish to continue to take part, then the person with dementia should be withdrawn from the study and this information should be recorded in the Withdrawal form in MACRO.

11.4. Advice received: person with dementia should continue to participate

If the consultee advises that the person would wish to continue in the study then you will need the consultee to initial, sign and date the ***Consent form for personal consultee 12 month follow-up***. You will then need to seek the personal consultee's advice about what the person's feelings and wishes would be in regard to giving the research team permission to

get further information about him/her from records that the NHS and other public organisations hold about him/her. If the personal consultee decides that the person would agree to data linkage then she/he needs to sign the ***Data linkage personal consultee form.*** The personal consultee will need to return the consent form(s) to you. Once you have the signed consent forms you will be able to commence your assessments with the person with dementia.

11.4.1. Participant payment

As stated in the ***Personal consultee information sheet*** the person with dementia will be offered a shopping voucher as a token of appreciation for taking part. If she/he is unable to spend the voucher then the personal consultee could use it to buy something suitable.

11.5. Taking on board the wishes of the person with dementia

Although the person with dementia may lack the capacity to consent to take part in the study, it is important to be aware of any **verbal or non-verbal** behaviour which might indicate that the person does not wish to take part in the study. People with dementia who have limited verbal communication can still indicate that they do not want to take part in the study. In addition, they may use non-verbal behaviour such as walking away from the assessment. In this situation, you will need to consider whether the person should be taking part in the study and whether you need to withdraw him/her. You could seek further advice from the consultee, and she/he may wish to withdraw consent.

12. The carer has changed

As far as possible we would like to engage with the same carer/relative who participated at T1 to gain a perspective on how things have changed and how things are since the last visit. We realise that things change for carers as well as for people with dementia, and that it may not be possible to have the same carer/relative involved at T2. If the previous carer cannot be involved we would encourage you to find someone who is close to the person with dementia who may be willing to take part (e.g. at T1 John's wife took part but has since died, but John's daughter is now happy to be involved). It is also possible that some people with dementia who did not have a carer at T1 may now have a carer willing to take part at T2. In these situations, you will need to:

1) Ask the carer to sign the ***Consent form for family member/friend 12 month follow-up.***
2) You will need to complete the **Contact details form: T2 (12 month) follow-up** with the carers contact details and return the form to the University of Exeter co-ordinating centre (if the carer has given permission for you to pass on his/her details).
3) You **do not** need to change the ID number for that dyad. (ID numbers remain constant throughout the study).
4) You will need to record in MACRO that the carer has changed. This information is recorded in *CONSORT Time-point 2* (**see Chapter 7**).

12.1. CRF completion for new carers: additional questions

We have developed the CRFs to record information about new carers. In Relative/ Friend Time 2 CRF Part 2 there is a section, **Section B**, which is only for carers who did not take part in the study at T1. The instructions state:

'These next set of questions are only for people who did not take part in the study last year and who did not provide background information about themselves. If you took part in the study last year please skip to Section C'.

In Section B new carers will complete questions about their education, employment history etc. These are the same questions that were in the Relative/Friend Time 1 CRF Part 1 at T1.

13. Changes in health status of the person with dementia or carer

There may be changes in the health of participants that could affect their involvement in the study or the timeframes for the follow-up visits.

If there have been changes in the health status of the person with dementia but she/he is still at home you will need to first find out whether she/he is willing to continue taking part in the study. If she/he is willing then you may need to postpone the follow-up visits until she/he is better. If the person is in hospital or respite care then you will need to monitor the situation and try to find out when she/he will be back home. The same applies to the carer.

In these circumstances, we do allow you to delay the follow-up assessments for a reasonable period. We advise researchers to use their own judgment on how long to delay follow-ups before withdrawing the participant(s) from the study. It will depend on the nature of the person's illness (e.g. whether it is acute or chronic). It is likely to be something you will need to monitor. In these circumstances, you will need to record the event using the ***Adverse event reporting form*** so that we understand why the assessments have been delayed. Carers could potentially be left with the consent form and CRF to complete when they are feeling better.

There may be situations where the health of the carer has significantly deteriorated or she/he has developed dementia. In this situation, you will need to consider:

- Whether the carer is still acting as the 'carer' for the person with dementia
- If she/he has dementia, does she/he have the capacity to consent?

It is quite common for carers to have health problems but to continue in the role of carer. Carers who have developed dementia can still continue to take part in the study as long as they have the capacity to consent. Be aware that they may require additional support with CRF completion and may tire during the visits.

14. The person with dementia and/or carer has moved

In T2, you may find that participants have moved. The participant may have informed you of his/her move or you may have found this out when you were trying to track down a participant who had not responded to your initial contact at follow-up. The process for dealing with participants who have moved will depend on:

- Who has moved
- Whether you can access the person's new contact information
- Where she/he has moved to

14.1. Who has moved?

14.1.1. Person with dementia has moved

If a person with dementia who took part in the study at T1 has now re-located to an area that your site covers we would ask for someone at your site to continue to conduct the T2 assessments with him/her.

If **only the person with dementia** has moved and you do not know the new address, you could contact the carer (if she/he has one) or the personal consultee. If you cannot locate the person with dementia, you would need to record this in the *CONSORT Time-point 2* in MACRO where it refers to lost to follow-up.

If you know the new address for the person with dementia but she/he has moved out of your site's catchment area you should contact the person with dementia at his/her new address and inform the University of Exeter co-ordinating centre so that we can explore other options for visiting the person with dementia. The procedure for reporting this is outlined in Figure 7 and information about what needs to be recorded *in CONSORT Time point 2* is explained in **Chapter 7**. You will need to:

Contact the person with dementia

1. Contact the person using his/her new contact details either by sending him/her the **Follow-up letter and reply slip** or by telephoning him/her.
2. If you get a response and she/he still wishes to take part in the study, you will need to speak to him/her to explain that as she/he has moved outside your site's catchment area, you are not able to continue conducting his/her assessments. If she/he wishes you can pass on his/her details to the University of Exeter co-ordinating centre so that they can arrange for another researcher to visit him/her. You will need to ask for permission for his/her new contact details to be passed on to the co-ordinating centre.

3. If the person gives verbal consent for you to pass on this information, you need to record this information in a ***Telephone summary form*** (so that we have a record of this). Ensure you sign and date the form. You will need to complete the **Contact details form: T2 (12 month) follow-up** with the new contact details for that person.
4. Send a copy of the ***Telephone summary form*** and the **Contact details form: T2 (12 month) follow-up** to the University of Exeter co-ordinating centre and record in *CONSORT Time-point 2* that the person has agreed for you to pass on their details. This should be posted to the Ruth Lamont, IDEAL RPSO, College of Life and Environmental Sciences – Psychology, Washington Singer, Perry Road, Exeter EX4 4QG as soon as possible and **not** put in the courier returns.

Informing the University of Exeter co-ordinating centre

You will also need to inform the University of Exeter co-ordinating centre through MACRO using the *CONSORT Time-point 2* (explained in **Chapter 7**).

For each person with dementia who has moved out of your site's catchment area you will need to record in MACRO:

a) Participant ID number
b) Diagnosis
c) Gender
d) Whether the person's new contact information is known (Yes/No)
e) Whether the site has made contact at the new address (Yes/No)
f) Whether the person agreed to be approached by Exeter (Yes/No)

What happens next?

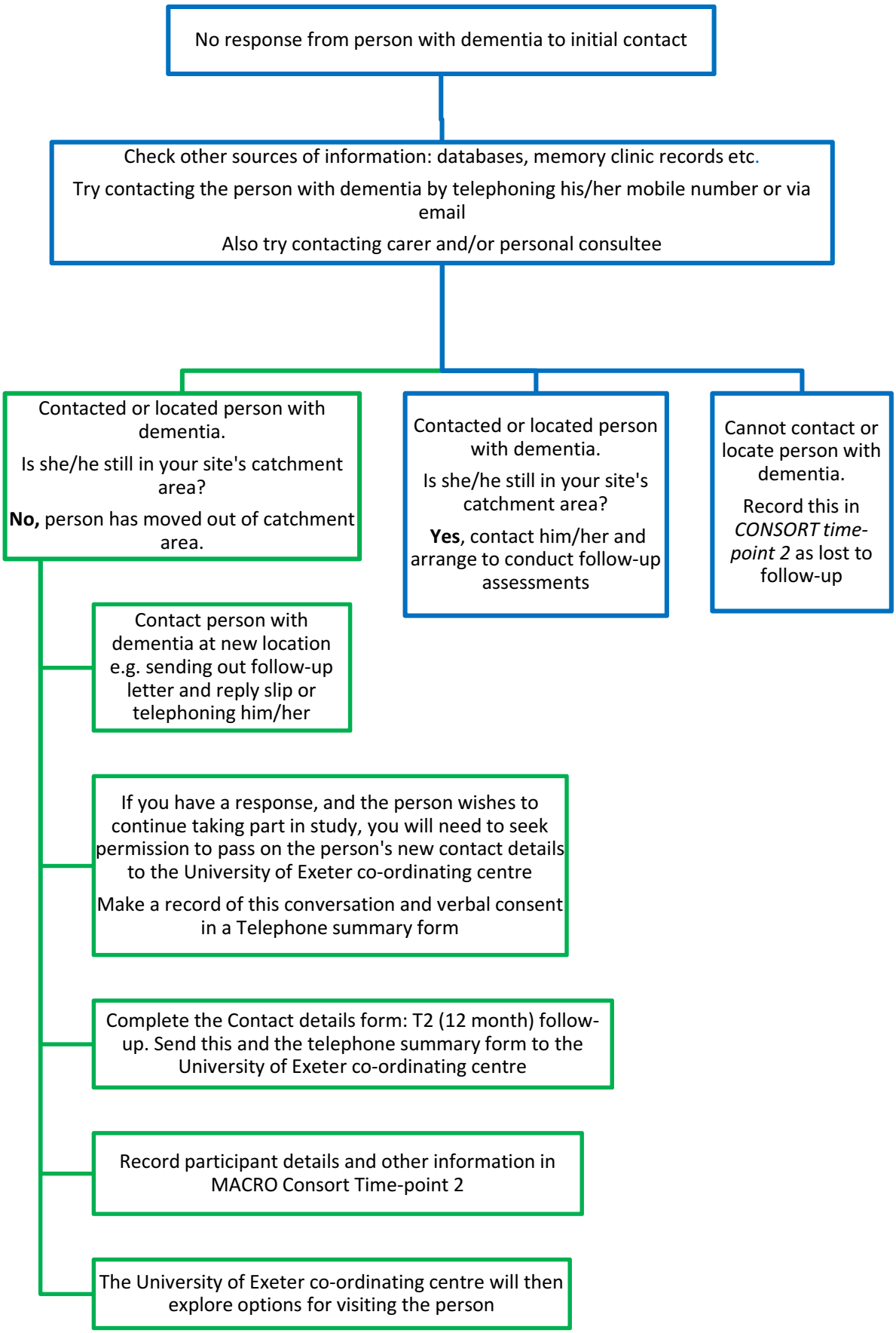
The University of Exeter co-ordinating centre will explore options for conducting follow-up assessments with that person:

a) If she/he has moved to another of the IDEAL research sites then we will approach the researchers based at that site who may be in a position to undertake the assessments.
b) If she/he has moved to an area outside the catchment area of the IDEAL study sites then a member of the IDEAL research team based at the co-ordinating centre will conduct the follow-up assessments.

14.1.2. Both the person with dementia and carer

If both the carer and person with dementia have moved then you would need to follow the same procedure as in the case where the person with dementia has moved (outlined in Figure 7). As with the person with dementia, you will need to record information about the carer who has moved out of the catchment area (as explained in **Chapter 7**).

Figure 7. Outline of procedure to follow if person with dementia has moved



14.1.3. Carer

14.1.3.1. If only the carer has moved

If only the carer has moved, you will first need to find out whether she/he wishes to continue to participate in the study. If she/he has not informed you of his/her new address then the person with dementia may be able to help you. If you cannot locate the carer then you would need to record this as a loss to follow-up in *CONSORT Time-point 2* in MACRO (see **Chapter 7**).

Depending on where the carer has moved to, she/he may still be able to be present when you are assessing the person with dementia. The carer may be willing to attend one of the visits. It would be helpful if the carer could attend the first visit, particularly if she/he is the personal consultee.

If the carer cannot attend any of the visits, you will need to:

1. Post the ***Consent form for family member/friend 12 month follow-up*** to him/her and explain that you need the signed consent form to be returned to you. If you do not receive the signed consent form, re-contact the carer to check that she/he is still interested in taking part in the study.
2. 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 she/he can contact you if she/he has any queries. Post the CRFs to the carer with an addressed return envelope. We suggest you provide the carer with a 'return by' date.
3. If the carer does not return the CRFs by the return date, re-contact him/her to check whether there are any problems completing the CRFs and remind him/her that she/he needs to return the CRFs.

14.1.3.2. The person with dementia has moved but the carer has not

If the person with dementia has moved outside your site's catchment area but the carer still resides in it, you can still visit the carer to take informed consent and explain the CRFs to him/her. She/he would still need to self-complete the CRFs (as the CRFs are designed to be self-completed). You would need to arrange for either the carer to post back the CRFs to you or you could arrange a time to collect the CRFs.

14.2. Transfer of participants to another site

Your site may be asked to conduct follow-up assessments with a person with dementia (or person with dementia **and** carer) who took part in the study at T1 and has now moved into your site's catchment area. You will need to record this information in *CONSORT Time-point 2*.

15. The person with dementia is now in a care home/residential setting

At T2 you can assess the person with dementia at his/her **place of residence**, so if she/he has entered a care home you can conduct assessments within this setting. This is because we wish to avoid attrition due to the person moving into a care home. For people with dementia who have moved into care, and do not have a carer taking part in the study, staff within the care home can be approached to provide some details and corroborating information about the person with dementia. As with home visits, the assessments must still be completed in **two visits**.

15.1. Where has the person moved to?

- If both the person with dementia and carer have moved into the same care home or a similar environment such as sheltered housing and are still resident within your site's catchment area, then you can assess them as you would if they were residing at home.
- If just the person with dementia has moved into a care home which is still in your site's catchment area then you can visit him/her in the care home.
- If the person with dementia has moved into a care home that is outside your site's catchment area you will need to inform the co-ordinating centre so that we can explore alternatives for assessing him/her (follow the procedure outlined in **Chapter 14).**
- If a person with dementia from another IDEAL site who has taken part in IDEAL at T1 has re-located into a care home that is in your site's catchment area then we would approach your site to ask for your site to follow this person up.

15.2. General guidance on conducting research in care settings

Generally, there are two types of homes: care homes and care homes with nursing. Some homes will just specialise in dementia care, and these are often referred to as Elderly Mentally Infirm (EMI) homes. Homes will vary in their size, the types of residents residing there and their management structures. Each home will have its own hierarchy with potential differences in who owns the home, who manages it, and who makes the decisions.

Key points to consider when conducting research in care homes (taken from Luff, Ferreira, & Meyer, 2011)

Who are the 'gatekeepers' to gain access to the person with dementia?

If the person has a carer then you can arrange the visit with him/her. You may also need to

inform and potentially seek permission from the home manager. If the person does not have a carer then you will need to inform and potentially seek permission from the home manager. When you are in the home, it is also important that care staff understand who you are and why you are there. It may be useful to send a copy of the information sheet for participants and paid carers to the home manager

When is the best time to visit?

Timing is important. For instance, homes are very busy during mealtimes and ideally you would want to visit during a quieter period when you can have uninterrupted time with the person with dementia. You also have to consider when the best time is to assess the person with dementia. You could seek advice from the carer or paid carers about when the person is most alert. For those people with dementia who are more impaired, you may also want advice on behavioural indicators that suggest they are distressed.

Where should you conduct your assessments?

Care homes can be noisy, busy environments and you will need to consider where to conduct your assessments. You can ask the home to arrange for you to conduct your assessments in a quiet room or you could do them in the person's bedroom (if permitted).

15.3. Visiting the person with dementia in a care home

The procedure for assessing the person with dementia in a care home will vary depending on whether the person has a carer who is taking part in the study.

15.4. The person has a carer who is participating in the study

The procedure for following up a person with dementia who has a carer taking part in the study is outlined in Figure 8. You should first contact the carer to find out if she/he is willing to continue take part in the study. You could also find out about how the person with dementia is doing, e.g. has there been a deterioration in his/her functioning. This information can help you to consider whether you should invite the personal consultee to the visit to potentially seek consent from the personal consultee for the person's continued involvement. You will then need to find out whether the carer would be willing to meet you at the care home.

15.4.1. Is the carer available to come to the care home?

15.4.1.1. Yes, the carer can come to the home

If the carer can come to the home, you should arrange a date and time to meet him/her there. You could seek his/her advice about the best time to visit.

You should contact the care home manager, or whoever is in charge, and inform him/her that you will be visiting the person with dementia accompanied by the carer. You may need to explain the study and perhaps request a quiet room to in which to speak with the participants. When you meet with the person with dementia and carer at the home, you should seek informed consent, checking that the person with dementia has the capacity to consent by following the guidance in **Chapter 4.**

Does the person have capacity?

If yes, then you can obtain informed consent for the study and then seek informed consent for data linkage. You can then commence the CRF completion. You will need to arrange another joint visit to complete the remaining CRF questions.

If no, then you would need to seek advice from the personal consultee **(as outlined in Chapter 11).** If the personal consultee is not the carer then you will need to end the visit and seek advice from the personal consultee. If she/he advises the person should continue to take part in the study and has signed a consent form to that effect then you will need to re-start your visits with the person with dementia.

15.4.1.2. No, the carer is not available to come to the home

Ideally, it would be helpful if the carer could come to the home, even if it is just for the first visit, particularly if she/he is also acting as the personal consultee. If the carer cannot attend any of the visits, you will need to:

1. Post the ***Consent form for family/member friend 12 month follow-up*** to him/her and the CRFs with an addressed envelope. You will need to explain that you need the signed consent form and CRFs to be returned to you. We suggest you provide the carer with a date to return the consent form and CRFs by.
2. If you do not receive the signed consent form and CRFs, re-contact the carer to check that she/he is still interested in taking part in the study. You can also check whether she/he has any problems completing the CRFs.

To arrange to visit the person without the carer present you will need to contact the care home manager, or whoever is in charge, and inform them of the visit. You may wish to seek advice about a good time of the day to visit and request a quiet room for you to meet with the person with dementia.

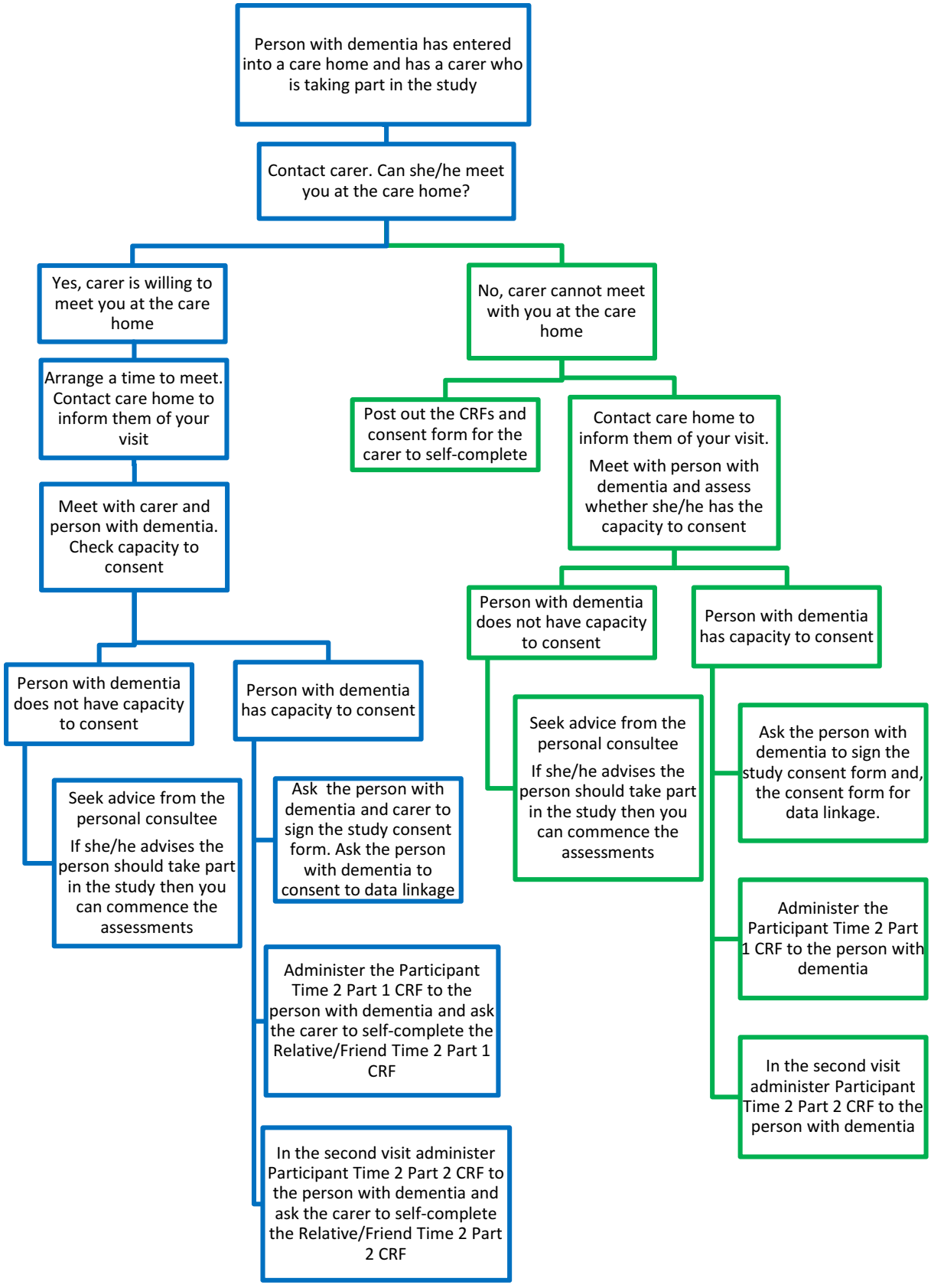
When you meet with the person with dementia at the home, you should seek informed consent, checking that the person with dementia has the capacity to consent by following the guidance in **Chapter 4**.

Does the person have capacity?

If yes, then you can obtain informed consent for the study and then seek informed consent for data linkage. You can then commence the assessments.

If no, then you would need to seek advice from the personal consultee **(as outlined in Chapter 11.** You will need to end the visit and seek advice from the personal consultee. If she/he advises the person should continue to take part in the study then you will need to re-start your visit with the person with dementia.

Figure 8. Guidance on assessing a person with dementia who is in a care home and has a carer taking part in the study



15.5. The person does not have a carer: involving a paid carer

The procedure for following up a person with dementia who does not have a carer taking part in the study is outlined in Figure 9. If the person does not have a carer, either because she/he did not have a friend or relative taking part at T1 or because the carer has withdrawn from the study, then we would like you to identify a paid carer who is working in the home who could provide some information about the person with dementia. Obtaining information from a paid carer gives us another source of information about the person, particularly where the person with dementia does not have a family member/friend taking part in the study. This additional source of information will be particularly helpful for people with dementia who are more impaired and who may not be able to answer all of the CRF questions. The paid carer will be asked to self-complete the **Paid carer Time 2 CRF,** a **short CRF,** which will asks questions about the person's well-being, behaviour and abilities.

You still need to complete your assessments with the person with dementia in **two visits.** Arrangements to meet with the paid carer should be made within these two visits. You would not be able to claim for a third visit just to meet with the paid carer.

15.5.1. Identifying a paid carer to complete the CRF

You will need to contact the care home manager, or whoever is in charge, and inform them that you will be visiting the person with dementia. In addition, you will need to explain the purposes of this visit and seek his/her help to identify a member of staff who could provide information about the person with dementia and complete the Paid carer Time 2 CRF. If the care home manager can identify a paid carer it is advisable to post the ***Information sheet for paid carers*** beforehand so that the paid carer has the opportunity to read about the study before you meet with them. Ideally, you should arrange for this person to meet with you when you come to the home to visit the person with dementia.

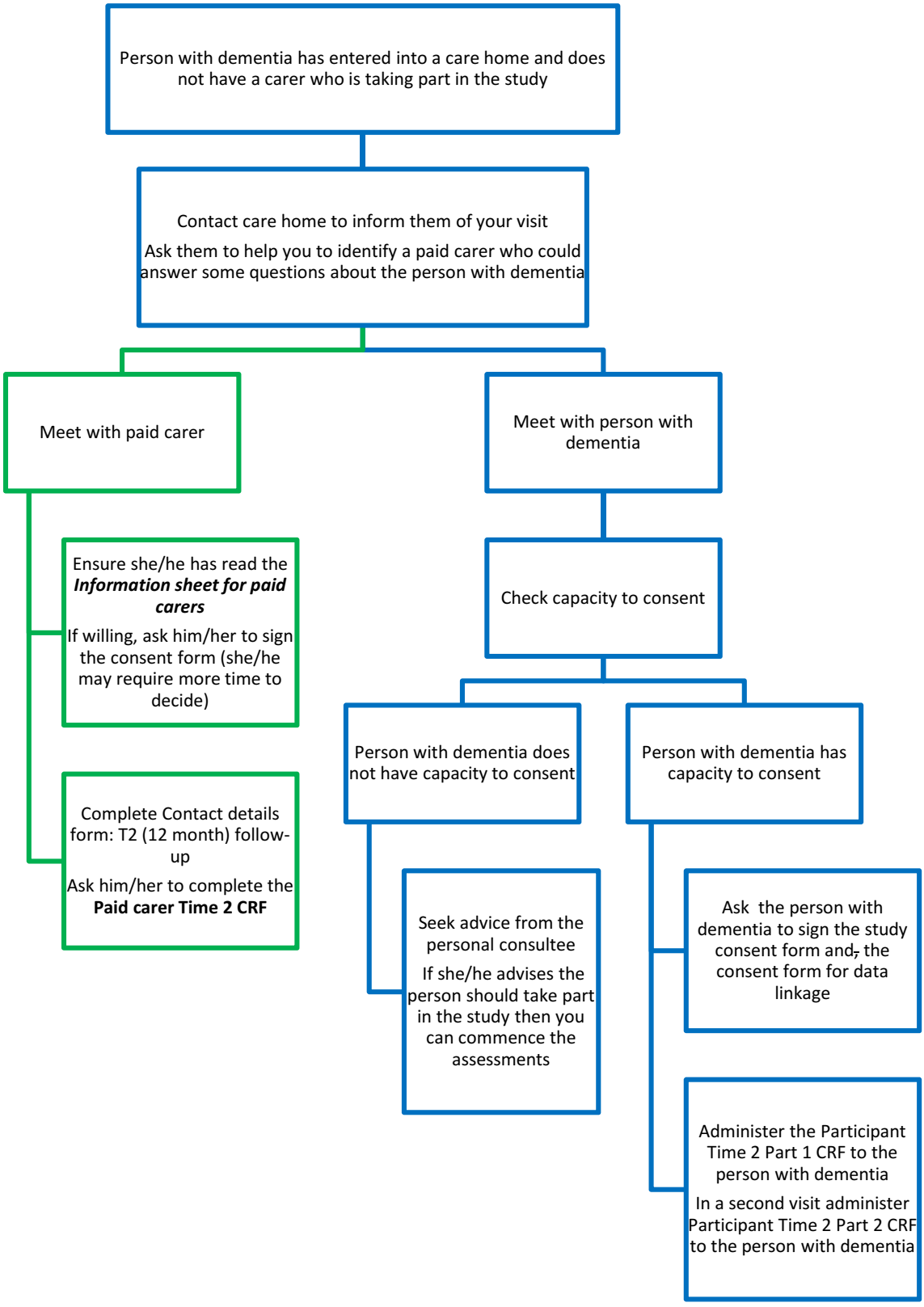
You may be able to identify someone to complete the CRF when you are at the home, but it is preferable to arrange this beforehand so that the paid carer is aware that you are coming to speak to him/her.

If you are unable to identify someone suitable to complete the Paid carer Time 2 CRF, you should record this in the field notes in one of the participant's CRFs.

Who should complete the Paid carer Time 2 CRF?

The CRF should be given to someone who knows the person with dementia well enough to be able to answer questions about his/her well-being and abilities. Ideally, this would be the person's key worker or someone who has been involved in his/her care for a while. In some homes, the most suitable person may be a nurse or matron. You should seek the manager's help to identify someone suitable who is in a position to complete the CRFs.

Figure 9. Guidance on assessing a person with dementia, who is in a care home, and a paid carer



General guidance on involving care staff in research (taken from Luff, Ferreira, & Meyer, 2011)

- Care home staff can have a high workload and you may need to be flexible to allow them to participate in the study.
- It would be best to negotiate with the care home manager (or someone else in charge) about whether you can take the paid carer 'off the floor' to spend time with you that she/he may have otherwise spent working.
- Paid carers may have concerns about taking part in research. You will need to explain what the study is about. The ***Information sheet for paid carers*** also contains information about the study.
- Paid carers may need to be reassured that when competing the CRFs there are no 'right' or 'wrong' answers.
- Some paid carers may not speak English as their first language and consequently it may be helpful if you are there when they complete the CRFs so that you can answer any questions.

15.5.2. Visiting the person with dementia and paid carer

15.5.2.1. Meeting with the person with dementia

As described in previous sections you will need to:

- Check the person's capacity to consent
- If she/he has capacity, you can ask him/her to sign the study consent form and the consent for data linkage. You can then commence the CRFs.
- If the person does not have the capacity to consent, you will need to seek advice from the personal consultee prior to completion of the CRFs.

15.5.2.2. Meeting with the paid carer

You will need to meet with the paid carer to explain the study to him/her. This should occur **during** your visit with the person with dementia. You will need to give him/her the ***Information sheet for paid carers*** (if you have not already posted it to him/her) and the ***Consent form for paid carer 12 month follow-up*** (see ***Appendix 11***)**.** If the paid carer consents to take part in the study, you can give him/her the CRF to self-complete. The paid carer will be assigned the **same seven digit ID** as the person with dementia.

If the paid carer requests additional time to consider whether to take part then you could meet with him/her during your **next visit** to the person with dementia. If she/he does not wish to take part, you may be able to ask the manager to identify another member of staff.

Contact details

If the paid carer consents to take part in the study, you should record his/her contact details in the *Contact details form T2 (12 month) follow-up.* You should also record the details of his/her line manager (e.g. care home manager), as this person would need to be contacted to access this participant in the future.

Completing CRFs

The CRF should take no more than 30 minutes to complete. The Participant ID should be added to the paid carer CRF. This is the same ID as used with the person with dementia and remains the same throughout the study.

There are various options for getting the paid carer to complete the CRF:

- Preferably, the paid carer would complete the CRF whilst you are assessing the person with dementia so that you are available to help him/her.
- You can leave the CRF with the paid carer to self-complete and collect it at the end of your visit or during your next visit (you will need to check that she/he is working on your next visit). However it may be difficult to locate him/her again, for instance s/he may not be working at the same time when you see the participant at the second assessment visit.
- You can leave the CRF with the paid carer to self-complete and ask that she/he post it back to you.

15.5.3. Recording the recruitment of paid carers

You will need to record in *CONSORT Time-point 2* the number of paid carers who are taking part in the study. You will also need to record the participant ID for the paid carer so we can monitor how many paid carers have been added to the study.

We encourage the active recruitment of paid carers, but we do not anticipate the involvement of large numbers of paid carers. We will not be recording accruals for paid carers.

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[All appendices have been removed from this archived document]

Appendices

The Appendix contains the versions of study documents that are the current versions at the time of printing. These documents may be updated and your site will be informed of any changes.

Appendix 1. Summary of the study for follow up

Appendix 2. Follow up letter and reply slip

Appendix 3. Demonstration of capacity checklist

Appendix 4. Consent form for participant 12 month follow up

Appendix 5. Consent form for family member/friend 12 month follow up

Appendix 6. Data linkage consent form

Appendix 7. Receipt of payment: Time 2

Appendix 8. Receipt of Participant Payment Vouchers: Time 2

Appendix 9. Consent form for personal consultee 12 month follow-up

Appendix 10. Data linkage personal consultee consent form

Appendix 11. Consent form for paid carer 12 month follow-up

[To be printed on Participant Identification Centre headed notepaper]

[Name and address of local research site/network staff/research team]
[Date]

Dear

Enhancing active life and living well: the IDEAL study

I am contacting you because your **[relative/friend]** **[name of participant]** previously agreed to take part in a research study entitled: Enhancing active life and living well: the IDEAL study.

All participants who take part in the study have the choice about whether to consent to continue taking part. However some of the participants may not have the capacity to consent because of a condition/illness they have that affects how they make some decisions. You have been approached as **[name of participant]** nominated you as someone I could contact if I felt that she/he lacked capacity to give consent for continued participation on his/her own behalf.

I would like to seek your advice on whether **[name of participant]** should continue to take part in the study. I have included an information sheet about the study so that you can understand why the research is being done and what it will involve.

I will call you to discuss the continued participation in IDEAL of **[name of participant]** and to discuss whether you would be willing to provide consent on behalf of **[name of participant]**. If you do advise that your relative (friend) would wish to give consent we will ask you to complete the personal consultee consent form.

In addition, we would like to know what you think your relative's (friend's) feelings and wishes would be about giving the research team permission for data linkage. This would involve getting further information from records that the NHS and other public organisations hold about your relative (friend). A pamphlet with further information on data linkage is enclosed. If you do advise that your relative (friend) would wish to give consent for data linkage we will ask you to complete a separate data linkage consent form.

If you have any queries in the meantime please call me on **[telephone number].**

Thank you for taking the time to read this information.

Yours sincerely

[local research site/network staff/research team]

[ENCLOSE]:
Personal Consultee Information Sheet
Data Linkage Information Pamphlet for Personal Consultee

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY
PAID CARER INFORMATION SHEET

What is the purpose of the study?

The study explores what living well means from the view of people who have experienced changes in their memory, other thinking abilities, or the ability to manage day-to-day activities, and of those close to them. Participation in the study will help us to identify what helps people to live well or what makes it difficult to live well in this situation.

Why has the person in care been chosen?

The person whose care you are involved with was invited to take part in the IDEAL study after attending a Memory Clinic or another specialist clinic within the NHS. S/he has previously taken part in the first phase of the study and was visited at home. We now want to follow up this him/her to see how things are now s/he is residing in care. A researcher will spend some time with the person and ask him/her to complete some questionnaires. S/he may also be asked to take part in an interview with another researcher.

Why are you being asked to take part as a paid carer?

We are inviting you to take part because you support a person with memory difficulties who is currently resident where you are employed. You may be in a position to provide some information on how the person is managing at this time and this would be very useful for the study.

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.

What is involved for you?

If you agree to take part we will ask you to sign a consent form. The researcher will provide you with a questionnaire to complete. We will ask some questions about how long you have known the resident and some information about yourself (e.g. gender, number of years in education, qualifications). We will also ask some questions about how the person is managing in everyday life and about his/her quality of life from your perspective. You would be able to complete the questions in a short time period.

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 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?

The information we get from this study will help us understand more about ways of living 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 but are not able to compensate you for your time.

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 or research staff from the co-ordinating centre will be involved in contacting participants and you about participation in the study and what is involved.

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. If you agree to take part, we will ask you to give permission for NHS staff / research team to have your personal information at the co-ordinating centre at the University of Exeter.

The University of Exeter University will keep this information confidential, and will only use this information to update you or contact you about the study in the future. 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.

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.

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. 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 Wales Research Ethics Committee 5.

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.

Who can I contact for further information?

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

[To be printed on study centre headed paper]

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

(Scotland – guardian, welfare attorney or nearest relative
Northern Ireland - relative)

Your relative, or close friend, previously agreed to take part in a research study, but is now thought to lack capacity to give consent for continued participation on his/her own behalf. Accordingly, we would like to seek your advice regarding whether s/he should continue to participate.

What is the purpose of the study?

The study explores, over a three-year period, what living well means from the view of people who have experienced changes in their memory, other thinking abilities, or the ability to manage day-to-day activities, and of those who are close to them.

Why has my relative (friend) been chosen?

Your relative (friend) was invited to take part after attending a Memory Clinic or another specialist clinic within the NHS.

Does my relative (or friend) have to continue to take part?
It is up to you to decide whether or not to advise that s/he should continue to be included.

What will happen to my relative (or friend) if s/he takes part?
A researcher will spend some time with your relative (or friend) and ask him/her to complete some questionnaires and some measures of mental fitness. These will be appropriate to the ability level of your relative (or friend). Some of the people taking part in the study will also be asked to take part in an interview with another researcher.

What will happen if I do not want my relative (or friend) to carry on with the study?

You will be free to withdraw your relative (or friend) from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care your relative (or friend) receives. 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: personal consultee information sheet.

[To be printed on study centre headed paper]

ENHANCING ACTIVE LIFE AND LIVING WELL: THE IDEAL STUDY
PERSONAL CONSULTEE INFORMATION SHEET

(Scotland – guardian, welfare attorney or nearest relative
Northern Ireland - relative)

Consultation regarding continued participation in a research study

Your relative (or close friend) previously agreed to take part in a research study. This study involves yearly visits over a three-year period. At the last visit, your relative (friend) was able to decide for him-/herself whether or not to take part, and chose to do so. However, it now seems that s/he may lack the capacity to decide about continued participation and to give informed consent on his/her own behalf. Accordingly, we would like to seek your advice regarding whether your relative (friend) should continue to participate. We would like to know what you think your relative's (friend's) feelings and wishes would be regarding continuing to take part. If the person has previously made an advance statement or advance decision that is relevant, we would want to act in accordance with the person's expressed wishes.

Before you give your advice, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Take time to decide whether or not your relative would wish to continue to take part. Thank you for reading this information sheet.

What is the purpose of the study?

The study explores what living well means from the view of people who have experienced changes in their memory, other thinking abilities, or the ability to manage day-to-day activities, and of those close to them. Participation in the study will help us to identify what helps people to live well or what makes it difficult to live well in this situation.

Why has my relative (friend) been chosen?

Your relative (friend) was originally invited to take part because s/he had attended a Memory Clinic or another specialist NHS clinic.

Does my relative (friend) have to take part?

It is up to you to decide whether or not to advise that your relative (friend) should continue to be included. If you do decide that your relative would wish to continue to participate, you will be given this information sheet to keep, and will be asked to sign a consent form. You are free to change your advice at any time without giving a reason. A decision to withdraw your relative from the study, or advise that s/he should not take part, will not affect the care s/he receives in any way.

What will happen to my relative (friend) if s/he takes part?

A researcher will spend some time with your relative (friend) and ask them to complete some questionnaires and measures of mental fitness. These will be at a level suitable for the current abilities of your relative (friend). 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. This would be audio-recorded and then printed out. We will remove any information that could identify the person who was interviewed 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 your relative (friend) or that it could cause any harm. In the very unlikely event that your relative (friend) was harmed by taking part in the study, there are no special compensation arrangements. If s/he 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?

Your relative (friend) may find it interesting and enjoyable to talk with the researcher and complete the questionnaires and tasks included in the study. The information we get from this study will help us understand more about ways of living 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. Your relative (friend) will be offered a small shopping voucher as a token of our appreciation for taking part. If s/he is unable to spend the voucher, then you could use it to buy something suitable for her/him.

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 to discuss your relative's/friend's wishes. The local NHS staff will also conduct all the home visits.

Will my relative's (friend's) participation in the study be kept confidential?

Participation in the study will be kept confidential. All information that is collected about your relative (friend) during the course of the study will in normal circumstances be kept strictly confidential. Only local NHS staff had access to your relative's (friend's) personal information initially. Your relative (friend) may also have given their permission for NHS staff to pass their personal information to the co-ordinating centre at the University of Exeter when they took part in the first phase of the study. We will ask you to consent to passing on any changes in personal details to the co-ordinating centre at the University of Exeter. We will also ask permission to pass your personal contact details as a personal consultee to the University of Exeter. Please be assured that the University of Exeter will keep this information confidential.

Any records that we make during the course of the study will be stored securely and will be kept separate from any personal details. No-one outside the research team will be able to identify your relative (friend) personally from these records, and no-one will ever be able to identify your relative (friend) 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 relative's (friend's) health, safety or well-being. If this happens the researchers have a duty to inform an appropriate professional, such as a GP or social worker. We would make every effort to explain to you why we need to share this information before doing so.

We will ask you if you are willing to allow the longer-term storage of the information we collect from your relative (friend). 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 your relative (friend) from this information.

What will happen if I do not want my relative (friend) to carry on with the study?

You will be free to withdraw your relative (friend) from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care your relative (friend) receives. We will continue to use the information collected up to the point of withdrawal, unless you tell us that you do not want us to do so.

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 if you would like to receive them.

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 Wales, England, 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]

Living well and enhancing active life
Living well and enhancing active life

Linking the information you provide to other records:

Thank you for taking part in Enhancing active life and living well: the IDEAL study. Your participation has already provided a lot of valuable information. There is another way in which you can help us collect useful information that will add to the answers you have already given.

What other information would we like to collect?

You can give the research team permission to get further information about your health from records that the NHS and public organisations hold about you. This includes information such as visits to hospitals, length of stay in hospital, contact with health professionals (such as General Practitioners and community nurses), information on any health problems, and when people pass away, the date and cause of their death. We would like to gather information relating to your present, past and future health circumstances and link this to the details you have already given.

We call this way of collecting information 'data linkage'. While we can learn about people's lives and experiences by direct questions, it is sometimes easier to obtain information from other sources and this is what we hope to do by data linkage.

What is involved?

We need your written permission for any information to be released. If you are happy for the research team to link information given in the IDEAL study with records the NHS and public organisations hold about you, then we will ask you to sign a consent form. By signing the form you will be giving us permission to pass your information (such as your name, date of birth, address, NHS/CHI number) to other approved organisations so that your data can be linked.

What will happen to my information?

Your personal details will be kept confidential at all times during this data linkage process. When we have made the link, all the personal information you have given (e.g. name, date of birth, address etc.) will be removed so that you cannot be personally identified from the data that has been linked.

Your personal information will be given a reference number instead. This reference number will be used to match the data we have collected with your other records. This personal reference number means that your details will be kept completely anonymous.

Who will use the linked data?

The linked data will only be available to researchers from organisations like universities for projects that have been approved by ethics boards. Names and addresses are never included in the results and no individual can ever be identified from the research.

Your information will only be used for research purposes and will not be passed on to any company for marketing purposes.

Do I have to have my information linked?

It is up to you whether you give your consent. Please ask the interviewer about anything that concerns you about the data linkage process.

If you do give consent you can withdraw consent at any time in the future by writing to us at the following address:

Project Manager
The IDEAL Study
Washington Singer Laboratories
Psychology
College of Life and Environmental Sciences
University of Exeter, Exeter, EX4 4QG

Please give your participant ID number noted below and we will ensure that the link between your interview answers and other records is removed.

Participant ID

_____

Thank you for reading this information on data linkage

If you would like to find out more about the IDEAL study please visit our website

www.IDEALproject.org.uk

Or contact researchers in your local area:

Name:

Address:

Phone:

E-mail:

IDEAL is funded by the Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR): ES/L001853/1

Living well and enhancing active life: the IDEAL study

Data Linkage

Information for participants

IDEAL Data Linkage Information pamphlet participant v3 28/05/15

This pamphlet has been approved for recruitment by the Wales REC 5 Bangor

Living well and enhancing active life
Living well and enhancing active life

Information about linking the information your relative (friend) provides in the study with other records:

Your relative, or close friend, previously agreed to take part in a research study, but is now thought to lack capacity to give consent for continued participation on his/her own behalf. Accordingly, if you have given your advice that s/he should continue to participate in the IDEAL study, we are also seeking your advice on another and valuable way in which your relative or close friend can help us collect different information to add to the answers he/she has already given.

What other information would we like to collect?

We would like to know what you think your relative's (friend's) feelings and wishes would be about 'data linkage'. This would involve giving the research team permission to get further information about your relative (friend) from records that the NHS and other public organisations hold about him/her. This includes information such as visits to hospitals, length of stay in hospital, contact with health professionals (such as General Practitioners and community nurses), information on any health problems, and when people pass away, the date and cause of their death. We would like to link information relating to his/her present, past and future health circumstances.

We call this way of collecting information 'data linkage'. While we can learn about people's lives and experiences by direct questions, it is sometimes easier to obtain information from other sources and this is what we hope to do by data linkage.

What is involved?

It is up to you to decide whether or not to advise that your relative (friend) would be happy for the research team to link information given in the IDEAL study to records that the NHS and public organisations hold about him/her.

If you do decide that your relative would agree to data linkage, you will be given this information sheet to keep, and will be asked to sign a consent form. We need your advice about whether your relative (friend) would want to give permission for any information to be released. You are free to change your advice at any time without giving a reason. A decision to withdraw your relative from the study, or advise that s/he should not take part, will not affect the care s/he receives in any way. By signing the consent form you will be giving us permission to pass your relative's (friend's) information (such as his/her name, date of birth, address, NHS/CHI number) to other approved organisations so that his/her data can be linked.

What will happen to my relative or friend's information?

Your relative's (friend's) personal details will be kept confidential at all times during this data linkage process. When we have made the link all personal information (e.g. name, date of birth, address etc.) will be removed so that he/she cannot be identified.

Your relative's (friend's) personal information will be given a reference number instead. This reference number would be used to match the data we have collected with his/her other records. This personal reference number means that his/her details will be kept completely anonymous.

Who will use the linked data?

The linked data will only be available to researchers from organisations like universities for projects that have been approved by ethics boards. Names and addresses are never included in the results and no individual can be identified from the research.

Your relative's (friend's) information will only be used for research purposes and will not be passed on to any company for marketing purposes.

Your information will only be used for research purposes and will not be passed on to any company for marketing purposes.

Do I have to have my relative or friend's information linked?

It is up to you whether or not to advise that your relative (friend) would wish to give consent. Please ask the interviewer about any concerns you have about the data linkage process. If you do advise that your relative (friend) would wish to give consent, you are free to change your advice at any time in the future without giving a reason by writing to us at the following address:

Project Manager
The IDEAL Study
Washington Singer Laboratories
Psychology
College of Life and Environmental Sciences
University of Exeter, Exeter, EX4 4QG

Please give your participant ID number noted below and we will ensure that the link between your relative's (friend's) interview answers and other records is removed.

Participant ID:

_____

Thank you for reading this information on data linkage

If you would like to find out more about the IDEAL study please visit our website

www.IDEALproject.org.uk

Or contact researchers in your local area:

Name:

Address:

Phone:

E-mail:

IDEAL is funded by the Economic and Social Research Council (ESRC) and the National Institute for Health Research (NIHR): ES/L001853/1

Living well and enhancing active life: the IDEAL study

Data Linkage

Information for Personal Consultee

IDEAL Data Linkage information pamphlet for personal consultee v2 28/05/15

This pamphlet has been approved for recruitment by the Wales REC 5 Bangor

[To be printed on Participant Identification Centre headed notepaper]

[Name and address of local research site/network staff/research team]

[Date]

Dear

Enhancing active life and living well

I am contacting you because you very kindly participated in the first stage of this research study a year ago, [together with [**name of relative/friend].** I am writing to invite you to consider taking part in the next stage of this project. Finding out your views will help us to identify what helps people to live well or what makes it difficult to live well in this situation.

Participation in the next stage of the study will involve talking with a researcher, filling in some questionnaires and completing some simple tasks. This will be very similar to what you did in the first stage of the study. [If possible we would also like to talk with [**name of relative/friend],** as we did previously, to gain his/her perspective**]**.

Please also find enclosed a pamphlet on 'data linkage', an additional feature of this year's study. [enclose data linkage pamphlet for participant]

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. We will be delighted to hear from you and will contact you to arrange to meet with you again.

Yours sincerely
[local research site/network staff/research team]

[To be printed on Participant Identification Centre headed notepaper]

ENHANCING ACTIVE LIFE AND LIVING WELL

REPLY SLIP

If you are interested in continuing to contribute 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 would like to continue to take part in the Enhancing active life and living well study. I would like someone from the local NHS research staff / research team to contact me to talk about my next involvement and to make arrangements to visit.

My name:

My telephone number:

My email address:

My postal address:

Living well and enhancing active life: the IDEAL study
Contact details form: T2 (12 month) Follow-Up

Please complete this form for all participants at T2 follow-up
PRINT CLEARLY

Date: _____

Participant Identification number: _____

Researcher Identification number: _____

- **For all participants who have consented (or their personal consultee has advised they would consent) to Data Linkage: please provide their NHS/CHI number to ensure that the co-ordinating centre can enable their records to be linked to IDEAL survey information.**

NHS/CHI Number: For the participants who have consented to data linkage (or their personal consultee has advised they would consent) please provide their:

NHS number (England & Wales) _____
or
CHI number (Scotland) _____

Please tick here if you were unable to obtain the NHS/CHI number: _____

- **For all participants who have agreed to have their personal contact details given to the research co-ordinating centre please confirm:**

Has the contact information for the participant changed from the previous timepoint?
No _____
Yes _____ **(If yes, please provide the new information below)**

Participant information:
Full Name: _____
Address _____
_____
_____
Postcode _____
Tel. (home) _____
Tel. (mobile) _____
Email: _____
Name of GP or clinic: _____
Address : _____
_____
Postcode _____
Tel.

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

_____

- **For all carer/informant who have agreed to have their personal contact details given to the research co-ordinating centre: please confirm**

Has the contact information for the carer/informant changed from the previous timepoint?
No _____
Yes _____ **(If yes, please provide the new information below)**
Is this a new carer/informant? No _____ **Yes** _____

Carer Information: *(if available)*
Full Name _____
Address _____
_____
_____
Postcode _____
Tel. (home) _____
Tel. (mobile) _____
Email: _____
Relationship to the participant *(e.g. spouse)*

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

_____

Is the carer also the personal consultee? (please tick) **No** _____ **Yes** _____

Has the contact information for the personal consultee changed from the previous timepoint?
No _____
Yes _____ **(If yes, please provide the new information below)**
Is this a new personal consultee? No _____ **Yes** _____

Full Name of Personal Consultee:
Address: _____
_____
_____
Postcode _____
Tel. (home) _____
Tel. (mobile) _____
Email: _____
Relationship to the participant *(e.g. spouse, friend)*

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

_____

Please:

- **<u>For paid carers who have participated in the study at this timepoint and agreed that their contact details given to the research co-ordinating centre</u> please add the following information:**

Name of Paid Carer:
If applicable

Work Address: _____

_____

_____

_____

Postcode _____
Tel. (mobile) _____
Email: _____

Name of Paid Carer Line Manager
If required for access/contact

Work Address: _____

_____

_____

_____

Postcode _____
Tel. (mobile) _____
Email: _____

Any other comments: (e.g. plans to move in the next year, change job, or retire etc.)

_____

_____

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